PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of **Illumina, Inc.,** **a corporation,** **and** **GRAIL, Inc.,** **a corporation.**	**DOCKET NO. 9401**

RESPONDENTS' REPLY TO COMPLAINT COUNSEL'S POST-TRIAL PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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INTRODUCTION

Respondents respectfully submit the following Reply to Complaint Counsel's Post-Trial Proposed Findings of Fact and Conclusions of Law, which distort the factual record, misstate the governing law and seek relief for which there is no justification in fact, law or common sense. Respondents incorporate into each of the responses their own Proposed Findings of Fact and Conclusions of Law as if set forth expressly herein. Respondents also incorporate herein their opening and reply post-trial briefs, which further demonstrate that Complaint Counsel's Proposed Conclusions of Law are, in all material respects, baseless. Consistent with the Court's Order on Post-Trial Filings, Respondents have "use[d] the same outline headings as used by [Complaint Counsel]" in this Reply to Complaint Counsel's Proposed Findings of Fact and Conclusions of Law. As evident from the substance of Respondents' detailed responses to the individual proposed findings and conclusions, Respondents do not agree with many of Complaint Counsel's headings.

I. BACKGROUND

A. ILLUMINA

1. Illumina is a publicly traded, for-profit Delaware corporation founded in 1998, with its headquarters in San Diego, California. (PX0061 at 004 (Illumina 2020 Form 10-K)).

Response to Finding No. 1:

Respondents have no specific response.

2. Illumina's principal product offerings are short-read NGS instruments used for DNA sequencing and associated consumables, analytical software, and ancillary service contracts. (PX0061 at 005 (Illumina 2020 Form 10-K)).

Response to Finding No. 2:

Respondents have no specific response except to note that the cited page of PX0061 (Illumina) does not mention "ancillary service contracts".

3. The majority of Illumina's revenue comes from the sale of NGS instruments and consumables. (PX0061 at 007-08 (Illumina 2020 Form 10-K)).

Response to Finding No. 3:

Respondents have no specific response.

1. Illumina Is a Dominant Provider of Next-Generation Sequencing Platforms

4. Illumina describes itself as "the global leader in sequencing- and array-based solutions for genetic and genomic analysis." (PX0061 at 005 (Illumina 2020 Form 10-K)).

Response to Finding No. 4:

Respondents have no specific response.

5. Illumina has "an extensive intellectual property portfolio," including ownership or exclusive licenses to over 900 U.S. patents and 600 pending U.S. patent applications. (PX0061 at 009 (Illumina 2020 Form 10-K)).

Response to Finding No. 5:

Respondents have no specific response except to note that the cited source also observes that Illumina's issued and pending patents, which cover various aspects of Illumina's arrays, assays, sequencing technology, instruments, and software, "have terms that expire between 2021 and 2041". (PX0061 (Illumina) at 009.) With respect to patents relating to Illumina's sequencing technology, Respondents incorporate PFF ¶ 588.2 and their responses to CCFF ¶ 341 herein.

6. [redacted] (PX5027 (Illumina) at 009 [redacted] (*in camera*)).

Response to Finding No. 6:

The proposed finding is not supported by the cited source. Nowhere does it indicate that the gross margins described on the cited slide are Illumina's actual gross margins and the source at the bottom of the slide indicates that the data is based on [redacted]

[redacted] (PX5027 (Illumina) at 009.) Additionally, Dr. Joydeep Goswami, Illumina's SVP of Corporate Development and Strategic Planning, testified that [redacted] (PX7087 (Goswami (Illumina) Dep. at 155.))

7. [redacted] (PX5027 (Illumina) at 009 [redacted] (*in camera*)).

Response to Finding No. 7:

Respondents have no specific response except incorporate their responses to CCFF ¶ 6 herein.

8. Illumina sells a variety of NGS sequencing instruments, including the "high-throughput" NovaSeq model; "mid-throughput" NextSeq models; and "low-throughput" MiSeq, MiniSeq, and iSeq models. (PX0091 (Illumina) at 011-013 (Illumina Source Book, August 2020); *see* PX0114, Illumina Sequencing Platforms, https://www.illumina.com/systems/sequencing-platforms.html (last visited Feb. 4, 2022) (listing Illumina sequencing platforms).

Response to Finding No. 8:

Respondents have no specific response.

9. Illumina's instruments are "based on [Illumina's] proprietary technologies." (PX0061 at 007 (Illumina 2020 Form 10-K)).

Response to Finding No. 9:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 5 herein.

10. [redacted] (PX6056 (Illumina) at 018 (Illumina, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 10:

Respondents have no specific response.

11. In 2020, Illumina's instrument sales accounted for 13 percent of Illumina's total revenue. (PX0061 at 007 (Illumina 2020 Form 10-K)).

Response to Finding No. 11:

Respondents have no specific response.

12. Illumina offers consumables, which include reagents, flow cells, and microarrays. (PX0061 at 007 (Illumina 2020 Form 10-K)).

Response to Finding No. 12:

Respondents have no specific response.

13. There are two primary types of consumables involved in NGS: library preparation or sample preparation reagents, and core consumables. (PX7045 (Chudova (Guardant) IHT at 83-84)).

Response to Finding No. 13:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross-examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

14. Library preparation reagents are used to prepare a sample for testing, for example by replicating DNA of interest so that it may be more easily examined. (PX7040 (Getty (Guardant) IHT at 63-64)).

Response to Finding No. 14:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross-examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also note that Illumina technology need not be, and often is not, used for library preparation. (Berry (Illumina) Tr. 815 (stating that the library preparation step "is very unique and specific to the particular test provider's sort of approach of methodology" and that there are "hundreds and hundreds of library preparation methods" and "potentially hundreds of providers of library preparation technology or kits".))

15. Core consumables are reagents that must be used together with an instrument to implement a sequencing assay, such as a flow cell. (PX7063 (Berry (Illumina) IHT at 28); PX7045 (Chudova (Guardant) IHT at 83-84)).

Response to Finding No. 15:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross-examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

16. Dr. Aravanis of Illumina testified that consumables are "the materials that are actually consumed in a sequencing run" and explained that for "every sequencing run you need a new set of consumables, but you use the same instrument." (Aravanis (Illumina) Tr. 1845-46).

Response to Finding No. 16:

Respondents have no specific response.

17. According to Illumina's Nicole Berry, Illumina is "the only supplier of the core consumables that run on [Illumina's] instrumentation." (PX7063 (Berry (Illumina) IHT at 28)).

Response to Finding No. 17:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross-examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

18. Illumina's consumables are "based on [Illumina's] proprietary technologies." (PX0061 at 007 (Illumina 2020 Form 10-K)).

Response to Finding No. 18:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 5 herein.

2. Formation of Grail

a) Illumina Began Researching MCED Test as Part of a Larger Exploration of cfDNA Technology

19. In early 2013, Illumina acquired Verinata Health, Inc. ("Verinata"). (DeSouza (Illumina) Tr. at 2420).

Response to Finding No. 19:

Respondents have no specific response.

20. Verinata was a provider of non-invasive prenatal tests that utilized NGS technology. (Chudova (Guardant) Tr. at 1143-44).

Response to Finding No. 20:

Respondents have no specific response.

21. Around the time of Illumina's acquisition of Verinata, NIPT companies including Natera and Sequenom had observed cancer signals when performing NIPTs. (PX7060 (Naclerio (Illumina) IHT at 33-34, 35-37)).

Response to Finding No. 21:

The proposed finding presents an incomplete picture of the relevant events. For example, the signal that had been observed at this time was a late stage cancer signal, not an early stage one; and Dr. Naclerio also testified that, even if it was beginning to be understood that detecting cancer in the blood at a late stage was a technical possibility, the notion that there could be a "blood screen test that would discover cancer while it was still localized and treatable" was "a pretty radical idea. . . . that most people said, you know, may be possible someday ten years from now" but was a moonshot concept. (PX7060 (Naclerio (Illumina) IHT at 192-193.) Dr. Aravanis, who was also instrumentally involved in the creation of GRAIL, similarly testified that he was not aware of any company exploring the development of an NGS-based multicancer screening detection test at that time. (Aravanis (Illumina) Tr. at 1870.)

Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross-examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

22. Subsequent to its acquisition of Verinata, Illumina observed cancer signals in its NIPT tests. (PX2184 (Illumina) at 001 (E-mail from R. Klausner, Illumina, to N. Naclerio, Illumina, Mar. 8, 2014)).

Response to Finding No. 22:

Respondents have no specific response.

23. In mid-2015, a team within Illumina including Jay Flatley assembled a presentation proposing the creation of a new company to develop a blood-based cancer detection test. (PX2007 (Illumina) at 013 (Illumina, ScreenCo Opportunity Overview, July 30, 2015)). The presentation stated: "Illumina is uniquely positioned to pioneer this field today. Forward pricing to ScreenCo enables the R&D to sequence at depths that are cost-prohibitive to others[.]" (PX2007 (Illumina) at 013 (Illumina, ScreenCo Opportunity Overview, July 30, 2015)).

Response to Finding No. 23:

The proposed finding is irrelevant because any special pricing and other benefits Illumina may have provided to GRAIL in its original supply agreement when GRAIL was formed and controlled by Illumina are irrelevant to evaluating the effects of the Transaction on competition. (PFF ¶ 979.) At the time of GRAIL's formation, the objective of creating a cancer screening test was a moonshot concept, and Illumina believed that without deep discounting, it would be impossible for GRAIL to develop a cancer screening test. (PFF ¶¶ 980–980.4.)

The proposed finding is also incomplete and misleading. Although the cited source is from July 2015, the proposed finding appears to suggest that, even today, more than seven years after the cited document was generated, the amount of sequencing required for an MCED test renders it cost prohibitive without "forward pricing". This is incorrect.

As Illumina's contemporaneous internal documents noted, in 2015, Illumina believed that "no customer has the ability to implement a pan-cancer screening test responsibly and economically anytime in the next 5 years"; therefore, to accelerate the growth of the segment, Illumina "felt an imperative to organize an entity" focused on that moonshot mission. (PFF

¶ 980.2 (RX1088 (Illumina) at 7; (PX7079 (Flatley (Illumina) Dep. at 111–12.))) These considerations from the time of GRAIL's formation no longer exist for many reasons, including because the cost of sequencing has come down substantially since 2015. (PFF ¶¶ 21, 981.)

The proposed finding also suggests that cancer detection today requires "sequenc[ing] at depths", which is likewise wrong and outdated. Illumina's assumptions in 2015 about the volume of sequencing required to develop a cancer screening test were significantly higher than what is actually required (PFF ¶ 981 (PX7079 (Flatley (Illumina) Dep. at 118–20.))) For example, GRAIL's Galleri test does not use "ultra-deep sequencing", but relies on targeted methylation for cancer signal detection and localization. *(See, e.g.*, PFF ¶¶ 56, 345, 384, 981, 1289.)

In addition, the proposed finding is incorrect to the extent it suggests that "ScreenCo" (now GRAIL) required and received "forward pricing" to complete its development of Galleri. That is not true. As Dr. Aravanis explained, "the pricing benefits that GRAIL had during the first year [of its existence], which were then eliminated for the majority of its life, ended up having . . . minimal benefit" because "[i]t turned out that the sequencing cost was not that significant in the development of these tests". (PX7065 (Aravanis (Illumina) IHT at 63–64.) In fact, the prices that Illumina charged GRAIL during the time frame of Galleri's development after Illumina no longer held a controlling stake in GRAIL, and today, as well as the price reductions it modelled for GRAIL as part of its modelling the Transaction, serve as the basis for the pricing now available to all test developers through the Open Offer and its universal grid. (PFF ¶ 1023.6.) [redacted]

[redacted] (PFF ¶ ¶ 886–97.)

The proposed finding is also incorrect to the extent it suggests that GRAIL receives more favorable pricing than other putative MCED test developers today. Any customer that signs the Open Offer "shall have access to Volume-Based Net Prices (under Appendix 1)" for sequencing instruments and core consumables "that are no less favorable (i.e., the same or better) than the Volume-Based Net Prices provided to GRAIL". (PFF ¶¶ 1013, 1021.1; deSouza (Illumina) Tr. 2402–03; PX0064 (Illumina) at 7–8.) If a customer chooses Universal Pricing, it will receive "most favored nation" pricing relative to other customers: that customer's prices will be no less favorable than the pricing any other equivalent customer receives. (Berry (Illumina) Tr. 893; PX0064 (Illumina) at 7–8.) Further, if an equivalent customer receives a discretionary discount higher than those listed in the Open Offer, then that discount will be offered to all other equivalent customers. (Berry (Illumina) Tr. 893–94; RX6002 (Guerin-Calvert Trial Dep. at 38–39.)) As an additional protection, under the Open Offer if GRAIL (or another customer) receives more favorable pricing than another customer, then Illumina is required to notify that other customer promptly and to refund any difference. (Berry (Illumina) Tr. 894, 914.)

b) Illumina Formed Grail in 2015-2016

24. Illumina's leadership considered several reasons to form Grail as a separate company, rather than a unit within Illumina. (PX2005 (Illumina) at 012 (Illumina, ScreenCo: Early Cancer Detection on a Global Scale, 2015)). According to a 2015 Illumina presentation, forming a new startup would enable Grail to "retain[] and attract[] best-in-class people through equity, culture, and quality of the science." (PX2005 (Illumina) at 012 (Illumina, ScreenCo: Early Cancer Detection on a Global Scale, 2015)).

Response to Finding No. 24:

Respondents have no specific response except to note that Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial

in this case, (CC Exhibit Index at 4), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also incorporate PFF ¶¶ 40–50 herein.

25. In a July 14, 2015, e-mail, Rick Klausner, Illumina's Chief Medical Officer, wrote to other Illumina executives that creating a separate company would also protect Illumina. (PX2006 (Illumina) at 001 (E-mail from R. Klausner, Illumina, to M. Stapley et al., Illumina, July 14, 2015)).

Response to Finding No. 25:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 4) and did not elicit any testimony regarding the cited language, either from Dr. Klausner or any other witness who was shown this document in any deposition or IH, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also incorporate PFF ¶¶ 40–50 herein.

26. Klausner wrote that creating a separate company would protect Illumina by "[n]ot competing with [Illumina's] customers"; "[b]eing able to fail without consequences to Illumina stock"; and "[b]eing able to create a novel clinical and consumer brand." (PX2006 (Illumina) at 001 (E-mail from R. Klausner, Illumina, to M. Stapley et al., Illumina, July 14, 2015)).

Response to Finding No. 26:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 25 herein. Respondents also incorporate PFF ¶¶ 40–50 herein.

27. Forming a separate company would allow Illumina to attract additional investment for Grail. (PX2006 (Illumina) at 001 (E-mail from R. Klausner, Illumina, to M. Stapley et al., Illumina, July 14, 2015)).

Response to Finding No. 27:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 25 herein. Respondents also incorporate PFF ¶¶ 40–50 herein.

28. Illumina's leadership assessed that creating a separate company would allow Grail to be "more nimble": "make decisions more quickly [and] . . . change directions more quickly." (PX7089 (Naclerio (Illumina) Dep. at 253)).

Response to Finding No. 28:

The proposed finding is incomplete and misleading. Dr. Naclerio later testified that the considerations surrounding GRAIL's formation would not apply today in the context of this Transaction: "[i]t's a very different situation today. I mean now GRAIL is a big, mature, multibillion-dollar company". (PX7089 (Naclerio (Illumina) Dep. at 274.)) Further, Dr. Naclerio testified that the reunification of Illumina and GRAIL "makes a lot of sense for Illumina. And obviously GRAIL thinks it's a good idea, too, otherwise they wouldn't have proposed it". (PX7089 (Naclerio (Illumina) Dep. at 276–77.)) Respondents also incorporate PFF ¶¶ 40–50 herein.

29. In January 2016, Illumina formed Grail as a separate corporate entity. (PX2543 (Illumina) at 001 (Illumina, Grail FAQs, Jan. 11, 2016)). At the time of Grail's creation, Illumina held a controlling stake in Grail. (PX2543 (Illumina) at 001 (Illumina, Grail FAQs, Jan. 11, 2016)).

Response to Finding No. 29:

Respondents have no specific response. Respondents also incorporate PFF ¶¶ 40–50 herein.

30. While Illumina controlled Grail, Illumina provided Grail with "forward pricing." (PX7089 (Naclerio (Illumina) Dep. at 250)). "Forward pricing" meant that Illumina charged Grail what Illumina expected its prices to be a number of years in the future. (PX7089 (Naclerio (Illumina) Dep. at 250)). The impact of providing forward pricing to Grail was that Illumina gave Grail discounts on reagents. (PX7089 (Naclerio (Illumina) Dep. at 251)). Dr. Naclerio negotiated Grail's initial supply agreements for Illumina. (PX7089 (Naclerio (Illumina) Dep. at 250)). Dr. Naclerio stated that it would have been difficult for Grail to develop its MCED test without forward pricing. (PX7060 (Naclerio (Illumina) IHT at 201-202)).

Response to Finding No. 30:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' response to CCFF ¶ 23, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross-examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

31. Illumina formed Grail or "ScreenCo" because the "complexity of cancer biology, number of cancers, combined with multiple technical approaches [would] require significant R&D investment." (PX2005 (Illumina) at 018 (ScreenCo: Early Cancer Detection on a Global Scale Presentation, 2015)).

Response to Finding No. 31:

Respondent have no specific response. Respondents also incorporate PFF ¶¶ 40–50 herein.

32. Illumina incorporated Grail in Delaware in September 2015 as a wholly-owned subsidiary of Illumina. (PX4082 (Grail) at 167, 211 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 32:

Respondents have no specific response.

33. Grail subsequently raised $100 million in Series A financing from investors including Illumina, Arch Ventures, Bill Gates, and Jeff Bezos. (RX0667 (Illumina) at 002 (Email from J. Flatley, Illumina, to W. Rastetter, Illumina, attaching "Illumina Forms New Company to Enable Early Cancer Detection via Blood Based Screening," Jan. 10, 2016; PX2069 (Illumina) at 005 (Python Board Approval, Dec. 20, 2015)).

Response to Finding No. 33:

Respondents have no specific response.

34. By forming Grail, Illumina assessed that it could "capitalize on [the] screening market years earlier AND own a substantial portion of the value created." (PX2069 (Illumina) at 018 (Python Board Approval, Dec. 20, 2015)).

Response to Finding No. 34:

The proposed finding is incomplete in that it omits that, as stated on the cited slide, Illumina also assessed that its formation of GRAIL would "accelerate[] development of the market" years earlier than it otherwise might have developed, possibly by "10 years". (PX2069 (Illumina) at 018 (Python Board Approval, Dec 20, 2015.)) As Jay Flatley, Illumina's CEO in 2015, testified, "we wanted to accelerate it for two reasons. Obviously we had economic advantage to accelerate it, but back to our earliest discussion today, it's the advantage of saving lives. The earlier we can get this to market, the more lives we're going to save and it's going to bend the curve of cancer mortality dramatically in our view". (PX7079 (Flatley (Illumina) Dep. at 111–112).) Respondents also incorporate PFF ¶¶ 40–50 herein.

35. [redacted] (PX2069 (Illumina) at 005-006 (Python Board Approval, Dec. 20, 2015) (*in camera*)).

Response to Finding No. 35:

Respondents have no specific response.

36. In an internal 2015 document, Illumina identified preferential, low-cost access to Illumina sequencing technology as a competitive advantage for Grail: Grail "is uniquely positioned to pioneer this field . . . at depths that are cost prohibitive for others." (PX2005 (Illumina) at 009 (ScreenCo: Early Cancer Detection on a Global Scale, 2015); *see* PX2069 (Illumina) at 018 (Python Board Approval, Dec. 20, 2015) (identifying the "cost of sequencing" as the first among four "most significant barriers and drivers of liquid biopsy innovation and adoption")).

Response to Finding No. 36:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' response to CCFF ¶ 23, which Respondents incorporate herein.

37. Illumina initially offered a 75 percent discount on Illumina products for use in Grail's "Foundational Study and commercial screening." (PX2557 (Illumina) at 017 (Minutes of the Meeting of the Board of Directors of Illumina, Inc., Dec. 20, 2015).

Response to Finding No. 37:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' response to CCFF ¶ 23, which Respondents incorporate herein.

Respondents also note that Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 23), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

38. Illumina forecast that the 75 percent discount offered to Grail would generate approximately "$100M savings to Python [Grail] over [the] first 3 years." (PX2557 (Illumina) at 017 (Minutes of the Meeting of the Board of Directors of Illumina, Inc., Dec. 20, 2015)).

Response to Finding No. 38:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' response to CCFF ¶ 23, which Respondents incorporate herein.

Respondents further note that Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 23), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

39. As set forth in Section VII.D.1. below, contemporaneous statements and testimony from Illumina executives as well as ordinary course documents show that Illumina identified tools that could favor its then-subsidiary Grail relative to its rivals and that the Illumina-Grail relationship changed from collaborator to customer following the spinoff of Grail.

Response to Finding No. 39:

The proposed finding is inaccurate, incomplete and misleading for numerous reasons, including because there were no rivals to GRAIL at the time (PFF ¶ 980.2); any special pricing Illumina provided to GRAIL at that time was a benefit of its vertical integration, not a harm, that

has helped accelerate patient access to an MCED test by years (PFF ¶¶ 980.2–980.4.); Complaint Counsel confuses the facts and mischaracterizes the documents relating to Illumina's collaboration with GRAIL prior to the spin-off (PFF ¶¶ 979–81.); and the Open Offer ensures that no customer is anticompetitively disadvantaged as a result of the Transaction (*See* PFF ¶¶ 1000–57.1.) To the extent Complaint Counsel relies on its Proposed Findings in Section VII.D.1 (CCFF ¶¶ 3669–3748), Respondents incorporate their responses to those Proposed Findings herein.

3. Spin-off of Grail (Reducing Ownership to Less Than 50%)

40. [redacted] (PX4082 (Grail) at 211 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, Morgan Stanley, attaching Grail 2020 S-1/Amended, Sept. 2020); PX6049 (Grail) at 103 (Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 40:

The proposed finding is vague and ambiguous as to the definition of [redacted]. To position GRAIL for its moonshot objective, Illumina seeded GRAIL with the talent, R&D capabilities, development plans and data it would need to investigate how to use NGS technology for multi-cancer early detection through foundational, population-scale trials. (PFF ¶ 47; PX7107 (deSouza (Illumina) Dep. at 182–83.))

41. [redacted] (PX6049 (Grail) at 103 (Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 41:

Respondents have no specific response.

42. [redacted] (PX0054 (Grail Closes Over $900 Million Initial Investment in Series B Financing to Develop Blood Tests to Detect Cancer Early, Mar. 1, 2017 (*in camera*)); *see also* deSouza (Illumina) Tr. 2202).

Response to Finding No. 42:

Respondents have no specific response.

43. [redacted] (deSouza (Illumina) Tr. 2202, 2453; PX6049 (Grail) at 103 (Narrative Response to Second Request, Mar. 1, 2021 (*in camera*)); PX2541 (Illumina) at 004 (Interim Review: K2-Grail, Feb. 2, 2017) (*in camera*)).

Response to Finding No. 43:

Respondents have no specific response except note that although Illumina reduced its investment in GRAIL in 2017, Illumina remained invested in GRAIL's success, not just through its equity stake in GRAIL (around 12% of GRAIL's outstanding shares on a fully diluted basis before the Transaction closed), but also in that Illumina has a long-term agreement to supply GRAIL with NGS instruments and reagents for its genomic testing needs, pursuant to which, prior to the close of the Transaction, Illumina had the right to receive approximately [redacted] of all future net sales of any GRAIL oncology products or services. (PFF ¶ 50; [redacted] *see also* Aravanis (Illumina) Tr. 1876–77; RX3984 (Illumina) at 14–15.))

44. Illumina sold Grail to outside investors in 2017 because the amount of investment required to develop Grail's MCED test was "untenable." (PX7057 (Flatley (Illumina) IHT at 157-60)).

Response to Finding No. 44:

The proposed finding is incomplete and misleading to the extent it suggests that the only reason the Illumina sold GRAIL to outside investors is because of the amount of investment required. Further, Illumina remained invested in GRAIL's success, not just through its equity stake in GRAIL (around 12% of GRAIL's outstanding shares on a fully diluted basis before the Transaction closed), but also in that Illumina has a long-term agreement to supply GRAIL with

NGS instruments and reagents for its genomic testing needs, pursuant to which, prior to the close of the Transaction, Illumina had the right to receive approximately [redacted] of all future net sales of any GRAIL oncology products or services. (PFF ¶ 50; [redacted] *see also* Aravanis (Illumina) Tr. 1876–77; RX3984 (Illumina) at 14–15.))

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross-examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate PFF ¶¶ 40–50 herein.

45. Illumina CEO Francis deSouza testified that Illumina's 2017 reduction of its interest in Grail changed Illumina's relationship from an affiliate relationship to a customer relationship. (DeSouza (Illumina) Tr. 2207).

Response to Finding No. 45:

Respondents have no specific response except incorporate their responses to CCFF ¶ 43 herein. Respondents also incorporate PFF ¶¶ 40–50 herein.

46. After the 2017 financing round, Illumina ceased providing special discounts to Grail. (DeSouza (Illumina) Tr. 2207).

Response to Finding No. 46:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' response to CCFF ¶ 23, which Respondents incorporate herein.

The proposed finding is also vague and ambiguous as to the meaning of "special". Mr. deSouza testified that Illumina provided GRAIL with "deeper" discounts before the 2017 financing round. (deSouza (Illumina) Tr. 2207.)

47. An Illumina investor Q&A document reviewed by Jay Flatley states that Illumina's reduction of its stake in Grail "actually leveled the playing field" for Illumina's other customers. (PX2406 (Illumina) at 005 (E-mail from J. Flatley, Illumina, to F. deSouza et al., Illumina, Jan. 2, 2017)).

Response to Finding No. 47:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 23 and 46, which Respondents incorporate herein.

The proposed finding is also incomplete and misleading because it omits Mr. Flatley's testimony concerning what he meant by the quoted language. Mr. Flatley explained that what he meant with this language is that "if GRAIL has the constraints taken off it in terms of field of use, it could now compete against customers where in the earlier format [before the spin-off] they could not have because the field was constrained". (PX7079 (Illumina) Dep. at 174.) Mr Flatley went on to explain that, prior to the spin-off, the question regarding the creation of an entity that would compete with customers more broadly in liquid biopsy was not a consideration because GRAIL was constrained to developing only an MCED test, "there were no customers in the screening market" and "there was a market that didn't exist and still doesn't, so there are no customers in the screening market". (PX7079 (Illumina) Dep. at 175.)

The proposed finding is also misleading to the extent it suggests that GRAIL will receive access to sequencing instruments and core consumables, as well as associated services, that are unavailable to other putative MCED test developers. This is incorrect. Any customer that signs the Open Offer shall have the same access to services that GRAIL or any other For-Profit Entity has access to, at the same prices. (PFF ¶ 1004; [redacted] Berry (Illumina) Tr. 865–66; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.).) Similarly, the Open Offer provides customers the same access to purchase sequencing instruments and core consumables to which GRAIL has access. (PFF ¶ 1005; [redacted]; Berry (Illumina) Tr. 878–79; deSouza (Illumina) Tr. 2434–35, 2437–38; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) Further, the timing of the access to these

services and sequencing products shall be the same for GRAIL as it is for its putative rivals: the Open Offer requires that "Customer shall have access to the Supplied Products for purchase that GRAIL . . . has access, within 5 days of when GRAIL . . . is offered such access (if not earlier) for purchase". (PFF ¶ 1005.1; RX3935 (Illumina) at 2.)

Respondents also note that in the context of this document, [redacted] (PX7107 (deSouza (Illumina) Dep. at 225-26).)

48. Prior to Illumina's reduction in its interest in Grail, "[Grail] had access to technology and pricing that was preferential to [Illumina's] customers." (PX2406 (Illumina) at 005 (E-mail from J. Flatley, Illumina, to F. deSouza et al., Illumina, Jan. 2, 2017)).

Response to Finding No. 48:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 23 and 47, which Respondents incorporate herein.

49. After Illumina's reduction of its stake in Grail, Grail had "access to technology on [the] same terms and price as [Illumina's] other large customers." (PX2406 (Illumina) at 005 (E-mail from J. Flatley, Illumina, to F. deSouza et al., Illumina, Jan. 2, 2017)). The Illumina Q&A document states that Illumina "believe[d] that this [would] accelerate the liquid biopsy market for all." (PX2406 (Illumina) at 005 (E-mail from J. Flatley, Illumina, to F. deSouza et al., Illumina, Jan. 2, 2017)).

Response to Finding No. 49:

The proposed finding is irrelevant because any special pricing and other benefits Illumina may have provided to GRAIL in its original supply agreement when GRAIL was formed and controlled by Illumina are irrelevant to evaluating the effects of the Transaction on competition. (PFF ¶ 979.) At the time of GRAIL's formation, the objective of creating a cancer screening test was a moonshot concept, and Illumina believed that without deep discounting, it would be impossible for GRAIL to develop a cancer screening test. (PFF ¶¶ 980–980.4.)

The proposed finding is incomplete and misleading. Respondents incorporate their responses to CCFF ¶ 47 herein.

50. By 2017, Grail had expanded its clinical trials from one study involving 50,000 individuals to five clinical trials involving over a million individuals. (PX2149 (Illumina) at 002-003 (Email from M. Stapley, Illumina, to D. Moriarty, Illumina, attaching Grail white paper, Sep. 24, 2016)).

Response to Finding No. 50:

Respondents have no specific response.

51. As a result of Grail expanding its clinical trials, Grail's research and development projections moved back by two years and its associated costs increased from approximately $400 million to $1.5 billion. (PX7057 (Flatley (Illumina) IHT at 158-159)).

Response to Finding No. 51:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross-examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate PFF ¶¶ 40–50 herein.

52. According to former CEO and Board Chairman, Mr. Jay Flatley, in light of Illumina's control of Grail, Grail's increased spending without corresponding revenues would have significantly diluted Illumina's reported earnings. (PX7079 (Flatley (Illumina) Dep. at 146-147)).

Response to Finding No. 52:

Respondents have no specific response. Respondents also incorporate PFF ¶¶ 40–50 herein.

53. According to former Illumina CEO and board chairman Jay Flatley, Illumina's board determined that that its shareholders would not have tolerated this magnitude of dilution from Grail spending without corresponding revenues. (PX7057 (Flatley (Illumina) IHT at 159)).

Response to Finding No. 53:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross-examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶ 52, and PFF ¶¶ 40–50 herein.

54. In a November 4, 2016 email, Mr. Flatley explained to a Grail executives that "[Illumina had] concerns that relinquishing control of Grail could result in the "[l]oss of [h]uge [u]pside potential in market value of GRAIL," the "[l]oss of [r]oyalty future value to [Illumina]," and a potential "[i]mpact to [Illumina's] external credibility." (PX2411 (Illumina) at 002 (Email from J. Flatley, Illumina, to J. Huber, Grail, et al., Nov. 4, 2016)).

Response to Finding No. 54:

The proposed finding is not supported by the cited source because the cited evidence does not contain the words "concerns that relinquishing control of Grail could result in the". Respondents also incorporate PFF ¶¶ 40–50 herein.

55. Francis deSouza stated publicly in June 2017:

> There are 70-plus players now in the liquid biopsy space. We want to encourage them to look at all different avenues because this is important and the outcome's terrific for mankind. There are different points of view. There are companies that believe it's going to be a combination of ultra-deep screening of the blood samples plus tissue, whole transcriptome analysis to identify tissue of origin. And to be honest, I think people are approaching it slightly differently and the market will sort of determine where the biology is and what the right answer is. In every case though, we're talking about a lot of sequencing.

(PX0376 at 007 (Illumina Inc. at Goldman Sachs Global Healthcare Conference, FD (Fair Disclosure) Wire, Conference Call Transcript, June 13, 2017)).

Response to Finding No. 55:

Respondents have no specific response except to note that, to the extent the proposed finding is meant to imply that today—five years after Mr. deSouza's quoted statement—the landscape for liquid biopsy testing is the same as it was in 2017, the implication is false and there is no support for it. Respondents also note that Complaint Counsel chose not to discuss this

document at trial, (CC Exhibit Index at 3), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

56. At the same conference, deSouza stated of the liquid biopsy market: "[W]e want to encourage that market because that market, I think, is very promising from a patient perspective, but it uses a lot of sequencing." (PX0376 at 007 (Illumina Inc. at Goldman Sachs Global Healthcare Conference, FD (Fair Disclosure) Wire, Conference Call Transcript, June 13, 2017)).

Response to Finding No. 56:

Respondents note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 3), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

57. Mr. Flatley testified that, prior to the spin-off of Grail, Illumina was hesitant to "go after markets . . . using a subsidiary of Illumina . . . that could compete more favorably with existing customers [Illumina] had in the marketplace." (PX7057 (Flatley (Illumina) IHT at 166)).

Response to Finding No. 57:

The proposed finding is incomplete and misleading in that it omits and mischaracterizes Mr. Flatley's testimony and the relevant facts. Mr. Flatley made it clear that he was not talking about the MCED space when referring to Illumina's hesitancy to "go after markets . . . using a subsidiary of Illumina". Rather, he explained that this concern related to Illumina competing with customers in mature, existing markets, but those same considerations did not apply to a nascent space like the MCED space. As to the MCED space, Mr. Flatley explained that, "this market did not exist – it still doesn't exist" and Illumina "had decided that we were going to focus on enabling new markets in – and in those cases Illumina could put application and sample prep products into the market. And we've done that in our history. We did it in, you know – in the DTC area. We did it with a company called Helix that we spun out. We were doing it here.

And those activities were to create markets where they otherwise would not get created or take many, many more years to get created. And so that's why" Illumina participated in nascent markets but not in mature markets. (PX7057 (Flatley (Illumina) IHT at 165–68.)

Further, the Proposed Finding is incomplete and misleading because Illumina's views at the time of the spin-off of GRAIL in 2017 are irrelevant to evaluating the effects of the Transaction on competition today, including because the evidence shows Illumina firmly believes the Transaction will not harm any of its customers, Illumina has no incentive to harm any customer, and the terms of the Open Offer guarantee Illumina cannot anticompetitively disadvantage any for profit oncology customer. (PFF ¶¶ 847–51, 1000–57.) The surge of investment in NGS-based liquid biopsy tests since the announcement of the Illumina/GRAIL merger agreement further rebuts any notion that the Transaction risks deterring Illumina customers from developing tests for Illumina's platform. (PFF ¶¶ 927–42.)

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross-examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

58. According to Illumina's former CEO and board member Jay Flatley, Illumina determined that its customers might not want to participate in markets where Illumina had a presence, in part "because they'd believe that Illumina could always underprice them if we wanted to." (PX7057 (Flatley (Illumina) IHT at 167).)

Response to Finding No. 58:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 23 and 57, which Respondents incorporate herein.

59. In a 2017 presentation to Sands Capital Management, Illumina told investors "We spun out Grail to encourage investment into many different NGS-based companies focused on early cancer detection to have as many shots on goal as possible." (PX2561 (Illumina) at 017 (Email from J. Cunningham, Illumina, to F. deSouza, Illumina, Oct. 30, 2020, attaching Sands Capital Management Call); deSouza (Illumina) Tr. 2204-5).

Response to Finding No. 59:

The proposed finding is incomplete and misleading. Mr. deSouza testified that early cancer detection screening companies would have "shots on goal" independent of whether Illumina spun GRAIL out or not. (deSouza (Illumina) Tr. 2204.) He further clarified that this language referred to the fact that Illumina wanted to see which scientific and technical approach to early cancer screening would be the "right way to go" because, at the time, given the nascent nature of the endeavor, it was not clear to any market participant what the best way to proceed was. (deSouza (Illumina) Tr. 2204.)

60. [redacted] (Respondents' Pretrial Brief at 2, Aug. 18, 2021; *see also* PX4291 (Grail) [redacted] (*in camera*) [redacted]

Response to Finding No. 60:

Respondents have no specific response.

61. Illumina stated in internal Q&A bullets that divesting Grail would "accelerate the liquid biopsy market for all." (PX2406 (Illumina) at 005 (email from J. Flatley, Illumina, to E. Endicott, Illumina, Jan. 2, 2017, attaching Illumina/Grail Q&A, Jan. 2, 2017)).

Response to Finding No. 61:

The proposed finding is incomplete and misleading. Mr. deSouza testified that he understood the language quoted by Complaint Counsel to refer to the fact that by investing in a company that was developing a liquid biopsy test Illumina signaled to the investment community that liquid biopsy was a valid investment. (deSouza (Illumina) Tr. 2206–208.) Such a signal from a company of Illumina's reputation would encourage further investment in the space, thereby accelerating the market for all. (deSouza (Illumina) Tr. 2206–208.) Respondents also incorporate their responses to CCFF ¶¶ 57 and 59, and PFF ¶¶ 40–50 herein.

62. [redacted] (*in camera*); PX6049 (Grail) at 031 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)). [redacted] (RX1371 (Illumina) at 010–12 [redacted] (*in camera*)).

Response to Finding No. 62:

Respondents have no specific response.

63. As noted in Illumina's Board Minutes, when Illumina owned a majority stake in Grail Illumina provided Grail with preferential terms and agreed not to "launch, invest in, or provide special discounts to competitive business[es]." (PX2557 (Illumina) at 017 (Minutes of the Meeting of the Board of Directors of Illumina, Inc., Dec. 20, 2015); PX2541 (Illumina) at 008 (Interim Review K-2 Grail presentation, Feb. 2, 2017)).

Response to Finding No. 63:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 23 and 47, which Respondents incorporate herein.

Respondents further note that Complaint Counsel did not present PX2557 to any fact witness during discovery or at trial in this case, (CC Exhibit Index at 23), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

64. As an independent company, Grail will move from a "collaborator" in assay development and software and data analysis to merely a "customer." (PX2541 (Illumina) at 008 (Interim Review K-2 Grail presentation, Feb. 2, 2017)).

Response to Finding No. 64:

The proposed finding is incomplete and misleading.

First, the only witness questioned about the cited document was Mr. deSouza, and as to that document, he testified: [redacted]

[redacted]

Second, Dr. Aravanis made clear in his testimony that the K2 collaboration referenced in the cited exhibit was not an MCED test, but a potential therapy selection test. As Dr. Aravanis explained, [redacted] Therefore, to be [redacted] "the technical improvements that GRAIL made to this one technical approach around these names here, K2/Napa, would be shared with Illumina so as to not have redundant research and development around that approach". (PX7065 (Aravanis (Illumina) IHT at 56–60.) Dr. Aravanis also explained that, to achieve those operational efficiencies, Illumina made "some minor alterations to the reagents for the purposes of developing this assay", and ultimate, "the discussion about the K2/Napa activity was a very minor, minor part of the R&D activities at GRAIL and a very minor, minor part of the R&D activities at Illumina when put in context of the overall R&D activities and overall activities of the company almost – again, kind of a very early, minor activity in the company's history . . . ." (PX7065 (Aravanis (Illumina) IHT at 60–61); *see also* PX7048 (Klausner (GRAIL) IHT at 120–121, 128 (describing agreement between GRAIL and Illumina whereby GRAIL agreed to finish work related to a therapy selection test that Illumina

(now GRAIL) employees had been working on prior to GRAIL's spinoff and deliver the results back to Illumina).)

Third, there is nothing anticompetitive about Illumina collaborating with GRAIL in ways it has not and would not with an arm's-length customer; to the contrary, that is an efficiency of vertical integration that benefits competition and consumers. To the extent the proposed finding is meant to suggest otherwise, it is wrong. Further, under the Open Offer, upon customer request, Illumina must enter into a development agreement on commercially reasonable terms relating to the design or modification of sequencing products to optimize interoperability with the customer's tests. (*See* PFF ¶¶ 1005, 1008, 1010.) Illumina has not historically collaborated with customers on such optimization, and so, in this regard, customers who see value in optimization are better off under the Open Offer than they were under the pre-Transaction status quo. (PFF ¶¶ 1010.3–10.10.)

Respondents also incorporate their responses to CCFF ¶ 47 herein.

65. Prior to Illumina spinning Grail out, Illumina treated Grail as a "collaborator" co-developing Grail's project development process, assay development workflow, software and data analysis, and designed a kit specially for Grail. (PX2541 (Illumina) at 008 (Interim Review K-2 Grail presentation, Feb. 2, 2017)).

Response to Finding No. 65:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' response to CCFF ¶ 64, which Respondents incorporate herein.

66. Illumina's ordinary course documents charted the "[c]hanging business dynamic" between Illumina and Grail after the spinoff. The "[c]hanging business dynamic will result in Illumina functioning as a supplier compared to a product development partner," noting that Grail will shift from being a "collaborator" to a "customer." In this relationship, Illumina would limit their assistance in Grail's project development process, assay development workflow, and software and data analysis. (PX2541 (Illumina) at 008, 010 (Interim Review K-2 Grail presentation, Feb. 2, 2017 ("Illumina and Grail no longer collaborating on developing [library prep] and sequencing kits"))).

Response to Finding No. 66:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' response to CCFF ¶ 64, which Respondents incorporate herein.

67. After the spinoff, Illumina provided Grail "RUO kits" instead of the customized kits Grail was originally receiving. (PX2541 (Illumina) at 008, 014 (Illumina, Interim Review K-2 Grail presentation, Feb. 2, 2017)).

Response to Finding No. 67:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' response to CCFF ¶ 64, which Respondents incorporate herein.

68. [redacted] (Berry (Illumina) Tr. 988 (*in camera*)).

Response to Finding No. 68:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' response to CCFF ¶ 64, which Respondents incorporate herein.

B. GRAIL

69. Grail's principal office and laboratory is located in Menlo Park, CA. (PX4082 (Grail) at 130 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 69:

Respondents have no specific response.

70. Aaron Freidin, Grail SVP of Finance, testified that Grail has completed four separate rounds of financing. (Freidin (Grail) Tr. 3015-16).

Response to Finding No. 70:

Respondents have no specific response.

71. [redacted] (PX4082 (Grail) at 086 (Email attaching Grail 2020 S-1/Amended, Sept. 2020); Freidin (Grail) Tr. 3015-16; PX5023 (Illumina) at 003 (Illumina, Project Grail, Phil Febbo & Corporate Development, Mar. 2020) (*in camera*)).

Response to Finding No. 71:

Respondents note that PX5023 (Illumina) was never used at trial (CC Exhibit Index at 54), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

[redacted] In order for GRAIL, and now Illumina, to [redacted] (PX7138 (Scott Morton Trial Dep. at 319.) Mr. Freidin testified that the Transaction would allow GRAIL to feel secure about its future funding and it would de-risk capital needs and accelerate GRAIL's ability to put capital to work. (Freidin (GRAIL) Tr. 2999.) As a witness from Morgan Stanley testified to at trial, [redacted] (Strom (Morgan Stanley) Tr. 3495-3500.) Even if GRAIL were to successfully raise capital through the capital markets, it would not come with all the expertise and infrastructure that Illumina has. (Freidin (GRAIL) Tr. 3008-10.)

72. [redacted] (PX5045 (Grail) at 014 (Grail, Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 72:

Respondents have no specific response.

73. Grail has employees across a diverse range of functions including R&D, sales, market access, and government and regulatory affairs. (RX0874 (Grail) at 001 (Grail Organizational Structure, Aug. 26, 2020)).

Response to Finding No. 73:

The proposed finding is incomplete and misleading. RX0874 (GRAIL) does not show how many people report to the individuals listed in the organizational chart. (RX0874 (GRAIL) at 001.) The organizational chart also shows that, as of August 26, 2020, GRAIL was still searching for a Vice President of Marketing. (RX0874 (GRAIL) at 001.)

Moreover, several witnesses have testified to GRAIL's relatively small team. Dr. Deverka testified**:** [redacted] Mr. Freidin testified that GRAIL only has about 10-20 employees in the U.K. facilitating their only international study. (Freidin (GRAIL) Tr. 3008.)

1. Grail's Galleri MCED Test

74. Grail's flagship test is its MCED test, called Galleri. (RX3256 (Grail, *Our Products*, https://grail.com/our-products) (last visited Aug. 12, 2021); RX3255 (Grail, *The Galleri Test,* https://www.galleri.com/the-galleri-test) (last visited Aug. 12, 2021)).

Response to Finding No. 74:

Respondents have no specific response except to note that RX3255 (GRAIL) and RX3256 (GRAIL) were never used at trial (Resps.' Exhibit Index at 153), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

a) Galleri Is an MCED Test Designed To Be Used by Asymptomatic Individuals

75. [redacted] (PX6049 (Grail) at 012 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*); *see also* PX4572 (Grail) at 006, 032 (Grail, Early Cancer Detection: Investor Presentation, Dec. 2020) (*in camera*)).

Response to Finding No. 75:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss PX4572 (GRAIL) and PX6049 (GRAIL) at trial, (CC Exhibit Index at 53, 55), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

76. Dr. Ofman testified that the Galleri test is intended to be used as a screening test for asymptomatic populations. (Ofman (Grail) Tr. 3431.)

Response to Finding No. 76:

Respondents have no specific response.

77. [redacted] (RX3255 (Grail, *The Galleri Test,* https://www.galleri.com/the-galleri-test) (last visited Aug. 12, 2021); (Jamshidi (Grail) Tr. 4042-43 (*in camera*)).

Response to Finding No. 77:

Respondents have no specific response, except to note that Galleri also uses DNA methylation patterns to predict where the cancer came from in the body (*i.e.*, the molecular cancer signal of origin.) (Ofman (GRAIL) Tr. 3287.) "[Galleri] looks at over a million of these methylation sites in over a hundred thousand regions of the genome. And so then you take these patterns, and [subject them] across cancer types and across cancer stages to train a machine learning algorithm to discriminate what is a cancer signal from what is a noncancer signal. And we made sure that the control group had lots of confounding indications and diseases to create a lot of biological noise so that our classifier was effectively trained and we didn't have models

that were overfit. So once you subject these patterns to the machine learning algorithm, it will classify the pattern as either a cancer-like signal or a noncancer signal. And then if a cancer signal gets detected, the patterns then get subjected to a second step, which is another classifier, which looks and weights different features from these patterns to predict the tissue of origin or where this cancer signal came from in the body, so we call it a cancer signal origin or a tissue of origin"..) Respondents also note that Complaint Counsel chose not to discuss RX3255 (GRAIL) at trial (Resps.' Exhibit Index at 153), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

78. [redacted] (Jamshidi (Grail) Tr. 4032 (*in camera*)).

Response to Finding No. 78:

Respondents have no specific response.

79. Grail claims that Galleri has the ability to detect over 50 cancers from a single blood draw. (RX3256 (Grail, *Our Products*, https://grail.com/our-products) (last visited Aug. 12, 2021); RX3255 (Grail, *The Galleri Test,* https://www.galleri.com/the-galleri-test) (last visited Aug. 12, 2021); *see infra* Section X, Appendix B (Galleri Has Not Been Clinically Shown to Provide Early Detection of More Than 50 Cancers in an Asymptomatic Population))).

Response to Finding No. 79:

Respondents have no specific response except to note that the use of the term "claim" is misleading. GRAIL has demonstrated that the Galleri test can identify over 50 cancer types, over 45 of which lack recommended screenings. (PX0043 (GRAIL) at 5, 97; *see also* Ofman (GRAIL) Tr. 3312; PFF, Section I.A.) To the extent Complaint Counsel relies on its Proposed Findings in CCFF Section X, Appendix B (CCFF ¶¶ 6206–6394), Respondents incorporate their responses to those Proposed Findings herein.

Respondents also note that Complaint Counsel chose not to discuss RX3255 (GRAIL) and RX3256 (GRAIL) at trial (Resps.' Exhibit Index at 153), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

80. Grail has not presented clinical evidence that Galleri can provide "early detection" of more than 50 cancer types. (*See* Section X, Appendix B (Galleri Has Not Been Clinically Shown to Provide Early Detection of More Than 50 Cancers in an Asymptomatic Population) below)).

Response to Finding No. 80:

The proposed finding is incorrect, incomplete, misleading and contrary to the weight of the evidence. To the extent Complaint Counsel relies on its Proposed Findings in CCFF Section X, Appendix B (CCFF ¶¶ 6206–6394), Respondents incorporate their responses to those Proposed Findings herein.

81. To date, Grail has presented clinical evidence that the Galleri test can detect seven types of Stage I-III cancer in an asymptomatic screening population. (Cote Tr. 4000-01; RX3041 at 005 (Interim Results of Pathfinder, June 4, 2021) (showing seven cancers as being detected in stages one through three: head and neck, liver/bile duct, lung, lymphoma, ovary, pancreas, and small intestine); *see generally* Section X, Appendix B (Galleri Has Not Been Clinically Shown to Provide Early Detection of More Than 50 Cancers in an Asymptomatic Population) below)).

Response to Finding No. 81:

The proposed finding is incorrect, incomplete, misleading and contrary to the weight of the evidence. Respondents incorporate their responses to CCFF Section X, Appendix B (CCFF ¶¶ 6206–6394) herein.

82. [redacted] (PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 82:

The proposed finding is incomplete and misleading. Dr. Ofman testified at trial that [redacted] Illumina is highly experienced in obtaining FDA approval. (RX6001 (Deverka Trial Dep. 62–64, 65); Febbo (Illumina) Tr. 4319, 4338–43, 4347, [redacted]; Qadan (Illumina) Tr. 4113–14.) Numerous Illumina and GRAIL fact witnesses testified that the reunion of Illumina and GRAIL will accelerate Galleri's path to FDA approval. (Aravanis (Illumina) Tr. 1945, 1948; Febbo (Illumina) Tr. 4345–46, 4360; Flatley (Illumina) Tr. 4082; Bishop (GRAIL) Tr. 1417; [redacted]; Friedin (GRAIL) Tr. 2980); [redacted] Echoing this unrefuted fact testimony, Dr. Deverka testified that the reunion of Illumina and GRAIL will accelerate FDA approval. (RX6001 (Deverka Trial Dep. at 62–64, 81; RX3867 (Deverka Expert Report ¶ 121.))

83. [redacted] (PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 83:

The Respondents have no specific response, except to note [redacted]

[redacted]

b) Galleri Launched as an LDT in April 2021

84. [redacted] (PX4171 (Grail) at 030 (Grail Board of Directors Meeting Presentation, Aug. 20, 2019) (*in camera*)).

Response to Finding No. 84:

Respondents have no specific response, except to note Dr. Ofman's testimony that breakthrough device designation does not guarantee approval from the FDA for a device. (Ofman (GRAIL) Tr. 3305.)

85. [redacted] (PX4213 (Grail) at 005 [redacted] (*in camera*); *see* PX4160 (Grail) at 094 (Grail, Board Session Meeting Materials, Nov. 10, 2020) (*in camera*) [redacted]).

Response to Finding No. 85:

The proposed finding is incomplete and misleading. [redacted]

Respondents also incorporate their responses to CCFF ¶ 83 herein.

Respondents note that Complaint Counsel chose not to discuss PX4160 (Grail) with any fact witness at trial (CC Exhibit Index at 38), or in any deposition, and therefore, the document

should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

86. [redacted] (PX6061 (Grail) at 013 (Grail, Responses and Objections to the Federal Trade Commission's First Set of Interrogatories, May 3, 2021) (*in camera*)).

Response to Finding No. 86:

The proposed finding is incomplete and misleading. Galleri was offered on a limited basis in April 2021 and was launched as an LDT in June 2021. (RX3279 (GRAIL) at 2-3); Bishop (GRAIL) Tr. 1322.)

87. [redacted] (PX6049 (Grail) at 020 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*); *see also* PX5044 (Grail) at 003 (Grail LRP Review, Aug. 20, 2020) (*in camera*) [redacted]

Response to Finding No. 87:

The proposed finding is incomplete and misleading. Several fact witnesses testified about how GRAIL has encountered delays and may encounter substantial delays in its clinical studies which may make it unable to complete its clinical studies on the timelines it expects. That could materially and adversely impact its ability to launch its products and seek regulatory clearance or approval. (PX0043 (GRAIL) at 11, [redacted] PX7104 (Aravanis (Illumina) Dep. at 75–76, 268–69); [redacted]

88. To sell the Galleri test as an LDT, Grail is targeting large, self-insured employers; concierge medicine practices; executive health programs; and other physicians whose clients have the financial means to enroll in preventative health programs. (PX4082 (Grail) at 009, 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 88:

Respondents have no specific response, except to note that it is in GRAIL's interest to seek wider adoption of Galleri and Illumina can help GRAIL reach that goal. (Bishop (GRAIL) Tr. 1405–06.) Widespread market access to Galleri will depend on FDA, CMS and payor approval. (Bishop (GRAIL) Tr. 1343–45); Conroy (Exact/Thrive) Tr. 1734–35; Gao (Singlera) Tr. 2889–91; [redacted] Rabinowitz (Natera) Tr. 298–99.) Although GRAIL would prefer to sell to a wider audience, at present, Galleri is currently selling for $950, a price that many individuals cannot afford. (deSouza (Illumina) Tr. 2342.) [redacted]

89. [redacted] (PX6061 (Grail) at 043 (Grail, "Responses and Objections to the Federal Trade Commission's First Set of Interrogatories," May 3, 2021) (*in camera*)).

Response to Finding No. 89:

The proposed finding is incomplete and misleading. [redacted]

90. As of trial, Grail [redacted] (Ofman (Grail) Tr. 3372, 3374-75 (*in camera*); *see also* Bishop (Grail) Tr. 1332-33 [redacted]

Response to Finding No. 90:

Respondents have no specific response, except to note that at the time of trial, GRAIL had only sold around 3,000 Galleri tests. (Freidin (GRAIL) Tr. 2969.) [redacted]

91. [redacted] (Della Porta (Grail) Tr. 464; Ofman (Grail) Tr. 3372 (*in camera*); *see also* Bishop (Grail) Tr. 1333 [redacted]

Response to Finding No. 91:

Respondents have no specific response, except to note that at the time of trial, GRAIL had only sold around 3,000 Galleri tests. (Freidin (GRAIL) Tr. 2969.)

92. At trial, Illumina and Grail's CEOs testified that Grail's Galleri test cost $949 out of pocket. (Bishop (Grail) Tr. 1322, 1404; deSouza (Illumina) Tr. 2342).

Response to Finding No. 92:

Respondents have no specific response except incorporate their responses to CCFF ¶ 88.

93. In the September 21, 2020 investor call where Illumina CEO Francis deSouza announced that Illumina would acquire Grail, deSouza stated that the price of Galleri would start at $1,200. (PX2575 (Illumina) at 070 (Illumina M&A Call, Sept. 21, 2020)).

Response to Finding No. 93:

The proposed finding is incomplete and misleading. During the September 21, 2020 Illumina M&A Call, Mr. deSouza made various assumptions in connection with the price of Galleri. Specifically, he stated on that call: "[The cancer screening] market is expected to grow quickly to about 150 million tests in 2035, a 75% CAGR, to approximately $46 billion. This assumes an ASP that starts around $1,200 and trends to about $300 in 2035 as we scale and drive

adoption with increasingly accessible pricing". (PX2575 (Illumina) at 070.) In this statement, Mr. deSouza did not state that the price of Galleri would start at $1,200, as the proposed finding suggests. On the contrary, he specifically indicated that the goal is to provide "increasingly accessible pricing". (PX2575 (Illumina) at 070.) Mr. deSouza even testified at trial that the Transaction would lead to lower prices for customers because of Illumina's ability to buy products more cheaply. (deSouza (Illumina) Tr. 2370.)

94. Grail Chief Medical Officer Joshua Ofman testified: "we don't expect that large U.S. payers are going to provide coverage for the [Galleri] test without FDA approval." (Ofman (Grail) Tr. 3319-20.)

Response to Finding No. 94:

Respondents have no specific response.

95. [redacted] (Ofman (Grail) Tr. 3352-54 (*in camera*) [redacted] PX4209 (Grail) at 004-008 (Grail, Market Access Strategy, June 2020) (*in camera*) [redacted]).

Response to Finding No. 95:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

96. [redacted] (PX7062 (Kollu (Grail), IHT at 166-167) (*in camera*)).

Response to Finding No. 96:

Respondents have no specific response.

97. Grail's Chief Medical Officer, Dr. Josh Ofman, testified at trial that Grail has assembled a capable team in Washington, D.C., to advocate for accelerated Medicare coverage of Galleri and MCED tests. (Ofman (Grail) Tr. 3356-57, 3450).

Response to Finding No. 97:

The proposed finding is incomplete and misleading. Dr. Ofman testified that [redacted] Respondents further note that the proposed finding is not supported by the citation to Dr. Ofman's testimony on pages 3356–57. [redacted] Contrary to the proposed finding, Dr. Deverka testified that [redacted]

[redacted] Specifically, a novel test like Galleri "needs to have a premarket authorization, so clearance by the FDA . . . . [F]or the Medicare pathway, it's actually a requirement to have an FDA-approved or cleared test". (RX6001 (Deverka Trial Dep. at 39.) [redacted]

c) [redacted]

98. [redacted] (Bishop (Grail) Tr. 1441 (*in camera*)).

Response to Finding No. 98:

Respondents have no specific response, except to note [redacted]

99. [redacted] (PX5044 (Grail) at 006-007 (Grail LRP Review, Aug. 20, 2020) (*in camera*)).

Response to Finding No. 99:

The proposed finding is misleading and incomplete. Mr. Della Porta testified that [redacted]

[redacted]

100. [redacted] (PX5044 (Grail) at 010-11 (Grail LRP Review, Aug. 20, 2020) (*in camera*)).

Response to Finding No. 100:

Respondents have no specific response except incorporate their responses to CCFF ¶ 98 herein.

101. [redacted] (Bishop (Grail) Tr. 1441-43 (*in camera*)).

Response to Finding No. 101:

Respondents have no specific response except incorporate their responses to CCFF ¶ 98 herein.

102. [redacted] (PX5044 (Grail) at 023 (Grail LRP Review, Aug. 20, 2020) (*in camera*)).

Response to Finding No. 102:

Respondents have no specific response except incorporate their responses to CCFF ¶ 98 herein.

103. [redacted] (PX5044 (Grail) at 024 (Grail LRP Review, Aug. 20, 2020) (*in camera*)).

Response to Finding No. 103:

Respondents have no specific response except incorporate their responses to CCFF ¶ 98 herein.

104. [redacted] (PX4016 (Grail) at 025 (Grail,

Grail Strategy Planning Roadmap (Workshop #2), Sept. 2, 2020) (*in camera*) [redacted]); PX4491 (Grail) at 007, 035-043 (Grail, Board of Directors Meeting, Apr. 30, 2019) (*in camera*)).

Response to Finding No. 104:

The proposed finding is incomplete and misleading. GRAIL has only one laboratory and limited experience in operating that laboratory. (deSouza (Illumina) Tr. 2370); Bishop (GRAIL) Tr. 1376; Aravanis (Illumina) Tr. 1892.) [redacted]

Combining Illumina and GRAIL will allow GRAIL to benefit from Illumina's laboratory operations capability. (deSouza (Illumina) Tr. 2371–72); Aravanis (Illumina) Tr. 1961); Flatley (Illumina) Tr. 4086); Bishop (GRAIL) Tr. 1405.) Specifically, Illumina's previous work with Verinata in NIPT and its experience in running laboratories and processing tests can facilitate GRAIL's efforts to improve its centralized scaled laboratory operations. (Freidin (Grail) Tr. 3007-08.) Respondents also note that Complaint Counsel chose not to discuss PX4016 (Grail) and PX4491 (Grail) at trial (CC Exhibit Index at 34, 50), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

105. [redacted] (PX5044 (Grail) at 003 (Grail LRP Review, Aug. 20, 2020) (*in camera*)).

Response to Finding No. 105:

The proposed finding is incomplete and misleading. [redacted]

[redacted] Mr. Della Porta testified that [redacted]

106. [redacted] (PX5044 (Grail) at 003 (Grail LRP Review, Aug. 20, 2020) (*in camera*)).

Response to Finding No. 106:

Respondents have no specific response.

107. [redacted] (Ofman (Grail) Tr. 3351 (*in camera*); PX7069 (Bishop (Grail) IHT at 193-94); PX4082 (Grail) at 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 107:

The proposed finding is incomplete and misleading. GRAIL is inexperienced in obtaining FDA approval. [redacted]; Freidin (GRAIL) Tr. 2980; Aravanis (Illumina) Tr. 1943, 1947); RX3867 (Deverka Expert Report) ¶ 113.)) [redacted]

[redacted] (Ofman (GRAIL) Tr. 3351.)

Respondents incorporate their responses to CCFF ¶ 82 herein.

Respondents also note that the proposed finding relies in part on IH testimony which Respondents had no opportunity to cross-examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

108. [redacted] (Ofman (Grail) Tr. 3351 (*in camera*); *see* PX7069 (Bishop (Grail) IHT at 193-4); PX4082 (Grail) at 011 (Email attaching Grail 2021 S-1/Amended, Sept. 2020); *see also* Febbo (Illumina) Tr. 4430 (*in camera*) [redacted]).

Response to Finding No. 108:

Respondents have no specific response except incorporate their responses to CCFF ¶¶ 82 and 107 herein.

109. [redacted] (PX5044 (Grail) at 018 (Grail LRP Review, Aug. 20, 2020) (*in camera*)).

Response to Finding No. 109:

Respondents have no specific response except incorporate their responses to CCFF ¶ 98 herein.

d) [redacted]

110. Dr. Joshua Ofman, Grail's Chief Medical Officer, testified that the clinical study program Grail has launched as an independent company is "one of the largest I've seen." (Ofman (Grail) Tr. 3445).

Response to Finding No. 110:

The proposed finding is misleading. Neither Dr. Ofman nor Complaint Counsel used the term "as an independent company" in the context of the cited evidence.

111. As of September 2021, Grail has enrolled over 130,000 participants in clinical studies. (PX0390 (ClinicalTrials.gov Search Results for "Grail," Sept. 23, 2021)).

Response to Finding No. 111:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss PX0390 at trial (CC Exhibit Index at 4), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

112. Grail has partnered with the Mayo Clinic, Cleveland Clinical, and Henry Ford Health System for clinical studies. (Qadan (Illumina) Tr. 4263).

Response to Finding No. 112:

Respondents have no specific response.

113. Grail began its clinical study program with the Circulating Cell-Free Genome Atlas ("CCGA") study, which Grail initiated "after Grail was spun out of Illumina and their – the R&D was externalized." (Ofman (Grail) Tr. 3291-92).

Response to Finding No. 113:

Respondents have no specific response.

114. [redacted] (PX4430 (Grail) at 021 [redacted] (*in camera*); PX6049 (Grail) at 015 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 114:

The proposed finding is incomplete and misleading. The CCGA is a prospective, multicenter (142 sites), case-control, observational study with longitudinal follow-up. (RX3430 (Liu, et al., 2020) at 3; Ofman (GRAIL) Tr. 3291–95; [redacted] RX0744 (GRAIL) at 47–48.) Respondents also note that Complaint Counsel chose not to discuss PX4430 at trial (CC Exhibit Index at 48), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

115. In observational studies, test results are not returned to the patients but rather, the patients are tracked over the duration of the study, and Grail compares the results of its tests with the patients' cancer diagnoses at the conclusion of a predetermined period. (PX7092 (Ofman (Grail) Dep. at 255-257)).

Response to Finding No. 115:

Respondents have no specific response.

116. [redacted] (PX6049 at 015 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 116:

Respondents have no specific response.

117. The CCGA study comprises three substudies: CCGA-1, CCGA-2, and CCGA-3. (PX7069 (Bishop (Grail) IHT at 79)).

Response to Finding No. 117:

Respondents have no specific response.

118. Grail used CCGA-1 and CCGA-2 to develop Galleri and gather information about Galleri's performance. (PX7069 (Bishop (Grail) IHT at 80); PX6049 (Grail) at 016 (Grail, Narrative Response to Second Request, Mar. 1, 2021 [redacted] (*in camera*)).

Response to Finding No. 118:

Respondents have no specific response.

119. [redacted] (PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 119:

Respondents have no specific response.

120. [redacted] (PX7092 (Ofman (Grail) Dep. at 252); PX6049 (Grail) at 016 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 120:

Respondents have no specific response.

121. [redacted] (PX6049 (Grail) at 015 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 121:

Respondents have no specific response.

122. [redacted] (RX3410 (National Institutes of Health, U.S. National Library of Medicine, The Circulating Cell-free Genome Atlas Study (CCGA), https://clinicaltrials.gov/ct2/show/NCT02889978) (last visited Jan. 3, 2022); PX6093 (Navathe Rebuttal Report) at 026-29 (*in camera*)).

Response to Finding No. 122:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss RX3410 (Resps.' Exhibit Index at 166) or PX6093 (CC Exhibit Index at 56) at trial, or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

123. Shortly after Grail launched the CCGA study, it launched "two very large cohort studies," STRIVE and SUMMIT. (Ofman (Grail) Tr. 3293).

Response to Finding No. 123:

Respondents have no specific response.

124. [redacted] (PX6049 (Grail) at 017 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 124:

Respondents have no specific response.

125. [redacted] (PX7092 (Ofman (Grail) Dep. at 255-256); *see* PX6049 (Grail) at 017 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 125:

Respondents have no specific response, except to note Dr. Ofman's testimony that GRAIL does not need the results of STRIVE to prove that Galleri works. (Ofman (GRAIL) at 3295.)

126. [redacted] (PX6049 (Grail) at 017 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 126:

Respondents have no specific response except incorporate their responses to CCFF ¶¶ 107 and 125 herein.

127. [redacted] (Ofman (Grail) Tr. 3294-95; PX4430 (Grail) at 021 (*in camera*); PX7092 (Ofman (Grail) Dep. at 256-257); PX6049 (Grail) at 017-18 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 127:

Respondents have no specific response, except to note that Complaint Counsel chose not to discuss PX4430 (GRAIL) at trial (CC Exhibit Index at 48), or in any deposition, and therefore,

the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

128. [redacted] (PX4430 (Grail) at 021 [redacted] (*in camera*); PX6049 (Grail) at 017 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 128:

Respondents have no specific response, except to note that Complaint Counsel chose not to discuss PX4430 (GRAIL) at trial (CC Exhibit Index at 48), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

129. [redacted] (PX6049 (Grail) at 018 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 129:

Respondents have no specific response.

130. [redacted] (PX6049 at 017 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 130:

Respondents have no specific response.

131. Grail's PATHFINDER 1 study is an interventional, real-world, clinical practice study of 6,600 individuals with no suspicion of cancer. (Ofman (Grail) Tr. 3293).

Response to Finding No. 131:

Respondents have no specific response.

132. [redacted] (PX6049 (Grail) at 017 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

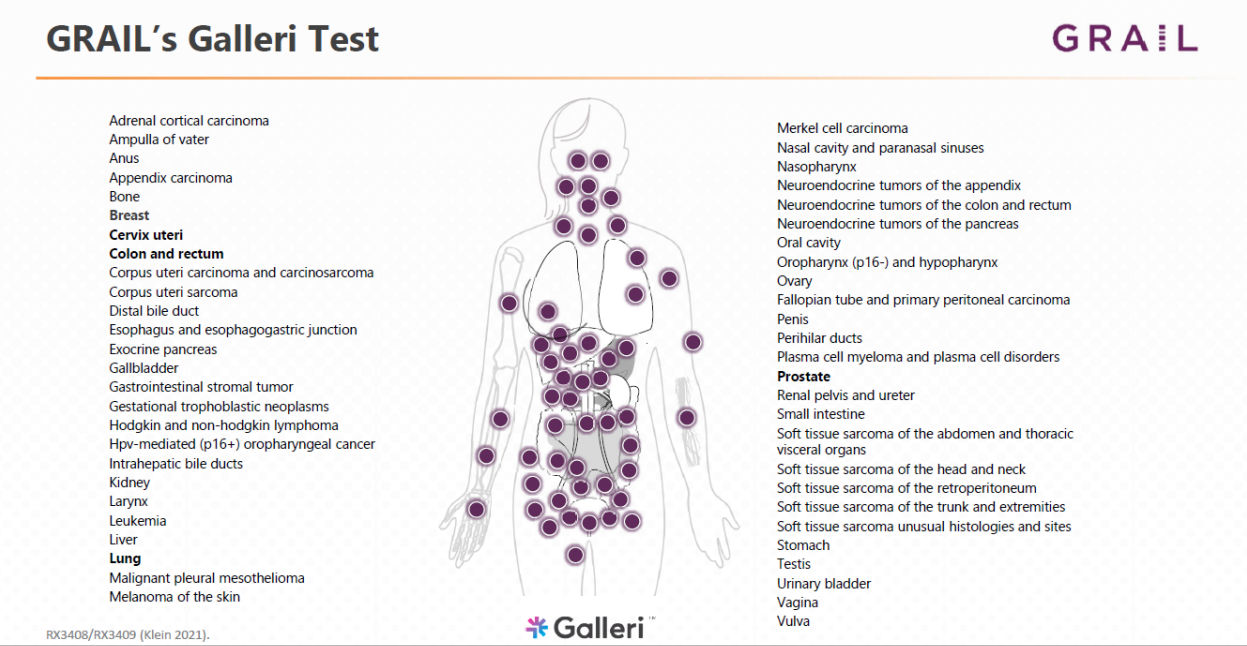
Response to Finding No. 132:

Respondents have no specific response.

133. Based on the PATHFINDER study, the Galleri test has been shown to detect seven types of stage one through three cancer in an asymptomatic screening population. (Cote Tr. 4000-01; RX3041 at 005 (Interim Results of Pathfinder, June 4, 2021) (showing 7 cancers as being detected in stages one through three: head and neck, liver/bile duct, lung, lymphoma, ovary, pancreas, and small intestine).

Response to Finding No. 133:

The proposed finding is incomplete and misleading. There is ample evidence from multiple clinical trials that the Galleri test can detect many more than seven types of early stage cancers in asymptomatic screening populations. In clinical studies, Galleri has detected over 50 types of cancers, of which 45 do not currently have a recommended screening procedure in the US. (PFF ¶¶ 39, 343, 1296; Bishop (GRAIL) Tr. 1373, 1391; RX3285 (GRAIL) at 1; RX3286 (GRAIL) at 2; RX3287 (GRAIL) at 1; Aravanis (Illumina) Tr. 1894–95, 1902; Cote Tr. 3791.) Specifically, the results of the CCGA2 study, published in Annals of Oncology in March 2020, showed that Galleri was capable of detecting more than 50 cancer types at a specificity of 99.3% and a false-positive rate of less than 1% across the more than 50 cancer types. (PFF ¶ 388; RX3430 (Liu, et al., 2020) at 1, 10.) Similarly, CCGA3 ultimately reported that GRAIL's Galleri v2 test achieved a specificity of 99.5% across more than 50 cancer types, a false-positive rate of 0.5%, sensitivity of 51.5% for all cancers, and a signal of origin prediction accuracy of 88.7%. (PFF ¶ 392; RX3408 (Klein, et al., 2021) at 10; RX3869 (Cote Expert Report) ¶ 144.)



(RDX0014-42.)

Independent analysts and external observers have also concluded that Galleri has been clinically shown to detect 50 types of cancers. For instance, a report on the liquid biopsy market from Cowen notes that GRAIL has "conducted systematic clinical studies" and that Galleri "has been shown to be capable of identifying >50 types of cancers by scanning methylation patterns". (PFF ¶ 717.1; PX2022 (Cowen) at 27.)) In addition, Dr. Cance of the American Cancer Society testified that Galleri can detect 50 types of cancer. (Cance (ACS) Tr. 633.)

As Dr. Cote testified at trial, PATHFINDER was never intended to provide clinical evidence of Galleri's ability to screen for more than 50 types of cancer in an asymptomatic population. (Cote Tr. 4001.) PATHFINDER was not designed to show that GRAIL could detect 50 cancers in a real-world population, because to do so a study would require enrollment of hundreds of thousands of people. (Ofman (Grail) Tr. 3298.) PATHFINDER was designed to understand the specificity and positive predictive value of Galleri. (Ofman (Grail) Tr. 3298.)

Nevertheless, Dr. Ofman testified that GRAIL was "thrilled that there was such a diversity of cancers that were found in PATHFINDER". (Ofman (Grail) Tr. 3298.)

Respondents also note that Complaint Counsel chose not to discuss RX3041 at trial (Resps.' Exhibit Index at 136), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

134. Accordingly, the PATHFINDER test does not provide clinical evidence of Galleri's ability to screen for more than 50 types of cancer in an asymptomatic screening population. (Cote Tr. 4000-02.)

Response to Finding No. 134:

The proposed finding is incomplete and misleading. As Dr. Cote testified at trial, PATHFINDER was never intended to provide clinical evidence of Galleri's ability to screen for more than 50 types of cancer in an asymptomatic population. (Cote Tr. 4001.) PATHFINDER was not designed to show that GRAIL could detect 50 cancers in a real-world population, because to do so a study would require enrollment of hundreds of thousands of people. (Ofman (Grail) Tr. 3298.) PATHFINDER was designed to understand the specificity and positive predictive value of Galleri. (Ofman (Grail) Tr. 3298.) Nevertheless, Dr. Ofman testified that GRAIL was "thrilled that there was such a diversity of cancers that were found in PATHFINDER". (Ofman (Grail) Tr. 3298.) Respondents also incorporate their responses to CCFF ¶ 133 herein.

135. [redacted] (PX4074 (Grail) at 031 (Grail, Science, Medicine, and Technology Board Subcommittee Meeting Pre-Read, Mar. 2, 2020) (*in camera*).)

Response to Finding No. 135:

The proposed finding is misleading. [redacted] (PX4074 (GRAIL) at 031.)

136. [redacted] (Ofman (Grail) Tr. 3293-94; PX7092 (Ofman (Grail) Dep. at 123); PX6049 (Grail) at 019 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 136:

Respondents have no specific response.

137. [redacted] (PX6049 (Grail) at 019 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 137:

Respondents have no specific response.

138. [redacted] (PX6049 (Grail) at 019 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 138:

Respondents have no specific response.

139. [redacted] (PX4430 (Grail) at 022 (*in camera*); PX6049 (Grail) at 019 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*) [redacted]

Response to Finding No. 139:

Respondents have no specific response, except to note that Complaint Counsel chose not to discuss PX4430 (Grail) at trial (CC Exhibit Index at 48), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

140. [redacted] (PX6049 (Grail) at 019 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 140:

Respondents have no specific response.

141. According to Dr. Patricia Deverka, one of Respondents' retained expert witnesses, the UK NHS study, as a "pragmatic clinical trial," will generate "important evidence of clinical utility" of the Galleri test. (RX6001 (Deverka Trial Dep. at 98)).

Response to Finding No. 141:

Respondents have no specific response.

142. Dr. Ofman testified that the U.K. NHS study is the "largest, real-world, what we call a pragmatic, randomized clinical trial" ever in genomics. (Ofman (Grail) Tr. 3293-94; *see also* Freidin (Grail) Tr. 3008, 3161).

Response to Finding No. 142:

Respondents have no specific response.

143. Grail negotiated its agreement with NHS before Illumina acquired Grail. (Freidin (Grail) Tr. 3161; *see also* Qadan (Illumina) Tr. 4263-64 (testifying that Grail accomplished its partnership with NHS as an independent company without assistance from Illumina)).

Response to Finding No. 143:

The proposed finding is incomplete and misleading. Dr. Febbo testified that while GRAIL's engagement with NHS in the United Kingdom is important, it does not demonstrate that GRAIL can expand internationally just as easily without Illumina: Dr. Febbo explained that the United Kingdom is particularly forward-thinking with genomics, and in Illumina's

experience, success there does not automatically lead to success in other countries. (Febbo (Illumina) Tr. 4354–55.)

144. [redacted] (PX6049 (Grail) at 017 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 144:

Respondents have no specific response.

145. [redacted] (PX4430 (Grail) at 021-022 [redacted] (*in camera*)).

Response to Finding No. 145:

Respondents have no specific response, except to note that Complaint Counsel chose not to discuss PX4430 (Grail) at trial (CC Exhibit Index at 48), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

146. [redacted] (PX6049 (Grail) at 017 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 146:

Respondents have no specific response.

147. [redacted] (RX3134 (National Institutes of Health, U.S. National Library of Medicine, Development Of A Blood Test To Improve The Performance Of Breast Cancer Screening, https://clinicaltrials.gov/ct2/show/NCT03372902) (last visited Jan. 3, 2022); PX6093 (Navathe Rebuttal Report) at 026-29 (*in camera*); PX6049 (Grail) at 020 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 147:

Respondents have no specific response, except to note that Complaint Counsel chose not to discuss RX3134 (Resps.' Exhibit Index at 143) at trial, or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

148. [redacted] (PX6049 (Grail) at 019 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 148:

Respondents have no specific response.

149. [redacted] (PX6049 (Grail) at 019 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*) [redacted]).

Response to Finding No. 149:

Respondents have no specific response.

2. [redacted]

150. [redacted] (PX7069 (Bishop (Grail) IHT at 45) (*in camera*)).

Response to Finding No. 150:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross-examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

151. [redacted] (PX6049 (Grail) at 013 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 151:

Respondents have no specific response.

152. Diagnostic Aid to Cancer ("DAC") tests are designed to confirm a cancer diagnosis by using genomic data to predict the likelihood that a patient has a particular cancer. (PX7069 (Bishop (Grail) IHT at 69-70); PX7072 (deSouza (Illumina) IHT at 160-61)).

Response to Finding No. 152:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross-examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

153. [redacted] (PX6049 (Grail) at 021 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 153:

Respondents have no specific response.

154. [redacted] (PX7069 (Bishop (Grail) IHT at 45) (*in camera*)).

Response to Finding No. 154:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross-examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

155. Minimal Residual Disease ("MRD") tests are designed to determine whether remnants of cancer remain in a patient who has been treated for cancer. (PX7092 (Ofman) Dep. at 94); PX7069 (Bishop) IHT at 71-72); PX6049 (Grail) at 013 (Grail, Narrative Response to Second Request, Mar. 1, 2021) [redacted] (*in camera*)).

Response to Finding No. 155:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross-examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

156. [redacted] *See* (PX7069 (Bishop (Grail) IHT at 45, 69-72) (*in camera*)).

Response to Finding No. 156:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross-examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

157. [redacted] (PX6049 (Grail) at 013 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 157:

Respondents have no specific response.

158. [redacted] (PX6049 (Grail) at 021 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 158:

Respondents have no specific response.

3. Grail's Intellectual Property Holdings

159. Grail owns or co-owns "more than 170 pending patent applications globally, including more than 90 pending U.S. non-provisional and provisional patent applications." (PX4082 (Grail) at 128 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 159:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this portion of the document (CC Exhibit Index at 36) at trial, or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

160. Grail holds "exclusive licenses to more than 230 issued or granted patents and more than 200 pending patent applications globally, including 30 issued U.S. patents." (PX4082 (Grail) at 128 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 160:

Respondents have no specific response except incorporate their responses to CCFF ¶ 159 herein.

161. Grail has entered into five license agreements with the Chinese University of Hong Kong, pursuant to which the Chinese University of Hong Kong granted Grail "exclusive, worldwide intellectual property licenses . . . . for the use of certain nucleic acid sequencing and analysis technologies in all fields under one license and in all field except prenatal diagnostics, prognostications, or analysis under four licenses." (PX4082 (Grail) at 129 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 161:

Respondents have no specific response except incorporate their responses to CCFF ¶ 159 herein.

162. Grail's acquisition of Cirina was a building block for its patent portfolio: "In June 2017, we acquired Hong Kong-based Cirina Limited, founded on the basis of the work of Dr. Dennis Lo, a pioneer in clinical applications of cfDNA sequencing, which provided us with a number of patents and exclusive licenses to patents related to the use of cfDNA for early detection of cancer." (PX4082 (Grail) at 086 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)

Response to Finding No. 162:

The proposed finding is not supported by the cited evidence. The term "building block" is not used in PX4082 (Grail.) Respondents incorporate their responses to CCFF ¶ 159 herein.

163. [redacted] (Freidin (Grail) Tr. 3079) (*in camera*).

Response to Finding No. 163:

Respondents have no specific response.

164. [redacted] (Freidin (Grail) Tr. 3079-80) (*in camera*).

Response to Finding No. 164:

Respondents have no specific response.

165. A May 2017 Grail board presentation stated that the acquisition of Cirina will "[e]nable GRAIL to enforce early IP against GRAIL's competitors." (PX4620 (Grail) at 015 (Project Knight – Board Update II, May 10, 2017)).

Response to Finding No. 165:

The proposed finding is incomplete and misleading to the extent it suggests that a May 2017 GRAIL board presentation from nearly five years ago reflects Illumina's IP enforcement strategy today. Respondents also incorporate their responses to CCFF ¶ 159 herein.

166. The May 2017 Grail board presentation recognized how the Cirina IP acquisition prevents Grail from the burden of an "expensive litigation/expensive settlement if GRAIL were to infringe." (PX4620 (Grail) at 015 (Project Knight – Board Update II, May 10, 2017)).

Response to Finding No. 166:

The proposed finding is incomplete and misleading. Respondents have no specific response except incorporate their responses to CCFF ¶ 165 herein.

167. The May 2017 Grail board presentation stated that "Cirina's Intellectual Property assets protect GRAIL's commercial strategy and may constrain competitors." (PX4620 (Grail) at 004 (Project Knight – Board Update II, May 10, 2017)).

Response to Finding No. 167:

The proposed finding is incomplete and misleading. Respondents have no specific response except incorporate their responses to CCFF ¶ 165 herein.

168. The Cirina transaction provided Grail with exclusive access to additional IP when Dr. Dennis Lo agreed to join Grail's Scientific Advisory Board, providing Grail with "rights to future Lo IP also going to GRAIL (rather than competitors) – e.g., joining forces with Lo, rather than competing with Lo[.]" (PX4620 (Grail) at 015 (Project Knight – Board Update II, May 10, 2017)).

Response to Finding No. 168:

The proposed finding is incomplete and misleading. Respondents have no specific response except incorporate their responses to CCFF ¶ 165 herein.

169. Grail's pre-Cirina IP related to specific barcode techniques. (PX4620 (Grail) at 015 (Project Knight – Board Update II, May 10, 2017)).

Response to Finding No. 169:

The proposed finding is incomplete and misleading. Respondents have no specific response except incorporate their responses to CCFF ¶ 165 herein.

4. Grail Prepared To Go Public Prior to Acquisition

170. Grail successfully raised $300 million as part of an "oversubscribed" Series C financing round in May 2018, bringing its total equity raised to more than $1.5 billion. (PX0051 at 001 (Grail Announces $300 Million Raised in Oversubscribed Series C Financing, May 21, 2018)).

Response to Finding No. 170:

The proposed finding is misleading to the extent it suggests that GRAIL would be successful without the Transaction. But for the Transaction, GRAIL may have failed to obtain additional financing and may be unable to expand its commercialization efforts with respect to Galleri and DAC and develop additional products. (PFF ¶ 68.7; PX0043 (GRAIL) at 29; Bishop (GRAIL) Tr. 1372; 1418-19; [redacted].) Respondents also incorporate their responses to CCFF ¶ 71 herein.

171. Grail successfully raised $390 million as part of a Series D financing round in May 2020, bringing its total equity raised to more than $1.9 billion. (PX0052 at 001-002 (Grail Announces $390 Million Series D Financing, May 6, 2020)).

Response to Finding No. 171:

The proposed finding is misleading to the extent it suggests that GRAIL would be successful without the Transaction. Respondents also incorporate their responses to CCFF ¶¶ 71 and 170 herein.

Respondents also note that Complaint Counsel chose not to discuss PX0052 (GRAIL) at trial (CC Exhibit Index at 1), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

172. [redacted]
(PX4341 (Grail) at 001 (Email from H. Bishop (Grail) to B. Nelson (Grail), Aug. 21, 2020) (*in camera*)).

Response to Finding No. 172:

The proposed finding is misleading to the extent it suggests that GRAIL would be successful without the Transaction. But for the Transaction, GRAIL may have failed to obtain additional financing and may be unable to expand its commercialization efforts with respect to Galleri and DAC and develop additional products. (PFF ¶ 68.7; PX0043 (GRAIL) at 29; Bishop (GRAIL) Tr. 1372; 1418-19; [redacted]

[redacted]

Respondents also incorporate their responses to CCFF ¶¶ 71 and 170 herein.

Respondents also note that Complaint Counsel chose not to discuss PX4341 (GRAIL) at trial (CC Exhibit Index at 45), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

173. Matthew Strom, Morgan Stanley Managing Director in the Healthcare Investment Banking Group, testified that Morgan Stanley was "the exclusive financial advisor to Grail" in its acquisition by Illumina. (Strom (Morgan Stanley) Tr. 3473).

Response to Finding No. 173:

Respondents have no specific response.

174. Morgan Stanley was "tasked to help GRAIL negotiate the transaction with Illumina, evaluate potential alternatives, including an IPO, as well as complete due diligence and help the board think about valuation and put the transaction in context from a financial perspective for the board to -- other transactions as well as other alternatives." (Strom (Morgan Stanley) Tr. at 3474).

Response to Finding No. 174:

Respondents have no specific response.

175. Morgan Stanley was the lead underwriter for Grail's planned IPO. (Strom (Morgan Stanley) Tr. 3591-92).

Response to Finding No. 175:

Respondents have no specific response.

176. Morgan Stanley assisted Grail in preparing of its Form S-1, which is the registration statement filed by a private company that enables it to sell public securities. (Strom (Morgan Stanley) Tr. 3591-92).

Response to Finding No. 176:

Respondents have no specific response.

177. Grail filed its S-1 registration statement on September 9, 2020. (PX0053 (Grail Announces Filing of Registration Statement for Proposed Initial Public Offering, Sept. 9, 2020)).

Response to Finding No. 177:

The proposed finding is misleading to the extent it suggests that GRAIL would be successful without the Transaction. Respondents incorporate their responses to CCFF ¶ 172 herein. Respondents also note that Complaint Counsel chose not to discuss PX0053 (GRAIL) at trial (CC Exhibit Index at 1), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

a) [redacted]

178. [redacted] (PX4175 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 178:

The proposed finding is misleading to the extent it suggests that GRAIL would be successful without the Transaction. Respondents incorporate their responses to CCFF ¶ 172 herein. The cited evidence also does not support the proposed finding. [redacted]

179. [redacted] (PX4175 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 179:

The proposed finding is incomplete and misleading. [redacted] Moreover, Dr. Ofman and Mr. Freidin testified that even if GRAIL chose the path of an IPO, it would not have helped GRAIL achieve the same scale, expertise and infrastructure as it would with Illumina. (Ofman (GRAIL) Tr. 3283; Freidin (GRAIL) Tr. 3008-10.) Respondents also incorporate their responses to CCFF ¶ 172 herein.

180. [redacted] (Strom (Morgan Stanley) Tr. at 3565 (*in camera*)).

Response to Finding No. 180:

The proposed finding is incomplete and misleading. Respondents have no specific response except incorporate their responses to CCFF ¶¶ 172 and 179 herein.

181. [redacted] (PX4175 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 181:

The proposed finding is incomplete and misleading. Respondents have no specific response except incorporate their responses to CCFF ¶¶ 172 and 179 herein.

182. [redacted] (PX4175 (Grail) at 030 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 182:

The proposed finding is incomplete and misleading. Respondents have no specific response except incorporate their responses to CCFF ¶¶ 172 and 179 herein.

183. [redacted] (PX4175 (Grail) at 030 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*); *see also* PX8463 (Morgan Stanley) at 007 [redacted] (*in camera*) [redacted]).

Response to Finding No. 183:

The proposed finding is incomplete and misleading. Respondents have no specific response except incorporate their responses to CCFF ¶¶ 172 and 179 herein.

184. [redacted] (PX4175 (Grail) at 030 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*); *see* PX8463 (Morgan Stanley) at 007 [redacted] (*in camera*) [redacted]

Response to Finding No. 184:

The proposed finding is incomplete and misleading. Respondents have no specific response except incorporate their responses to CCFF ¶¶ 172 and 179 herein.

185. [redacted] (PX4175 (Grail) at 030 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*); *see also* PX8463 (Morgan Stanley) at 007 [redacted] (*in camera*) [redacted]

Response to Finding No. 185:

The proposed finding is incomplete and misleading. Respondents have no specific response except incorporate their responses to CCFF ¶¶ 172 and 179 herein.

b) [redacted]

186. [redacted] (Strom (Morgan Stanley) Tr. at 3532 (*in camera*)).

Response to Finding No. 186:

The proposed finding is incomplete and misleading. Respondents have no specific response except incorporate their responses to CCFF ¶¶ 172 and 179 herein.

187. [redacted] X4137 (Grail) at 008 (The Roundtable, Sep. 30, 2020); *see also* PX7108 (Freidin (Grail) Dep. at 54-55) (*in camera*)).

Response to Finding No. 187:

The proposed finding is incomplete and misleading. Respondents have no specific response except incorporate their responses to CCFF ¶¶ 172 and 179 herein.

Respondents also note that Complaint Counsel chose not to discuss PX4137 (Grail) at trial (CC Exhibit Index at 38), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

188. Because Illumina and Grail entered into an acquisition agreement on September 20, 2020, Grail never went public. (PX7108 (Freidin (Grail) Dep. at 113)).

Response to Finding No. 188:

Respondents have no specific response.

c) [redacted]

189. [redacted] (Freidin (Grail) Tr. 3072 (*in camera*)).

Response to Finding No. 189:

The proposed finding is misleading to the extent it suggests that GRAIL would be successful without the Transaction. But for the Transaction, GRAIL may have failed to obtain additional financing and may be unable to expand its commercialization efforts with respect to Galleri and DAC and develop additional products. (PFF ¶ 68.7; PX0043 (GRAIL) at 29; Bishop (GRAIL) Tr. 1372; 1418-19; [redacted].) Respondents also incorporate their responses to CCFF ¶ 71 herein. [redacted] However, the Transaction has closed.

[redacted]

[redacted]

190. [redacted] (Freidin (Grail) Tr. 3072 (*in camera*)).

Response to Finding No. 190:

The proposed finding is incomplete and misleading. [redacted]

191. [redacted] (Freidin (Grail) Tr. 3073 (*in camera*)).

Response to Finding No. 191:

The proposed finding is incomplete and misleading. [redacted]

192. [redacted] (Freidin (Grail) Tr. 3073-74 (*in camera*)).

Response to Finding No. 192:

Respondents do not have a specific response, except to note that [redacted]

193. Grail did not approach any other life sciences companies that have successfully obtained PMA approval for IVD tests about partnering or merging with Grail. (Ofman (Grail) Tr. 3447-49).

Response to Finding No. 193:

Respondents have no specific response, except to note that Illumina's regulatory team has extensive expertise obtaining FDA clearances and approvals for diagnostic tests. Illumina has successfully obtained 510(k) clearance for a cystic fibrosis test and a PMA in cancer treatment selection for an extended RAS panel called Praxis. (Febbo (Illumina) Tr. 4338–43.) [redacted] Illumina also has experience bringing its next-generation sequencing products through FDA clearance. (Febbo (Illumina) Tr. 4338–39.)

194. [redacted] (Strom (Morgan Stanley) Tr. at 3573-75 (*in camera*); PX8472 (Morgan Stanley) at 028 [redacted] (*in camera*)).

Response to Finding No. 194:

The proposed finding is misleading to the extent it suggests that GRAIL would be successful without the Transaction. But for the Transaction, GRAIL may have failed to obtain additional financing and may be unable to expand its commercialization efforts with respect to Galleri and DAC and develop additional products. (PFF ¶ 68.7; PX0043 (GRAIL) at 29; Bishop (GRAIL) Tr. 1372; 1418-19; [redacted].) None of these alternative companies in the proposed finding made an offer for GRAIL. Mr. Freidin testified that [redacted] this is because [redacted] (Fredin (GRAIL) Tr. 3073–74.) [redacted] (Freidin (GRAIL) Tr. 3072–

73.) [redacted] (Freidin (GRAIL) Tr. 3073.)

195. If the Illumina-Grail transaction is unwound, investors have expressed interest "in making a more significant investment in GRAIL should [GRAIL] choose to access the capital markets." (*See, e.g.,* PX4468 (Grail) at 002 (Email from N. Cornell, Bluewater Life Science Advisors, to J. Craighead, Grail, Apr. 13, 2021)).

Response to Finding No. 195:

The proposed finding is based on hearsay and should be accorded little weight.

Respondents also incorporate their responses to CCFF ¶¶ 172 and 179 herein.

Respondents also note that Complaint Counsel chose not to discuss PX4468 (Grail) at trial (CC Exhibit Index at 49), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

196. Grail's VP of Investor Relations, John Craighead, told investors that Grail will be "well positioned for any outcome" with the Illumina transaction. (PX4468 (Grail) at 001 (Email from J. Craighead, Grail, to N. Cornell, Bluewater Life Science Advisors, Apr. 16, 2021)); *see* PX4467 (Grail) at 002 (Text message exchange between V. Demas, Grail, and H. Kiarie, Grail, Mar. 31, 2021) (noting that "we can still IPO" if the Proposed Acquisition falls through).

Response to Finding No. 196:

The proposed finding is incomplete and misleading. Complaint Counsel cites no evidence that Vasiliki ("Vicky") Demas, former Platform Product Manager and New Products Program Lead at GRAIL, had any involvement in the IPO process at GRAIL. Moreover, PX4467 (Grail) is dated the day after Complaint Counsel filed suit in federal court and before the Commission. Other portions of the message exchange which show how Ms. Demas was "disappointed" and "hope[d] [that] it w[ould] all work out in the ned [sic]". ((PX4467 (GRAIL) at 001.) She writes: "I think there is still a chance that logic and desire to help patients will

prevail[,] but if FTC really messes this up, I am sure that we can still IPO". (PX4467 (GRAIL) at 002.) Respondents also incorporate their responses to CCFF ¶¶ 172 and 179 herein.

Respondents also note that Complaint Counsel chose not to discuss PX4467 (GRAIL) and PX4468 (Grail) at trial (CC Exhibit Index at 49), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

C. THE TRANSACTION

197. On September 20, 2020, Illumina entered into an Agreement and Plan of Merger to acquire Grail for total consideration of $8 billion, consisting of $3.5 billion in cash and $4.5 billion in shares of Illumina common stock, subject to a collar. (PX0061 at 005 (Illumina 2020 Form 10-K); *see also* Bishop (Grail) Tr. 1353 (stating that the total transaction value for the Grail acquisition was approximately $8 billion "[a]s measured by the common accounting standards"); deSouza (Illumina) Tr. 2215; PX5048 at 002-03 (Grail, Notification and Report Form, Oct. 9, 2020) (stating that on September 20, 2020, Respondents entered into an Agreement and Plan of Merger for Illumina to acquire all of Grail's outstanding voting shares, for a combination of cash and stock consideration valued at about $7.1 billion)).

Response to Finding No. 197:

Respondents have no specific response.

198. [redacted] (Freidin (Grail) Tr. 3070-71 (*in camera*)).

Response to Finding No. 198:

The proposed finding is misleading to the extent it suggests that GRAIL would be successful without the Transaction. But for the Transaction, GRAIL may have failed to obtain additional financing and may be unable to expand its commercialization efforts with respect to Galleri and DAC and develop additional products. (PFF ¶ 68.7; PX0043 (GRAIL) at 29; Bishop (GRAIL) Tr. 1372; 1418-19; [redacted].) Respondents also incorporate their responses to CCFF ¶¶ 172 and 179 herein.

199. [redacted] (Freidin (Grail) Tr. 3071 (*in camera*)).

Response to Finding No. 199:

Respondents have no specific response.

200. Illumina consummated its acquisition of Grail on August 18, 2021. (deSouza (Illumina) Tr. 2234; Bishop (Grail) Tr. 1353; Berry (Illumina) Tr. 857).

Response to Finding No. 200:

Respondents have no specific response.

201. Illumina filed an 8-K report with the Securities and Exchange Commission as a result of consummating the acquisition of Grail. (deSouza (Illumina) Tr. 2234).

Response to Finding No. 201:

Respondents have no specific response.

202. Illumina has now paid Grail the $8 billion consideration owed under the merger agreement. (deSouza (Illumina) Tr. 2239)

Response to Finding No. 202:

Respondents have no specific response.

203. [redacted] (deSouza (Illumina) Tr. 2282 (*in camera*)).

Response to Finding No. 203:

Respondents have no specific response.

204. "Once the deal closed," Illumina eliminated patent-related royalties that Grail previously paid to Illumina. (deSouza (Illumina) Tr. 2358-59).

Response to Finding No. 204:

The proposed finding is incomplete and misleading and not supported by the cited evidence insofar as it suggests that GRAIL paid "patent-related" royalties to Illumina prior to the Transaction. The royalties GRAIL owed Illumina were not related to any patent rights; rather, [redacted]

[redacted]

Mr. deSouza's cited testimony does not indicate that the royalties GRAIL owed to Illumina were "patent-related" and his earlier testimony indicates that the royalty was based on GRAIL's future sales. (deSouza (Illumina) Tr. 2334 ("[B]efore [Illumina] signed the agreement or the intent to acquire [GRAIL], we were an -- a part-owner, so an equity investor in GRAIL, and they were a customer of ours, and we had an arrangement where we received a royalty on tests they would sell in the future"..)) [redacted]; RX6000 (Carlton Trial Dep. at 68–69); PX7073 (Aravanis (Illumina) IHT at 27.))

205. When Illumina completed its acquisition of Grail, Illumina immediately eliminated the royalty that Grail had been required to pay on all future sales. (Aravanis (Illumina) Tr. 1959).

Response to Finding No. 205:

Respondents have no specific response except to note that the [redacted] Respondents also incorporate their responses to CCFF ¶ 204.

1. [redacted]

206. [redacted] (PX2488 (Illumina) at 009 [redacted] (*in camera*)).

Response to Finding No. 206:

The proposed finding is misleading and incomplete. Those same documents show that the downstream profit pool shifts and estimated revenue projected from clinical testing services will not reach the levels described in the proposed finding until 2035, and the evidence uniformly shows that Illumina's NGS business will remain its core business and will account for most of its profits for "many, many years". (PFF ¶¶ 869–872 (deSouza (Illumina) Tr. 2382–83, 2386.))) Further, Complaint Counsel overlooks the significance of these projections; as [redacted] (PFF at ¶ 910.) [redacted] Respondents further incorporate their responses to CCFF ¶ 3107 herein.

207. Jay Flatley, Chairman of the Illumina Board at the time of the acquisition, testified that increasing shareholder value was one reason the Board approved the acquisition. (Flatley (Illumina) Tr. 4095-96). Mr. Flatley expects the acquisition to increase both revenue and profits once the Galleri test "got into the marketplace." (Flatley (Illumina) Tr. 4096-97).

Response to Finding No. 207:

Respondents have no specific response except to note that only "after 2026" will Illumina get "its first dollar of profit" from GRAIL. (PFF ¶¶ 871–72 (deSouza (Illumina) Tr. 2382–83.)) Respondents further incorporate their responses to CCFF ¶¶ 206, 3107 herein.

208. [redacted] (PX2316 (Illumina) at 008 (Email from J. Goswami, Illumina, to A. Qadan et al., Illumina, attaching "Board of Directors M&A Landscape," Apr. 29, 2020) (*in camera*).

Response to Finding No. 208:

The proposed finding is incomplete and misleading. Nothing in the cited source supports the proposition that [redacted] (*See* PX2465 (Illumina) at 12 [redacted]

209. Internal Illumina documents indicate that Illumina intends to use its acquisition of Grail to [redacted] (PX2465 (Illumina) at 003 [redacted] (*in camera*)).

Response to Finding No. 209:

The proposed finding is misleading. Dr. Goswami provided the following context when shown this slide:

[redacted]

210. Illumina's Strategic Plan for 2021-2025 declares, [redacted]

(PX2169 (Illumina) at 045 (Illumina, "Illumina Strategic Plan 2021-2025, Board Discussion Document," Oct. 23, 2020) (*in camera*)).

Response to Finding No. 210:

The proposed finding is misleading. As Mr. deSouza explained, "the testing business for many, many years will not have a profit, will lose business, and that's very typical in clinical testing businesses". (PFF ¶ 869 (deSouza (Illumina) Tr. 2386.)) [redacted] It is only "after 2026" that Illumina gets "its first dollar of profit" from GRAIL, but "it's not until 2030 where we've recouped the losses we've made in GRAIL", and therefore, "about the next decade even, we really need and are really fueled by the profit pools associated with our sequencers". (PFF ¶ 871.)

[redacted]

Respondents further incorporate their responses to CCFF ¶¶ 206, 3107 herein.

211. According to Illumina's internal documents, [redacted] X2465 (Illumina) at 003 [redacted] (*in camera*)).

Response to Finding No. 211:

The proposed finding is misleading to the extent it suggests that [redacted] Illumina has already organically developed its own clinical testing applications through its therapy selection test, TSO-500. (PFF ¶ 964.) Respondents also note that Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses at trial (CC Exhibit Index at 20), nor did it elicit any testimony regarding the specific language it relies upon in the source cited when it showed the exhibit to Dr. Goswami at his deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it (PX7087 (Goswami (Illumina) Dep. at 140–56.)

Respondents further incorporate their responses to CCFF ¶¶ 206, 3107 herein.

212. [redacted] (PX2488 (Illumina) at 009 [redacted] (*in camera*)).

Response to Finding No. 212:

Respondents have no specific response except to note that [redacted] (PFF ¶ 849.1.) Because Illumina's "core business is to sell sequencers and consumables", its "strong incentive is to continue to be successful selling sequencers and consumables into the market segments that we serve". (PFF ¶ 849.1.)

Respondents further incorporate their responses to CCFF ¶¶ 206, 3107 herein.

213. [redacted] (PX2488 (Illumina) at 009 [redacted] (*in camera*)).

Response to Finding No. 213:

Respondents have no specific response except to note that NGS costs will be a very small percentage of MCED test revenues and margins in the future. (PFF ¶ 884.) Respondents further incorporate their responses to CCFF ¶¶ 206, 3107 herein.

214. [redacted] (PX2464 (Illumina) at 025, 036 (Illumina, April BoD M&A Strategy Presentation, Apr. 28, 2020) (*in camera*)).

Response to Finding No. 214:

The proposed finding is incomplete and misleading and not supported by the cited evidence insofar as it suggests [redacted]

[redacted]

The proposed finding is also incomplete and misleading and not supported by the cited evidence insofar as it suggests Illumina was deciding between acquiring GRAIL and other companies developing screening tests. [redacted]

Further, Illumina did not consider purchasing any other putative "MCED test" developers, as Complaint Counsel refers to them. (deSouza (Illumina) Tr. 2335.) Illumina "did an exhaustive study of the market, and we had been keeping up with the market since we were the ones who . . . . came up with GRAIL, and we still don't see anybody in the market that has an offering that's like GRAIL's in terms of looking at 50 cancers, identifying the tissue of origin, and so there really isn't anybody else that we felt, you know, was like GRAIL". (deSouza (Illumina) Tr. 2335.)

2. [redacted]

215. [redacted] (PX2055 (Illumina) at 005 (Grail Integration Planning Update, Oct. 22, 2020) (*in camera*); *see also* PX2008 (Illumina) at 015 (Board of Directors Strategic Plan, Nov. 4, 2020) (*in camera*) [redacted] PX5032 (Illumina)

at 010 [redacted]).

Response to Finding No. 215:

The proposed finding is incomplete and misleading as well as contradicted by the weight of the evidence.

First, as a general matter, Respondents have offered unrefuted evidence that the Transaction will lead to merger-specific efficiencies, including (1) saving of thousands of lives, (2) acceleration of market access to Galleri, (3) R&D efficiencies, (4) reduction of GRAIL's royalty burden, (5) elimination of double marginalization and (6) supply chain efficiencies, operational efficiencies and acceleration of international expansion of Galleri. (PFF ¶ 1106.) In addition to the testimony of Illumina and GRAIL executives, [redacted]

Second, with respect to the language cited in PX2055, [redacted]

[redacted]

[redacted] Respondents note that Complaint Counsel chose not to discuss PX2008 or PX5032 at trial, (CC Exhibit Index at 4, 55), or in any deposition, and therefore, the documents should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from them.

216. [redacted] (PX2464 (Illumina) at 031, 039 (April BoD M&A Strategy Presentation, Apr. 28, 2020) (*in camera*)).

Response to Finding No. 216:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

Further, Respondents incorporate their responses to CCFF ¶ 215 herein.

217. In a September 2020 Illumina FAQ document relating to Illumina's acquisition of Grail, an "Employee FAQ" section stated: "We do not expect material synergies to the transaction." (PX2575 (Illumina) at 013 (E-mail from T. Friedman, Illumina, to J. Cunningham, Illumina, Sept. 29, 2020)).

Response to Finding No. 217:

Respondents incorporate their responses to CCFF ¶ 215 herein. Further, Respondents note that Complaint Counsel did not elicit any testimony regarding the specific language it relies upon in the source cited when it showed PX2575 to Mr. deSouza at trial (deSouza (Illumina) Tr. 2217-23) and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3. The Parties Closed the Transaction Despite the Possibilities of Fines, Reputation Consequences and Other Government Enforcement Action

218. Illumina closed the transaction despite knowing that doing so could result in the imposition of "fines, penalties, remedies or restrictions" by government or regulatory authorities. (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021)).

Response to Finding No. 218:

Respondents have no specific response.

219. Illumina disclosed that consummating the transaction when it did could lead to "other adverse consequences to, among other things, its reputation[.]" (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2236-37 (stating that Illumina decided to close the transaction despite the potential risk to its reputation)).

Response to Finding No. 219:

Respondents have no specific response except to note that Mr. deSouza explained that, although there is *a risk* of reputational harm that has to be disclosed, Illumina believes that "once people hear what we did . . . . there won't be damage to our reputation" given the reasons for closing and the impact of the Transaction on cancer care and saving lives. (PFF ¶ 865.) In other words, Mr. deSouza, and Illumina, believe that closing the Transaction will *in fact* have a positive impact on Illumina's reputation. (PFF ¶ 865.1.) Also, there is nothing in the SEC disclosure that suggests that closing the Transaction would harm Illumina's reputation for lowering costs and innovating to encourage development on its platforms—and it is *that* reputation that an attempted foreclosure strategy would undoubtedly injure. (PFF ¶ 865.2.)

220. Illumina acknowledged in an SEC filing that:

> The European Commission had previously notified Illumina asserting that as a result of the Referral [of the transaction for European Union merger review under Article 22(1) of Council Regulation (EC) No 139/2004], pursuant to Article 22(4) of the EU Merger Regulation, Illumina was prohibited from implementing the Acquisition (i) until the European Commission clears the Acquisition under the EU Merger Regulation or (ii) until the European Commission refuses the Referral, and therefore the European Commission's acceptance of the Referral continued the purported standstill on the completion of the Acquisition until such time as the European Commission completes its review and approves the Acquisition.

(PX0378 at 004 (Illumina Form 8-K, Aug. 18, 2021)).

Response to Finding No. 220:

Respondents have no specific response.

221. Illumina understood that by consummating the transaction during the pendency of the European Commission's review, it would "likely" cause the European Commission to seek to fine Illumina:

> As a result of Illumina's decision to proceed with the completion of the Acquisition during the pendency of the European Commission's review, the European Commission will likely seek to impose a fine on Illumina pursuant to Article 14(2)(b) of the EU Merger Regulation of up to 10% of Illumina's consolidated annual turnover.

(PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2235 (stating that Illumina decided to close the transaction despite the potential fines from the European Commission)).

Response to Finding No. 221:

Respondents have no specific response except to note that the disclosure also says that "Illumina intends to vigorously defend against any such fines, penalties, remedies or restrictions". (PX0378 (Illumina) at 5.) In addition, Mr. deSouza testified that Illumina does not believe that any such fines, penalties, remedies or restrictions "would be appropriate". (deSouza (Illumina) Tr. 2236.)

222. When Respondents closed the Acquisition despite a standstill order from the European Commission, Respondents promised to hold Grail separate from Illumina, meaning that Grail "will be run as a separate entity, and where it engages with Illumina, it will do so on an arm's length basis." (deSouza (Illumina) Tr. 2463; *see also* PX2851 (Illumina) (Hold-Separate Commitments, Aug. 18, 2021) (*in camera*) [redacted] (*in camera*)).

Response to Finding No. 222:

Respondents have no specific response.

223. [redacted] (PX2851 (Illumina) at 001 (Hold-Separate Commitments) (*in camera*)).

Response to Finding No. 223:

Respondents have no specific response.

224. Illumina publicly described its hold-separate commitment as "voluntarily offered." (PX0378 at 004 (Illumina Form 8-K, Aug. 18, 2021)).

Response to Finding No. 224:

Respondents have no specific response.

225. [redacted] (PX2851 (Illumina) at 002 (Hold-Separate Commitments) (*in camera*); *see also* PX0378 at 004 (Illumina Form 8-K, Aug. 18, 2021)).

Response to Finding No. 225:

Respondents have no specific response.

226. On October 14, 2021, Illumina appointed its Chief Operations Officer, Bob Ragusa, as Chief Executive Offer of Grail. (PX0405, (Illumina Appoints Ragusa as Chief Executive Officer (CEO) of GRAIL, Oct. 14, 2021, https://www.illumina.com/company/news-center/press-releases/press-release-details.html?newsid=2e72344d-ceaf-4453-868a-423516a4ba49 (last visited Oct. 25, 2021)).

Response to Finding No. 226:

Respondents have no specific response.

II. INDUSTRY BACKGROUND

A. CANCER IS THE SECOND LEADING CAUSE OF DEATH IN THE UNITED STATES

227. Cancer is the second-leading cause of death in the United States. (PX4095 (Grail) at 005 (A New War on Cancer, Investor Presentation, July 2020); Nolan (Freenome) Tr. 2724; Conroy (Exact) Tr. 1735; *see* RX3030 at 003 (American Cancer Society, Cancer Facts & Figures 2019) (ACS estimated that over 1.7 million new cancer cases would be diagnosed in 2019 in the United States)).

Response to Finding No. 227:

Respondents have no specific response.

228. Approximately 630,000 Americans die from cancer each year. (PX4095 (Grail) at 005 (New War on Cancer, Investor Presentation, July 2020)).

Response to Finding No. 228:

Respondents have no specific response.

229. [redacted] (PX8317 (Exact) at 004 [redacted] (*in camera*)).

Response to Finding No. 229:

[redacted]

230. Cancer treatment costs the United States $150 billion annually. (PX4095 (Grail) at 005 (A New War on Cancer, Investor Presentation, July 2020)).

Response to Finding No. 230:

Respondents have no specific response.

B. CURRENT CANCER SCREENING METHODS

1. Cancer Screening Methods Currently Exist for Only a Handful of Cancer Types

231. Single-cancer screening tests are used to identify five cancer types in the United States: breast, cervical, colon, lung, and prostate. (Bishop (Grail) Tr. 1374; Ofman (Grail) Tr. 3308; Abrams Tr. at 3729).

Response to Finding No. 231:

Respondents have no specific response.

232. "Standard of care" screening methods refer to existing cancer screening methods approved and accepted in the medical field. (Lengauer (Third Rock Ventures) Tr. 168).

Response to Finding No. 232:

Respondents have no specific response.

233. [redacted] (PX7040 (Getty

(Guardant) IHT at 26-27); PX5027 (Illumina) at 018 [redacted] (*in camera*) [redacted]).

Response to Finding No. 233:

Respondents have no specific response except to note that the proposed finding relies in part on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

234. [redacted] (Abrams Tr. at 3616-17; Conroy (Exact) Tr. 1736-37; PX7040 (Getty (Guardant) IHT at 26-27); PX5027 (Illumina) at 018 [redacted] (*in camera*) [redacted]).

Response to Finding No. 234:

Respondents have no specific response except to note that the proposed finding relies in part on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

235. The USPSTF also recommends that clinicians offer prostate cancer screening, in the form of a prostate-specific antigen (PSA) test, to a limited set of patients. (RX3729, USPSTF, Final Recommendation Statement – Prostate Cancer: Screening, May 8, 2018 (https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prostate-cancer-screening (last visited July 16, 2021)).

Response to Finding No. 235:

Respondents have no specific response.

236. The ACS also issues cancer screening guidelines in collaboration with cancer research experts for various cancers including breast, colorectal, lung, cervix, and prostate cancer. (Cance (American Cancer Society) Tr. 605-06).

Response to Finding No. 236:

Respondents have no specific response.

237. Existing screening methods are highly effective at detecting these cancers in patients. (*See, e.g.*, PX2165 (Illumina) at 011 (Exact Sciences Q3 2020 Earnings Call, Oct. 27, 2020)).

Response to Finding No. 237:

Respondents have no specific response except to note that the cited source also observes that "the important aspect of a multi-cancer screening test is that you are for the first time ever able to screen for cancers *that today aren't screened for*". (PX2165 (Illumina) at 011 (Exact Sciences Q3 2020 Earnings Call, Oct.. 27, 2020) (emphasis added).) Respondents also note that while the features of the existing screening methods are effective for single-cancer screening tests, these same characteristics are unlikely to be effective as part of a multi-cancer screening test. For example, existing single cancer screening tests typically have very high sensitivity rates and correspondingly lower specificity/higher false positive rates. (PFF ¶ 180.1 (Cote Expert Report ¶ 95).) By contrast, a test developer of a multi-cancer screening test must focus on attaining a very high specificity rate—leading to a low false positive rate—and a high positive predictive value, which will often result in correspondingly lower sensitivity rates. (PFF ¶ 173, 181 (Cote Tr. 3778-81; RX3869 (Cote Expert Report) ¶ 95).) Further, Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 10), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

238. [redacted] (PX5024 (Illumina) at 022 (Board of Directors M&A Landscape Presentation, Apr. 28, 2020) (*in camera*)).

Response to Finding No. 238:

Respondents have no specific response, except note that the cited [redacted]

[redacted] (PX5024 (Illumina) at 022 (Board of Directors M&A Landscape Presentation, Apr. 28, 2020 (*in camera*) (emphasis added).) Further, Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 10), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

239. [redacted] (PX5024 (Illumina) at 022 (Board of Directors M&A Landscape Presentation, Apr. 28, 2020) (*in camera*)).

Response to Finding No. 239:

Respondents have no specific response.

240. Radiologic tests are used to screen for breast cancer and lung cancer. (Cance (American Cancer Society) Tr. 606).

Response to Finding No. 240:

Respondents have no specific response.

241. Pap smears and examinations of the human papilloma virus DNA in blood screen for cervical cancer. (Cance (American Cancer Society) Tr. 606).

Response to Finding No. 241:

Respondents have no specific response.

242. Examinations of prostate-specific antigen levels screen for prostate cancer. (Cance (American Cancer Society) Tr. 606).

Response to Finding No. 242:

Respondents have no specific response.

243. Colonoscopy is the gold standard for colon cancer screening. (Conroy (Exact) Tr. 1547).

Response to Finding No. 243:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 237 herein.

244. Exact's Cologuard test has also been approved by the FDA as a screening test for colon cancer. (Conroy (Exact) Tr. 1547).

Response to Finding No. 244:

Respondents have no specific response except to note that Exact's Cologuard test uses PCR technology as a platform. (PFF ¶ 1743.)

245. [redacted] (Conroy (Exact) Tr. 1736-37; Nolan (Freenome) Tr. 2725; PX2009 (Illumina) at 017 (April BoD M&A Strategy Presentation, Apr. 28, 2020) (*in camera*); PX7040 (Getty (Guardant) IHT at 32)).

Response to Finding No. 245:

Respondents have no specific response.

246. [redacted] (PX5027 (Illumina) at 018 (*in camera*) [redacted] PX7040 (Getty (Guardant) IHT at 28 (65 percent compliance with colorectal screening recommendations))).

Response to Finding No. 246:

Respondents have no specific response.

247. An Illumina Board document cites Grail for the proposition that [redacted] (PX2009 (Illumina) at 017 (April BoD M&A Strategy Presentation, Apr. 28, 2020) (*in camera*)).

Response to Finding No. 247:

Respondents have no specific response.

2. Most Cancers Detected at Late Stages, Leading to Poor Outcomes

248. The American Cancer Society's Chief Medical and Scientific Officer, Dr. William Cance, testified that "[t]oday, there is no screening test available for all but five cancers, meaning that the vast majority of cancers are often diagnosed at very advanced stages of disease when treatment options are limited." (PX8398 (Cance (American Cancer Society) Decl. ¶ 6)).

Response to Finding No. 248:

Respondents have no specific response except to note that the cited reference—Dr. Cance's declaration—was drafted by Complaint Counsel. (Cance (American Cancer Society) Tr. 628.)

249. The American Cancer Society describes cancer staging as follows: "Stage describes the extent or spread of cancer at the time of diagnosis." (RX3030 at 011 (American Cancer Society, Cancer Facts & Figures 2019)).

Response to Finding No. 249:

Respondents have no specific response.

250. Stages of cancer range from 0 to Stage IV. (RX3030 at 011 (American Cancer Society, Cancer Facts & Figures 2019)).

Response to Finding No. 250:

Respondents have no specific response except to note that some cancers do not have a Stage IV and other cancers have alternative staging systems. (RX3030 at 011 (American Cancer Society, Cancer Facts & Figures 2019).) Respondents also incorporate their responses to CCFF ¶¶ 254 and 6210 herein.

251. Stage 0 correlates with "in situ" cancer, which means that "cancer cells are present only in the layer of cells where they developed and have not spread." (RX3030 at 011 (American Cancer Society, Cancer Facts & Figures 2019) (further explaining that "[i]f cancer cells have penetrated beyond the original layer of tissue, the cancer has become invasive and is categorized as local, regional, or distant based on the extent of the spread); RX3500 at 003 (Cancer Staging – National Cancer Institute, https://www.cancer.gov/about-cancer/diagnosis-staging/staging (last visited July 14, 2021) ("Stage 0 [means] [a]bnormal cells are present but have not spread to nearby tissue.")).

Response to Finding No. 251:

Respondents have no specific response.

252. Stage I cancer is "early" stage cancer and stage IV connotes "the most advanced disease." (RX3030 at 011 (American Cancer Society, Cancer Facts & Figures 2019)).

Response to Finding No. 252:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 250 herein.

253. From Stage 0 to Stage IV, "[t]he higher the number, the larger the cancer tumor and the more it has spread into nearby tissues[,]" until Stage IV, which means the "cancer has spread to distant parts of the body." (RX3500 at 003 (Cancer Staging – National Cancer Institute, https://www.cancer.gov/about-cancer/diagnosis-staging/staging (last visited July 14, 2021)).

Response to Finding No. 253:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 250 herein.

254. [redacted] (PX4172 (Grail) at 050 (Grail Board of Directors Meeting, Nov. 21, 2019) (*in camera*)).

Response to Finding No. 254:

The proposed finding is incomplete and misleading to the extent that it suggests that GRAIL refers to both Stages III and IV as "late stage" cancer in all circumstances. The cited Board of Directors presentation [redacted] (PX4172 (Grail) at 050 (Grail Board of Directors Meeting, Nov. 21, 2019) (*in camera*).) Thus, the presentation [redacted] (PX4172 (Grail) at 050 (Grail Board of Directors Meeting, Nov. 21, 2019 (in camera)).) Respondents also note that not all stage three cancers are the same: each stage has

subdivisions that "have prognostic importance", and thus "even within a stage, . . . the patients can be subdivided". (Cote Tr. 3732.)

Further, Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 39), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also refer to PFF ¶¶ 89-89.5.

255. By the time symptoms appear, cancer may already have grown and spread. (Conroy (Exact) Tr. 1736).

Response to Finding No. 255:

Respondents have no specific response.

256. Most cancers are discovered after they have grown and spread in a person's body. (Nolan (Freenome) Tr. 2724-25).

Response to Finding No. 256:

Respondents have no specific response.

257. A majority of cancers are discovered too late. (Conroy (Exact) Tr. 1736).

Response to Finding No. 257:

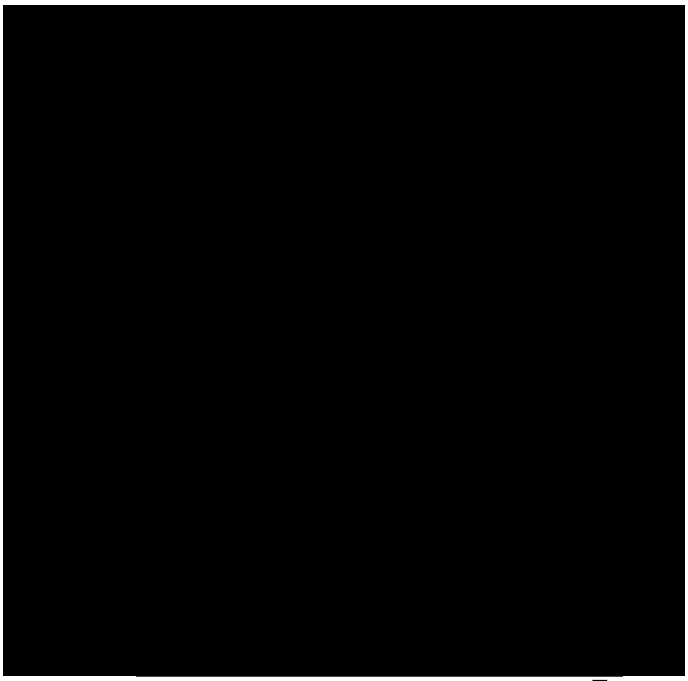
Respondents have no specific response.

258. Over half of cancers in the United States are diagnosed at Stages III and IV. (PX2005 (Illumina) at 002 (ScreenCo – Early Cancer Detection on a Global Scale)).

Response to Finding No. 258:

Respondents have no specific response.

259. [redacted]



(PX5027 (Illumina) at 019 (Board of Directors Project Valor Presentation, Aug. 3, 2020) (*in camera*)).

Response to Finding No. 259:

The proposed finding is incomplete and misleading to the extent that it suggests that Respondents also note that the cited presentation also observes that (PX5027 (Illumina) at 019 (Board of Directors Project Valor Presentation, Aug. 3, 2020) (*in camera*). The cited presentation also states that (PX5027 (Illumina) at 019 (Board of Directors Project Valor Presentation, Aug. 3, 2020) (*in camera*).)

260. [redacted] (PX5024 (Illumina) at 022 ((Board of Directors M&A Landscape Presentation, Apr. 28, 2020) (*in camera*); PX8317 (Exact) at 020 [redacted] (*in camera*)).

Response to Finding No. 260:

Respondents have no specific response except to note that the cited presentation observes [redacted] (PX8317 (Exact) at 020 [redacted] (*in camera*).)

261. Detection of cancer after it has progressed leads to high mortality rates. (PX2005 (Illumina) at 003 (ScreenCo – Early Cancer Detection on a Global Scale); Conroy (Exact) Tr. 1736 (explaining that by detecting cancer earlier, the odds of survival increase significantly)).

Response to Finding No. 261:

Respondents have no specific response except to note that all agree that accelerating the adoption of a cancer screening test with save lives, the unrefuted evidence shows that reuniting Illumina and GRAIL will accelerate the adoption of the Galleri test, and that there is no evidence that any putative MCED test developer will launch in the foreseeable future a cancer screening test that is a close substitute to the Galleri test. (PFF ¶¶ 476 (RX3869 (Cote Expert Report) ¶ 203), 1117.2-17.3 (*see e.g.* Conroy (Exact/Thrive) Tr. 1739; Chahine (Helio) Tr. 1132–33; [redacted] Fiedler (FMI) Tr. 4474; deSouza (Illumina) Tr. 2411; [redacted])

262. Patients that have cancer detected at an early stage by cancer screening tests benefit dramatically relative to patients that have cancer diagnosed at later stages. (Cance (American Cancer Society) Tr. 626).

Response to Finding No. 262:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 261 herein.

263. Treatment and/or surgical costs are typically lower for cancers detected at earlier stages. (Conroy (Exact) Tr. 1736).

Response to Finding No. 263:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 261 herein.

264. Dr. Cance described the benefits of screening early: "Screening for cancer increases the chances of detecting certain cancers early, when they might be easier to treat." (PX8398 (Cance (American Cancer Society) Decl. ¶ 5)).

Response to Finding No. 264:

Respondents have no specific response except to note that Dr. Cance also testified that GRAIL is further ahead in its development process than other companies that are developing purported MCED tests, that he is not aware of any other purported MCED test that is commercially available today, that he does not know of other companies detecting the same number of cancers as GRAIL, and that accelerating an early cancer detection test's ability to commercialize at scale is consistent with ACS's mission. (Cance (ACS) Tr. 631–33.) Respondents also incorporate their responses to CCFF ¶¶ 248 and 261 herein.

265. [redacted] (PX8506 (Guardant) at 004 [redacted] (*in camera*)).

Response to Finding No. 265:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 261 herein.

266. [redacted] (PX8506 (Guardant) at 004 [redacted] *n camera*)).

Response to Finding No. 266:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 261 herein.

C. MCED TESTS ARE POISED TO REVOLUTIONIZE HOW CANCER IS DETECTED AND TREATED

267. "[A]dvancements in blood-based cancer diagnostics present the possibility that some cancers previously undetectable until the late stages of disease could be detected at earlier stages, when treatment has higher likelihood of success." (PX8398 (Cance (American Cancer Society) Decl. ¶ 6)).

Response to Finding No. 267:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 248 and 264 herein.

268. "We always dreamt that it would be great to detect cancer early, because early cancer detection saves lives. Even with the current treatments that we have, if you use the same treatment and you were tested back for cancer earlier, most individuals not only live longer but actually get cured." (Lengauer (Third Rock Ventures) Tr. 273).

Response to Finding No. 268:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 261 herein.

269. Guardant's Nitin Sood testified how important MCED test development is: "cancer is a very serious disease, so it has a, you know, life altering impact on people. And we all know that with cancer, the sooner you detect it, the more localized it is, the more treatable it is and could mean the difference between life and death. And, therefore, the broader it's available to the community as a large -- not only in the U.S. but globally, the greater benefit to the world." (PX7090 (Sood (Guardant) Dep. at 111)).

Response to Finding No. 269:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 261 herein.

1. The Advantages of Liquid Biopsy

270. "Traditionally, cancers are detected and diagnosed through a tissue biopsy or involve an invasive procedure like a colonoscopy." (PX8398 (Cance (American Cancer Society) Decl. ¶ 5)).

Response to Finding No. 270:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 248 herein.

271. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 28-29) (*in camera*)).

Response to Finding No. 271:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

272. Liquid biopsy tests are a new type of cancer screening test being developed. (Cance (American Cancer Society) Tr. 608).

Response to Finding No. 272:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 264 herein.

273. Prior to liquid biopsies, "in order to get information about a tumor, you were dependent on tissue samples of that tumor such that you could sequence it and then determine what was wrong in that particular individual's genome." (Getty (Guardant) Tr. 2489).

Response to Finding No. 273:

Respondents have no specific response.

274. Dr. Cance of the American Cancer Society testified: "Liquid biopsy offers several advantages over tissue biopsy. Most patients are comfortable and familiar with blood draws. Whereas tissue biopsy requires the surgical removal of tumor tissue for common pathology testing, liquid biopsy extracts similar information from the patient's blood." (PX8398 (Cance (American Cancer Society) Decl. ¶ 8)).

Response to Finding No. 274:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 248 and 264 herein.

275. [redacted] (PX7053 (Fesko (Natera) IHT at 21); PX7068 (Perettie (FMI-Roche) IHT at 21-23) (*in camera*); Cance (American Cancer Society) Tr. 608-09; PX8398 (Cance (American Cancer Society) Decl. ¶ 8)).

Response to Finding No. 275:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 264 herein. Respondents also note that the proposed finding relies in part on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶ 248 herein.

276. In traditional tissue biopsies, a portion of tissue must be removed—sometimes surgically, which takes more time and is expensive. (PX7053 (Fesko (Natera) IHT at 21); PX7040 (Getty (Guardant) IHT at 51-54); PX8398 (Cance (American Cancer Society) Decl. ¶ 8)).

Response to Finding No. 276:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 261 herein. Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶ 248 herein.

277. Liquid biopsy has a quicker turnaround time than a tissue biopsy and can be more accurate. (PX7040 (Getty (Guardant) IHT at 51-54); *see* PX4082 (Grail) at 012 (Email attaching Grail 2020 S-1/Amended, Sept. 2020) (noting that today patients are subjected to "potentially invasive and time-consuming workups" for "non-specific signs")). Natera's Mr. Fesko testified that "there is a lot of heterogeneity within tumors, and so you may get a cleaner and more accurate signal from liquid biopsy than a tumor biopsy." (PX7053 (Fesko (Natera) IHT at 21-22)).

Response to Finding No. 277:

Respondents have no specific response except to note that turnaround time is not a critical feature for early cancer screening tests. (Goswami (Illumina) Tr. 3196–3200 (fast turnaround times are not important for early cancer screening tests); Cote Tr. 151–52 ("But as I pointed out, for the purposes of cancer screening, this was probably the least important attribute because the differences in turnaround time are really not important when it comes to the specific application of -- of a cancer screening application.").) The proposed finding relies in part on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

278. "[L]iquid biopsy relies on blood, a regenerating and readily accessible sample. It can be difficult, and sometimes impractical, to obtain a tissue biopsy for some cancers. With liquid biopsy, however, the patient could readily give more blood for additional testing." (PX8398 (Cance (American Cancer Society) Decl. ¶ 8); *see also* PX2010 (Illumina) at 022 (TruSight Oncology 500 ctDNA: Sales Training) ("Up to 25% of cancer tissue needle biopsies yield insufficient material for clinical sequencing[.]"). [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 22-23) (*in camera*)).

Response to Finding No. 278:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 248 and 264 herein.

279. Natera's Chief Business Officer, Jon Fesko, testified about the benefits of liquid biopsy: "The most obvious advantage is sometimes you cannot get tissue to test. In fact, I think in about a quarter of all lung cancer patients, there is no attainable tissue. So if you can use a liquid biopsy, you can guide a patient to the appropriate treatment without having access to -- you would not have access to that information otherwise." (PX7053 (Fesko (Natera) IHT at 21); PX2010 (Illumina) at 022 (TruSight Oncology 500 ctDNA: Sales Training) ("Up to 25% of cancer tissue needle biopsies yield insufficient material for clinical sequencing[.]")).

Response to Finding No. 279:

Respondents have no specific response.

280. Liquid biopsy is generally safer and less uncomfortable for the patient than other current cancer screening tests. (PX8398 (Cance (American Cancer Society) Decl. ¶ 8); PX7040 (Getty (Guardant) IHT at 51-54); PX7042 (Gao (Singlera) IHT at 25-26); PX7044 (Stahl (Invitae) IHT at 45-46); PX0059 at 010-011 (Guardant 2020 10-K); PX8313 (Guardant) at 002 (Guardant 360 CDx Original PMA Application Attachment 6-1: Background Information on Liquid Biopsy for NGS Tests)).

Response to Finding No. 280:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 248 and 264 herein. Respondents also note that the proposed finding relies in part on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

281. Liquid biopsy tests are easier to repeat over time to observe changes than are tissue biopsy tests. (PX7040 (Getty (Guardant) IHT at 51-54)).

Response to Finding No. 281:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

282. Patient compliance is also a recognized strength for liquid biopsy: "Where liquid biopsy has significant advantages over the current standard of care is simply around compliance most importantly." (PX7040 (Getty (Guardant) IHT at 28)).

Response to Finding No. 282:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

283. [redacted]

Response to Finding No. 283:

Respondents have no specific response.

284. A liquid biopsy test begins with the collection of a blood (or other fluid) sample from the patient and is sent to the receiving laboratory. (PX4035 (Grail) at 016 (PiperJaffray, The 2015 Liquid Biopsy Report, Sep. 2015)).

Response to Finding No. 284:

Respondents have no specific response except to note that liquid biopsy test developers do not use Illumina technology for blood or other fluid sample collection from the patient. (*See* Berry (Illumina) Tr. 814 ("Illumina does not participate specifically in this space" of "isolating the genetic material to be sequenced from [a blood] sample").)

285. Once at the laboratory, the test developer performs a "series of chemistry steps to isolate the DNA from" the patient's blood and prepares it for sequencing in a process known as library preparation. (Bishop (Grail) Tr. 1379-81); *see also* Ofman (Grail) Tr. 3286; Chudova (Guardant) Tr. 1157-59; PX4035 (Grail) at 016 (PiperJaffray, The 2015 Liquid Biopsy Report, Sep. 2015); Rabinowitz (Natera) Tr. 306-09).

Response to Finding No. 285:

Respondents have no specific response except to note that many liquid biopsy tests, including those being developed for multi-cancer screening, do not involve sequencing. (*See, e.g.*, PFF ¶¶ 547-49.2 (StageZero); 554 (Genesys Biolabs); 558 (InterVenn Biosciences).) Respondents also note that liquid biopsy test developers do not use Illumina technology for library preparation. (Berry (Illumina) Tr. 815 (stating that the library preparation step "is very unique and specific to the particular test provider's sort of approach of methodology" and that there are "hundreds and hundreds of library preparation methods" and "potentially hundreds of providers of library preparation technology or kits").)

286. Following library preparation, the test sample is sequenced on a sequencing instrument to identify the order of base pairs in each molecule in the library. (PX0043 at 105-06 (Grail 2020 Form S-1); *see also* Berry (Illumina) Tr. 818-19 (explaining that Illumina sequencers'

primary analysis involves "base calling" by translating florescent signals to bases); Chudova (Guardant) Tr. 1159)).

Response to Finding No. 286:

Respondents have no specific response except to note that many liquid biopsy tests, including those being developed for multi-cancer screening, do not involve sequencing. (*See, e.g.*, PFF ¶¶ 547-549.2 (StageZero); 554 (Genesys Biolabs); 558 (InterVenn Biosciences).)

287. [redacted] (Chudova (Guardant) Tr. 1159; PX7051 (Lengauer (Third Rock Ventures) IHT at 37) (*in camera*); PX7048 (Klausner (Grail) IHT at 119)).

Response to Finding No. 287:

Respondents have no specific response except to note that many liquid biopsy tests, including those being developed for multi-cancer screening, do not involve sequencing. (*See, e.g.*, PFF ¶¶ 547-549.2 (StageZero); 554 (Genesys Biolabs); 558 (InterVenn Biosciences).) Respondents also note that liquid biopsy test developers do not use Illumina technology for bioinformatic and analytical analysis to identify the potential presence of cancer. (Berry (Illumina) Tr. 821 (stating that "secondary analysis and finally tertiary analysis, that tends to be the domain of other providers. And specifically, the tertiary analysis piece tends to correlate very closely with library preparation. And oftentimes the library preparation provider will also provide the data analysis piece because those two pieces of the workflow go hand in hand."); Tr. 815 (stating that the library preparation step "is very unique and specific to the particular test provider's sort of approach of methodology" and that there are "hundreds and hundreds of library preparation methods" and "potentially hundreds of providers of library preparation technology or kits").)

2. Analyte Molecules Present in Blood and Other Body Fluids

a) Cell-Free DNA (cfDNA) and Circulating Tumor DNA (ctDNA)

288. Nearly all cells, including cancer cells, contain deoxyribonucleic acid ("DNA"). (PX0043 at 105 (Grail 2020 Form S-1)).

Response to Finding No. 288:

Respondents have no specific response.

289. DNA is typically double stranded and is made up of complementary pairs of nucleotides, also known as base pairs. (PX0043 at 105 (Grail 2020 Form S-1)).

Response to Finding No. 289:

Respondents have no specific response.

290. Each nucleotide in a DNA molecule contains one of four nitrogenous bases: Cytosine (C), Guanine (G), Adenosine (A), or Thymine (T). (Rabinowitz (Natera) Tr. 304).

Response to Finding No. 290:

Respondents have no specific response.

291. DNA resides in the nucleus of most cells in the form of long (up to hundreds of millions of base pairs) molecules called chromosomes. (PX4035 (Grail) at 010 (PiperJaffray, The 2015 Liquid Biopsy Report, Sept. 2015); PX0043 at 105 (Grail 2020 Form S-1)).

Response to Finding No. 291:

Respondents have no specific response.

292. As cells within the body die, their chromosomes are broken down into small pieces and released into the blood stream as cell-free DNA ("cfDNA"). These cfDNA fragments are typically less than 200 base pairs long. (PX2010 (Illumina) at 008 (TruSight Oncology 500 ctDNA Sales Training); *see also* Chudova (Guardant) Tr. 1157-62; PX8313 (Guardant) at 002 (Guardant 360 CDx Original PMA Application Attachment 6-1: Background Information on Liquid Biopsy for NGS Tests)).

Response to Finding No. 292:

Respondents have no specific response.

293. cfDNA is thus a harmless byproduct of cell death that is present in all human bloodstreams. (PX4035 (Grail) at 010-011 (PiperJaffray, The 2015 Liquid Biopsy Report, Sept. 2015) (noting 50 to 70 million cells die every 24 hours)).

Response to Finding No. 293:

Respondents have no specific response.

294. Cancerous cells go through the same process; when cancer cells die, their chromosomes are broken down into short fragments that are shed into the bloodstream as cfDNA. (PX2010 (Illumina) at 008 (TruSight Oncology 500 ctDNA Sales Training)).

Response to Finding No. 294:

Respondents have no specific response.

295. The subset of cfDNA in the blood that originated from cancerous tumor cells is specifically called circulating tumor DNA ("ctDNA"). ctDNA reflects the genetic makeup of the tumor cells that released it and can differ from normal non-cancerous cfDNA in a variety of ways. (PX2010 (Illumina) at 009 (TruSight Oncology 500 ctDNA Sales Training); PX4035 (Grail) at 011-012 (PiperJaffray, The 2015 Liquid Biopsy Report, Sept. 2015)).

Response to Finding No. 295:

Respondents have no specific response.

296. "ctDNA is a direct measurement of cancer DNA, rather than an indirect measure of the effects of cancer." (PX2005 (Illumina) at 005 (ScreenCo: Early Cancer Detection on a Global Scale, Presentation)).

Response to Finding No. 296:

Respondents have no specific response except to note that there are other direct measurements of cancer including RNA biomarkers (PFF ¶ 110 (Cote Tr. 3733; RX3869 (Cote Expert Report) ¶¶ 48–50)), protein biomarkers (PFF ¶ 115 (Cance (ACS) Tr. 612-13; Cote Tr. 3736-37; RX3869 (Cote Expert Report) ¶¶ 51–53)), metabolomic biomarkers (PFF ¶ 120 (Cance (ACS) Tr. 609-10, 612-13; PX7131 (Cote Dep. at 112); RX3869 (Cote Expert Report) ¶¶ 54–55)), and exosome biomarkers (PFF ¶ 121.1 (RX3745 (Wong, et al., 2019) at 2, 5; PX7131 (Cote Dep. at 111-12); RX3869 (Cote Expert Report) ¶ 56)).

297. Because "most of the DNA in blood is derived from normal cells[,]" there is a very small amount of ctDNA in blood relative to normal cfDNA. (Lengauer (Third Rock Ventures) Tr. 161-62).

Response to Finding No. 297:

Respondents have no specific response.

298. [redacted] (PX2013 (Illumina) at 009 (Science & Technology Committee: Cancer Screening, Apr. 28, 2020) (*in camera*); PX7040 (Getty (Guardant) IHT at 39) ("you truly are finding a needle in a haystack"); PX7042 (Gao (Singlera) IHT at 39-40) (explaining that "the cancer signal [in the blood is] very subtle" at early stages); PX7045 (Chudova (Guardant) IHT at 30-31) (analogizing finding cancer signals to "find[ing] that needle in the haystack").

Response to Finding No. 298:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

299. The level of ctDNA in the blood can vary between individuals and tumor entities, but generally correlates to tumor size and stage, known as the "tumor burden." (Chudova (Guardant) Tr. 1162-64).

Response to Finding No. 299:

Respondents have no specific response.

300. [redacted] PX7111 (Fesko (Natera) Dep. at 29) (*in camera*)).

Response to Finding No. 300:

Respondents have no specific response except to note that some developers of cancer tests do use ctDNA as a biomarker to detect brain cancer. (*See* PX7095 (Hill (Emory Health) Dep. at 92-93 ("In the particular case of what we're doing [single-nucleotide extension], which is very heavily geared toward lung cancer and glial tumors, brain tumors . . . we can detect up to -- we have quantified it at 44 mutations in 10 different genes, and it's 44 very specific mutations.")).)

301. Dr. Chudova, Guardant's SVP of Technology, testified that "the challenges of detecting [ctDNA] become more significant as you go from late-stage disease to early-stage and then into screening." (Chudova (Guardant) Tr. 1163).

Response to Finding No. 301:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 261 herein.

b) Cell-Free RNA (cfRNA)

302. [redacted] (*See* Jamshidi (Grail) Tr. 4055-56 (*in camera*)).

Response to Finding No. 302:

Respondents have no specific response.

303. Nearly all cells, including cancer cells, contain ribonucleic acid ("RNA"). (PX0043 at 105 (Grail 2020 Form S-1)).

Response to Finding No. 303:

Respondents have no specific response.

304. [redacted] (*See* Jamshidi (Grail) Tr. 4055-56 (*in camera*)).

Response to Finding No. 304:

Respondents have no specific response.

305. [redacted] (Bishop (Grail) Tr. 1481-82 (*in camera*)).

Response to Finding No. 305:

Respondents have no specific response.

306. [redacted] (*See, e.g.*, Nolan (Freenome) Tr. 2816 (*in camera*); Jamshidi (Grail) Tr. 4056 (*in camera*) [redacted].

Response to Finding No. 306:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests [redacted]

To the contrary, GRAIL has locked version 2 of Galleri, which is the version currently on the market, and is working on an updated version of Galleri that meets current performance standards while sequencing fewer regions of the genome, thereby reducing the cost of the test. (PFF ¶ 1607 (Ofman (GRAIL) Tr. 3301–03).) GRAIL does not plan to incorporate cfRNA as an analyte into the Galleri test. (Ofman (GRAIL) Tr. 3304 (testifying that GRAIL does not have any plans at this time to modify its Galleri test to include other biomarkers, apart from ctDNA).) Respondents also incorporate their responses to CCFF ¶ 312 herein.

c) Proteins

307. [redacted] (*See* Jamshidi (Grail) Tr. 4056-576 (*in camera*)).

Response to Finding No. 307:

The proposed finding is incomplete and misleading to the extent that it suggests that [redacted]. Rather, Dr. Jamshidi testified at trial that [redacted]. (*See* Jamshidi (Grail) Tr. 4056–57 (*in camera*).)

308. [redacted] (*See, e.g.*, Jamshidi (Grail) Tr. 4055-56 (*in camera*)); Nolan (Freenome) Tr. 2711 (*in camera*).

Response to Finding No. 308:

The proposed finding is incomplete and misleading to the extent that it suggests that GRAIL is planning to incorporate protein as an analyte into its Galleri test. To the contrary, GRAIL has locked version 2 of Galleri, which is the version currently on the market, and is working on an updated version of Galleri that meets current performance standards while sequencing fewer regions of the genome, thereby reducing the cost of the test. (PFF ¶ 1607

(Ofman (GRAIL) Tr. 3301–03.) GRAIL does not plan to incorporate proteins as an analyte into the Galleri test. (Ofman (GRAIL) Tr. 3304 (testifying that GRAIL does not have any plans at this time to modify its Galleri test to include other biomarkers apart from ctDNA).) Respondents also incorporate their responses to CCFF ¶ 312 herein.

3. Classes of Biomarkers Utilized for Cancer Detection

309. "A biomarker is some form of signature or fingerprint" that may indicate the existence of cancer. (Lengauer (Third Rock Ventures) Tr. 160).

Response to Finding No. 309:

Respondents have no specific response.

310. Mr. Conroy testified that a "biomarker is either a protein or DNA or RNA or other molecule in the body that is present when cancer is present and not present when cancer is not present." (PX7058 (Conroy (Exact) IHT at 31-32)).

Response to Finding No. 310:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

311. [redacted] (*See, e.g.*, Lengauer (Third Rock Ventures) Tr. 160, 175) (*in camera*); Aravanis (Illumina) Tr. 1880-81)).

Response to Finding No. 311:

Respondents have no specific response.

312. Dr. Cance of the American Cancer Society explained that "[a]t this stage, it is unclear whether analyzing DNA mutations, DNA methylation patterns, chromosomal variants, RNA variations, protein markers, or some other method for detecting cancer in the blood will prove most effective." (PX8398 (Cance (American Cancer Society) Decl. ¶ 11).

Response to Finding No. 312:

The proposed finding is incomplete and misleading to the extent that it suggests that GRAIL has not analyzed which of the classes of biomarkers is most effective, when it designed a

study precisely to determine the most effective way to identify multiple cancers and their signal of origin (PFF ¶¶ 377, 380) and ultimately chose to detect cfDNA shed by cancer cells using a targeted methylation assay (PFF ¶ 345). Respondents also incorporate their responses to CCFF ¶¶ 248 and 264 herein.

a) DNA Mutations (Genomics)

313. Mutations are changes to the sequence of nucleotides in a DNA molecule. (Chudova (Guardant) Tr. 1166-67).

Response to Finding No. 313:

Respondents have no specific response.

314. **There are multiple types of DNA mutations.** An example of a mutation would be a single nucleotide variant, where for example a C nucleotide changes to a T nucleotide. (Chudova (Guardant) Tr. 1166-67)).

Response to Finding No. 314:

Respondents have no specific response.

315. A mutation that occurs in any cell in the body that is not a germ line cell is called a "somatic mutation." (Chudova (Guardant) Tr. 1165.)

Response to Finding No. 315:

Respondents have no specific response.

316. [redacted] (PX7091 (Lengauer (Third Rock Ventures) IHT at 25) (*in camera*)).

Response to Finding No. 316:

The proposed finding is incomplete and misleading to the extent it suggests that there are certain universal cancer mutations or changes that are indicative of cancer. (PFF ¶¶ 308–309 (Cote Tr. 3787; Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106).) Respondents also note that the proposed finding relies on IH testimony which Respondents had

no opportunity to cross examine and therefore the cited testimony should be given no weight.

(*See* Resps.' Post-Trial Br. at 275–76.)

317. Interrogating mutations in cfDNA falls within the larger field of study called "genomics." (*See, e.g.*, PX2369 (Illumina) at 014 (Email from J. Godsey, Illumina, to D. Baker et al., Illumina, Apr. 12, 2020, attaching "Recent Advances in Genomics-based Cancer Screening" draft, Apr. 28, 2020) [redacted] (*in camera*)).

Response to Finding No. 317:

Respondents have no specific response.

318. [redacted] (*See, e.g.*, Chudova (Guardant) Tr. 1164-65; Lengauer (Third Rock Ventures) Tr. 175 (*in camera*); Nolan (Freenome) Tr. 2711 (*in camera*); PX7074 (Perettie (FMI-Roche) Dep. at 75) (*in camera*)).

Response to Finding No. 318:

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and that Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

b) DNA Methylation (Epigenomics)

319. Methylation is a process that plays a role in regulating gene expression, protein function, and RNA processing. (PX0043 at 106 (Grail 2020 Form S-1); *see also* Ofman (Grail) Tr. 3286 (stating that methylation refers to "little methyl groups that actually attach to the DNA" but do not change the DNA code); Rabinowitz (Natera) Tr. 357-58 (*in camera*)

(explaining that [redacted]).

Response to Finding No. 319:

Respondents have no specific response.

320. "[A] methylated nucleotide undergoes a specific chemical modification that has a chemical mark added to that nucleotide that really changes how the cell functions." For example, "we[] have the same DNA in our heart cells and our liver cells, generally, but [the] heart and liver function very differently. This is achieved partially by different methylation status of different genes, and so they can trigger a different development program or different expression program for the cells based on that chemical mark." (Chudova (Guardant) Tr. 1167).

Response to Finding No. 320:

Respondents have no specific response.

321. Each cell type in the body has a unique methylation pattern, known as its "fingerprint," and modifications to such patterns can result in pronounced changes to cellular function. (PX0043 at 106 (Grail 2020 Form S-1)).

Response to Finding No. 321:

Respondents have no specific response.

322. Methylation changes can lead to genes becoming over-expressed, under-expressed, or silenced altogether, thus resulting in excessive, reduced, or no protein production (respectively). (PX0043 at 106 (Grail 2020 Form S-1)). These deviations from normal cellular function can cause disease. For example, certain methylation modifications can turn off a tumor suppressor gene, leading to tumor growth and cancer. (PX0043 at 106 (Grail 2020 Form S-1)).

Response to Finding No. 322:

Respondents have no specific response.

323. Abnormal methylation patters are a hallmark of cancer, such as where unmethylated C in a nucleotide becomes a methylated C, or vice versa. (Chudova (Guardant) Tr. 1167; Ofman (Grail) Tr. 3286)).

Response to Finding No. 323:

The proposed finding is incomplete and misleading to the extent it suggests that there are certain universal cancer mutations or changes that are indicative of cancer. (PFF ¶¶ 308–309 (Cote Tr. 3787; Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106).)

324. [redacted] (Chudova (Guardant) Tr. 1166 ("We call these modifications epigenetic changes or methylation changes."); PX7068 (Perettie (FMI-Roche), IHT at 53-54) (*in camera*)).

Response to Finding No. 324:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

c) DNA Fragmentation (Fragmentomics)

325. [redacted] (Lengauer (Third Rock Ventures) Tr. 175 (*in camera*)).

Response to Finding No. 325:

Respondents have no specific response.

326. [redacted] (*See, e.g.*, Lengauer (Third Rock Ventures) Tr. 175 (*in camera*); Chudova (Guardant) Tr. 1243 (*in camera*)).

Response to Finding No. 326:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 318 herein.

d) DNA Aneuploidy

327. [redacted] (Lengauer (Third Rock Ventures) Tr. 1776 (*in camera*)).

Response to Finding No. 327:

Respondents have no specific response.

328. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 36-37) (*in camera*); *see also* Lengauer (Third Rock Ventures) Tr. 175-76 (*in camera*)).

Response to Finding No. 328:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

329. [redacted] (Lengauer (Third Rock Ventures) Tr. 175-76 (*in camera*)).

Response to Finding No. 329:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 318 herein and to note that the cited testimony indicates that [redacted]. (Lengauer (Third Rock Ventures) Tr. 175–76.).

e) RNA Expression (Transcriptomics)

330. [redacted] (*See, e.g.,* PX7092 (Ofman (Grail) Dep. at 264) [redacted]) (*in camera*); Nolan (Freenome) Tr. 2817 (explaining [redacted]) (*in camera*)).

Response to Finding No. 330:

Respondents have no specific response.

331. [redacted] (*See, e.g.*, Nolan (Freenome) Tr. 2711; Jamshidi (Grail) Tr. 4055-56 (*in camera*)).

Response to Finding No. 331:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 318 herein.

f) Protein Levels (Proteomics)

332. Proteomics describes the analysis of proteins. (Nolan (Freenome) Tr. 2711).

Response to Finding No. 332:

Respondents have no specific response.

333. [redacted] (*See, e.g.*, Lengauer (Third Rock Ventures) Tr. 175) (*in camera*)).

Response to Finding No. 333:

Respondents have no specific response.

334. Interrogating protein expression levels falls within the field of study called "proteomics." (Nolan (Freenome) Tr. 2711).

Response to Finding No. 334:

Respondents have no specific response.

335. Proteomics platforms, which are separate from and "not direct replacements for" NGS platforms, are used to analyze proteins in patient samples. (deSouza (Illumina) Tr. 2325).

Response to Finding No. 335:

Respondents have no specific response except to note that the proposed finding is incomplete and misleading to the extent it suggests that proteomics platforms alone cannot be used for cancer screening tests. To the contrary, while a screening test that will identify 50 types of cancer from a single blood sample that can also identify the cancer signal of origin is likely to use NGS technology, a screening test for fewer types of cancer, particularly two or three types of cancer, can use other diagnostic platforms, such as proteomics, PCR or microarray technology. (PFF ¶ 1971; *see also* PFF ¶¶ 557–573.) For example, Genesys Biolabs' OneTest is a

proteomics-based test that measures seven cancer protein biomarkers that screen for lung, liver, pancreatic, ovarian, prostate and colon cancers. (PFF ¶ 692.2 (RX3259 (Genesys Biolabs); RX3869 (Cote Expert Report) ¶ 253); *see also* PFF ¶¶ 554–555.1; 693.)

336. [redacted] (*See, e.g.*, Cance (American Cancer Society) Tr. 613; Nolan (Freenome) Tr. 2759 (*in camera*)).

Response to Finding No. 336:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 261 and 318 herein. Respondents also note that Mr. Nolan testified that [redacted] (PX7094 (Nolan (Freenome) Dep. at 307).) [redacted] (PFF ¶¶ 459-70.) Accordingly, there is no indication based on Freenome's work to date that [redacted] (PFF ¶ 458 [redacted]; RX3869 (Cote Expert Report) ¶ 193).)

337. [redacted] (*See, e.g.*, Cance (American Cancer Society) Tr. 613; Nolan (Freenome) Tr. 2759 (*in camera*)).

Response to Finding No. 337:

The proposed finding is inaccurate, incomplete and misleading because several purported MCED test developers *are* developing tests exclusively utilizing proteomics biomarkers. (*See* PFF ¶ 1971; *see also* PFF ¶¶ 557–573.) For example, Genesys Biolabs' OneTest is a proteomics-based test that measures seven cancer protein biomarkers that screen for lung, liver,

pancreatic, ovarian, prostate and colon cancers. (PFF ¶ 692.2 (RX3259 (Genesys Biolabs); RX3869 (Cote Expert Report) ¶ 253); *see also* PFF ¶¶ 554–555.1; 693.) InterVenn currently provides an AI-enabled, mass spectrometry glycoproteomics-based proteomics platform, called VISTA, which is used by InterVenn to develop early cancer detection tests for advanced adenoma, colorectal cancer and nasopharyngeal carcinoma. (Leite (Illumina/InterVenn) Tr. 2171–74; RX3389 (InterVenn) at 1; PFF ¶¶ 557–563.1.) Seer is developing a Proteograph™ automated workflow proteomics platform that is used by PrognomiQ to develop early cancer detection tests. (RX1605 (Blume et al., 2020) at 1–14; RX3587 (PrognomiQ) at 2; PFF ¶¶ 564–569.)

g) Multiomics

338. [redacted] (*See* Della Porta (Grail) Tr. 492 (*in camera*); Nolan (Freenome) Tr. 2710-11)).

Response to Finding No. 338:

Respondents have no specific response.

339. [redacted] (*See, e.g.*, Cance (American Cancer Society) Tr. 613; Chudova (Guardant) Tr. 1166, 1243 (*in camera*); Nolan (Freenome) Tr. 2710-11 (describing Freenome's multiomics platform as spanning genomics, transcriptomics, and proteomics)).

Response to Finding No. 339:

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer

early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

4. MCED Tests Rely on Illumina NGS to Simultaneously Examine Thousands of Cancer Biomarkers in cfDNA

340. [redacted]

Response to Finding No. 340:

The proposed finding is inaccurate, incomplete and misleading. To the extent Complaint Counsel relies on its Proposed Findings in CCFF ¶¶ 341–348, Respondents incorporate their responses to those Proposed Findings herein.

341. [redacted]
(PX7102 (Gao (Singlera) Dep. at 131); PX7096 (Song (Omniome) Dep. at 141); PX7070 (Felton (Thermo Fisher) IHT at 26-28) (*in camera*); *see* PX7046 (George (Invitae) IHT at 74-75) ("Illumina emerged as the dominant player…about six years ago…"); PX7054 (Rabinowitz (Natera) IHT at 36, 41-42) ("[E]ven at that time [around 2010 and 2011] . . .Illumina was pretty dominant in the sequencing market."); *see also infra* Section V.D. (Only Illumina NGS Platforms Meet the Requirements of MCED Tests)).

Response to Finding No. 341:

The proposed finding relies in part on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is inaccurate, incomplete and misleading. Contrary to Complaint Counsel's unproven contention that all MCED tests require Illumina's NGS platforms, there are several other NGS platforms that can support purported MCED tests in development. (PPF ¶¶ 776–781.) BGI already has a commercially available NGS platform. (PFF ¶¶ 777–777.5.) BGI

recently won a jury verdict that held three of Illumina's patents to be invalid, meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022). [redacted] (PFF ¶¶ 778–778.2; 2085.) In addition to BGI and [redacted] Oxford Nanopore is a viable alternative for MCED developers. (PFF ¶¶ 779–779.3.) There are also many NGS platforms in development that are likely to enter the market in the near future and will be viable platforms for MCED tests. (PFF ¶¶ 782–787.)

Purported MCED test developers treat these NGS platforms as viable substitutes for Illumina's NGS platform. (PFF ¶ 780.) [redacted] (RX0055 (Exact/Thrive) at 2.) [redacted] (PFF ¶ 780.1.) [redacted] Dr. Gao of Singlera testified that the PanSeer test can be run using Thermo Fisher equipment. (PFF ¶ 780.4.) [redacted]

To the extent Complaint Counsel relies on its Proposed Findings in Section V.D. (CCFF ¶¶ 1019–1211), Respondents incorporate their responses to those Proposed Findings herein.

342. MCED tests examine blood samples to detect cancer at an early stage. (Cance (American Cancer Society) Tr. 609).

Response to Finding No. 342:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 264 and 318 herein.

343. Dr. Cance explained in general terms how an MCED test works: "Many of these [MCED] tests examine fragments of DNA in the bloodstream and determine whether any DNA has been shed from cancer cells." (PX8398 (Cance (American Cancer Society) Decl. ¶ 7)).

Response to Finding No. 343:

Respondents have no specific response except to note that the cited source [redacted] (PX8398 (Cance (American Cancer Society) Decl. ¶ 7.) Respondents also incorporate their responses to CCFF ¶ 248 herein.

344. [redacted] (*See, e.g.*, Lengauer (Third Rock Ventures) Tr. 179-80 (*in camera*) [redacted]

Response to Finding No. 344:

The proposed finding is inaccurate, incomplete and misleading, including because it appears to suggest that [redacted] To the contrary, many test developers are pursuing cancer screening tests for multiple cancers using other analytes. For example, StageZero's Aristotle test is a microarray-based liquid biopsy test that interrogates mRNA to detect 10 cancers and Genesys Biolabs' OneTest is a proteomics-based test that measures seven cancer protein biomarkers to screen for lung, liver,

pancreatic, ovarian, prostate and colon cancers. (*See* PFF ¶¶ 691–696.) Protein biomarkers have also been used for many years for early stage cancer detection and screening. (*See* PFF ¶¶ 155–157.) An increasing number of companies are developing "multi-omic" tests which combine information from multiple analytes, including DNA (genome), RNA (transcriptome) and protein (proteome) for increased sensitivity in cancer detection. (*See* PFF ¶¶ 169–169.3.)

345. MCED tests require the ability to detect on the order of one molecule of DNA in ten milliliters of blood. (*See, e.g.*, Lengauer (Third Rock Ventures) Tr. 162-63). NGS can detect one molecule of DNA in ten milliliters of blood. (Lengauer (Singular Genomics) Tr. 162-63).

Response to Finding No. 345:

The proposed finding is not supported by the cited evidence. In the cited testimony, Dr. Lengauer merely commented on the ability for current technologies to "detect one molecule of DNA in ten milliliter of blood", which "becomes stochastic, because the ten next milliliters might not contain any cancer molecules." (Lengauer (Exact/Thrive) Tr. 162–63.) Dr. Lengauer did not testify that only NGS can detect one molecule of DNA in ten milliliters of blood or what specific techniques are so sensitive that can detect one molecule of DNA in ten milliliters of blood. (Lengauer (Exact/Thrive) Tr. 162–63.) For example, PCR is highly sensitive and requires only minimal amount of sample for detection and amplification of specific sequences. (*See* PFF ¶¶ 158–162.)

346. As Jay Flatley, former Illumina CEO, told Illumina investors in a 2016 investor call:

> To reliably detect ctDNA across cancer types with the needed sensitivity and specificity requires ultra-deep sequencing, thousands or more times the depth and breadth that has been used routinely in a [sic] clinical settings to date. . . .
>
> We expect the clinical trials required to show statistical significance could require sequencing between 100K and 300K genomes at 60X depth, or the equivalent of two whole genomes per sample, implying a project that could be as large as 6 times the scope of Genomics England. Only Illumina can sequence at the price points necessary to enable the required trials, . . .

(PX0037 at 004-005 (Illumina, Grail Investor Call Script, Jan. 10, 2016)).

Response to Finding No. 346:

Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 1), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

The proposed finding is incomplete and misleading. Although the cited source is from January 2016, the proposed finding appears to suggest that, even today, more than six years after the earnings call, "[o]nly Illumina can sequence at the price points necessary to enable the required trials." Contrary to Complaint Counsel's unproven contention, there are other viable NGS platforms on the market today that can support MCED tests in development. (*See* PFF ¶¶ 776–796.) In addition to the viable platforms on the market, there are also many NGS platforms in development and likely to enter the market in the near future that will be viable platforms for MCED tests. (*See* PFF ¶¶ 782–796.) Respondents also incorporate their responses to CCFF ¶¶ 341, 375, 378, 382 and 398 herein.

The proposed finding also appears to suggest that MCED testing today requires "ultra-deep sequencing", which is wrong. For example, GRAIL's Galleri test does not use "ultra-deep sequencing", but relies on targeted methylation for cancer signal detection and localization. *(See, e.g.*, PFF ¶¶ 56, 345, 384, 1289.)

Respondents also note that the cited source observes that:

"And, there is simply no screening program for the vast majority of cancers, including pancreatic and ovarian, so those diseases are detected when the patient becomes symptomatic, which is typically in later stages, with the resulting poor prognosis. . . ."

"[A] test must be able to determine tissue of origin and to distinguish lethal from non-lethal cancers that may not progress. . . ." (PX0037 at 004–007 (Illumina, Grail Investor Call Script, Jan. 10, 2016).) These observations support the need for the Galleri test and show that other putative MCED test developers are unlikely to compete with the Galleri test in the foreseeable future.

347. NGS technology allows for the detection of a broad range of DNA mutations within a blood sample, which in turn allows for the analysis of many mutations associates with cancer. (PX8313 (Guardant) at 002 (Background Information on Liquid Biopsy for NGS Tests)).

Response to Finding No. 347:

Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 59), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

The proposed finding is inaccurate, incomplete, and misleading, including because it appears to suggest that only NGS technology may be used for the detection of a broad range of DNA mutations. To the contrary, many test developers are pursuing cancer screening tests for multiple cancers using other platform technologies such as PCR, microarray and proteomics. For example, StageZero's Aristotle test is a microarray-based liquid biopsy test that interrogates mRNA to detect 10 cancers and Genesys Biolabs' OneTest is a proteomics-based test that measures seven cancer protein biomarkers to screen for lung, liver, pancreatic, ovarian, prostate and colon cancers. (*See* PFF ¶¶ 691–696.) Protein biomarkers have also been used for many years for early stage cancer detection and screening. (*See* PFF ¶¶ 155–157.) An increasing number of companies are developing "multi-omic" tests which combine information from multiple analytes using multiple platform technologies, including DNA (genome), RNA

(transcriptome) and protein (proteome) for increased sensitivity in cancer detection. (*See* PFF ¶¶ 169–169.3.)

Respondents also note that the cited source also [redacted] (PX8313 (Guardant) at 004 (Background Information on Liquid Biopsy for NGS Tests).)

348. Unlike other testing technologies, NGS can simultaneously screen for thousands of biomarkers (such as mutations or methylation patterns) that potentially signal cancer within the body. (PX7042 (Gao (Singlera) IHT at 38-40)).

Response to Finding No. 348:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is inaccurate, incomplete and misleading, and contradicted by the weight of the evidence. For example, multiplex PCR can generate higher throughput than traditional (single-plex) PCR and obtains more information with less sample. Thermo Fisher's microfluidic digital PCR OpenArray system can generate over 12,000 data points in a single run. (*See* PFF ¶¶ 159–160.2.) Similarly, microarrays can also simultaneously screen tens of thousands of biomolecular interactions. (*See* PFF ¶¶ 164-164.5.) Respondents also incorporate their responses to CCFF ¶ 347 herein.

5. Illumina and Grail Were Not the First to Discover the Use of ctDNA for Cancer Screening Technology

349. A May 2017 Grail board presentation stated that Dr. Dennis Lo is the Director of the "[l]aboratory at forefront of cfDNA in NIPT & cancer since 1997." (PX4620 (Grail) at 007 (Grail, Project Knight – Board Update II, May 10, 2017)).

Response to Finding No. 349:

Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 54), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

Respondents note that the cited source also observes that [redacted]

(PX4620 (Grail) at 007 (Grail, Project Knight – Board Update II, May 10, 2017).)

350. Singlera Genomics co-founder and scientific advisor, Dr. Gary Gao, began collaborating with Dr. Dennis Lo of the Chinese University of Hong Kong on noninvasive prenatal testing ("NIPT") research in 2007. (Gao (Singlera) Tr. 2863-64; 2867-68).

Response to Finding No. 350:

Respondents have no specific response.

351. A noninvasive prenatal test ("NIPT") is a blood-based test performed on expectant mothers designed to determine whether the fetus has chromosomal abnormalities, including Down syndrome. (Qadan (Illumina) Tr. 4121).

Response to Finding No. 351:

Respondents have no specific response.

352. [redacted] (PX7113 (Rabinowitz (Natera) Dep. at 36) (*in camera*)).

Response to Finding No. 352:

Respondents have no specific response.

353. Together, Dr. Gao, Singlera's Co-Founder and current Scientific Advisor, and Dr. Dennis Lo, a professor at the Chinese University of Hong Kong, developed a protocol for sequencing cfDNA in blood samples of pregnant women to identify the presence of fetal chromosome 21 trisonomy (down syndrome). (Gao (Singlera) Tr. 2863-64; 2867-68).

Response to Finding No. 353:

Respondents have no specific response.

354. Dr. Gao, Singlera's Co-Founder and current Scientific Advisor, and Dr. Dennis Lo, a professor at the Chinese University of Hong Kong, published a paper in the Proceedings of National Academy of Science journal in 2008 presenting the results of their research on the detection of fetus chromosome trisomy using cfDNA. (Gao (Singlera) Tr. 2863-64; 2867-68). Dr. Gao used the research from his 2008 paper with Dr. Dennis Lo, a professor at the Chinese University of Hong Kong, to begin research on the use of cfDNA for cancer screening. (Gao (Singlera) Tr. 2863-65; 2867-68).

Response to Finding No. 354:

The proposed finding is inaccurate and misleading to the extent that it suggests that Singlera and Dr. Gao developed the technology that GRAIL uses for its Galleri test. To the contrary, Respondents note that Dr. Gao also testified that Singlera Genomics was started in July 2014 to use cell-free DNA for early detection of cancer, that methylation technology is a difficult technology, and that he was not aware of any efforts being made by Dr. Dennis Lo to develop cancer screening technology in 2008. (Gao (Singlera) Tr. 2863–68.) Singlera has not launched any product of any kind in the U.S. and only a SCED for colorectal cancer—ColonES—as an LDT in China. (Gao (Singlera) Tr. 2872–73.) Dr. Gao also testified that Singlera is "far away" from starting clinical trials for PanSeer in the United States, and that it is "still not in the really starting clinical trial state." (*See* PFF ¶¶ 527–542.)

355. Dr. Gao published a paper on DNA methylation for use in applications such as cancer detection in 2009 with Singlera co-founder Professor Kun Zhang of the University of California San Diego. (Gao (Singlera) Tr. 2863-65).

Response to Finding No. 355:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 354 herein.

356. Dr. Gao testified at trial that he was not aware of efforts by Grail to develop cancer screening technology when he began his research related to cancer detection. (Gao (Singlera) Tr. 2869). Dr. Gao further testified that Singlera was "way ahead of Grail" in its efforts to develop a cancer screening technology. (Gao (Singlera) Tr. 2869).

Response to Finding No. 356:

Respondents have no specific response except to note that Singlera has not launched any product of any kind in the U.S. and only a SCED for colorectal cancer—ColonES—as an LDT in China. (Gao (Singlera) Tr. 2872–73.) Respondents also incorporate their responses to CCFF ¶ 354 herein.

357. Dr. Dave Alquist, a gastroenterologist at Mayo Clinic, conducted research for years looking for biomarkers that could provide early detection of colon cancer. (Conroy (Exact) Tr. 1538-39).

Response to Finding No. 357:

Respondents have no specific response except to note that Dr. Ahlquist only had research data demonstrating the ability to detect colon cancer and precancerous polyps accurately from a stool sample. (Conroy (Exact) Tr. 1538–40.)

358. In March 2009, Dr. Ahlquist told Mr. Conroy of his vision for detecting many or most cancers from a simple blood draw. (Conroy (Exact) Tr. 1539). Dr. Ahlquist called this vision a "pan-cancer" test, which would look for tiny fragments of cancer DNA in a patient's blood. (Conroy (Exact) Tr. 1539-40).

Response to Finding No. 358:

Respondents have no specific response except to note that [redacted] (Conroy (Exact) Tr. 1597.) [redacted]

[redacted]

Respondents also incorporate their responses to CCFF ¶ 357 herein.

359. Dr. Ahlquist's vision for a pan-cancer test was the genesis of Exact's mission to detect cancer earlier. (Conroy (Exact) Tr. 1540-41).

Response to Finding No. 359:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 357–358 herein.

360. Exact and Mayo Clinic entered into a research and development partnership in June 2009 that has continued for 12 years. (Conroy (Exact) Tr. 1536-37). Dr. Ahlquist participated in the Exact-Mayo Clinic partnership. (Conroy (Exact) Tr. 1536-37; 1539-40).

Response to Finding No. 360:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 357–358 herein.

361. Dr. Bert Vogelstein's lab at Johns Hopkins University "published the first description of cancer genomes, what we called cancer genome landscapes" in approximately 2009 or 2010. (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 61)).

Response to Finding No. 361:

Respondents have no specific response except to note that Dr. Vogelstein started PapGene in 2014, now Thrive, an Exact company, and it has still not launched a commercial version of its cancer screening test, CancerSEEK, eight years later. (*See* PFF ¶¶ 296–296.3 (PX7101 (Vogelstein (Johns Hopkins University) Dep.) at 27–28; [redacted].)

362. Alongside teams of researchers, Dr. Vogelstein helped discover that "a relatively small number of genes play[ ] a major role in most human cancer types." (PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶ 2)).

Response to Finding No. 362:

Respondents have no specific response except to note that Dr. Vogelstein's discovery focused on "a relatively small number of genes". (PX8400 (Vogelstein (Johns Hopkins University) Decl.) ¶ 2.) These genes and corresponding protein biomarkers only focus on epithelial cancers and not non-epithelial cancers. (Cote Tr. 3810–11.) Therefore, the biomarkers interrogated by the CancerSEEK test, now owned by Exact, are not capable of detecting "all" types of cancer, but only a subset of cancer types. (Cote Tr. 3810–11.) Respondents also incorporate their responses to CCFF ¶ 361 herein.

363. Dr. Vogelstein and the group of researchers with whom he works was awarded the international prize from the American Association of Cancer Research for "pioneering the development of liquid biopsies." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 78-79)).

Response to Finding No. 363:

The proposed finding is incomplete and misleading to the extent it uses the term "liquid biopsies", which does not refer only to early cancer screening. (*See, e.g.*, PFF ¶¶ 123–139.) Respondents also incorporate their responses to CCFF ¶¶ 361–362 herein. The proposed finding is also irrelevant because Dr. Vogelstein testified in the cited testimony that "our lab's current work, which considerably is quite different from what Thrive is doing". (PX7101 (Vogelstein (Johns Hopkins University), Dep.) at 54–55.)

364. CancerSEEK was developed by Dr. Bert Vogelstein within his lab at Johns Hopkins University. (Conroy (Exact) Tr. 1542-43).

Response to Finding No. 364:

Respondents have no specific response except to note that [redacted] (Conroy (Exact) Tr. 1621.) Respondents also incorporate their responses to CCFF ¶¶ 361–62 herein.

365. Dr. Vogelstein ran clinical studies to demonstrate the ability from a single blood draw to detect cancer earlier across many different types of cancer. (Conroy (Exact) Tr. 1542-43).

Response to Finding No. 365:

Respondents have no specific response except to note that the Cohen study only looked at eight cancer types and did not look at any other cancer types. (Conroy (Exact) Tr. 1698–1700.) Respondents also incorporate their responses to CCFF ¶¶ 361–62 herein.

366. Dr. Vogelstein is a co-founder of Thrive Earlier Detection Corp. ("Thrive"). (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 27)). Dr. Vogelstein's CancerSEEK became part of Thrive. (Conroy (Exact) Tr. 1542-43).

Response to Finding No. 366:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 357–365 herein.

367. The original version of CancerSEEK underwent its first study about three to four years ago. (Conroy (Exact) Tr. 1545-46).

Response to Finding No. 367:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 357–365 herein.

368. Using methods similar to those used in NIPT, Dr. Lo developed a method for detecting cancer signals in circulating cfDNA. (PX2858 (Illumina) at 001 (Email from R. Bookstein, Illumina, to N. Naclerio, Illumina, Aug. 9, 2012)).

Response to Finding No. 368:

Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 33), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

369. In August 2012, Illumina's Director of Corporate and Venture Development, Robert Bookstein, wrote to Illumina's SVP of Corporate and Venture Development, Nicholas

Naclerio, to alert Mr. Naclerio of research by Dr. Dennis Lo. (PX2858 (Illumina) at 001 (Email from R. Bookstein, Illumina, to N. Naclerio, Illumina, Aug. 9, 2012)).

Response to Finding No. 369:

Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 33), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also note that Complaint Counsel never called Dr. Bookstein as a witness and there is no record evidence suggesting that Dr. Bookstein's views are indicative of either Illumina's or GRAIL's strategy with respect to early cancer screening.

370. Mr. Bookstein wrote to Dr. Naclerio that, because Dr. Lo's method of detecting cancer through cfDNA "requires huge numbers . . . of random genomic reads, it's a perfect application for [Illumina's] largest-capacity instruments." (PX2858 (Illumina) at 001 (Email from R. Bookstein, Illumina, to N. Naclerio, Illumina, Aug. 9, 2012)).

Response to Finding No. 370:

Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 33), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also note that Complaint Counsel never called Dr. Bookstein as a witness and there is no record evidence suggesting that Dr. Bookstein's views are indicative of either Illumina's or GRAIL's strategy with respect to early cancer screening.

The proposed finding is also incomplete and misleading. Although the cited source is from August 2012, the proposed finding appears to suggest that, even today, nearly ten years later, "it's the perfect application for Illumina's largest-capacity instruments." Contrary to Complaint Counsel's unproven contention, there are other viable NGS platforms on the market today that can support MCED tests in development. (*See* PFF ¶¶ 776–796.) In addition to the

viable platforms on the market, there are also many NGS platforms in development and likely to enter the market in the near future that will be viable platforms for MCED tests. (*See* PFF ¶¶ 782–796.) Respondents further note that Illumina's "largest-capacity instruments" in 2012, the HiSeq, had much lower throughput than the NovaSeq instrument today (PFF Table 3; RX3869 (Cote Expert Report) ¶ 277), and other instruments currently available (PFF Table 5 (BGI's DNBSEQ-T7), PFF Table 6 (ONT's PromethION 48)). Respondents also incorporate their responses to CCFF ¶¶ 341, 375, 378, 382 and 398 herein.

371. Mr. Bookstein wrote to Dr. Naclerio that he thought that Dr. Lo's method of detecting cancer through cfDNA "could be built into a business rivaling or exceeding [noninvasive prenatal testing]." (PX2858 (Illumina) at 001 (Email from R. Bookstein, Illumina, to N. Naclerio, Illumina, Aug. 9, 2012)).

Response to Finding No. 371:

Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 33), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also note that Complaint Counsel never called Dr. Bookstein as a witness and there is no record evidence suggesting that Dr. Bookstein's views are indicative of either Illumina's or GRAIL's strategy with respect to early cancer screening.

372. Mr. Bookstein suggested to Dr. Naclerio that Illumina "scoop up [Dr. Lo's] entire IP portfolio and build it inside Illumina." (PX2858 (Illumina) at 001 (Email from R. Bookstein, Illumina, to N. Naclerio, Illumina, Aug. 9, 2012)).

Response to Finding No. 372:

Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 33), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also note that Complaint Counsel never called Dr.

Bookstein as a witness and there is no record evidence suggesting that Dr. Bookstein's views are indicative of either Illumina's or GRAIL's strategy with respect to early cancer screening.

373. On September 3, 2012, Illumina held a call with Dr. Dennis Lo relating to his discovery that cancer signals could be detected through cfDNA and sought next to review Dr. Lo's "filed patent applications." (PX2859 (Illumina) at 001-002 (Email from R. Bookstein, Illumina, to P. Fromen, Illumina, et al., Sept. 5, 2012)). In notes from the call, Illumina's attendees wrote the question, "How will a clinician use this type of data?" (PX2859 (Illumina) at 004 (Email from R. Bookstein, Illumina, to P. Fromen, Illumina, et al., attaching notes "Dennis Lo's talk 9/03/12," Sept. 5, 2012)). Responses to the question included "Blood biopsy – non-invasive screening" and "Potential for detecting cancer prior to actual detection of a primary tumor." (PX2859 (Illumina) at 004 (Email from R. Bookstein, Illumina, to P. Fromen, Illumina, et al., attaching notes "Dennis Lo's talk 9/03/12," Sept. 5, 2012)).

Response to Finding No. 373:

Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 33), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also note that Complaint Counsel never called Dr. Bookstein as a witness and there is no record evidence suggesting that Dr. Bookstein's views are indicative of either Illumina's or GRAIL's strategy with respect to early cancer screening.

374. It was not until "a little before 2015" that Illumina began work related to Grail and then created Grail as a corporate entity in 2016. (deSouza (Illumina) Tr. 2195-96).

Response to Finding No. 374:

Respondents have no specific response.

6. MCED Test Background

a) MCED Tests Seek to Detect Multiple Cancers Simultaneously in Asymptomatic Individuals

375. As discussed in detail below in Section III., MCED tests screen for multiple cancers in an asymptomatic population and all use Illumina's NGS platforms.

Response to Finding No. 375:

The proposed finding is inaccurate, incomplete and misleading and is not supported by any cited evidence. In addition, contrary to Complaint Counsel's unproven contention that all MCED tests require Illumina's NGS platforms, there are several other NGS platforms that can support purported MCED tests in development. (PPF ¶¶ 776–781.) BGI already has a commercially available NGS platform. (PFF ¶¶ 777–777.5.) BGI recently won a jury verdict that held three of Illumina's patents to be invalid, meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. [redacted] (PFF ¶¶ 778–778.2; 2085.) In addition to BGI and [redacted], Oxford Nanopore is a viable alternative for MCED developers. (PFF ¶¶ 779–779.3.) There are also many NGS platforms in development that are likely to enter the market in the near future and will be viable platforms for MCED tests. (PFF ¶¶ 782–787.)

Purported MCED test developers treat these NGS platforms as viable substitutes for Illumina's NGS platform. (PFF ¶ 780.) [redacted] (PFF ¶ 780.1.) [redacted] Dr. Gao of Singlera testified that the PanSeer test can be run using Thermo Fisher equipment. (PFF ¶ 780.4.) [redacted]

[redacted]

Purported MCED test developers today, such as StageZero, Genesys Biolabs, Intervenn Biosciences, Seer, and Somalogic, are also using non-NGS platforms, including proteomics and microarray platforms. (PFF ¶¶ 543–73.) Respondents also incorporate their responses to CCFF ¶¶ 341 and 344 herein.

376. [redacted] (PX2005 (Illumina) at 004-05, 009 (ScreenCo – Early Cancer Detection on a Global Scale Presentation, 2015); *see also* PX5027 (Illumina) at 016-17 (Board of Directors Meeting, Aug. 4, 2020) (*in camera*)).

Response to Finding No. 376:

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. [redacted] (PX2005 (Illumina) at 004–05, 009 (ScreenCo – Early Cancer Detection on a Global Scale Presentation, 2015).) Most of the putative MCED developers identified by Complaint Counsel, including [redacted] do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Respondents also note that the cited Board of Directors presentation confirms that [redacted] (PX5027 (Illumina) at 016 (Board of Directors Meeting, Aug. 4, 2020) (*in camera*).)

Respondents also incorporate their responses to CCFF ¶¶ 605–606 herein.

377. [redacted] (*See, e.g.*, PX0086 at 001 (Grail Press Release: GRAIL Presents Interventional PATHFINDER Study Data at 2021 ASCO Annual Meeting and Introduces Galleri, a Groundbreaking Multi-Cancer Early Detection Blood Test, June 4, 2021) (describing Galleri as a "multi-cancer early detection (MCED) blood test"); PX8314 (Guardant) (Multi-Cancer Screening, Dec. 2020) (*in camera*); PX8324 (Roche) at 003 [redacted] (*in camera*); PX8392 (Exact) at 002 (Pipeline Review, Jan. 2021) (*in camera*)).

Response to Finding No. 377:

The proposed finding is not supported by the cited evidence. Only GRAIL's Press Release refers to the Galleri test as a "multi-cancer early detection (MCED) blood test". (PX0086 at 001 (Grail Press Release: GRAIL Presents Interventional PATHFINDER Study Data at 2021 ASCO Annual Meeting and Introduces Galleri, a Groundbreaking Multi-Cancer Early Detection Blood Test, June 4, 2021).) [redacted]

The proposed finding also relates to irrelevant subject matter. Whether industry participants use the term "MCED test" to describe early cancer screening tests that detect

multiple cancers simultaneously has no bearing on whether MCED tests constitute a relevant product market. (PFF ¶¶ 679–772; *see also* Resps.' Post-Trial Br. Section I.A.)

378. [redacted] (*See, e.g.*, PX4082 (Grail) at 008-009 (Email attaching Grail 2020 S-1/Amended, Sept. 2020); PX7051 (Lengauer (Third Rock Ventures) IHT at 28-29) (*in camera*); PX7100 (Chudova (Guardant) Dep. at 15-16); PX7094 (Nolan (Freenome) Dep. at 252-53) (*in camera*)); PX4116 (Grail) at 013 (Email from M. Podoll, Morgan Stanley, to A. Freidin, Grail, et al., attaching IPO Roadshow Video Outline: Project Galileo, Aug. 2020)).

Response to Finding No. 378:

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including [redacted] do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Mr. Nolan testified that Freenome is [redacted] (PX7094 (Nolan (Freenome) Dep. at 307); PFF ¶¶ 459–72.) [redacted]

[redacted]

Dr. Chudova testified that Guardant's "platform in its foundation doesn't have anything specific for [] individual cancer types other than selection of the regions of the genomes that are most representative for that specific cancer" and [redacted] (PX7100 (Chudova (Guardant) Dep. at 24, 134; PFF ¶¶ 479–479.5.1.) Dr. Chudova also testified that [redacted] Accordingly, there is no evidence that Guardant will launch in the foreseeable future a cancer screening test that is a close substitute to the Galleri test. (PFF ¶ 476.) Further, the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

379. An Illumina Board presentation analyzing the potential acquisition of Grail notes that [redacted] (*in camera*)).

Response to Finding No. 379:

The proposed finding is incomplete and misleading. The cited presentation states that [redacted] (PX5027 (Illumina) at 005 (Board of Directors Project Valor Presentation, Aug. 4, 2020) (*in camera*).) The cited presentation also [redacted]

[redacted] (PX5027 (Illumina) at 016 (Board of Directors Project Valor Presentation, Aug. 4, 2020) (*in camera*).)

380. [redacted] (PX5027 (Illumina) at 005 [redacted] (*in camera*)).

Response to Finding No. 380:

Respondents have no specific response except to note that many liquid biopsy tests, including those being developed for multi-cancer screening, do not require NGS technology as they rely on analytes other than ctDNA. *See, e.g.*, PFF ¶¶ 547-49.2 (StageZero); 554 (Genesys Biolabs); 558 (InterVenn Biosciences). For example, StageZero's Aristotle test is a microarray-based liquid biopsy test that interrogates mRNA to detect 10 cancers, and Genesys Biolabs' OneTest is a proteomics-based test that measures seven cancer protein biomarkers to screen for lung, liver, pancreatic, ovarian, prostate and colon cancers. (*See* PFF ¶¶ 691–696.) Respondents also incorporate their responses to CCFF ¶ 344 herein.

381. [redacted] (PX7040 (Getty (Guardant) IHT at 29-32); *see also* PX4082 (Grail) at 008-009 (Email attaching Grail 2020 S-1/Amended, Sept. 2020); PX7051 (Lengauer (Third Rock Ventures) IHT at 28-29) (*in camera*); PX7100 (Chudova (Guardant) Dep. at 15-16)); PX7094 (Nolan (Freenome) Dep. at 252-53) (*in camera*)).

Response to Finding No. 381:

The proposed finding is not supported by the cited evidence. *First*, Mr. Getty's testimony about "tests [that] would take place at [an annual physical]" (PX7040 (Getty (Guardant) IHT at 31–32) was in response to a question about all liquid biopsy screening tests, not just putative MCED tests. (PX7040 (Getty (Guardant) IHT at 29 ("Q. Going back to

something you said, how would liquid biopsy help improve compliance for screening of -- existing cancer screening methods?").) *Second*, the cited portion of GRAIL's S-1 does not discuss "MCED tests" broadly as the proposed finding suggests, but only that GRAIL intends for Galleri to be used at an annual physical. *Third*, nowhere in the cited portions of Dr. Chudova's testimony (or anywhere in the deposition) does she testify that MCED tests are to be used at annual routine appointments. (PX7100 (Chudova (Guardant) Dep. at 15–16.)

[redacted]

Respondents also note that the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Respondents also incorporate their responses to CCFF ¶¶ 378, 382, 398 and 709 herein.

382. Because MCED tests are targeted towards patients who do not have symptoms of, and have not been treated for, cancer, [redacted] (*See, e.g.*, PX7058 (Conroy (Exact) IHT at 103-04) (*in camera*); PX7040 (Getty (Guardant) IHT at 29-32)).

Response to Finding No. 382:

The proposed finding is misleading and contrary to the weight of the evidence. [redacted] Mr. Getty also identified other potential customers in the future, including OB/GYNs for female patients, "healthcare customers like employers", and "health systems". (Getty (Guardant) Tr. 2502–03; *see also* CCFF ¶ 2288.)

The proposed finding is also incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including [redacted] do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

For example, [redacted] (PFF ¶ 440.) [redacted]

[redacted]

Further, the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Respondents also incorporate their responses to CCFF ¶ 710 herein.

383. Singlera's Dr. Gao explained that sensitivity of a cancer screening test indicates "a true positive, so when the person has a disease, your test tells positive results." (PX7042 (Gao (Singlera) IHT at 32)).

Response to Finding No. 383:

Respondents have no specific response.

384. In describing what the specificity of an MCED test means, Singlera's Gao explained that, for example, when a test subject "does not have cancer, [they] have negative test results." (PX7042 (Gao (Singlera) IHT at 31)).

Response to Finding No. 384:

Respondents have no specific response.

385. Christoph Lengauer, former Chief Officer and Co-Founder of Thrive, testified that, as an example to describe sensitivity, if you have ten individuals with cancer and your test identifies three of those individual as having cancer, the sensitivity of that test would be 30 percent. So seven individuals would be false-negatives. (Lengauer (Third Rock Ventures) Tr. 245). (Lengauer (Third Rock Ventures) Tr. 245).

Response to Finding No. 385:

Respondents have no specific response.

386. In explaining the importance of high sensitivity (i.e., minimizing false negatives) to cancer screening tests, Guardant's Chudova testified:

> Any patient that you miss as a result of that screening will continue to develop their cancer in an asymptomatic, potentially, state and not be diagnosed until either they become symptomatic or they will be diagnosed with another modality, and so any missed patients in the context of screening will continue on to develop the disease without awareness that at early stage could have been helpful in preventing more advanced disease.

(PX7045 (Chudova (Guardant) IHT at 63-64)).

Response to Finding No. 386:

Respondents have no specific response except to note that there is typically a tradeoff between specificity and sensitivity. (PFF ¶ 180 (RX3869 (Cote Expert Report) ¶ 95).) [redacted] Given the same conditions, a test applying cutoff thresholds that minimizes false positives, *i.e.*, higher specificity, may often have a lower sensitivity than a test that results in a higher false positive

rate. (PFF ¶ 180 (RX3869 (Cote Expert Report) ¶ 95).) [redacted]

Despite Guardant's purported focus on sensitivity, however, Respondents also note that, [redacted] In contrast, Galleri's current sensitivity rate for version 2 of its test (which is the version that is available as an LDT) is 51.5% for all cancer types across stages. (PFF ¶ 335.)

Respondents also note that the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶ 656 herein.

387. Guardant's Chudova explained the consequences of a false positive cancer screening test result:

> [T]he physician would need to follow up with all sorts of radiological and other interventions to try to localize the cancer that the test is suggesting they have, whereas in fact they don't, and so the risk is exposure to a lot of subsequent diagnostic procedures that would have been totally unnecessary because the result is a false positive result.

(PX7045 (Chudova (Guardant) IHT at 64)).

Response to Finding No. 387:

Respondents have no specific response.

388. [redacted] (PX7058 (Conroy (Exact) IHT at 95-96) (*in camera*)).

Response to Finding No. 388:

Respondents have no specific response except to note that [redacted] (PFF ¶ 1743 (Lengauer (Exact/Thrive) Tr. 238–40).) Respondents note that Exact's Cologuard colorectal cancer screening test, which uses PCR technology, has a sensitivity of 92.3%, which is comparable to colonoscopy's sensitivity of 92.5%, but higher than Galleri's sensitivity of 82.0% for colorectal cancer. (PPF ¶ 180.2 (RX3222 (FDA) at 19); RX3409 (Klein et al., 2021) at 7, Fig. 3B.)

Respondents also note that the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

389. [redacted] (PX7058 (Conroy (Exact) IHT at 93) (*in camera*)).

Response to Finding No. 389:

The proposed finding is incomplete and misleading to the extent it seems to suggest that [redacted] To the contrary, Respondents note that [redacted]

[redacted] (PFF ¶¶ 173 ("Specificity . . . measures the proportion of actual negative samples that are correctly identified as such", so that a 95.3% specificity corresponds to a true negative rate of 95.3% and a false positive rate of 100% minus 95.3%), 428, 431 ("In the DETECT-A study, CancerSEEK obtained [a] specificit[y] of 95.3% in its baseline blood test (that is, with a single blood test).").) In the DETECT-A study, out of the 490 patients who had a positive test result under Exact/Thrive's CancerSEEK baseline blood test, only 26 were actually found to have cancer in the end, leading to unnecessary and time-consuming work-ups for the patients with false positives. (Lengauer (Exact/Thrive) Tr. 251–54; RX3419 (Lennon et al., 2020) at 5.) Respondents also note that the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

390. [redacted] (PX7058 (Conroy (Exact) IHT at 96) (*in camera*)).

Response to Finding No. 390:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 389 herein. Respondents also note that the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

391. [redacted]

[redacted]

(PX7058 (Conroy (Exact) IHT at 96-97 (*in camera*)).

Response to Finding No. 391:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 389 herein. Respondents also note that the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

392. Guardant's Getty explained that a false positive screening test could harm a "patient mentally" and also trigger "very invasive" follow-up procedures. (PX7040 (Getty (Guardant) IHT at 36-37)).

Response to Finding No. 392:

Respondents have no specific response.

393. [redacted] (PX7055 (Otte (Freenome) IHT at 84) (*in camera*)).

Response to Finding No. 393:

Respondents have no specific response.

394. Singlera's Gao indicated that a false positive test result is a "potentially damaging, worrisome thing." (PX7042 (Gao (Singlera) IHT at 31)).

Response to Finding No. 394:

Respondents have no specific response.

395. In discussing the importance of high sensitivity and specificity of cancer screening tests, Singlera's Gao explained that MCED test providers "don't want to miss any disease diagnosis. . . . You don't [want to] have any false negative [results]. . . . When[, for example, an individual] has a gastric cancer, your test" must really be able to detect the presence of gastric cancer. (PX7042 (Gao (Singlera) IHT at 32)).

Response to Finding No. 395:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 386 herein. Respondents also note that the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

396. Grail's former CEO, Hans Bishop, testified that "[i]t's very important" to have a low false positive rate for a cancer screening test. (Bishop (Grail) Tr. 1385-86).

Response to Finding No. 396:

Respondents have no specific response except to note that the proposed finding provides support for the proposition that MCED tests with higher false positive rates—such as Exact/Thrive's CancerSEEK baseline blood test—are not reasonably interchangeable with an MCED test with a low false positive rate, such as GRAIL's Galleri test. (*See* Resps.' Post-Trial Br. at 48; PFF ¶¶ 725–726.3.) Respondents also incorporate their responses to CCFF ¶ 389 herein.

397. Grail's former CEO, Hans Bishop, testified that "the lower the false positive rate, the lower the unnecessary stress, the lower the risk of investigational harms, and the lower the wasted money on unnecessary work-ups" following a false diagnosis. (Bishop (Grail) Tr. 1385-86).

Response to Finding No. 397:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 396 herein.

b) Multiple Companies Are Developing MCED Tests

398. As discussed in detail below in Sections VI. and VII.B.3.-5., several competitors are racing to develop MCED tests and competing head-to-head with Grail's Galleri test.

Response to Finding No. 398:

The proposed finding is inaccurate, incomplete and misleading as well as contradicted by the weight of the evidence. The characterization of test developers as "competitors" and "competing" with GRAIL's Galleri test is contradicted by the weight of the evidence. There is no indication that any of the putative MCED test developers will be competitors to GRAIL in the foreseeable future. (RX3869 (Cote Expert Report ¶¶ 174 (Exact/Thrive), 184 (FMI/Roche), 193 (Freenome), 202 (Guardant), 217 (Helio), 227 (Natera), 238 (Singlera)).) All other purported MCED tests in development would not be substitutes for Galleri because of their highly differentiated performance metrics (PFF ¶¶ 722–740.1), [redacted]

For example, [redacted]

[redacted]

Respondents also incorporate their responses to CCFF ¶¶ 1902–2606; 3516–69 (in response to Sections VI. and VII.B.3–5) herein.

399. [redacted] (*See infra* Section VI. (Competitors Are Racing to Develop MCED Tests); PX7109 (Daly (Singular Genomics) Dep. at 20 (*in camera*) (stating that [redacted]; *see generally* PX6090 (Scott Morton Report) ¶¶ 85-126 (*in camera*)).

Response to Finding No. 399:

The proposed finding is inaccurate and misleading. The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation and relies on improper expert testimony.

First, the proposed finding inaccurately characterizes Mr. Daly's testimony. Mr. Daly testified that [redacted] (Daly (Singular Genomics) Dep. at 20 (*in camera*).) That is, he testified [redacted]

Second, the proposed finding is misleading, as no test developer other than GRAIL has in fact brought an MCED test to market. Unlike GRAIL, all other companies listed in the proposed finding fall far behind GRAIL in the development of an MCED test. (PFF ¶¶ 413–542; *see*

Resps.' Post-Trial Br. at 30–37.) Respondents also incorporate their responses to CCFF ¶¶ 1902–2606 herein.

Third, the proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. Mr. Daly testified that [redacted] (Daly (Singular Genomics) Dep. at 20 (*in camera*).) However, Mr. Daly does not provide any basis for his conclusion and there is no evidence in the record that [redacted] to support it.

Fourth, the proposed finding relies on improper expert testimony. Dr. Scott Morton impermissibly usurps the role of the fact finder by opining on the credibility of witness testimony and weighing the evidence, rending her opinions unreliable. (*See* Resps.' Post-Trial Br. at 265–66.)

400. [redacted]
(Cance, Tr. 612-13; PX5024 (Illumina) at 025 (Illumina Board of Directors Meeting Minutes) (*in camera*)). *See generally* PX6090 (Scott Morton Report) at Table 1 (*in camera*)).

Response to Finding No. 400:

The proposed finding relies on improper expert testimony. Dr. Scott Morton lacks the expertise to opine on scientific and technical issues, rendering her opinions unreliable. (*See* Resps.' Post-Trial Br. at 261–62.) Respondents also incorporate their responses to CCFF ¶ 398 herein.

401. The American Cancer Society's Chief Medical Officer testified at trial that he is aware that several companies are developing MCED tests in the United States. (Cance (American Cancer Society) Tr. 610-12).

Response to Finding No. 401:

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Dr. Cance also testified that GRAIL is further ahead in its development process than other companies that are developing purported MCED tests, that he is not aware of any other purported MCED test that is commercially available today, that he does not know of other companies detecting the same number of cancers as GRAIL, and that accelerating an early cancer detection test's ability to commercialize at scale is consistent with ACS's mission. (Cance (ACS) Tr. 631–33.)

402. Mr. Nolan, Freenome's CEO, testified that the one true competitor in oncology screening tests is cancer itself and each screening test companies is taking their own approach to beat this ultimate competitor. (Nolan (Freenome) Tr. 2727).

Response to Finding No. 402:

The proposed finding relates to irrelevant subject matter because, here, Mr. Nolan uses "competitor" as a layman's term rather than as a legal term within the antitrust context. Further, the proposed finding is incomplete and misleading insofar as it suggests that other purported MCED test developers are competitors of GRAIL or will be in the foreseeable future. [redacted]

[redacted]

Most of the putative MCED developers identified by Complaint Counsel, including [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698).

403. MCED test developers are taking different technical approaches. (Cance (American Cancer Society) Tr. 612).

Response to Finding No. 403:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 401 herein.

404. In terms of the technical approaches used by MCED test developers, some companies focus on methylation sites in DNA found in blood samples, and others combine a multi-omic approach, which focuses on genomics, proteomics, and metabolomics. (Cance (American Cancer Society) Tr. 612-13).

Response to Finding No. 404:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 401 herein.

405. Dr. Chahine testified that "where Grail has chosen to do multiple cancers at one time, Helio and a few others have taken a strategic approach to say let's get one cancer done right and then add a second and a third and a fourth"—"it's really a matter of strategy" for developing a multicancer test "that we're really debating." (Chahine (Helio) Tr. 1032).

Response to Finding No. 405:

The proposed finding is incomplete and misleading to the extent it suggests that it is a viable option to convert from a single cancer screening test to a multi-cancer screening test. While the proposed finding accurately quotes Dr. Chahine's testimony, it suggests that Helio and other test developers can in fact develop a multi-cancer test using the single-cancer to multi-cancer strategy. To the contrary, even once a company has developed a cancer screening test for a single cancer type, it does not become easier to add additional cancer types because "[t]he development of biomarkers for a particular cancer will not be adequate for other cancers" and "[w]hile there may be overlap, one still needs to go through all of the [development] steps," including "go[ing] through the case-control verification to determine whether or not the assay has the performance characteristics needed . . . for the new target cancer," and "go[ing] through a prospective trial depending on which cancer is being targeted." (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123; PFF ¶¶ 328–328.1.)

Dr. Aravanis testified that GRAIL considered developing a single cancer screening test as a route to multicancer screening test but abandoned it because it would take far too long; building a multicancer test by developing single cancer tests seriatim could take four or five years for each cancer; to develop a 50-cancer test one cancer at a time a developer would need to do a research study, discovery study and collect relevant samples, determine the right technology, go into a new test development phase and clinical trials for each new cancer; GRAIL was able to develop a test capable of detecting 50 cancer types simultaneously directly by

undergoing a much more intensive process to develop a test for 50 cancer types at the same time. (Aravanis (Illumina) Tr. 1895–97.)

Dr. Chahine also testified that [redacted]

406. Dr. Chahine further testified that "everyone understands that the value of going to a blood-based test is this ability to now be able to . . . interrogate not just for a single cancer but for multiple cancers," that "it would be hard to find anyone in this industry that would say that all of these tests aren't eventually going to become a multicancer screening test," and "what we're witnessing today is really just a strategy for how you get there." (Chahine (Helio) Tr. 1031-32).

Response to Finding No. 406:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 401 and 405 herein.

407. [redacted] (Aravanis (Illumina) Tr. at 1802-1804 (*in camera*) (referencing PX4075)).

Response to Finding No. 407:

The proposed finding is incomplete and misleading to the extent that it suggests that any [redacted] (Aravanis (Illumina) Tr. 1802 (*in camera*) (referencing PX4075).) Dr. Aravanis also clarified that [redacted]

[redacted] (Aravanis (Illumina) Tr. 1803-04.) [redacted]

[redacted], and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698).

(1) Grail

408. Grail's Galleri test aims to detect cancer signals by identifying abnormal methylation patterns in a patient's DNA. (Bishop (Grail) Tr. 1319-20; 1373).

Response to Finding No. 408:

Respondents have no specific response.

409. Galleri identifies regions of a patient's DNA that are hypermethylated or hypomethylated. (Bishop (Grail) Tr. 1320). Galleri seeks to differentiate hyper- or hypomethylation patterns from those in healthy patients. (Bishop (Grail) Tr. 1320).

Response to Finding No. 409:

Respondents have no specific response.

410. At trial, Dr. Ofman described Galleri's analysis of DNA methylation: "Grail's test looks at over a million of these methylation sites in over a hundred thousand regions of the genome." (Ofman (Grail) Tr. 3287).

Response to Finding No. 410:

Respondents have no specific response.

411. [redacted] (Jamshidi Tr. 4055-56 (*in camera*); *see also* Bishop (Grail) Tr. 1481-82 (*in camera*) [redacted]; PX4082 (Grail) at 014 (Grail Amended S-1) ("We seek to continually enhance the performance and features of our tests, including seeking ways to improve sensitivity and reduce sequencing costs")).

Response to Finding No. 411:

The proposed finding is incomplete and misleading to the extent that it suggests that GRAIL is planning to incorporate cfRNA, proteins or biofluids as an analyte into its Galleri test. To the contrary, GRAIL has locked version 2 of Galleri, which is the version currently on the market, and is working on an updated version of Galleri that meets current performance standards while sequencing fewer regions of the genome, thereby reducing the cost of the test. (PFF ¶ 1607 (Ofman (GRAIL) Tr. 3301–03.) Respondents also note that there is no evidence that an MCED test using proteins or other biofluids (urine) as analytes would use NGS technology, nor have Complaint Counsel contended that such a test would be within the alleged product market. Respondents also incorporate their responses to CCFF ¶¶ 306, 312 herein.

Respondents also note that GRAIL has demonstrated that the Galleri test can identify over 50 types of cancers, over 45 of which lack recommended screenings (PFF ¶ 62), localize the cancer signal with high accuracy (PFF ¶ 62.1), has high sensitivity and specificity for forms of cancer that have no routine screening options, are usually detected at late stage, and thus are often lethal (PFF ¶ 344), and that the Galleri test as currently constructed has the ability to save lives by detecting dangerous cancers at an earlier, potentially curable stage (PFF ¶ 356).

412. Grail's Dr. Jamshidi [redacted] (PX7103 (Jamshidi (Grail) Dep. at 87-88) (*in camera*)).

Response to Finding No. 412:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 411 herein.

413. [redacted]

[redacted] (PX4250 (Grail) at 012 (Grail, [redacted]) (*in camera*)). [redacted] *See* (PX4054 (Grail) at 004 [redacted] (*in camera*)).

Response to Finding No. 413:

The proposed finding is incomplete and misleading. [redacted] Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 41), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

The proposed finding is also incomplete and misleading to the extent that it suggests that the described [redacted] are actual competitors to Galleri or GRAIL. [redacted]

Most of the putative MCED developers identified by Complaint Counsel, including [redacted] do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents also incorporate their responses to CCFF ¶ 398 herein.

The proposed finding is also incomplete and misleading to the extent that it suggests that GRAIL is planning to incorporate cfRNA, proteins or biofluids as an analyte into its Galleri test. To the contrary, GRAIL has locked version 2 of Galleri, which is the version currently on the market, and is working on an updated version of Galleri that meets current performance standards while sequencing fewer regions of the genome, thereby reducing the cost of the test. (PFF ¶ 1607 (Ofman (GRAIL) Tr. 3301–03.) Respondents also note that there is no evidence that an MCED test using proteins or other biofluids (urine) as analytes would use NGS technology, nor have Complaint Counsel contended that such a test would be within the alleged product market.

Complaint Counsel chose not to discuss PX4250 at trial, (CC Exhibit Index at 41), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

Respondents also incorporate their responses to CCFF ¶¶ 306, 312 and 761 herein.

(2) Thrive/Exact

414. Dr. Lengauer testified that [redacted] (Lengauer (Third Rock Ventures) Tr. 194 (*in camera*)).

Response to Finding No. 414:

The proposed finding is inaccurate, incomplete and misleading as well as contradicted by the weight of the evidence. Galleri detects more than 50 cancer types (PFF ¶ 61), while Dr. Lengauer testified that the DETECT-A study of CancerSEEK only detected cancers of 10 organs (Lengauer (Exact/Thrive) Tr. 245; RX3869 (Cote Expert Report) ¶ 177; PFF ¶¶ 429–430.1). [redacted] By contrast, CancerSEEK must use a whole body PET-CT scan to attempt to localize any detected cancers. (*See* Lengauer (Exact/Thrive) Tr. 248; RX3419 (Lennon et al., 2020) at 3; PFF ¶¶ 419, 425, 739, 760, 841.3, 1723–24.) Dr. Lengauer also observes that the DETECT-A study of CancerSEEK only detected cancers of 10 organs, as opposed to the more than 50 cancer types that Galleri detects. (PFF ¶ 429 (Lengauer (Exact/Thrive) Tr. 245; RX3869 (Cote Expert Report) ¶ 177).) Dr. Lengauer also testified that CancerSEEK obtained a 30% sensitivity rate in the DETECT-A trial, as opposed to the 51.5% sensitivity rate of Galleri. (PFF ¶¶ 725 (RX3409 (Klein et al., 2021) at 5; RX3419 (Lennon et al., 2020) at 7; RX3115 (Chen et al., 2020) at 4).) Thus, [redacted] (PFF ¶ 421.)

Respondents also incorporate their responses to CCFF ¶ 362 herein.

415. Exact/Thrive's CancerSEEK test combines NGS-based DNA mutation detection technology and protein detection technology. (Conroy (Exact) Tr. 1544).

Response to Finding No. 415:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 414 herein.

416. [redacted] (PX8572 (Exact) at 046 (Exact Sciences, Innovation & Technology Committee Spring Meeting Presentation, April 16, 2021) (*in camera*)).

Response to Finding No. 416:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 414 herein.

417. [redacted] *camera*).

Response to Finding No. 417:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 414 herein.

418. [redacted] (Della Porta (Grail) Tr. 483) (*in camera*)).

Response to Finding No. 418:

The proposed finding is incomplete and misleading insofar as it suggests that Thrive is developing a product that is reasonably interchangeable with Galleri. (*See* Resps.' Post-Trial Br. at 18.) *First*, as Mr. Della Porta testified, [redacted] (Della Porta (GRAIL) Tr. 547–50.)

Second, as Dr. Katz testified, because "there's still a high degree of uncertainty" surrounding the development of these putative tests and their various characteristics, the views of the competitors are not probative of the actual contours of the relevant market. (RRFF ¶ 775 (RX6004 (Katz Trial Dep. at 21-22).) "[I]t may well be they think of these firms as their competitor or prospectively so, but that's not really enough I think to reliably tell us what the market boundaries are going to be." (RRFF ¶ 775 (RX6004 (Katz Trial Dep. at 21-22).) Statements by competitors "are not going to answer these questions about the trade-offs or . . . the degree of differentiation or how consumers are going to really behave." (RRFF ¶ 774 (RX6004 (Katz Trial Dep. at 21).) [redacted] (RRFF ¶ 773 (RX6004 (Katz Trial Dep. at 105) (emphasis added).)

Respondents further incorporate their responses to CCFF ¶¶ 413–14, 697, 773–76 herein.

419. [redacted]

Response to Finding No. 419:

Respondents have no specific response except to note that Complaint Counsel has presented no evidence that the current version of CancerSEEK in development is capable of competing with the Galleri test. (PFF ¶¶ 418-43.) Respondents incorporate their responses to CCFF ¶¶ 413–14 and 1904–2184 (in response to Section VI.A) herein.

(3) [redacted]

420. [redacted] (*in camera*)).

Response to Finding No. 420:

The proposed finding is incomplete and misleading insofar as it suggests that [redacted] (PFF ¶¶ 508–09.) The evidence suggests that [redacted] and that Natera is unlikely to accelerate the development of a cancer screening test for multiple cancer types or to add a new cancer type to an existing screening test, [redacted] (PFF ¶¶ 509–10.) There is no evidence based on Natera's [redacted] (PFF ¶ 511 (RX3869 (Cote Expert Report) ¶ 227; [redacted]).)

421. [redacted]

Response to Finding No. 421:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 420 herein. Respondents also note that Natera is not developing any test called the [redacted] Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

422. [redacted]

Response to Finding No. 422:

The proposed finding is inaccurate, incomplete and misleading. Although the proposed finding accurately cites from the [redacted] Steve Chapman, the CEO of Natera, stated, "***We are not focused on asymptomatic cancer screening or early detection.***" (PFF ¶ 526.3.) Further, while Natera's goal may be to create an MCED test, the evidence suggests that [redacted] and that Natera is unlikely to accelerate the development of a cancer screening test for multiple cancer types or to add a new cancer type to an existing screening test, [redacted] (PFF ¶¶ 509–10.) [redacted] Accordingly, there is no evidence based on [redacted] (PFF ¶ 511 (RX3869 (Cote Expert Report) ¶ 227; [redacted]).)

423. [redacted]

Response to Finding No. 423:

The proposed finding is incomplete and misleading. Respondents incorporate their responses to CCFF ¶¶ 420, 422 herein.

424. [redacted]

Response to Finding No. 424:

The proposed finding is incomplete and misleading. Respondents incorporate their responses to CCFF ¶¶ 420, 422 herein. Respondents also note that even other purported MCED test developers recognize that Natera is not developing a cancer screening test: Dr. Lengauer of Exact/Thrive testified at trial that [redacted] (Lengauer (Exact/Thrive) Tr. 206.)

425. [redacted]

Response to Finding No. 425:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 420, 422, 2185–2256 herein.

(4) Guardant

426. [redacted] (Getty, Tr. 2495-96; PX7045 (Chudova (Guardant) IHT at 98, 101-102) (*in camera*)).

Response to Finding No. 426:

The proposed finding is incomplete and misleading insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. [redacted]

[redacted]

[redacted] (PFF ¶¶ 476–92.)

Respondents also note that the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

427. Guardant is developing methylation-based technology to augment its existing somatic mutation technology. (Chudova (Guardant) Tr. 1165-66).

Response to Finding No. 427:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 426 herein and to note that Dr. Chudova testified that [redacted]

428. Guardant's therapy selection tests and minimal residual test for colorectal cancer look for mutations. (Chudova (Guardant) Tr. 1148-52; 1164-65).

Response to Finding No. 428:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 426–27 herein and note that as Complaint Counsel admitted, therapy selection and minimal residual disease (MRD) tests are not part of the relevant product market and are irrelevant here. (*See* Section III.C.4 (CCFF ¶¶ 728–31) below.)

429. Dr. Chudova, SVP of Technology for Guardant, explained that Guardant's technology "look[s] for nucleotide changes that are distinct between fragments of interest and [the] majority of the fragments in the body and that . . . links it to the tumor origin." (Chudova (Guardant) Tr. 1165).

Response to Finding No. 429:

The proposed finding is inaccurate, incomplete and misleading insofar as it suggests that Guardant has developed tumor of origin capabilities for its putative MCED test. [redacted]

[redacted]

Respondents also incorporate their responses to CCFF ¶¶ 426–27 and 2315 herein.

430. Guardant is working on extending its minimal residual disease technology platform into an MCED testing platform to detect "a majority of the known cancers." (Chudova (Guardant) Tr. 1152-53).

Response to Finding No. 430:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 426–27 herein.

431. Dr. Chudova testified that cancer screening "requires higher sensitivity of the assay, because there's fewer [ctDNA] fragments, and you cannot rely exclusively on somatic mutations to identify presence of tumor." (Chudova (Guardant) Tr. 1165).

Response to Finding No. 431:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 426–27 herein. Respondents also note that, [redacted] In contrast, Galleri's current sensitivity rate for version 2 of its test (which is the version that is available as an LDT) is 51.5% for all cancer types across stages. (PFF ¶ 335.)

432. Because of the higher sensitivity required for MCED screening, Guardant has "significantly augmented" its somatic mutation technology with methylation as a second, distinct type of cancer biomarker. (Chudova (Guardant) Tr. 1165-66).

Response to Finding No. 432:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 426–27, 433 herein.

433. [redacted] (Chudova (Guardant) Tr. at 1243 (*in camera*)).

Response to Finding No. 433:

The proposed finding is incomplete and misleading insofar as it suggests [redacted] (Chudova (Guardant) Tr. 1243 (*in camera*)), which screens for early-stage colorectal cancer alone (PFF ¶ 486). Dr. Chudova also testified that [redacted] Accordingly, there is no indication based on Guardant's work to date that [redacted] (PFF ¶¶ 476–92.) Respondents also incorporate their responses to CCFF ¶¶ 426–27 herein.

434. [redacted] (Getty, Tr. 2625 (*in camera*)).

Response to Finding No. 434:

The proposed finding is incomplete and misleading insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. As noted, even once a company has developed a cancer screening test for a single cancer type (which Guardant has not yet completed), it does not become easier to add additional cancer types. Respondents also incorporate their responses to CCFF ¶¶ 405 and 426–427 herein.

435. [redacted] (Getty, Tr. 2628 (*in camera*)).

Response to Finding No. 435:

The proposed finding is inaccurate, incomplete and misleading. Respondents incorporate their responses to CCFF ¶¶ 405 and 426–427 herein.

436. [redacted] (Della Porta (Grail) Tr. 482 (*in camera*)).

Response to Finding No. 436:

The proposed finding is incomplete and misleading insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. The proposed finding is incomplete and misleading insofar as it suggests that [redacted] (*See* Resps.' Post-Trial Br. at 18.).

First, [redacted]

Second, like Mr. Della Porta, Complaint Counsel's own witness, Dr. Lengauer of Thrive, testified at trial that [redacted] (Lengauer (Exact/Thrive) Tr. 205–06.)

Third, as Dr. Katz testified, because "there's still a high degree of uncertainty" surrounding the development of these putative tests and their various characteristics, the views of the competitors are not probative of the actual contours of the relevant market. (RRFF ¶ 775 (RX6004 (Katz Trial Dep. at 21-22).) "[I]t may well be they think of these firms as their competitor or prospectively so, but that's not really enough I think to reliably tell us what the market boundaries are going to be." (RRFF ¶ 775 (RX6004 (Katz Trial Dep. at 21-22).) Statements by competitors "are not going to answer these questions about the trade-offs or . . . the degree of differentiation or how consumers are going to really behave." (RRFF ¶ 774 (RX6004 (Katz Trial Dep. at 21).). [redacted] (RRFF ¶ 773 (RX6004 (Katz Trial Dep. at 105) (emphasis added).)

Respondents further incorporate their responses to CCFF ¶¶ 433–434, 771, 773–76 herein.

437. [redacted] (PX4145 (Grail) at 009 (Grail, "An Overview," Aug. 14, 2019) (*in camera*)).

Response to Finding No. 437:

The proposed finding is incomplete and misleading. [redacted]

[redacted] The proposed finding is also incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Respondents also incorporate their responses to CCFF ¶¶ 405, 426–427, 433 and 436 herein.

438. [redacted]

Response to Finding No. 438:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2257–2352 herein.

(5) Freenome

439. Freenome's CEO, Mike Nolan, testified that Freenome is "starting with detection of colorectal cancer and advanced adenomas from a blood sample and then taking a stepwise approach to get to other cancer types so that we can deliver benefits of early detection across a range of different cancers." (Nolan (Freenome) Tr. 2706).

Response to Finding No. 439:

The proposed finding is incomplete and misleading insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. As noted, even once a company has developed a cancer screening test for a single cancer

type (which Freenome has not yet completed), it does not become easier to add additional cancer types. Respondents also incorporate their responses to CCFF ¶ 405 herein.

Mr. Nolan testified that [redacted] (PX7094 (Nolan (Freenome) Dep. at 307).) [redacted] (PFF ¶¶ 459-70.) [redacted] Accordingly, there is no indication based on Freenome's work to date that [redacted] (PFF ¶ 458 [redacted] RX3869 (Cote Expert Report) ¶ 193).)

Mr. Otte, Freenome's former CEO, also testified that [redacted]

440. Freenome's Nolan further testified that Freenome currently has "a multicancer program" and has prospectively collected samples "for the purpose of product development, across a range of cancer types." (Nolan (Freenome) Tr. 2709).

Response to Finding No. 440:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 439 herein. Mr. Nolan has also testified that [redacted]

441. [redacted] (PX7121 (Otte (Freenome) Dep. at 105) (*in camera*); *see also* Nolan (Freenome) Tr. 2711 (stating that Freenome's multiomics platform analyzes [redacted])).

Response to Finding No. 441:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 439 herein.

442. [redacted] (PX7121 (Otte (Freenome) Dep. at 56) (*in camera*)).

Response to Finding No. 442:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 439 herein.

443. [redacted] (Nolan (Freenome) Tr. 2748 (*in camera*)).

Response to Finding No. 443:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 439 herein.

444. [redacted] (Della Porta (Grail) Tr. 483 (*in camera*)).

Response to Finding No. 444:

The proposed finding is incomplete and misleading insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. The proposed finding is also incomplete and misleading insofar as it suggests that Freenome is developing a product that is reasonably interchangeable with Galleri. (*See* Resps.' Post-Trial Br. at 18.)

First, [redacted]

Second, and similar to Mr. Della Porta, Complaint Counsel's own witness, Dr. Lengauer of Thrive, testified at trial that [redacted]

Third, as Dr. Katz testified, because "there's still a high degree of uncertainty" surrounding the development of these putative tests and their various characteristics, the views of the competitors are not probative of the actual contours of the relevant market. (RRFF ¶ 775 (RX6004 (Katz Trial Dep. at 21-22).) "[I]t may well be they think of these firms as their competitor or prospectively so, but that's not really enough I think to reliably tell us what the market boundaries are going to be." (RRFF ¶ 775 (RX6004 (Katz Trial Dep. at 21-22).) Statements by competitors "are not going to answer these questions about the trade-offs or . . . the degree of differentiation or how consumers are going to really behave." (RRFF ¶ 774 (RX6004 (Katz Trial Dep. at 21).). [redacted]

[redacted] (RRFF ¶ 773 (RX6004 (Katz Trial Dep. at 105) (emphasis added).).

Respondents further incorporate their responses to CCFF ¶¶ ¶ 439, 771, 773–76 herein.

445. [redacted] (PX4145 (Grail) at 009 (Grail, "An Overview," Aug. 14, 2019) (*in camera*)).

Response to Finding No. 445:

The proposed finding is incomplete and misleading. [redacted] The proposed finding is also incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Respondents also incorporate their responses to CCFF ¶¶ 439–440, 444 herein.

446. [redacted]

Response to Finding No. 446:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2353–2400 herein.

(6) Singlera

447. Dr. Gao testified that Singlera's "goal is to detect cancer early, all kinds of cancer. (PX7042 (Gao, IHT at 21, 118-19)).

Response to Finding No. 447:

The proposed finding is incomplete and misleading. Although Singlera's "goal" may be to detect all kinds of cancer, Dr. Gao has also testified that Singlera is "far away" from starting clinical trials for PanSeer in the United States, and that it is "still not in the really starting clinical trial state." (Gao (Singlera) Tr. 2926; PX7102 (Gao (Singlera) Dep. at 113–14, 81–82; PFF ¶ 536.1.) By Dr. Gao's own calculation, PanSeer is at least eight to ten years away from potential launch in the United States, and Singlera does not currently have any clinical trials relating to screening for multiple cancers listed on clinicaltrials.gov. (PFF ¶¶ 536.1-36.2.) Accordingly, [redacted] Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

448. Singlera's PanSeer test is designed to detect "all kinds of cancer" using a blood-based approach. (Gao (Singlera) Tr. 2873).

Response to Finding No. 448:

The proposed finding is incomplete and misleading. In the cited testimony, Dr. Gao was testifying specifically about "products in development", not products that have already been developed and launched on the market as an LDT, like Galleri. (Gao (Singlera) Tr. 2873 ("Q. Just to make sure I have it clear for the record, what products does Singlera currently have in

development? A. We have a number of products in development. . . . [T]he most important one is called PanSeer, so pan – it's for discovering all kinds of cancer through basically liquid biopsy.").) As explained in Respondents' response to CCFF ¶ 447, which Respondents incorporate herein, [redacted]

449. Singlera's PanSeer test analyzes cfDNA using methylation patterns as biomarkers to detect cancer. (Gao (Singlera) Tr. 2875; PX7042 (Gao (Singlera) IHT at 21)).

Response to Finding No. 449:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 447 herein.

450. Singlera published a paper in Nature Communications in 2020 demonstrating the performance of its platform for five different cancers in terms of sensitivity and specificity. (Gao (Singlera) Tr. 2875).

Response to Finding No. 450:

The proposed finding is incomplete and misleading. Even though Singlera published a paper in 2020 describing the performance of its test for "five different cancers", Dr. Gao subsequently testified in late 2021 that Singlera is "far away" from starting clinical trials for PanSeer in the United States, and that it is "still not in the really starting clinical trial state." (Gao (Singlera) Tr. 2926; PX7102 (Gao (Singlera) Dep. at 113–14, 81–82; PFF ¶ 536.1.) By Dr. Gao's own calculation, PanSeer is at least eight to ten years away from potential launch in the United States, and Singlera does not currently have any clinical trials relating to screening for multiple cancers listed on clinicaltrials.gov. (PFF ¶¶ 536.1–36.2.) Accordingly, [redacted]

[redacted]

451. [redacted] (Della Porta (Grail) Tr. 483 (*in camera*)).

Response to Finding No. 451:

The proposed finding is incomplete and misleading insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. The proposed finding is also incomplete and misleading to the extent it suggests Singlera is developing a product that is reasonably interchangeable with Galleri. (*See* Resps.' Post-Trial Br. at 18.)

First, Galleri does not compete with Singlera's PanSeer test, which is very different from Galleri. Singlera's data from a 418-sample case control study shows only that Singlera's PanSeer assay detected five types of cancer and achieved only 96.1% specificity. (RX3115 (Chen et al 2020) at 3; [redacted] Indeed, Singlera is "far, far away" from launching its PanSeer test" (PX7102 (Gao (Singlera) Dep. at 118-19) and does not currently have a price for the product. (Gao (Singlera) Tr. 2893.) Respondents also incorporate their responses to CCFF ¶ 447 herein.

Second, as Dr. Katz testified, because "there's still a high degree of uncertainty" surrounding the development of these putative tests and their various characteristics, the views of the competitors are not probative of the actual contours of the relevant market. (RRFF ¶ 775

(RX6004 (Katz Trial Dep. at 21-22).) "[I]t may well be they think of these firms as their competitor or prospectively so, but that's not really enough I think to reliably tell us what the market boundaries are going to be." (RRFF ¶ 775 (RX6004 (Katz Trial Dep. at 21-22).) Statements by competitors "are not going to answer these questions about the trade-offs or . . . the degree of differentiation or how consumers are going to really behave." (RRFF ¶ 774 (RX6004 (Katz Trial Dep. at 21).) [redacted] (RRFF ¶ 773 (RX6004 (Katz Trial Dep. at 105) (emphasis added).) Respondents also incorporate their responses to CCFF ¶¶ 773–76 herein.

452. [redacted] (PX4145 (Grail) at 009 (Grail, "An Overview," Aug. 14, 2019) (*in camera*)).

Response to Finding No. 452:

The proposed finding is incomplete and misleading. [redacted] The proposed finding is also incomplete and misleading to the extent that it suggests that [redacted] (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the

market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 447 and 451 herein.

453. [redacted]

Response to Finding No. 453:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2401–77.

(7) Helio

454. Helio is "a company in the space of early cancer detection using blood as the specimen trying to determine initially the early detection of liver cancer but with ambitions to do additional cancers, including ultimately a multicancer test." (Chahine (Helio) Tr. 1000).

Response to Finding No. 454:

Respondents have no specific response except to note that the cited testimony confirms that Helio has ambitions to create a multicancer test, but does not presently have a multicancer test. Dr. Chahine also testified that [redacted] (Chahine (Helio) Tr. 1090, 1092–93.) Further, Dr. Chahine testified that [redacted] Accordingly, there is no indication based on Helio Health's work to date that [redacted]

[redacted] (PFF ¶ 498.)

455. [redacted] (PX7077 (Chahine (Helio) Dep. at 15)).

Response to Finding No. 455:

The proposed finding is incomplete and misleading. The proposed finding mischaracterizes the cited testimony, in which Dr. Chahine testified that Helio is "interested in" other cancers, not that Helio plans to add cancers to its liver test. (PX7077 (Chahine (Helio) Dep. at 15 ("Q. What blood-based cancer screening products is Helio currently developing? A. Our lead product is in liver, but we have a pipeline of other cancers that we're interested in, including colon, breast, lung.").) Further, the cited testimony confirms that Helio is only "interested in" other cancers but has not in fact developed a test that screens for multiple cancer types simultaneously. In the cited trial testimony Dr. Chahine referred to "many others [i.e., cancer types] that we have done, you know, very limited research on" and noted that "ovarian cancer is a huge killer" and "[e]sophageal cancer is another one" but did not refer to a "HelioLiver test platform" or specifically discuss adding those or other cancer types to any such platform. (Chahine (Helio) Tr. 1039.) Respondents also incorporate their responses to CCFF ¶ 454 herein.

456. [redacted] (PX7077 (Chahine (Helio) Dep. at 16) (*in camera*)).

Response to Finding No. 456:

The proposed finding is incomplete and misleading insofar as it suggests that [redacted],

[redacted] (Chahine (Helio) Tr. 1090, 1092–93.) Accordingly, there is no indication based on Helio Health's work to date that [redacted] (PFF ¶ 498.)

457. [redacted] (Chahine (Helio) Tr. 1000-01; PX7077 (Chahine (Helio) Dep. at 16) (*in camera*)).

Response to Finding No. 457:

Respondents have no specific response except note that Dr. Chahine also testified that [redacted] (Chahine (Helio) Tr. 1090, 1092–93.) Further, Dr. Chahine testified that [redacted] Accordingly, there is no indication based on [redacted]. (PFF ¶ 498.)

458. [redacted] (Della Porta (Grail) Tr. 483-84 (*in camera*)).

Response to Finding No. 458:

The proposed finding is incomplete and misleading insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. The proposed finding is also incomplete and misleading to the extent it suggests Helio is developing a product that is reasonably interchangeable with Galleri. (*See* Resps.' Post-Trial Br. at 18.)

First, [redacted]

Second, Respondents also note that Complaint Counsel's own witness, Dr. Lengauer of Thrive, confirmed at trial that [redacted] (Lengauer (Exact/Thrive) Tr. 206.)

Third, as Dr. Katz testified, because "there's still a high degree of uncertainty" surrounding the development of these putative tests and their various characteristics, the views of the competitors are not probative of the actual contours of the relevant market. (RRFF ¶ 775 (RX6004 (Katz Trial Dep. at 21-22).) "[I]t may well be they think of these firms as their competitor or prospectively so, but that's not really enough I think to reliably tell us what the market boundaries are going to be." (RRFF ¶ 775 (RX6004 (Katz Trial Dep. at 21-22).) Statements by competitors "are not going to answer these questions about the trade-offs or . . . the degree of differentiation or how consumers are going to really behave." (RRFF ¶ 774 (RX6004 (Katz Trial Dep. at 21).). [redacted]

[redacted] (RRFF ¶ 773 (RX6004 (Katz Trial Dep. at 105) (emphasis added).) Respondents further incorporate their responses to CCFF ¶¶ 454–57 and 773–76 herein.

459. [redacted] (PX4145 (Grail) at 009 (Grail, "An Overview," Aug. 14, 2019) (*in camera*)).

Response to Finding No. 459:

The proposed finding is incomplete and misleading. [redacted] The proposed finding is also incomplete and misleading to the extent that it suggests [redacted] (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Respondents also incorporate their responses to CCFF ¶ 454–58 herein.

460. [redacted]

Response to Finding No. 460:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2478–2556 herein.

(8) [redacted]

461. [redacted]

Response to Finding No. 461:

Respondents have no specific response.

462. [redacted]

Response to Finding No. 462:

The proposed finding is incomplete and misleading insofar as it suggests that [redacted] to GRAIL today or will be a competitor to GRAIL in the foreseeable future. Dr. Fielder testified that [redacted] (PX7074 (Perettie (FMI) Dep. at 73, 74, 77–78); Fiedler (FMI) Tr. 4476–77) [redacted] (PX7074 (Perettie (FMI) Dep. at 72, 73, 79, 160–61).) [redacted]

[redacted] (PX7074 (Perettie (FMI) Dep. at 79–80); PX8447 (Roche) at 5.)

Accordingly, [redacted]

463. [redacted]

Response to Finding No. 463:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 462 herein.

464. [redacted]

Response to Finding No. 464:

The proposed finding is incomplete and misleading. Complaint Counsel mischaracterizes Ms. Perettie's testimony in which she testified not that she expected FMI's purported future MCED test to be "competitive or better" than GRAIL's test but merely that FMI's "*goal* would be to be as competitive or better". Further, [redacted]

[redacted] Respondents also note that Complaint Counsel's own witness, Dr. Lengauer of Thrive, confirmed at trial that [redacted] (Lengauer (Exact/Thrive) Tr. 206.) Further, the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

465. [redacted]

Response to Finding No. 465:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2557–94.

c) MCED Tests Are Designed to Complement Existing Screening Methods

466. [redacted] (PX7040 (Getty (Guardant) IHT at 154-155); PX7051 (Lengauer (Third Rock Ventures) IHT at 176) (*in camera*); PX7083 (Bishop (Grail) Dep. at 24-25)).

Response to Finding No. 466:

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including [redacted], do not expect (and none can

reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706**)** and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Respondents also note that the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

467. [redacted] (Conroy (Exact) Tr. 1647 (*in camera*)).

Response to Finding No. 467:

The proposed finding is inaccurate and misleading to the extent it suggests that [redacted], which there is no evidence to support. Dr. Lengauer testified, [redacted] Additionally, [redacted] Respondents also incorporate their responses to CCFF ¶ 640 herein.

468. Dr. Cance anticipates that MCED tests will be part of annual physicals for certain individuals: "I expect that, once available, these tests might be used as part of patients' annual primary (wellness) care. For example, any individual above the age of 50 could receive a multi-cancer early detection test at their annual physical through their primary physician." (PX8398 (Cance (American Cancer Society) Decl. ¶ 9)).

Response to Finding No. 468:

Respondents have no specific response except to note that certain of the putative MCED developers Complaint Counsel has identified intend to market their putative tests to other customers: Natera plans to offer its purported cancer screening test to oncology offices (CCFF ¶ 2219) and Freenome plans to market its MCED test to primary care physicians *and OB-GYNs*. (CCFF ¶ 2389.)

Respondents also note that Dr. Cance also testified that GRAIL is further ahead in its development process than other companies that are developing purported MCED tests, that he is not aware of any other purported MCED test that is commercially available today, that he does not know of other companies detecting the same number of cancers as GRAIL, and that accelerating an early cancer detection test's ability to commercialize at scale is consistent with ACS's mission. (Cance (ACS) Tr. 631–33.) Respondents also incorporate their responses to CCFF ¶ 248 herein.

469. Dr. Cance declared that MCED tests will complement existing screening methods: "Until they are fully validated and studied, multi-cancer early detection tests may complement but not replace the existing screening methods." (PX8398 (Cance (American Cancer Society) Decl. ¶ 9)).

Response to Finding No. 469:

Respondents have no other specific response except to note that this proposed finding provides support for the proposition that Galleri will be a complement to single cancer screening tests, including those that are available as the standard of care today, as well as complementary to screening tests for a handful of cancer types that many purported MCED test developers are pursuing. (*See* PFF ¶ 358 (RX0744 (GRAIL) at 76–90; [redacted] RX0867 (Clinical Overview Deck) at 15; PX7086 (Cance (ACS) Dep. at 50–53); [redacted]; RX3869 (Cote Expert Report) ¶ 136).)

Respondents also note that certain putative MCED test developers identified by Complaint Counsel are developing cancer screening test that are intended to be substitutes for USPSTF-recommended screening tests and/or single-cancer blood-based tests. For example, [redacted]

Respondents also incorporate their responses to CCFF ¶ 248 herein.

470. Dr. Cance described the potential to use MCED tests as a preliminary screening tool: "These multi-cancer early detection tests could ultimately be used as a preliminary screening test to determine whether further cancer-specific screening, such as a colonoscopy or other more invasive diagnostic methods, is needed." (PX8398 (Cance (American Cancer Society) Decl. ⁋ 9)).

Response to Finding No. 470:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 248 and 468 herein. Respondents note that Dr. Cance also described in the cited reference that [redacted] (PX8398 (Cance (American Cancer Society) Decl.) ⁋ 9.) Respondents also note that at this time, Galleri is not meant as an alternative or replacement to standard cancer screening procedures, but rather as a complement to recommended screenings (*See* PFF ¶ 358 (RX0744 (GRAIL) at 76–90; [redacted] RX0867 (Clinical Overview Deck) at 15).)

471. Mr. Bishop testified on the distinction between single cancer and MCED tests:

> [T]he reason we should not use Galleri instead of any of those single tests is because those single tests are optimized for detecting those single cancers. They

> have a higher detection rate than we do for those individual cancers. And the clinical goal here is to maximize the number of cancers we detect early. And we do that by using Galleri in conjunction with single-cancer screening tests.

(Bishop (Grail) Tr. 1390-91).

Response to Finding No. 471:

Respondents have no other specific response except to note that this proposed finding confirms that Galleri will be a complement to single cancer screening tests, including those that are available as the standard of care today, as well as to the screening tests for a handful of cancer types that many purported MCED test developers are pursuing. (*See* PFF ¶ 358 (RX0744 (GRAIL) at 76–90; [redacted] RX0867 (Clinical Overview Deck) at 15; PX7086 (Cance (ACS) Dep. at 50–53); [redacted]; RX3869 (Cote Expert Report) ¶ 136).) Respondents also note that certain putative MCED test developers identified by Complaint Counsel are developing cancer screening test that are intended to be substitutes for USPSTF-recommended screening tests and/or single-cancer blood-based tests. For example, [redacted]

Respondents further note that there is typically a tradeoff between specificity and sensitivity, where a test seeking higher specificity may often have lower sensitivity. (PFF ¶ 180 (RX3869 (Cote Expert Report) ¶ 95).) Subsequently, existing single cancer screening tests typically have very high sensitivity rates and correspondingly lower specificity/higher false positive rates. **(**PFF ¶ 180.1 (RX3869 (Cote Expert Report) ¶ 95).) In contrast, a test developer

focusing on a cancer screening test for a large number of cancer types must focus on attaining a very high specificity rate, and a high PPV, which will often result in correspondingly lower sensitivity rates. (PFF ¶ 181 (RX3869 (Cote Expert Report) ¶ 95).) Based on the performance of Galleri in the CCGA-2 study and using 2006 to 2015 SEER data for ages 50–79, GRAIL estimates that by adding Galleri to diagnosis by usual care, there is potential to detect nearly 70% of cancers resulting in death within five years at an earlier stage (excluding cancers that grow too quickly to be detected by any screening program), which would translate to averting potentially 100,000 deaths annually, or 39% of the five-year deaths expected if not for early detection by Galleri. (PFF ¶ 64.)

472. Mr. Bishop explained that, in comparison to the existing standard of care screening tests, Galleri is not as sensitive:

> [W]ithout exception, the single-cancer tests used today for prostate, cervix, breast and colon -- and I can list the particular tests that are regarded as standard of care today -- their detection rate for those single cancers at their specificity is higher than the detection rate for those individual single cancers that the Galleri test has. That's the essential reason why these tests should be used alongside each other.

(Bishop (Grail) Tr. 1392).

Response to Finding No. 472:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 471 herein.

473. [redacted] (Della Porta (Grail) Tr. 544 (*in camera*)).

Response to Finding No. 473:

Respondents have no specific response except to note that Mr. Della Porta also testified that [redacted] (Della Porta (Grail) Tr.

544 (*in camera*) [redacted] Respondents also incorporate their responses to CCFF ¶ 471 herein.

474. [redacted] (PX7058 (Conroy (Exact) IHT at 119-120) (*in camera*)).

Response to Finding No. 474:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

475. [redacted] (PX7058 (Conroy (Exact) IHT at 112-13) (*in camera*)).

Response to Finding No. 475:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

D. THE U.S. MCED TEST MARKET IS EXPECTED TO REACH TENS OF BILLIONS OF DOLLARS ANNUALLY IN REVENUES

1. Illumina Expects Cancer Screening to Be "Probably the Single Biggest Market Segment That We Can Imagine"

476. In 2016, Jay Flatley, then the Chairman and Chief Executive Officer of Illumina, told investors that cancer screening is a "gigantic opportunity" and "probably the single biggest market segment that we can imagine." (PX0045 at 023 (Illumina, Illumina Q1 2016 Results Earnings Call Transcript, May 4, 2016)).

Response to Finding No. 476:

Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 1), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

The proposed finding is incomplete and misleading. Although the cited source is from January 2016, the proposed finding appears to suggest that Mr. Flatley's statement governs the behavior of Illumina today with respect to the GRAIL transaction.

477. "Illumina has recognized that cancer screening is [redacted] with a projected market size of tens of billions of dollars by 2035. . . ." (Answers and Defenses of Respondents Illumina and Grail at 018 (¶ 10) (*in camera*)).

Response to Finding No. 477:

Respondents have no specific response except to note that the cited source refers to "cancer screening" via liquid biopsy broadly and not multicancer screening. As noted, in addition to multicancer screening, there is cancer screening for single cancer types via liquid biopsy. (*See* CCFF ¶¶ 634, 671-72.).

478. Driving its proposed acquisition of Grail was Illumina's recognition that, [redacted] (*See* PX2465 (Illumina) at 006-008 [redacted] (*in camera*); PX2488 (Illumina) at 007-009 [redacted],

[redacted] (*in camera*)).

Response to Finding No. 478:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 3121 herein.

479. [redacted] (PX2035 (Illumina) at 002 (Illumina, Oncology Testing 5-Year Strategy Refresh, 2020) (*in camera*)).

Response to Finding No. 479:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 5), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

480. [redacted] (PX2488 (Illumina) at 003 [redacted] (*in camera*)).

Response to Finding No. 480:

Respondents have no specific response except to note that [redacted]

481. [redacted] (PX2488 (Illumina) at 003, 007 [redacted]

[redacted] (*in camera*)).

Response to Finding No. 481:

Respondents have no specific response except to note that [redacted]

482. [redacted] (PX2316 (Illumina) at 023 (Email from J. Goswami, Illumina, to A. Qadan, Illumina, et al., Apr. 29, 2020, attaching presentation entitled "Board of Directors M&A Landscape") (*in camera*)).

Response to Finding No. 482:

Respondents have no specific response except to note that [redacted]

483. In presentations to Illumina's board of directors, Illumina executives warned, [redacted] (PX2488 (Illumina) at 009 [redacted] (*in camera*); *see also* PX2465 (Illumina) at 008 [redacted] (*in camera*)).

Response to Finding No. 483:

The proposed finding is incomplete and misleading to the extent it characterizes Illumina's executives as "warn[ing]" the board about the observation it made. Respondents otherwise have no specific response except to incorporate their responses to CCFF ¶¶ 3115, 3121, 3125, 3127, 3129 herein.

484. [redacted] (PX2488 (Illumina) at 009 [redacted] (*in camera*); *see also* PX2465 (Illumina) at 008 [redacted] (*in camera*); PX2169 (Illumina) at 043 [redacted] (*in camera*)).

[redacted]

Response to Finding No. 484:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 212–13, 3129 herein.

2. Other MCED Developers Also Project Tens of Billions of Dollars in Revenues for the MCED Test Market

485. [redacted] (PX8324 (Roche) at 012 [redacted] (*in camera*)).

Response to Finding No. 485:

Respondents have no specific response except to note that [redacted] Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 59), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

486. Guardant Senior Vice President of Commercial, Bill Getty, testified that Guardant estimates the multi-cancer early detection testing market will exceed $50 billion in revenue. (Getty (Guardant) Tr. 2503; PX7105 (Getty (Guardant) Dep. at 50-51)).

Response to Finding No. 486:

Respondents have no specific response.

487. As Guardant's Getty explained, "[t]he sequencing business is a much, much smaller slice . . . relative to that 60-billion-dollar [blood-based cancer screening business] opportunity. So as an organization, [Illumina's] acquisition of Grail is ostensibly geared to moving into this much bigger opportunity and maximizing that opportunity." (PX7105 (Getty (Guardant) Dep. at 68)).

Response to Finding No. 487:

Respondents have no specific response except to note that as an executive at Guardant Health, Mr. Getty lacks personal knowledge to opine on what Illumina's motivations and incentives might be.

488. [redacted] (Berry (Illumina) Tr. 767-768) (*in camera*).

Response to Finding No. 488:

Respondents have no specific response.

489. [redacted] (RX0894 (Helio) at 10 (Helio, Helio Health) (*in camera*)).

Response to Finding No. 489:

Respondents have no specific response except to note that the cited slide [redacted] Respondents further note that Complaint Counsel chose not to discuss this document at trial, (Resps.' Exhibit Index at 49), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

490. Freenome's Mr. Nolan testified that the MCED market "is huge and the unmet need is huge." (Nolan (Freenome) Tr. 2727).

Response to Finding No. 490:

Respondents have no specific response.

491. Cowen—a financial services firm—identified multi-cancer screening tests for asymptomatic patients as its own market and assessed that it would have approximately a $5 to $50 billion target addressable market in its report on liquid biopsy. (PX2752 (Illumina) at 007 (Liquid Biopsy Report: Early Detection of a Huge Opportunity, Sept. 18, 2020)). Cowen's market assessment noted that single cancer tests, tests targeting high risk patients, and tests with a non-screening function as separate market opportunities.

(PX2752 (Illumina) at 007 (Liquid Biopsy Report: Early Detection of a Huge Opportunity, Sept. 18, 2020).

Response to Finding No. 491:

Respondents have no specific response except to note that the same report notes that: GRAIL has "conducted systematic clinical studies" and that Galleri "has been shown to be capable of identifying >50 types of cancers by scanning methylation patterns"; the only other entity it recognizes as pursuing a multicancer screening test is Thrive. By contrast, the cited report notes that Freenome and Guardant are among the companies in a separate market segment pursuing *single-cancer screening tests to detect colorectal cancer* (PX2022 (Cowen) at 30–31 (emphasis added)), while it lists Singlera in passing under the heading "[s]ome [o]thers" following its summary of the colorectal cancer screening market (PX2022 (Cowen) at 33), and considers Helio in a separate segment for "High Risk Cancer Detection" for its liver cancer screening test. The cited report does not even recognize [redacted] as pursuing early cancer detection at all: it notes [redacted] as a participant in the recurrence monitoring/MRD and "liquid biopsy for biopharma" (*i.e.* companion diagnostic) segments (PX2022 (Cowen) at 46–53), and [redacted] in the therapy selection and "liquid biopsy for biopharma" market segments. (PFF ¶¶ 717.1–717.1.3.)

For clarity, Respondents note that Respondents cited a different exhibit that contains the same Cowen report in Respondents Proposed Findings of Fact. (*Compare* PX2022 (Illumina) at 2-59 *with* PX2752 (Illumina) at 2-59.) Respondents further incorporate their responses to CCFF ¶ 820 herein.

E. REGULATORY APPROVAL PROCESS AND REIMBURSEMENT FRAMEWORK FOR MCED TESTS

492. [redacted]

[redacted] (Bishop (Grail) Tr. 1331-33; Della Porta (Grail) Tr. 456-58; Ofman (Grail) Tr. 3371-72 (*in camera*)).

Response to Finding No. 492:

The proposed finding is incomplete and misleading. *First*, the proposed finding is incomplete and misleading to the extent it suggests that MCED tests are [redacted] (Ofman (GRAIL) Tr. 3352–53; RX6001 (Deverka Trial Dep.) at 49.) As Dr. Ofman testified, [redacted] (Ofman (GRAIL) Tr. 3352.) [redacted] (Ofman (GRAIL) Tr. 3352; RX6001 (Deverka Trial Dep.) at 52; *see also* PX4082 at -001 (GRAIL's Amended Form S-1 dated Sept. 2020) ("approval under traditional fee-for-service Medicare reimbursement . . . will take several years to obtain, if at all").)

MCED tests are also not currently covered by any private insurers. Private insurers will require evidence of analytic validity, clinical validity, clinical utility and economic utility when determining whether to cover a new test. (RX6001 (Deverka Trial Dep.) at 33–36).) [redacted] (Ofman Tr. 3354–55.) As Dr. Ofman testified, [redacted] (Ofman (GRAIL) Tr. 3354–55.)

Second, the proposed finding is incomplete and misleading to the extent it suggests that MCED tests are [redacted] Galleri is the only MCED test that is commercially available through any of these channels, and its availability is limited to [redacted] (Ofman (GRAIL) Tr. 3373–74.)

493. Grail has begun entering into contracts with some health systems and self-employed customers for the Galleri test, but, according to Grail Chief Medical Officer Josh Ofman, Grail does not expect to receive widespread payer coverage until after obtaining premarket approval ("PMA") from the FDA. (*See* PX7092 (Ofman (Grail) Dep. at 175-176)).

Response to Finding No. 493:

The proposed finding is misleading to the extent it refers to GRAIL entering contracts with "self-employed customers". [redacted]

Respondents also note that the proposed finding is incomplete and misleading to the extent it implies that premarket approval from the FDA is sufficient for GRAIL to obtain widespread payor coverage for Galleri. *First*, [redacted] (Ofman (GRAIL) Tr. 3354–55; *see also* RX6001 (Deverka Trial Dep. at 37–38.) *Second*, [redacted] (Ofman (GRAIL) Tr. 3354;

RX6001 (Deverka Trial Dep.) at 49–50.) Obtaining premarket approval would be a helpful step to achieving payor coverage, but it will not be enough on its own.

Respondents also note that the proposed finding supports Respondents' position regarding the amount of time it could take for GRAIL to achieve payor coverage for Galleri.

[redacted] (Ofman (GRAIL) Tr. 3351.) [redacted]

1. Laboratory Developed Tests (LDTs)

494. A laboratory-developed test ("LDT") is a test developed on-site at a single clinical laboratory, which uses components from multiple suppliers to put together a specific test that is then validated in that laboratory. (Febbo (Illumina) Tr. 4320; *see also* PX0043 at 041 (Grail 2020 Form S-1) ("LDTs are in vitro diagnostic tests that are intended for clinical use and are designed, manufactured, and used within a single laboratory")).

Response to Finding No. 494:

Respondents have no specific response except to note that the cited testimony does not specify that a clinical laboratory developing an LDT uses components from "multiple suppliers". With respect to LDTs, Dr. Febbo testified that "a clinical laboratory uses components to put together a specific test that they validate in their laboratory". (Febbo (Illumina) Tr. 4320.)

495. [redacted] (Goswami (Illumina) Tr. 3185-86; *see also* Rabinowitz (Natera) Tr. 382 (*in camera*)).

Response to Finding No. 495:

Respondents have no specific response except to note that the CLIA and CAP guidelines require clinical evidence supporting a test's performance in order to achieve and maintain CLIA/CAP certification. Laboratory-developed test manufacturers and laboratories are

dependent on this certification to offer their tests, and after initial certification they continue to undergo routine audits. (Febbo (Illumina) Tr. 4322; *see also* Goswami (Illumina) Tr. 3221 ("[T]hey have to certify robustness of results . . . And that certification has to be renewed over – you know, over the years.").) The United States allows a laboratory-developed test developed under CLIA/CAP guidelines "to be ordered by doctors". (Goswami (Illumina) Tr. 3222.)

496. LDTs, in order to be offered to patients, must be performed in labs that have CLIA certification. (Febbo (Illumina) Tr. 4320).

Response to Finding No. 496:

Respondents have no specific response.

497. The Centers for Medicare & Medicaid Services ("CMS") certifies CLIA compliance of the laboratories themselves. (Ofman (Grail) Tr. 3317-18).

Response to Finding No. 497:

Respondents have no specific response.

498. [redacted] (PX7111 (Fesko (Natera) Dep. at 181 (*in camera*)); *see also* Goswami (Illumina) Tr. 3186 (stating that the test developer "takes all responsibility for certifying the test and validating it"); PX7097 (Felton (Thermo Fisher) Dep. at 51) (stating that an LDT test itself is "self-validated" under CLIA/CAP regulation in the U.S.)).

Response to Finding No. 498:

Respondents have no specific response except to note that the proposed finding is incomplete and misleading to the extent it implies that test developers certify and validate their own LDTs without any regulatory oversight. To the contrary, for a test developer to validate its test under the CLIA/CAP guidelines, it must run the test at a CLIA-certified laboratory, which in turn must undergo routine audits in order to retain the CLIA certification. (Febbo (Illumina) Tr. 4322–23.) During those audits, CMS reviews the clinical data supporting an LDT and the test developer's claims about the data. (Febbo (Illumina) Tr. 4322–23.) If CMS found there was

insufficient data to support the LDT, the laboratory would risk losing its CLIA license. (Febbo (Illumina) Tr. 4323.)

499. CLIA/CAP guidelines for LDTs are not overseen by the FDA. (Goswami (Illumina) Tr. 3221-22, 3262; *see also* PX4035 (Grail) at 038 (PiperJaffray, The 2015 Liquid Biopsy Report, Sept. 2015) (stating that LDTs are exempt from FDA's oversight but laboratories with LDTs must follow CLIA)).

Response to Finding No. 499:

Respondents have no specific response except to note that the proposed finding is incomplete and misleading to the extent it implies that LDTs are never subject to FDA oversight. GRAIL is selling the Galleri test as an LDT while simultaneously seeking premarket approval from the FDA. Therefore, even though GRAIL is operating the Galleri test as an LDT, it is seeking to comply with FDA's additional evidentiary and other requirements in order to work towards obtaining regulatory approval. (Ofman (GRAIL) Tr. 3319; *see also* Ofman (GRAIL) Tr. 3318 ("if you have an LDT in the market, you still need to follow all the major guidances from the FDA about supportable claims and having evidence to support your claims").) Respondents also incorporate their responses to CCFF ¶ 498 herein.

500. The FDA does not review or validate safety or efficacy data associated with a test sold as an LDT. (Goswami (Illumina) Tr. 3262; *see also* PX0043 at 041 (Grail 2020 Form S-1) (stating that "[a]lthough LDTs are classified as medical devices and FDA has statutory authority to ensure that medical devices are safe and effective for their intended uses, FDA has historically exercised enforcement discretion and has not enforced certain applicable FDA requirements, including premarket review, with respect to LDTs")).

Response to Finding No. 500:

Respondents have no specific response except to note that the proposed finding is incomplete and misleading to the extent it implies that the safety or efficacy data associated with a test sold as an LDA is never subject to FDA oversight. GRAIL is selling the Galleri test as an LDT while simultaneously seeking premarket approval from the FDA. Therefore, even though

GRAIL is operating the Galleri test as an LDT, the FDA will review safety or efficacy data as part of its regulatory approval process. (Ofman (GRAIL) Tr. 3319.) Respondents also incorporate their responses to CCFF ¶ 498 herein.

501. [redacted] (*See* PX7111 (Fesko (Natera) Dep. at 171) (*in camera*)).

Response to Finding No. 501:

The proposed finding is incomplete and misleading because a laboratory-developed test must be supported by clinical evidence in order to obtain and maintain CLIA certification, regardless of whether the clinical evidence has been published. (Febbo (Illumina) Tr. 4322 (referring to clinical evidence as "very important" because "laboratory-developed test manufacturers and laboratories are dependent on CLIA certification to continue to offer their tests").) To the extent that the proposed finding suggests that certain putative MCED test developers are validating their tests to CLIA standards without publishing data, Respondents further note that [redacted]. (*See*, *e.g.*, RX5009–10 (subpoenas to Exact), RX5044–45 (subpoenas to Thrive); RX5015–16 (subpoenas to Guardant); RX5012–13 (subpoenas to Freenome); RX5022–23 (subpoenas to [redacted]); RX5035–36 (subpoenas to Singlera); RX5011 (subpoena to [redacted]).)

Respondents also note that GRAIL has published clinical validity data for Galleri, and published that data before launching Galleri in June 2021 as an LDT. (*See*, *e.g.*, RX3410 (CCGA study published 2018); RX3409 (clinical validation study presented April and May 2021); RX3041 (interim results of Pathfinder study presented June 4, 2021); *see also* Febbo (Illumina) Tr. 4322 (referring to the CCGA study that "demonstrated that the Galleri test could detect cancer in over 50 types of cancer"); Della Porta (GRAIL) Tr. 558 [redacted]

[redacted] RX6001 (Deverka Trial Dep.) at 83–84 (discussing "a number of" clinical validity studies that GRAIL has conducted for Galleri and the published clinical validity results from the CCGA study).)

502. [redacted] (*See* PX7051 (Lengauer (Third Rock Ventures) IHT at 146-147) (*in camera*); PX7058 (Conroy (Exact) IHT at 142) (*in camera*)).

Response to Finding No. 502:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also note that no test developer other than Galleri is currently selling an MCED, including as an LDT.

503. Grail's Galleri test is an LDT. (Ofman (Grail) Tr. 3317; Goswami (Illumina) Tr. 3222).

Response to Finding No. 503:

Respondents have no specific response.

504. As an LDT, Grail's Galleri test does not currently require FDA approval or oversight to be sold. (Goswami (Illumina) Tr. 3222).

Response to Finding No. 504:

Respondents have no specific response except to note that GRAIL is selling the Galleri test as an LDT while simultaneously seeking premarket approval from the FDA. Therefore, even though GRAIL is operating the Galleri test as an LDT and does not require FDA approval or oversight to be sold, it is seeking to comply with the FDA's additional evidentiary and other requirements in order to obtain regulatory approval. (Ofman Tr. 3319.) Respondents also incorporate their responses to CCFF ¶ 498 herein.

505. [redacted] (PX7050 (Nolan (Freenome) IHT at 279-280) (*in camera*); *see also* PX7051 (Lengauer (Third Rock Ventures) IHT at 149) (*in camera*)).

Response to Finding No. 505:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Respondents also incorporate their responses to CCFF ¶¶ 498–504 herein.

2. FDA Approval Process

506. [redacted] (PX7092 (Ofman (Grail) Dep. at 175-176); PX0043 at 115, 132 (Grail 2020 Form S-1); PX7058 (Conroy (Exact) IHT at 87-88) (*in camera*)).

Response to Finding No. 506:

Respondents have no specific response except to note the proposed finding is incomplete and misleading to the extent it implies that [redacted] There are numerous factors that will contribute to whether an MCED test achieves [redacted], including the development of robust clinical utility evidence and health economic evidence. (RX6001 (Deverka Trial Dep.) at 34–39).) FDA approval is helpful for achieving payor coverage because it "gives confidence" that a new test passed the FDA's evidence thresholds (RX6001 (Deverka Trial Dep.) at 39–40)), but payors will apply additional clinical and economic evidentiary considerations when evaluating whether to cover a new test. (RX6001 (Deverka Trial Dep.) at 41–42.) Even with payor coverage, the widespread commercialization of an MCED test will also require physician education regarding "appropriate use of the test, how to interpret test results and how to refer people that have a positive test result for further diagnostic workup". (RX6001 (Deverka Trial Dep.) at 42–43.)

Respondents also note that the proposed finding relies in part on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

507. [redacted] (*See* PX7055 (Otte (Freenome) IHT at 32-33) (*in camera*); PX7068 (Perettie (FMI-Roche) IHT at 33) (*in camera*)).

Response to Finding No. 507:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

508. Grail CEO Hans Bishop testified at trial that FDA approval is "very necessary for getting American citizens access to our test." (Bishop (Grail) Tr. 1368).

Response to Finding No. 508:

Respondents have no specific response except to note that Mr. Bishop further explained that he views FDA premarket approval as "necessary" because it will help to achieve payor coverage, which is in turn a "prerequisite" to broad-scale adoption of the Galleri test. (Bishop Tr. 1369–70.) He testified that he believes becoming part of Illumina will "increase[] our chances of success to be successful with our PMA and indeed even the timing of it". (Bishop Tr. 1372.) Respondents also incorporate their responses to CCFF ¶ 506 herein.

509. Illumina, Grail, and MCED test developer witnesses, ordinary course documents, and external industry researchers state that FDA approval is a necessary input to achieve Medicare coverage of MCED testing from CMS. (deSouza (Illumina) Tr. 2414); Ofman (Grail) Tr. 3319-20; Conroy (Exact) Tr. 1734; Chahine (Helio) Tr. 1029 (explaining that CMS issued guidance "stating that it would require FDA approval for reimbursement under CMS" for early cancer detection); PX4172 (Grail) at 059 (Grail Board of Directors Meeting, Nov. 21, 2019) (*in camera*) [redacted]; PX9090 (Roche) at 019 (Cowen, The Liquid Biopsy Report: Early Detection of a Huge Opportunity, Sep. 18, 2020) (stating that it "is

clear that CMS reimbursement [for asymptomatic cancer screening tests] will require FDA approval")).

Response to Finding No. 509:

Respondents have no specific response except to note that Illumina and GRAIL witnesses testified that they believe Illumina's acquisition of GRAIL is likely to accelerate both FDA approval and Medicare coverage for Galleri. (*See, e.g.*, Bishop Tr. 1372; Ofman Tr. 3320; Febbo Tr. 4326–27, 4337–38; *see also* RX6001 (Deverka Trial Dep.) at 63.) Respondents also incorporate their responses to CCFF ¶ 506 herein.

510. A Premarket Approval ("PMA") is a regulatory approval from the FDA that applies to high-risk, Class III diagnostic tests. (Febbo (Illumina) Tr. 4324; Ofman (Grail) Tr. 3319).

Response to Finding No. 510:

Respondents have no specific response except to clarify that a PMA applies to all Class III medical devices. (Febbo (Illumina) Tr. 4445–46.) [redacted] (Febbo (Illumina) Tr. 4443.)

511. [redacted]

(Chudova (Guardant) Tr. at 1208-09) (*in camera*).

Response to Finding No. 511:

Respondents have no specific response except to note that the cited testimony also states that [redacted]

[redacted] (Chudova (Guardant) Tr. 1208–09.)

512. Unless a MCED test can be shown to be "substantially equivalent to a legally marketed predicate device," the test will be "automatically classified under the [Food, Drug, and Cosmetic Act] into class III, which generally requires PMA approval." (PX0043 at 043 (Grail 2020 Form S-1)).

Response to Finding No. 512:

Respondents have no specific response.

513. Galleri will be considered a Class III medical device and will require Premarket Approval. (Febbo (Illumina) Tr. 4445; PX7099 (Febbo (Illumina) Dep. at 83-84); PX0043 at 043-44 (Grail 2020 Form S-1)).

Response to Finding No. 513:

Respondents have no specific response except to note that the cited trial testimony also states that GRAIL has plans to submit an application for a single-site premarket approval and that a unified Illumina and GRAIL will continue to focus on premarket approval for Galleri. (Febbo (Illumina) Tr. 4337.) Respondents also incorporate their responses to CCFF ¶ 509 herein.

514. [redacted] (Conroy (Exact) Tr. 1548-49; *see also* Rabinowitz (Natera) Tr. 394-95 (*in camera*) [redacted]).

Response to Finding No. 514:

Respondents have no specific response except to note that the proposed finding relies on testimony for which the witnesses lack personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

515. The quality of a product is part of safety and efficacy with respect to FDA approval. (Conroy (Exact) Tr. 1548-49).

Response to Finding No. 515:

The proposed finding is irrelevant as it does not relate to MCED tests.

Respondents have no specific response except to note that the cited testimony was in response to a question about whether Exact needed to provide any information to the FDA regarding Cologuard's suppliers as part of the FDA approval process. Mr. Conroy testified that the "key suppliers are inspected by the FDA to help ensure that the quality measures are put into place", and that "the suppliers are an absolutely critical part of that quality assurance". (Conroy (Exact) Tr. 1548–49.)

516. Dr. Ofman testified at trial that the FDA's requirements for a PMA approval exceed those to meet LDT standards: "[T]he FDA has many additional requirements in terms of quality, manufacturing, inspections. The evidence requirements are quite different." (Ofman (Grail) Tr. 3319). "[T]here's just a lot more to getting an FDA approval above and beyond what it takes to get CAP/CLIA certification." (Ofman (Grail) Tr. 3319; *see also* Bishop (Grail) Tr. 1345 (stating that a PMA has "an entirely different set of requirements" than an LDT).

Response to Finding No. 516:

Respondents have no specific response except to note that Dr. Ofman also testified that a test must be "analytically and clinically validated" in order to obtain CLIA/CAP certification and operate a test as an LDT. (Ofman (GRAIL) Tr. 3317.) He testified that GRAIL is additionally working to meet the FDA's requirements because he believes FDA approval will enable GRAIL to "provide broad access of [the Galleri] test to as many adult Americans and adults worldwide as possible". (Ofman (GRAIL) Tr. 3319.) Dr. Ofman also testified that he believes Illumina's reacquisition of GRAIL could accelerate the process of making the Galleri test accessible to doctors and their patients "as soon as possible". (Ofman Tr. 3320.) Respondents also incorporate their responses to CCFF ¶ 498 herein.

517. [redacted] (Rabinowitz (Natera) Tr. 395 (*in camera*)).

Response to Finding No. 517:

Respondents have no specific response except to note that the cited testimony also states that [redacted]

(Rabinowitz (Natera) Tr. 395–96.)

518. A PMA requires submitting a lengthy application involving clinical and analytical validation data collected during clinical trials using the device. (PX4082 (Grail) at 135 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 518:

Respondents have no specific response.

519. According to Dr. Ofman, analytical validation means ensuring that a test measures what it purports to measure at certain levels of precision. (Ofman (Grail) Tr. 3284).

Response to Finding No. 519:

Respondents have no specific response.

520. Analytical validation is typically followed by clinical validation, which means demonstrating that a test performs as indicated to detect the given disease in the intended use population. (Ofman (Grail) Tr. 3284-85).

Response to Finding No. 520:

Respondents have no specific response.

521. Clinical validation is critical for the commercialization of a test such as Galleri, as it is necessary to receive FDA approval, Medicare coverage, and reimbursement by private insurance. (*See* Gao (Singlera) Tr. 2886-87; PX7099 (Febbo (Illumina) Dep. at 36) (testifying that clinical validation is necessary for FDA approval); *see also* PX4160 (Grail) at 094 (Grail, Board of Directors Meeting, Nov. 10, 2020) (*in camera*) [redacted]).

Response to Finding No. 521:

Respondents have no specific response except to note that GRAIL has already conducted clinical validity studies for Galleri and published clinical validity data from the CCGA study. (RX6001 (Deverka Trial Dep.) 83.)

522. Like clinical validation, demonstrating clinical utility requires evidence that a test can detect disease in the intended use population. (Qadan (Illumina) Tr. 4110).

Response to Finding No. 522:

Respondents have no specific response.

523. Establishing clinical utility also involves assessing how a test's results may impact patient management and outcomes. (Qadan (Illumina) Tr. 4110-11).

Response to Finding No. 523:

Respondents have no specific response.

524. Dr. Navathe testified that because evidence of clinical validity and clinical utility overlap, a single study may develop evidence of both clinical validity and clinical utility, such as Grail's PATHFINDER 1, Clinical Practice Learning Program, Strive, Summit, and NHS studies. (RX3853 (Navathe Trial Dep. at 182)).

Response to Finding No. 524:

The proposed finding relies on improper expert testimony. Dr. Navathe lacks the expertise to opine on payor reimbursement, rendering his opinions unreliable. (*See* Resps.' Post-Trial Br. at 266.)

Respondents have no other specific response except to note that Dr. Navathe testified that evidence of clinical validity and clinical utility, while overlapping in certain respects, are distinct. Dr. Navathe testified that clinical validity "would reflect whether the results of the test, for example, are valid, are they consistent, are they reliable, and od they have meaning clinically". (RX3853 (Navathe Trial Dep.) 178.) In contrast, he testified that "clinical utility means in practice is there benefit from implementation or use of a given test or diagnostic".

(RX3853 (Navathe Trial Dep.) 178–79; *see also* RX6001 (Deverka Trial Dep.) 34 ("Q: And is clinical utility the same thing as clinical validity? A: It is not.").)

525. [redacted] (PX4389 (Grail) at 036 [redacted] (*in camera*) [redacted]).

Response to Finding No. 525:

Respondents have no specific response except to note that GRAIL's PATHFINDER study was only meant to be a proof of concept study: "it was really a feasibility study about implementing Galleri into actual clinical practice" and "was not designed or powered to replicate the sensitivity of Galleri or to try to find . . . all the cancers that Galleri can find, because that would require hundreds of thousands of people." (Ofman (GRAIL) Tr. 3296–97; *see also* PFF ¶¶ 394–402.).

526. Evidence of clinical utility relates to how a test changes patient management and outcomes. (PX7084 (Qadan (Illumina) Dep. at 14) ("'[C]linical utility' . . . "mean[s] how does the test change the management of a patient, resulting in better outcomes.")).

Response to Finding No. 526:

Respondents have no specific response.

527. Dr. Navathe testified that interventional studies are an important step in the generation of clinical utility evidence. (RX3853 (Navathe Trial Dep. at 183) ("Q: What evidence of clinical utility is expected to be generated by PathFinder 1? A: The effectiveness, the real world effectiveness, of implementing Galleri into clinical practice.")).

Response to Finding No. 527:

The proposed finding relies on improper expert testimony. Dr. Navathe lacks the expertise to opine on payor reimbursement, rendering his opinions unreliable. (*See* Resps.' Post-Trial Br. at 266.) Respondents also note that Dr. Navathe did not testify that "interventional

studies are an important step in the generation of clinical utility evidence", as formulated by Complaint Counsel.

528. MCED test developers must conduct clinical trials for their tests to obtain regulatory approval. (Della Porta (Grail) Tr. 584; *see also* Lengauer (Third Rock Ventures) Tr. 170 (explaining that for FDA approval, test developers must undergo a "registrational trial," which allows the FDA to evaluate the benefit-to-risk ratio of a test or device).

Response to Finding No. 528:

The proposed finding is based on testimony for which the witnesses lack personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

529. [redacted] (*See, e.g.*, Rabinowitz (Natera) Tr. 302-303; PX7091 (Lengauer (Third Rock Ventures) Dep. at 134-135 (*in camera*)) [redacted] PX7077 (Chahine (Helio) Dep. at 32-33 (*in camera*)) [redacted]

Response to Finding No. 529:

The proposed finding is based on testimony for which the witnesses lack personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents also note that Illumina has experience with multi-year, large-scale clinical studies and could therefore help GRAIL to conduct such studies for the Galleri test. (*See, e.g.*, Qadan Tr. 4158–59; RX6001 (Deverka Trial Dep.) 61–62.)

530. [redacted] (PX7111 (Fesko (Natera) Dep. at 33-34); PX7050 (Nolan (Freenome) IHT at 67-70, 72) (*in camera*).

Response to Finding No. 530:

Respondents object to the proposed finding as inaccurate and misleading on the following grounds: *First*, it is inaccurate and misleading to [redacted] because neither of those companies (nor any other company, as the facts show) has a multi-cancer early detection test commercially available today: Their prospective multi-cancer early detection tests are, at best, in the development phase. Respondents also incorporate their responses to CCFF ¶¶ 414, 420, 426, 439, 447, 454 and 462 herein.

Second, it is inaccurate and misleading to claim these companies have [redacted] To the contrary, other test developers have not yet performed clinical trials for most or all of the cancer types they aspire to include in an MCED test. For example:

[redacted] (Rabinowitz Tr. 394, 399.)

[redacted] (Getty Tr. 2593, 2599; Chudova Tr. 1154; 1240:7–12.)

[redacted]

[redacted] (Nolan Tr. 2811.)

Respondents also note that the proposed finding relies on IH testimony with respect to Freenome which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Singlera is also "far away" from starting clinical trials for PanSeer in the United States, and that it is "still not in the really starting clinical trial state." (Gao (Singlera) Tr. 2926; PX7102 (Gao (Singlera) Dep. at 113–14, 81–82; PFF ¶ 536.1.)

[redacted]

531. As part of the FDA's review of a PMA, the FDA will typically inspect the manufacturer's facilities for compliance with Quality System Regulation (QSR) requirements, which impose requirements related to design controls, manufacturing controls, documentation, and other quality assurance procedures. (PX4082 (Grail) at 135 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 531:

Respondents have no specific response.

532. Grail employees have already begun discussions with the FDA regarding a PMA application for Galleri. (Bishop (Grail) Tr. 1345).

Response to Finding No. 532:

Respondents have no specific response except to add that GRAIL employees have not yet submitted a PMA application. (Ofman (GRAIL) Tr. 3301–02, 3319.)

533. Grail's S-1 explains that the FDA is continuing to gather input from industry, academic, and clinical stakeholders to "inform its thinking on how to assess" MCED tests. (PX4082 (Grail) at 047 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 533:

Respondents have no specific response.

534. [redacted] (PX4430 (Grail) at 026, 028 [redacted] (*in camera*); PX4475 (Grail) at 012 [redacted] (*in camera*)).

Response to Finding No. 534:

Respondents have no specific response.

535. [redacted] (PX4475 (Grail) at 081 (*in camera*)).

Response to Finding No. 535:

Respondents have no specific response.

a) Single-Site IVDs

536. A single-site PMA is also referred to as a single-site IVD. (Goswami (Illumina) Tr. 3186).

Response to Finding No. 536:

Respondents have no specific response.

537. A single-site, or centralized, IVD test is approved by the FDA to run in a single approved lab, typically the MCED test developer's own laboratory. (Goswami (Illumina) Tr. 3186; PX7112 (Bailey (PGDx) Dep. at 14); PX7093 (Young (Illumina) Dep. at 43-44); PX7065 (Aravanis (Illumina) IHT at 139-140); PX7055 (Otte (Freenome) IHT at 41-42); PX7063 (Berry (Illumina) IHT at 202); PX7064 (Goswami (Illumina) IHT at 28-31); PX7040 (Getty (Guardant) IHT at 78-79); PX7049 (Bailey (PGDx) IHT at 25)).

Response to Finding No. 537:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

538. [redacted] (PX4082 (Grail) at 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020); PX7100 (Chudova (Guardant) Dep. at 55-57) (*in camera*)).

Response to Finding No. 538:

The proposed finding is incomplete and misleading to the extent it implies that companies other than GRAIL are at a similar stage in seeking a PMA for the use of an MCED test. While other companies are developing or have plans to develop an MCED test, their prospective MCED tests are, at best, in the development phase. Respondents also incorporate their responses to CCFF ¶¶ 414, 420, 426, 439, 447, 454, 462 and 530 herein.

539. [redacted] (PX7069 (Bishop (Grail) IHT at 94-95) (explaining that FDA approval is "a prerequisite for getting broad-based reimbursement. And secondly, it's something that confirms the performance attributes of the test"); PX7055 (Otte (Freenome) IHT at 32-33) (*in camera*) [redacted]).

Response to Finding No. 539:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also note that FDA approval is helpful for achieving payor coverage because it "gives confidence" that a new test passed the FDA's evidence thresholds (RX6001 (Deverka Trial Dep.) at 39–40)),

but payors will apply additional clinical and economic evidentiary considerations when evaluating whether to cover a new test. (RX6001 (Deverka Trial Dep.) at 41–42.) Respondents incorporate their responses to CCFF ¶ 506 herein.

b) Distributed or Kitted IVDs

540. A distributed or "kitted" IVD is an IVD test that has received PMA approval from the FDA permitting analysis by independent testing providers, such as hospitals or large reference labs like LabCorp or Quest. (Goswami (Illumina) Tr. 3186-87; Leite (Illumina) Tr. 2150; PX7049 (Bailey (PGDx) IHT at 68-69); PX7063 (Berry (Illumina) IHT at 202); PX7112 (Bailey (PGDx) Dep. at 14-18); PX7093 (Young (Illumina) Dep. at 44)).

Response to Finding No. 540:

Respondents have no specific response.

541. An approved IVD test must "lock-in" its specific NGS instrument, reagents, and other system components as part of the final FDA approval. (PX7045 (Chudova (Guardant) IHT at 73-74); PX7044 (Stahl (Invitae) IHT at 60-61)).

Response to Finding No. 541:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) The proposed finding is based on testimony for which the witnesses lack personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

542. Modifying any component of the approved IVD could require conducting an additional clinical trial with the modified component. (PX7045 (Chudova (Guardant) IHT at 73–74).

Response to Finding No. 542:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) The proposed

finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

543. Because the test is locked-in with a particular NGS platform, switching to new technology platforms is difficult. (PX7045 (Chudova (Guardant) IHT at 73-74); PX7044 (Stahl (Invitae) IHT at 60-61)).

Response to Finding No. 543:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) The proposed finding is based on testimony for which the witnesses lack personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

544. The distributed kit IVD test developer has "responsibility for quality control and quality analysis" of the distributed kit IVD test. (Goswami (Illumina) Tr. 3187).

Response to Finding No. 544:

Respondents have no specific response.

545. A distributed kit IVD test developer must follow FDA guidelines and submit to regular FDA audits following PMA approval of a distributed kit IVD. (Goswami (Illumina) Tr. 3187).

Response to Finding No. 545:

Respondents have no specific response.

546. [redacted] (PX7040 (Getty (Guardant) IHT at 81-82) (*in camera*)).

Response to Finding No. 546:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding is also misleading to the extent it implies that a distributed IVD model is always the best way for a test to reach the largest market. Several features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (PFF ¶ 675; RX3869 (Cote Expert Report) ¶ 359.) The test developer's decision whether to proceed with an IVD kit as opposed to a centralized model is an economic decision driven by test-specific factors. (Goswami (Illumina) Tr. 3197.) IVD kits are most suitable for tests that have precious samples, that present shipping challenges and require fast turnaround times. (Goswami (Illumina) Tr. 3196–3200; *see also* RX3869 (Cote Expert Report) § XI, ¶¶ 360–63.)

547. [redacted] (PX7055 (Otte (Freenome) IHT at 40-41) (*in camera*); PX7049 (Bailey (PGDx) IHT at 25)).

Response to Finding No. 547:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

Respondents also note that shortening the turnaround time for test results is not always necessary. For example, in oncology, it may be more important to shorten the turnaround time for therapy selection tests because patients with Stage III or Stage IV cancer require treatment right away. (Goswami (Illumina) Tr. 3219.) In contrast, it may be less important to shorten the turnaround time for early screening tests because patients the intervention at an early stage often requires to wait and watch or perform a secondary test. (Goswami (Illumina) Tr. 3200; *see also* Cote Tr. 151–52 ("But as I pointed out, for the purposes of cancer screening, this was probably the least important attribute because the differences in turnaround time are really not important when it comes to the specific application of -- of a cancer screening application.").)

548. [redacted] (PX7094 (Nolan (Freenome) Dep. at 234-35) (*in camera*)).

Response to Finding No. 548:

Respondents have no specific response except to note that Mr. Nolan testified [redacted] (PX7094 (Nolan (Freenome) Dep. at 234-35)); *see also* Nolan Tr. 2772.

549. Helio's Dr. Chahine testified that, [redacted] (PX7077 (Chahine (Helio) Dep. at 19) (*in camera*)).

Response to Finding No. 549:

The proposed finding is misleading and lacks foundation to the extent it is based on [redacted] (PX7077 (Chahine (Helio) Dep. at 19)). The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

550. [redacted] (PX7100 (Chudova (Guardant) Dep. at 57-58) (*in camera*)).

Response to Finding No. 550:

The proposed finding is misleading and lacks foundation to the extent it adopts Dr. Chudova's deposition testimony as fact. [redacted] (PX7100 (Chudova (Guardant) Dep. at 57–58)). The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

551. An MCED test developer that relies on Illumina sequencing would need an IVD agreement with Illumina to distribute its test to third-party labs. (Goswami (Illumina) Tr. 3262-63).

Response to Finding No. 551:

Respondents have no specific response except to clarify that an IVD agreement is not required for a test developer to pursue either an LDT or single-site PMA. (Goswami (Illumina) Tr. 3273; Leite (Illumina) Tr. 2154–55; *see also* (RX3373 (Illumina Vertical Foreclosure and Efficiencies Submission) at 41–43.)

3. Payer Reimbursement

552. [redacted] (PX7055 (Otte (Freenome) IHT at 34-35) (*in camera*); PX7058 (Conroy (Exact) IHT at 87-88) (*in camera*)).

Response to Finding No. 552:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is incomplete and misleading. FDA approval will be required for most payors to cover an MCED test, but test developers may begin to seek reimbursement coverage from CMS and private insurers before or in parallel with seeking FDA approval. With respect to CMS, the Parallel Review Pilot Program is a mechanism for the FDA and CMS to simultaneously review clinical data, decreasing the time between FDA approval and CMS NCD development. (RX3556 (FDA) at 3; RX3867 (Deverka Expert Report) ¶ 56.) With respect to private payors, Dr. Ofman testified [redacted] (Ofman (GRAIL) Tr. 3354–55.)

553. [redacted] (PX7083 (Bishop (Grail) Dep. at 145-146) (*in camera*)).

Response to Finding No. 553:

Respondents have no specific response.

554. [redacted] (Conroy (Exact) Tr. 1734; Bishop (Grail) Tr. 1343-44; PX7055 (Otte (Freenome) IHT at 32-33) (*in camera*); PX7068 (Perettie (FMI-Roche) IHT at 33) (*in camera*)).

Response to Finding No. 554:

Respondents have no specific response except to note that the proposed finding relies in part on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is also inaccurate and misleading to the extent it refers to [redacted] Complaint Counsel alleges an MCED market consisting of the Galleri test and any other test in development, so long as its developers contend that it will detect more than one cancer type and use NGS, no matter its anticipated features, functions, or launch timeline. (*See* FTC Pretrial Br. at 43–44; Compl. ¶ 3; PX6090 (Scott Morton Expert Report) ¶¶ 141–46.) This "MCED market" definition is impermissibly speculative. (PFF ¶¶ 680.1–680.5.) The third-parties whose testimony is cited in support of Complaint Counsel's proposed finding [redacted] Respondents also incorporate their responses to CCFF ¶¶ 341, 375, 378, 382 and 398 herein.

555. There are two major sources of insurance in the United States: The Centers for Medicare & Medicaid Services ("CMS") and private payers. (Chahine (Helio) Tr. 1029).

Response to Finding No. 555:

Respondents have no specific response.

556. Illumina admits that "[t]o make Galleri broadly available in the U.S., it is essential that Galleri obtain coverage from both Medicare and private insurers." (PX6060 (Illumina) at 023 (Illumina's Responses & Objections to FTC's First Set of Interrogatories)).

Response to Finding No. 556:

Respondents have no specific response.

557. Broad-based adoption refers to coverage by government insurers and private insurers. (Bishop (Grail) Tr. 1330).

Response to Finding No. 557:

Respondents have no specific response.

558. Reimbursement of an MCED test will depend on many factors, including sensitivity and specificity of the test. (Conroy (Exact) Tr. 1735).

Response to Finding No. 558:

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

559. Reimbursement of an MCED test will also depend on whether the test is reliable, safe, effective, and medically necessary. (Conroy (Exact) Tr. 1735).

Response to Finding No. 559:

The proposed finding is inaccurate to the extent it states that reimbursement will depend on a test being "medically necessary". Payors are more likely to focus instead on a test having "clinical utility", which is "a comparative evaluation" of whether "use of the test compared to not using the test . . . lead[s] to a behavior change, typically on the part of providers and patients, that then leads to a change in health outcomes". (RX6001 (Deverka Trial Dep.) 33–34.)

560. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 163-165) (*in camera*)).

Response to Finding No. 560:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

561. Respondents' expert Dr. Carlton [redacted] (RX3864 (Carlton Rebuttal Report) ¶ 13) (*in camera*)).

Response to Finding No. 561:

Respondents have no specific response.

562. Respondents' expert Dr. Abrams [redacted] (PX6097 (Abrams Rebuttal Report) ¶ 30) (*in camera*)).

Response to Finding No. 562:

Respondents have no specific response.

563. Grail's Galleri test is not yet covered by Medicare or private insurance. (PX7083 (Bishop Grail) Dep. at 87)).

Response to Finding No. 563:

Respondents have no specific response.

a) Private Payers

564. [redacted] (Bishop (Grail) Tr. 1331-33; Della Porta (Grail) Tr. 456-58; Ofman (Grail) Tr. 3371-72 (*in camera*)).

Response to Finding No. 564:

The proposed finding mischaracterizes the cited testimony. Mr. Bishop, Mr. Della Porta and Dr. Ofman [redacted] (Bishop (GRAIL) Tr. 1331-33; Della Porta (GRAIL) Tr. 456-58; Ofman (GRAIL) Tr. 3371-72 (*in camera*)). But these are not necessarily examples of "private payers". A "payer" is an entity that pays for healthcare services. (RX6001 (Deverka Trial Dep.) 29.) Private insurance companies are examples of private payers (RX6001 (Deverka Trial Dep.) 29), but [redacted] (RX6001 (Deverka Trial Dep.) 85–86.)

Dr. Ofman confirmed this in his testimony, stating that [redacted]

565. [redacted] (Bishop (Grail) Tr. 1401; Ofman (Grail) Tr. 3371-72 (*in camera*); PX4082 (Grail) at 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 565:

Respondents have no specific response except to note that [redacted] are not payers. Respondents also incorporate their responses to CCFF ¶ 565 herein.

566. In its 2020 Form S-1 filing, Grail stated that "[m]any of the nation's premier healthcare institutions have robust programs in population health management and precision management" and noted that one of Grail's "planned strategies upon commercial launch is to offer Galleri at select certain [sic] regional health systems." (PX0043 at 115 (Grail 2020 Form S-1)).

Response to Finding No. 566:

Respondents have no specific response.

567. As of trial, Grail [redacted] health systems. (Ofman (Grail) Tr. 3372 (*in camera*)).

Response to Finding No. 567:

Respondents have no specific response except incorporate their responses to CCFF ¶¶ 567 and 571 herein.

568. [redacted] (PX4610 (Grail) at 002-003 (Email from Stephanie Gutendorf, Grail, to Grail "Weekly Market Access Summary" distribution list, July 19, 2021) (*in camera*).

Response to Finding No. 568:

Respondents have no specific response except to note that [redacted] (Ofman (GRAIL) Tr. 3372.) Respondents also incorporate their responses to CCFF ¶ 571 herein.

569. Self-insured employers are employers that are responsible for the healthcare costs of their employees. (Della Porta (Grail) Tr. 457-58).

Response to Finding No. 569:

Respondents have no specific response.

570. As of trial, Grail [redacted] self-insured employers. (Ofman (Grail) Tr. 3374-75 (*in camera*)).

Response to Finding No. 570:

Respondents have no specific response except to note that [redacted] (Ofman (GRAIL) Tr. 3374–75.)

571. [redacted] (PX4610 (Grail) at 003-004 (Email from Stephanie Gutendorf, Grail, to Grail "Weekly Market Access Summary" distribution list, July 19, 2021) (*in camera*).

Response to Finding No. 571:

Respondents have no specific response except to note that [redacted] (Ofman (GRAIL) Tr. 3374–75.)

572. Concierge practices are primary care practices in which patients pay a fee for preferred access to doctors. (Bishop (Grail) Tr. 1333; Della Porta (Grail) Tr. 462).

Response to Finding No. 572:

Respondents have no specific response.

573. Grail estimates that the total addressable U.S. market for Galleri within physician-directed channels (including concierge practices) is 1 million individuals. (PX4082 (Grail) at 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 573:

The proposed finding is incomplete and misleading. GRAIL estimates that the "overall early detection market" is 107 million individuals between the ages of 50 to 79 in the United States. (PX4082 (GRAIL) at 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020).) Out of that population, GRAIL estimates that the total addressable U.S. market for "physician-directed channels, including concierge practices and executive health programs" is 1 million individuals—less than 1 percent of the overall market. (PX4082 (GRAIL) at 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020).)

574. [redacted] (Della Porta (Grail) Tr. 464; Ofman (Grail) Tr. 3372 (*in camera*) [redacted]).

Response to Finding No. 574:

Respondents have no specific response except to note that Dr. Ofman testified [redacted] (Ofman (GRAIL) Tr. 3372.)

575. As of trial, Grail [redacted] Galleri tests. (Ofman (Grail) Tr. 3375 (*in camera*)).

Response to Finding No. 575:

Respondents have no specific response.

576. Galleri is not covered by private insurance. (Bishop (Grail) Tr. 1323; 1401-02).

Response to Finding No. 576:

Respondents have no specific response.

577. Grail Chief Medical Officer Joshua Ofman testified: "we don't expect that large U.S. payers are going to provide coverage for the [Galleri] test without FDA approval." (Ofman (Grail) Tr. 3319-20).

Response to Finding No. 577:

Respondents have no specific response.

578. Grail CEO Hans Bishop testified that "PMA approval with FDA" is a "prerequisite" to making Galleri "accessible to many more patients than are in [Grail's] starting channels [made up of health systems, large self-insured employers, and concierge practices]." (Bishop (Grail) Tr. 1402-03).

Response to Finding No. 578:

Respondents have no specific response.

579. Dr. Lengauer explained that FDA approval is "very, very important for acceptance of tests in the community" and "is very often a requirement for potential reimbursement of the test." (Lengauer (Third Rock Ventures) Tr. 170).

Response to Finding No. 579:

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

580. FDA approval also lends credibility to MCED tests, which many primary care physicians will likely require before prescribing MCED tests to patients. (Lengauer (Third Rock Ventures) Tr. 231).

Response to Finding No. 580:

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

b) CMS

581. Individuals 65 or over are covered by Medicare. (Freidin (Grail) Tr. 2991).

Response to Finding No. 581:

Respondents have no specific response except to note that certain younger people with disabilities may also be covered by Medicare. (RX3742 (Who is Eligible for Medicare?) at 1.)

582. [redacted] (deSouza (Illumina) Tr. 2414; Ofman (Grail) Tr. 3319-20; PX4172 (Grail) at 059 (Grail, Board of Directors Meeting, Nov. 21, 2019) (*in camera*) [redacted]); (Conroy (Exact) Tr. 1734; Chahine (Helio) Tr. 1054-55 (*in camera*); [redacted]); Febbo (Illumina) Tr. 4335).

Response to Finding No. 582:

Respondents have no specific response.

583. CMS stated in January 2021 that it would require FDA approval to grant reimbursement for early cancer detection testing. (Chahine (Helio) Tr. 1029).

Response to Finding No. 583:

The proposed finding lacks foundation because it relies on the testimony of a third party without citing any specific statement or guidance from CMS. The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

584. The processes for receiving FDA approval and CMS reimbursement are not the same. (Freidin (Grail) Tr. 2981).

Response to Finding No. 584:

Respondents have no specific response except to note that the Parallel Review Pilot Program is a program in which the FDA and CMS agree to review a new test in parallel so that, if the test achieves FDA approval, CMS coverage could follow more quickly than if the test developer applied for CMS reimbursement separately. (RX6001 (Deverka Trial Dep) at 53.)

585. First, a test must get FDA approval, and then CMS performs a cost-benefit analysis to see whether it will pay for the test. (Freidin (Grail) Tr. 2981-82).

Response to Finding No. 585:

The proposed finding is incomplete, misleading and overly simplistic. CMS (like other payors) considers a variety of factors beyond a "cost-benefit analysis" to determine whether it will pay for an FDA-approved test. In particular, CMS considers the analytic validity, clinical validity, clinical utility and health economic evidence associated with the test. (RX6001 (Deverka Trial Dep.) at 33–34; RX3867 (Deverka Expert Report) ¶ 31.) The costs associated with the test and appropriate clinical follow-up care relative to the benefits of the test (*e.g.*, in the form improved health outcomes) is part of this analysis. (RX3867 (Deverka Expert Report) ¶ 101.) The costs and benefits of the test relative to the current standard of care is also part of this analysis. (RX3867 (Deverka Expert Report) ¶ 101.)

586. According to Mr. Conroy, an MCED test "would be viable only as a niche product" in the United States if it was not covered by Medicare. (Conroy (Exact) Tr. 1734-35).

Response to Finding No. 586:

The proposed finding lacks foundation because it relies on the opinion testimony of a third party.

587. [redacted]

[redacted] (Ofman (Grail) Tr. 3352-53 (*in camera*)).

Response to Finding No. 587:

Respondents have no specific response

588. Congress introduced a bill called the Medicare MCED Screening Coverage Act that targets early cancer screening. (Bishop (Grail) Tr. 1323-24).

Response to Finding No. 588:

Respondents have no specific response except to note that the Multi-Cancer Early Detection Screening Coverage Act (H.R. 1946), was re-introduced by Representative Terri Sewell (D-AL) on March 16, 2021 following its initial introduction as H.R. 8845 during the 116th Congressional session in 2020. (PX0095 (H.R. 8845); RX3602 (H.R. 1946); [redacted]

589. The Medicare MCED Screening Coverage Act would give CMS the authority to reimburse cancer screening tests including Galleri once approved by the FDA. (Bishop (Grail) Tr. 1324).

Response to Finding No. 589:

Respondents have no specific response except to note that under the Medicare MCED Screening Coverage Act, reimbursement of cancer screening tests like Galleri would not be automatic, even once approved by the FDA. There are still "evidence hurdles", including the need for clinical utility data, that Medicare would evaluate in making a coverage determination. (RX6001 (Deverka Trial Dep.) 111–12.)

590. Grail has advocated in favor of and supported the passage of the Medicare MCED Screening Coverage Act. (Bishop (Grail) Tr. 1324).

Response to Finding No. 590:

Respondents have no specific response.

591. [redacted] (Ofman (Grail) Tr. 3356 (*in camera*)).

Response to Finding No. 591:

Respondents have no specific response.

592. [redacted]
(Ofman (Grail) Tr. 3354 (*in camera*)).

Response to Finding No. 592:

Respondents have no specific response.

c) USPSTF

593. [redacted] (PX7110 (Conroy (Exact) Dep. at 58-59) (*in camera*)).

Response to Finding No. 593:

The proposed finding lacks foundation because it cites the deposition testimony of a third party without established expertise regarding the USPSTF. The United States Preventive Services Task Force ("USPSTF") is an independent panel of experts that makes recommendations about clinical preventive services (such as cancer screening) which influence the coverage and adoption of medical services. (*See* RX3867 (Deverka Report) ¶ 39; *see also* RX3723 (USPSTF) (listing USPSTF recommendations for various services.)

594. [redacted] (PX7058 (Conroy (Exact) IHT at 137 (*in camera*))).

Response to Finding No. 594:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) The proposed finding also lacks foundation because it cites the deposition testimony of a third party without established expertise regarding the USPSTF. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents note that USPSTF recommendations impact whether a screening test can be covered by Medicare. Unless Congress enacts new legislation, Medicare has statutory authority to cover only preventive tests with a USPSTF A or B rating. (RX3646 (Social Security Act § 1833, 42 U.S.C. § 1395I); RX6001 (Deverka Trial Dep.) at 50; RX3867 (Deverka Expert Report) ¶ 39.)

595. [redacted] (PX7058 (Conroy (Exact) IHT at 27) (*in camera*)).

Response to Finding No. 595:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) The proposed finding also lacks foundation because it cites the deposition testimony of a third party without established expertise regarding the USPSTF.

596. [redacted]

[redacted] (PX7110 (Conroy (Exact) Dep. at 59-60 (*in camera*))).

Response to Finding No. 596:

The proposed finding lacks foundation because it cites the deposition testimony of a third party without established expertise regarding the USPSTF. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

597. [redacted] (PX7058 (Conroy (Exact) IHT at 29-30) (*in camera*)).

Response to Finding No. 597:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) The proposed finding also lacks foundation because it cites the deposition testimony of a third party without established expertise regarding the USPSTF.

Respondents note that [redacted]

[redacted]

[redacted] (*See* RX3867 (Deverka Report) ¶¶ 39, 49.)

598. When USPSTF approves a product it "allows Medicare to cover a new screening test if that test is recommended by USPSTF. The way the Medicare Act works, which is under the Social Security Act, is that Medicare only pays for taking care of people who are sick and, unless otherwise specifically spelled out, it doesn't pay for preventive services. So it's only if – either in the law, like for mammography or colon cancer screening, where the Medicare Act specifically allows and provides for Medicare to pay for certain services or if the USPSTF ranks a new service as an A – or B-rated service, then Medicare can make the decision to cover the test." (PX7058 (Conroy (Exact) IHT at 30)).

Response to Finding No. 598:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) The proposed finding also lacks foundation because it cites the deposition testimony of a third party without established expertise regarding the USPSTF. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

599. "USPSTF is hugely influential in whether a new cancer screening technology ever gets to see the light of day and used by people throughout the country." (PX7058 (Conroy (Exact) IHT at 30-31)).

Response to Finding No. 599:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) The proposed finding also lacks foundation because it cites the deposition testimony of a third party without established expertise regarding the USPSTF. The proposed finding also relies on improper lay

opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

600. [redacted] (Conroy (Exact) Tr. 1629 (*in camera*)).

Response to Finding No. 600:

Respondents have no specific response except to note that the proposed finding lacks foundation because it cites the deposition testimony of a third party without established expertise regarding the USPSTF. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

601. [redacted] (Ofman (Grail) Tr. 3355 (*in camera*)).

Response to Finding No. 601:

Respondents have no specific response.

602. [redacted] (Ofman (Grail) Tr. 3355 (*in camera*)).

Response to Finding No. 602:

Respondents have no specific response.

603. [redacted] (Ofman (Grail) Tr. 3355 (*in camera*)).

Response to Finding No. 603:

Respondents have no specific response.

604. [redacted] (Ofman (Grail) Tr. 3355 (*in camera*)).

Response to Finding No. 604:

Respondents have no specific response.

III. THE RELEVANT PRODUCT MARKET IS THE MARKET FOR THE RESEARCH, DEVELOPMENT, AND COMMERCIALIZATION OF MCED TESTS

605. [redacted] (*See, e.g.*, PX4082 (Grail) at 008-009 (Email attaching Grail 2020 S-1/Amended, Sept. 2020); PX7100 (Chudova (Guardant) Dep. at 15-16); PX7094 (Nolan (Freenome) Dep. at 252-253) (*in camera*); PX4116 (Grail) at 013 (Email from M. Podoll, Morgan Stanley, to A. Freidin, Grail, et al., attaching IPO Roadshow Video Outline: Project Galileo, Aug. 2020); PX8392 (Exact) at 002 (Pipeline Review, Jan. 2021) (*in camera*); PX7051 (Lengauer (Third Rock Ventures) IHT at 27-29) (*in camera*)).

Response to Finding No. 605:

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

606. [redacted] (*See, e.g.*, PX2005 (Illumina) at 004-005, 009, 013 (Illumina, ScreenCo – Early Cancer Detection on a Global Scale Presentation, 2015) [redacted]); PX5027 (Illumina) at 015 (Illumina, Board of Directors Meeting, Aug. 3, 2020) (*in camera*).

Response to Finding No. 606:

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. [redacted] (PX2005 (Illumina) at 004–05, 009 (ScreenCo—Early Cancer Detection on a Global Scale Presentation, 2015).)

Respondents also note that most of the putative MCED developers identified by Complaint Counsel, [redacted] do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and that Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Respondents also note that the cited Board of Directors presentation [redacted] (PX5027 (Illumina) at 016 (Board of Directors Meeting, Aug. 4, 2020) (*in camera*).)

Respondents also incorporate their responses to CCFF ¶¶ 376 and 605 herein.

607. Witnesses similarly described MCED tests. (*See infra* Section VI. (Competitors Are Racing to Develop MCED Tests).

Response to Finding No. 607:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 605–606 herein.

608. [redacted] (Bishop (Grail) Tr. 1373; *see also* Cance (American Cancer Society) Tr. 609).

Response to Finding No. 608:

Respondents have no specific response.

609. [redacted] (*See* PX4082 (Grail) at 008-009 (Email attaching Grail 2020 S-1/Amended, Sept. 2020); PX4116 (Grail) at 013 (Email from M. Podoll, Morgan Stanley, to A. Freidin, Grail, et al., attaching IPO Roadshow Video Outline: Project Galileo, Aug. 2020); PX2169 (Illumina) at 048 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*)).

Response to Finding No. 609:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 605 herein.

610. [redacted] (*See* PX2169 (Illumina) at 048 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*); PX4289 (Grail) at 002, 004-005 (Email and attachment from J. Ofman, Grail, to all Grail employees, Apr. 9, 2020); PX4159 (Grail) at 011, 014-015 (Grail, Investor Presentation, Aug. 2020); *see also* PX5027 (Illumina) at 017 [redacted]) (*in camera*)).

Response to Finding No. 610:

Respondents have no other specific response except to note that this proposed finding provides support for the proposition that Galleri will be a complement to single cancer screening tests, including those that are available as the standard of care today, as well as complementary

to screening tests for a handful of cancer types that many purported MCED test developers are pursuing. (*See* PFF ¶ 358 (RX0744 (GRAIL) at 76–90; [redacted] RX0867 (Clinical Overview Deck) at 15; PX7086 (Cance (ACS) Dep. at 50–53); [redacted]; RX3869 (Cote Expert Report) ¶ 136).)

Respondents also note that [redacted]

Respondents also note that the proposed finding undermines Complaint Counsel's assertion that test developers like [redacted] are developing products that will be substitutes for GRAIL's Galleri test.

For example, [redacted]

Similarly, the evidence in the record shows that [redacted]

[redacted] 428, 431 ("In the DETECT-A study, CancerSEEK obtained [a] specificit[y] of 95.3% in its baseline blood test (that is, with a single blood test).").) In the DETECT-A study, out of the 490 patients who had a positive test result under Exact/Thrive's CancerSEEK baseline blood test, only 26 were actually found to have cancer in the end, leading to unnecessary and time-consuming work-ups for the patients with false positives. (Lengauer (Exact/Thrive) Tr. 251–54; RX3419 (Lennon, *et al.*, 2020) at 5.) Exact/Thrive also admitted that, based on the DETECT-A trial, "[a]t present, we cannot be certain that the DETECT-A blood test"—the CancerSEEK test—"helped any participant." (RX3419 at 11.)

Respondents also incorporate their responses to CCFF ¶ 605 herein.

A. BLOOD-BASED CANCER DETECTION TESTS DESIGNED FOR PURPOSES OTHER THAN CANCER SCREENING ARE NOT SUBSTITUTES FOR MCEDS

1. Other Blood-Based Cancer Detection Tests Serve a Different Function

611. Guardant's R&D efforts include three oncology related clinical applications—a therapy selection test, a minimal residual disease test ("MRD"), and a cancer screening test. (Chudova (Guardant) Tr. 1138-39). These three applications span the different phases of a cancer diagnosis, from an undiagnosed patient to patients currently undergoing various stages of treatment. (Chudova (Guardant) Tr. 1138-39).

Response to Finding No. 611:

The proposed finding is incomplete and misleading insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future.

[redacted]

612. (PX4074 (Grail) at 066 (Grail, Science, Medicine, and Technology Board Subcommittee Meeting, 2020-03-02 Pre-Read, Mar. 2, 2020) (*in camera*)).

Response to Finding No. 612:

Respondents have no specific response.

613. (Rabinowitz (Natera) Tr. 287-289, 354 (*in camera*)).

Response to Finding No. 613:

The proposed finding is incomplete and misleading insofar as it suggests that

[redacted]

Natera's CEO has publicly stated that "[Natera is] ***not focused on asymptomatic cancers [screening] or early detection***." (RX3492 (Natera) at 6.)

614. An MRD test monitors responsive therapy in treating cancer, including immunotherapy. (Rabinowitz (Natera) Tr. 287-289).

Response to Finding No. 614:

Respondents have no specific response.

615. [redacted] (Rabinowitz (Natera) Tr. 353-54 (*in camera*)).

Response to Finding No. 615:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 613 herein.

616. Grail is developing three separate blood-based tests—DAC, MRD, and MCED tests—for three separate purposes. [redacted]

Response to Finding No. 616:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 37), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

617. Grail's Mr. Kollu testified that MRD is a "different product" which is sometimes "referred to as the post-diagnostic product." "[T]he MRD product aims to be able to give the doctor an advance warning if [] cancer is about to recur." (PX7062 (Kollu (Grail) IHT at 31-32)).

Response to Finding No. 617:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

a) Therapy Selection Tests Serve a Different Purpose

618. [redacted] (PX7061 (Davy (Illumina) IHT at 153) (*in camera*)).

Response to Finding No. 618:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

619. A blood-based therapy selection test identifies the mutational profile of a tumor using a blood sample, instead of an invasive biopsy procedure, to help identify a drug therapy that works well when a patient's tumor contains a specific mutation. (Chudova (Guardant) Tr. 1150).

Response to Finding No. 619:

Respondents have no specific response.

620. For example, Guardant''s current flagship product—named Guardant360—is a therapy selection test that analyzes a blood sample to help clinicians choose the appropriate treatment for patients diagnosed with advanced cancer. (Chudova (Guardant) Tr. 1146-47).

Response to Finding No. 620:

Respondents have no specific response.

621. Therapy selection tests are intended for patients with "advanced cancer" and assist the physician with determining "the course of therapy they will pursue" to treat the cancer. (*See* PX7040 (Getty (Guardant) IHT at 44-45) (describing Guardant360, a 74-gene therapy selection assay)).

Response to Finding No. 621:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

622. [redacted] (PX7061 (Davy (Illumina) IHT at 153) (*in camera*)).

Response to Finding No. 622:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

623. Oncologists typically order therapy selection tests for patients who have already received a cancer diagnosis. (PX7080 (Silvis (Tempus) Dep. at 30-32)).

Response to Finding No. 623:

Respondents have no specific response.

b) Minimal Residual Disease Tests Serve a Different Purpose

624. Minimal Residual Disease tests are used to determine whether remnants of cancer remain in a patient who has been treated for cancer. (PX7092 (Ofman (Grail) Dep. at 94)).

Response to Finding No. 624:

Respondents have no specific response.

625. An MRD test is used with early-stage cancer patients to analyze any traces of residual disease in the blood after treatment. (Chudova (Guardant) Tr. 1151; PX4082 (Grail) at 012 (Email attaching Grail 2020 S-1/Amended, Sept. 2020) (describing MRD tests as intended for monitoring for cancer in "[p]atients with cancer, primary or metastatic, following completion of therapy"); PX4133 (Grail) at 006 (Grail, Investor Presentation, Aug. 2020) ("Minimal Residual Disease product designed to detect cancer after diagnosis and treatment")).

Response to Finding No. 625:

Respondents have no specific response, except to note that Complaint Counsel chose not to discuss PX4133 at trial, (CC Exhibit Index at 37), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

626. An MRD test can help physicians determine whether to perform additional treatments on a patient after a resection of a cancerous tumor based on the potential for any remaining disease to progress. (Chudova (Guardant) Tr. 1151-52).

Response to Finding No. 626:

Respondents have no specific response.

627. The clinical context for an MRD test is different than for a therapy selection test, in that a physician uses an MRD test for patients with earlier stages of cancer and a therapy selection test for patients with later-stages of cancers. (Chudova (Guardant) Tr. 1146-47, 1151-52).

Response to Finding No. 627:

Respondents have no specific response.

628. An MRD test is given to patients who have already been diagnosed with cancer, which differs from a cancer screening test that is given to asymptomatic patients who have not yet been diagnosed with cancer. (PX7092 (Ofman (Grail) Dep. at 94-95).

Response to Finding No. 628:

Respondents have no specific response.

c) Diagnostic Aid to Cancer Tests Serve a Different Purpose

629. A diagnostic aid to cancer ("DAC") test helps a doctor confirm or rule out a cancer diagnosis. (PX7069 (Bishop (Grail) IHT at 69-70); PX7072 (deSouza (Illumina) IHT at 160-61)).

Response to Finding No. 629:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

630. [redacted] *see also* Della Porta (Grail) Tr.Tr. 514 (*in camera*); PX4074 (Grail) at 067 (Grail, Science, Medicine, and Technology Board Subcommittee Meeting, 2020-03-02 Pre-Read, Mar. 2, 2020) (*in camera*); PX4133 (Grail) at 030 (Grail, Investor Presentation, Aug. 2020)).

Response to Finding No. 630:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss PX4116 at trial, (CC Exhibit Index at 37), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

631. [redacted] (PX4337 (Grail) at 005-006 [redacted] (*in camera*)).

Response to Finding No. 631:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 44), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

632. [redacted] (PX4337 (Grail) at 005 [redacted] (*in camera*)).

Response to Finding No. 632:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 44), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

633. [redacted] (PX4337 (Grail) at 006-007 [redacted] (*in camera*)).

Response to Finding No. 633:

The proposed finding is incorrect. PX4337 does not refer to the [redacted]

The proposed finding is also incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including [redacted] do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701-706), and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 44), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

B. OTHER CANCER SCREENING TESTS ARE NOT SUBSTITUTES FOR MCED TESTS

634. As Grail's Chief Medical Officer Dr. Ofman testified at trial, single-cancer screening tests are "very different" from MCED tests: "People who want to do single-cancer screening tests, that's very different than doing a multicancer early detection test." (Ofman (Grail) Tr. 3311).

Response to Finding No. 634:

Respondents have no other specific response except to note that this proposed finding provides support for the proposition that Galleri will be a complement to single cancer screening tests, including those that are available as the standard of care today, as well as complementary to screening tests for a handful of cancer types that many purported MCED test developers are pursuing. (*See* PFF ¶ 358 (RX0744 (GRAIL) at 76–90; [redacted] RX0867 (Clinical Overview Deck) at 15; PX7086 (Cance (ACS) Dep. at 50–53); [redacted]; RX3869 (Cote Expert Report) ¶ 136).) Respondents also note that [redacted] For example, [redacted] Respondents also incorporate their responses to CCFF ¶¶ 469, 605 and 610 herein.

1. USPSTF Cancer Screening Methods Are Complementary to MCED Tests

635. USPSTF recommends a [redacted] (PX5027 (Illumina) at 018 (*in camera*)).

Response to Finding No. 635:

Respondents have no specific response except to note that whole body PET-CT scans are not recommended for routine early cancer screening, because of cost and radiation concerns, as well as the inability of PET-CT scanning to detect very small tumors. (RX3624 (Schöder & Gonen 2007) at 9–10; Cote Tr. 3812–13; RX3869 (Cote Expert Report) ¶ 72.) Diagnostic PET-CT will necessitate further evaluation of true-positive or false-positive finding and therefore impose downstream costs on the health care system as a whole. (RX3624 (Schöder & Gonen 2007) at 9–10.)

636. [redacted] (PX2009 (Illumina) at 017 (Illumina, April BoD M&A Strategy Presentation, Apr. 28, 2020) (*in camera*); Lengauer (Third Rock Ventures) Tr. 168-169).

Response to Finding No. 636:

Respondents have no specific response.

637. Grail explained in a document to address common questions and misperceptions about its test: "There is a misperception that current single cancer screening tests alone are doing the job. These critically important screens are saving lives, but given performance and compliance they collectively are only finding about 16% of the US cancer incidence." (PX4164 (Grail) at 004 (Key Points to Address Common Questions and Misperceptions, Oct. 26, 2020)).

Response to Finding No. 637:

Respondents note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 39), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also incorporate their responses to CCFF ¶ 634 herein.

a) MCED Tests Offer Unique Benefits That Existing Screening Methods Do Not

638. Grail documents explain that MCED tests are being designed to detect cancer earlier than traditional methods of cancer detection. (PX0037 (Grail) at 002-006 (Grail Investor Call Script, Jan. 10, 2016)).

Response to Finding No. 638:

The proposed fact is incomplete and misleading. PX0037 is a transcript of an Illumina investor call dated Jan. 10, 2016. It does not discuss MCED tests generally, but rather discusses GRAIL as a new venture. (PX0037 (Grail) at 002-006 (Grail Investor Call Script, Jan. 10, 2016).) Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 1), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

639. Mr. Bishop—Grail's CEO—testified that MCED tests will have the ability to detect cancer much earlier. (PX7069 (Bishop (Grail) IHT at 122-23) (Explaining that Grail's Galleri differs from current screening methodologies: "The first is, it's a multicancer test. The – you know, the problem with cancer mortality associated with late detection is that 70 percent of cancer deaths are occurring – in spite of all those tests we just talked about, Will, 70 percent of cancer deaths are occurring in cancers where there is absolutely zero early detection, so the first way that Galleri differs is it gives us a way looking for all those cancers where today there is no early detection at all.")).

Response to Finding No. 639:

The proposed finding is not supported by the source provided. Mr. Bishop testified that Galleri—not "MCED tests"—" "gives us a way of looking for cancers where today there is no early detection at all." (PX7069 (Bishop (Grail) IHT at 122–23).) The proposed finding also relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

640. [redacted] (Lengauer (Third Rock Ventures) Tr. 190 (*in camera*); PX7091 (Lengauer (Third Rock Ventures) Dep. at 148-50) (*in camera*) ([redacted])).

Response to Finding No. 640:

The proposed finding is not supported by the source provided and is inaccurate and misleading to the extent it suggests that [redacted], which there is no evidence to support. Dr. Lengauer testified, [redacted] (Lengauer (Exact/Thrive) Dep. Tr. 151). [redacted] (Lengauer (Exact/Thrive) Tr. 189.) Additionally, [redacted] (Conroy (Exact/Thrive) Tr. 1651–52, 1709; Cote Tr. 3814; RX3869 (Cote Expert Report) ¶ 174.) Respondents also incorporate their responses to CCFF ¶ 467 herein.

641. Blood-based cancer screening tests are generally safer and less uncomfortable for the patient than other current cancer screening methods such as colonoscopy, mammogram, or tissue biopsy because it is generally easier on a patient for a clinician to draw a blood sample than to remove a tissue sample or perform a procedure for which the patient requires sedation or anesthesia. (*See, e.g.*, PX0059 at 011 (Guardant 2020 10-K); PX8313 (Guardant) at 002 (Guardant, Guardant 360 CDx Original PMA Application (M180021) - Module 5, Attachment 6-1: Background Information on Liquid Biopsy for NGS Tests); PX7044 (Stahl (Invitae) IHT at 45); PX7040 (Getty (Guardant) IHT at 50-51); PX7042 (Gao (Singlera) IHT at 25-26); PX7068 (Perettie (FMI-Roche) IHT at 22-23)).

Response to Finding No. 641:

Respondents have no specific response except to note that the proposed finding supports the proposition that [redacted] RX3419 (Lennon et al., 2020); Cote Tr. 3811–14.) Respondents also note that Complaint Counsel chose not to discuss PX8313 at trial, (CC Exhibit Index at 59), or in any

deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

642. Dr. Cance—from the American Cancer Society—also explained that blood-based biopsy tests are a less invasive screening method than tissue tumor biopsies. (Cance (American Cancer Society) Tr. 608-09; PX8398 (Cance (American Cancer Society) Decl. ¶ 8)).

Response to Finding No. 642:

Respondents have no specific response except to note that Dr. Cance also testified that GRAIL is further ahead in its development process than other companies that are developing purported MCED tests, that he is not aware of any other purported MCED test that is commercially available today, that he does not know of other companies detecting the same number of cancers as GRAIL, and that accelerating an early cancer detection test's ability to commercialize at scale is consistent with ACS's mission. (Cance (ACS) Tr. 631–33.)

643. Some advantages of blood-based biopsies over tissue biopsies include a quicker turnaround time and the ability to repeat the test over time to observe changes. (*See* PX7040 (Getty (Guardant) IHT at 51-54); PX0043 at 005, 101 (Grail, Form S-1 Registration Statement, Sept. 9, 2020); PX7044 (Stahl (Invitae) IHT at 44-46)).

Response to Finding No. 643:

Respondents have no specific response except to note that turnaround time is not a critical feature for early cancer screening tests. (Goswami (Illumina) Tr. 3196–3200 (fast turnaround times are not important for early cancer screening tests); PX7131 (Cote Dep. at 151–52 ("But as I pointed out, for the purposes of cancer screening, this was probably the least important attribute because the differences in turnaround time are really not important when it comes to the specific application of -- of a cancer screening application.").) The proposed finding relies in part on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

644. The benefits of blood-based tests over tumor-based tests will likely lead to higher patient compliance, as patients that were previously reluctant to undergo invasive tests like a colonoscopy agree to receive non-invasive blood-based tests. Higher rates of cancer screening should, in turn, produce better patient outcomes. (*See* PX7040 (Getty (Guardant) IHT at 27-31); PX2022 (Illumina) at 009 (Cowen, The Liquid Biopsy Report: Early Detection of a Huge Opportunity, Sept. 18, 2020) (among the benefits of blood-based tests: "Ease of use/better outcomes – broader screening, expanded use of optimal targeted therapeutic decision making (even in the community setting where most cancers are treated), earlier recurrence detection.")).

Response to Finding No. 644:

Respondents have no specific response, except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

645. As Guardant's SVP of Commercial, Bill Getty, testified, "If you could find those [cancers] early on, you may be able to intervene and actually stop the course of that disease and therefore spare that person of the mortality associated with the disease." (PX7040 (Getty (Guardant) IHT at 33)).

Response to Finding No. 645:

Respondents have no specific response except to note that all agree that accelerating the adoption of a cancer screening test to will save lives, the unrefuted evidence shows that reuniting Illumina and GRAIL will accelerate the adoption of the Galleri test, and there is no evidence that [redacted] (PFF ¶¶ 476 (RX3869 (Cote Expert Report) ¶ 203), 1117.2-17.3 (*see, e.g.,* Conroy (Exact/Thrive) Tr. 1739; Chahine (Helio) Tr. 1132–33; [redacted]; Fiedler (FMI) Tr. 4474; deSouza (Illumina) Tr. 2411; [redacted].)

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(1) Witnesses and Ordinary Course Documents State That MCED Tests and USPSTF Screening Tests Are Complements

646. Market participants, including the parties, recognize that MCED tests should "complement" these "standard of care screening tests . . . rather than replace them." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 51-52); *see also* PX7092 (Ofman (Grail) Dep. at 92) ("Grail's multi-cancer early detection test is a complement to, not a replacement for, the standard of care single-cancer screening tests."); PX2165 (Illumina) at 011 (Exact Sciences Q3 2020 Earnings Call, Oct. 27, 2020)).

Response to Finding No. 646:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss PX2165 at trial, (CC Exhibit Index at 10), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also incorporate their responses to CCFF ¶ 634 herein.

647. [redacted] (PX7040 (Getty (Guardant) IHT at 154-155); PX7051 (Lengauer (Third Rock Ventures) IHT at 176) (*in camera*); PX7083 (Bishop (Grail) Dep. at 24-25)).

Response to Finding No. 647:

Respondents have no specific response, except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶ 634 herein.

648. "CancerSEEK as a test is meant to be in addition to standard of care." Thrive wants "an individual to continue to comply with standard of care, like mammography or colonoscopy, and these tests should augment, which is an additional standard of care to detect cancer." (Lengauer (Third Rock Ventures) Tr. 167-68).

Response to Finding No. 648:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 634 herein.

649. Dr. Vogelstein testified that the goal of blood-based cancer screening tests is not to replace the existing standard of care screening tests because "standard of care screening tests have been extensively evaluated over a number of years" and it "would be a disservice to the public" for patients to "use blood tests to substitute for the currently recommended screening tests." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 51-52)).

Response to Finding No. 649:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 634 herein.

650. As the Grail website explains, "[t]he Galleri test is intended to be complementary to, and not a replacement of, U.S. guideline-recommended cancer screening." (PX0063 at 001 (Grail, Galleri Multi-Cancer Early Detection Test, https://grail.com/galleri/ (last visited Apr. 29, 2021))).

Response to Finding No. 650:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss PX0063 at trial, (CC Exhibit Index at 1), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also incorporate their responses to CCFF ¶ 634 herein.

651. Illumina also acknowledged in its due diligence of Grail that Grail's MCED test would be [redacted] (PX2167 (Illumina) at 003 (Illumina, Early Cancer Detection: Market Access / Health Economic Considerations, circulated June 24, 2020) (emphasis in original) (*in camera*)).

Response to Finding No. 651:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss PX2167 at trial, (CC Exhibit Index at 10), or in any deposition, and therefore the

document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also incorporate their responses to CCFF ¶ 634 herein.

652. Grail in its Form S-1 told potential investors that "Galleri is designed to detect unscreened cancers and to complement the United States Preventive Services Task Force (USPSTF)-recommended screenings (specifically, lung for high-risk smokers, breast, cervical, prostate, and colorectal cancers have recommended screenings)." (PX0043 at 005 (Grail, Form S-1 Registration Statement, Sept. 9, 2020)).

Response to Finding No. 652:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 634 herein.

653. [redacted] (PX4031 (Grail) at 016, 062-067 (Grail, Master Slide Deck_V1_061520) (*in camera*) [redacted] (PX4031 (Grail) at 069-070 (Grail, Master Slide Deck_V1_061520) (*in camera*)).

Response to Finding No. 653:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss PX4031 at trial, (CC Exhibit Index at 34), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also incorporate their responses to CCFF ¶ 634 herein.

654. Grail witnesses, such as ex-CEO Hans Bishop, testified that Galleri should be used alongside existing standard of care screening tests. (Bishop (Grail) Tr. 1320-21).

Response to Finding No. 654:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 634 herein.

655. Grail's Dr. Jamshidi—Senior Vice President of Data Sciences—testified: "So our focus is not to replace [existing screening methods]. It's very much to complement the standard screening approaches that are available today so that we can address this unmet need around cancers that don't have any screenings available to them." (PX7103 (Jamshidi (Grail) Dep. at 38-39)).

Response to Finding No. 655:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 634 herein.

656. Existing standard of care single-cancer screening tests are "optimized" for the single cancers they detect. (Bishop (Grail) Tr. 1321). Mr. Bishop explained that, in comparison to the existing standard of care screening tests, Galleri is not as sensitive:

> [W]ithout exception, the single-cancer tests used today for prostate, cervix, breast and colon -- and I can list the particular tests that are regarded as standard of care today -- their detection rate for those single cancers at their specificity is higher than the detection rate for those individual single cancers that the Galleri test has. That's the essential reason why these tests should be used alongside each other.

(Bishop (Grail) Tr. 1392).

Response to Finding No. 656:

Respondents have no specific response except to note that there is typically a tradeoff between specificity and sensitivity. (PFF ¶ 180 (RX3869 (Cote Expert Report) ¶ 95).) Existing single cancer screening tests typically have very high sensitivity rates and correspondingly lower specificity/higher false positive rates. (PFF ¶ 180.1 (Cote Expert Report ¶ 95).) A test developer of a multi-cancer screening test must focus on attaining a very high specificity rate, and low false positive rate, which will often result in correspondingly lower sensitivity rates. (PFF ¶ 181 (Cote Tr. 3778-81; RX3869 (Cote Expert Report) ¶ 95).) [redacted]

[redacted]

Respondents also incorporate their responses to CCFF ¶¶ 386 and 634 herein.

657. Respondents' expert, Dr. Abrams, testified that he "would not substitute a multicancer early detection test for any of the standard recommended screening tests." (Abrams Tr. at 3631; *see also* PX7137 (Abrams Dep. at 34); PX6097 (Abrams Rebuttal Report) ¶ 31 (*in camera*) [redacted]")).

Response to Finding No. 657:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 634 herein.

658. Exact Sciences' CEO explained that [redacted] (Conroy (Exact) Tr. 1647-48 (*in camera*); *see also* Lengauer (Third Rock Ventures) Tr. 167-68).

Response to Finding No. 658:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 634 herein.

659. Mr. Getty does not expect Guardant's MCED test to replace current screening methodologies. He explained, for example, that "the goal of noninvasive screening in large part is to have a noninvasive test up front that says positive or negative, and if you're positive, then go for the colonoscopy." (PX7040 (Getty (Guardant) IHT at 154)).

Response to Finding No. 659:

The proposed finding is inaccurate and misleading because [redacted]

[redacted] The proposed finding also relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2. Other Non-USPSTF Single-Cancer Blood-Based Tests Are Not Close Substitutes for MCED Tests

660. [redacted] (PX4031 (Grail) at 006 (Master Slide Deck_V1_061520) (*in camera*)). [redacted] (*See* PX4031 (Grail) at 018, 020 (Master Slide Deck_V1_061520) (*in camera*) (identifying benefits of "Multi-Cancer Early Detection Test" including low false positives, maximizing compliance, high PPV, and avoiding overdiagnosis, among others).

Response to Finding No. 660:

Respondents have no other specific response except to note that this proposed finding provides support for the proposition that Galleri will be a complement to single cancer screening tests, including those that are available as the standard of care today, as well as complementary to the screening tests for a handful of cancer types that many purported MCED test developers are pursuing. (*See* PFF ¶ 358 (RX0744) (GRAIL) at 76–90; [redacted] RX0867 (Clinical Overview Deck) at 15; PX7086 (Cance (ACS) Dep. at 50–53); [redacted]; RX3869 (Cote Expert Report) ¶ 136).)

Respondents also note that certain putative MCED test developers identified by Complaint Counsel are developing cancer screening test that *are* intended to be substitutes for USPSTF-recommended screening tests (or "standard of care screening" tests) and/or single-cancer blood-based tests.

For example, Bill Getty of Guardant testified "Galleri is going after something very different, which is just a larger population, test for more things. We are saying use us for colorectal cancer screening ostensibly when we are commercialized." (PX7040 (Getty (Guardant) IHT at 156).)

Similarly, Mr. Nolan of Freenome also testified that

This proposed finding also supports the proposition that a "collection" or "basket" of individual screening tests

(PX4031 (Grail) (Master Slide Deck_V1_061520) at 006.) For instance,

[redacted]

Respondents also note that [redacted] For example, Exact/Thrive's CancerSEEK test in development requires a whole-body PET-CT, which [redacted] (*see*, *e.g.*, Lengauer (Exact/Thrive) Tr. 248; RX3419 (Lennon et al., 2020) at 3; [redacted]; PFF ¶¶ 419, [redacted], 425, [redacted] 739, 760, [redacted], 841.3, [redacted], 1723–24), [redacted] In addition, in DETECT-A study, CancerSEEK obtained PPV (positive predictive value) of only 5.9% with its single baseline blood test and 28.3% with both blood tests and whole body PET-CT imaging. (PFF ¶ 432 (RX3419 (Lennon et al., 2020) at 8 & Table 2; Lengauer (Exact/Thrive) Tr. 257–59).) Exact/Thrive also admitted that, based on the DETECT-A trial, "[a]t present, we cannot be certain that the DETECT-A blood test"—the CancerSEEK test—"helped any participant." (RX3419 at 11.)

Respondents also note that Complaint Counsel chose not to discuss PX4031 at trial, (CC Exhibit Index at 34), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also incorporate their responses to CCFF ¶ 634 herein.

661. [redacted] (PX4430 (Grail) at 012 (*in camera*)). [redacted] (PX4430 (Grail) at 012 (*in camera*)).

Response to Finding No. 661:

Respondents have no specific response except to note that [redacted]

For example, Bill Getty of Guardant testified "Galleri is going after something very different, which is just a larger population, test for more things. We are saying use us for colorectal cancer screening ostensibly when we are commercialized." (PX7040 (Getty (Guardant) IHT at 155–56).) [redacted]

[redacted] (Chudova (Guardant) Tr. 1189, 1237–38; PFF ¶ 1802.)

Similarly, Mr. Nolan of Freenome also testified that [redacted] 428, 431 ("In the DETECT-A study, CancerSEEK obtained [a] specificit[y] of 95.3% in its baseline blood test (that is, with a

single blood test).").) In the DETECT-A study, out of the 490 patients who had a positive test result under Exact/Thrive's CancerSEEK baseline blood test, only 26 were actually found to have cancer in the end, leading to unnecessary and time-consuming work-ups for the patients with false positives. (Lengauer (Exact/Thrive) Tr. 251–54; RX3419 (Lennon et al., 2020) at 5.)

Respondents also note that Complaint Counsel chose not to discuss PX4430 at trial, (CC Exhibit Index at 48), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also incorporate their responses to CCFF ¶ 634 herein.

662. Grail told investors that "[m]ulti-cancer early detection is needed (single cancer screening won't get us there, as detects 15-20% of cancers)." (PX4133 (Grail) at 007 (Investor Presentation, Aug. 2020)).

Response to Finding No. 662:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 660–61 herein.

a) MCED Tests Offer Unique Benefits from Single-Cancer Screening Tests

663. Grail's Galleri tests screen for more than one type of cancer, including cancer types that currently do not have existing screening mechanisms. [redacted]

Response to Finding No. 663:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss PX4116 at trial, (CC Exhibit Index at 37), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also incorporate their responses to CCFF ¶¶ 660–61 and 666 herein.

664. In a PowerPoint regarding its IPO Roadshow Video, Grail noted that "screening for single cancers individually 'misses the forest for the trees'" as "[a]pproximately 3x as many cancer cases can be found with a test that is able to detect multiple cancers at the [redacted] *see also* (PX4031 (Grail) at 013 (Master Slide Deck_V1_061520) (*in camera*)) [redacted]**)).**

Response to Finding No. 664:

Respondents note that Complaint Counsel chose not to discuss PX4116 or PX4031 at trial, (CC Exhibit Index at 34, 37), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also incorporate their responses to CCFF ¶¶ 660–61 and 666 herein.

665. Illumina's Dr. Aravanis explained in an ordinary course document that "[t]he potential benefits of a multi-cancer test are much larger than that of a single cancer test. For cancers like pancreatic cancer which have lower prevalence, but very deadly, it would be difficult to implement as a single cancer test vs part of a multi-cancer test that has a much higher aggregate prevalence." (PX2346 (Illumina) at 001 (Email from A. Aravanis, Illumina, to J. Cunningham, Illumina, Nov. 25, 2020)).

Response to Finding No. 665:

Respondents note that Complaint Counsel chose not to discuss PX2346 at trial, (CC Exhibit Index at 16), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also incorporate their responses to CCFF ¶¶ 660–61 and 666 herein.

666. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 28-29) (*in camera*); Gao (Singlera) Tr. 2873-74, 2914; PX7105 (Getty (Guardant) Dep. at 13-14)).

Response to Finding No. 666:

The proposed finding is inaccurate, incomplete, and misleading as well as contradicted by the weight of the evidence. The proposed finding is not supported by the sources provided. In the portion of the investigational hearing transcript cited, [redacted]

Dr. Gao testified that Singlera is "far [a]way" from starting clinical trials in the United States, and that it is "still not in the really starting clinical trial state." (Gao (Singlera) Tr. 2926; PX7102 (Gao (Singlera) Dep. at 113–14, 81–82).) Dr. Gao testified that the PanSeer test is at least eight to 10 years away from potential launch in the United States (Gao (Singlera) Tr. 2925–26; RX3869 (Cote Expert Report) ¶ 242.) Dr. Gao testified it could take 50 years before it was able to develop a MCED test that could detect 50 cancer types (Gao (Singlera) Tr. 2883.)

For many of these products in early stages of development, [redacted]

[redacted] Bill Getty of Guardant testified [redacted] (PX7040 (Getty (Guardant) IHT at 155–56).)

The proposed finding also relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

667. Dr. Ofman testified at trial that single cancer screening tests are "very different" from MCED tests: "People who want to do single-cancer screening tests, that's very different than doing a multicancer early detection test." (Ofman (Grail) Tr. 3311).

Response to Finding No. 667:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 660–61 and 666 herein.

668. According to Dr. Ofman, the intended use of an MCED test differs from a single cancer screening test: "[W]hen you order Galleri as a physician, you're not suspecting any particular type of cancer. That's why you order Galleri." (Ofman (Grail) Tr. 3312).

Response to Finding No. 668:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 660–661 and 666 herein.

669. Grail's documents explain that MCED tests offer a unique benefit from single cancer tests in that MCED tests "[d]etect[] multiple deadly cancer types at early stages rather than creating multiple single cancer tests which may be logistically impractical and more costly overall." (PX4012 (Grail) at 001 (Email from K. Grossman, Grail, to K. Eng, Grail, July 11, 2019)).

Response to Finding No. 669:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 660–61 and 666 herein. Respondents also note that the proposed finding undermines Complaint Counsel's assertion that [redacted] To the contrary, the evidence in the record shows that Freenome will not launch a cancer screening test that will compete with the Galleri test in the foreseeable future given that [redacted]

[redacted]

Respondents also note that Complaint Counsel chose not to discuss PX4012 at trial, (CC Exhibit Index at 34), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

670. [redacted] (*See* PX2169 (Illumina) at 048 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 30, 2020) (*in camera*); PX4289 (Grail) at 002, 004-006 (Email from J. Ofman, Grail, to All Grail Employees, attaching comment for FDA Workshop, Apr. 9, 2020); PX4159 (Grail) at 015 (Email from J. Craighead, Grail, to Grail Board of Directors et al., attaching Early Cancer Detection - Investor Presentation, Aug. 2020); s*ee also* PX5027 (Illumina) at 025 [redacted] (*in camera*)).

Response to Finding No. 670:

The proposed finding is incomplete and misleading to the extent it suggests that [redacted]

Respondents note that [redacted]

[redacted]

Respondents also incorporate their responses to CCFF ¶¶ 660–61 and 666 herein. Respondents also note that Complaint Counsel chose not to discuss PX4289 at trial, (CC Exhibit Index at 43), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

b) [redacted]

671. [redacted] (*in camera*); s*ee* PX4031 (Grail) at 011 (Master Slide Deck V1 061520) (explaining that [redacted] (*in camera*)).

Response to Finding No. 671:

Respondents have no specific response except to note that the proposed finding provides support for the proposition that test developers developing single cancer tests cannot simply stack single cancer tests together to make a multicancer test. (PFF ¶ 846; *see also* RRFF ¶ 405.)

For example, [redacted]

Respondents also note that the proposed finding undermines Complaint Counsel's assertion that test developers like [redacted] In the DETECT-A study, out of the 490 patients who had a positive test result under Exact/Thrive's CancerSEEK baseline blood test, only 26 were actually found to have cancer in the end, leading to unnecessary and time-consuming work-ups for the patients with false positives. (Lengauer (Exact/Thrive) Tr. 251–54; RX3419 (Lennon et al., 2020) at 5.)

Similarly, [redacted]

Complaint Counsel chose not to discuss PX4031 at trial, (CC Exhibit Index at 34), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also incorporate their responses to CCFF ¶¶ 660–61 and 666 herein.

672. [redacted] (PX5027 (Illumina) at 015 (*in camera*)). [redacted] (PX5027 (Illumina) at 017 (*in camera*)).

Response to Finding No. 672:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 660–61, 666, and 671 herein.

c) Witnesses and Documents from Illumina and Grail Show That Single-Cancer Tests Do Not Compete with MCED Tests

673. At trial, Grail's Dr. Ofman explained that single cancer tests are "not really competing" with MCED tests. (Ofman (Grail) Tr. 3311).

Response to Finding No. 673:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 660–61, 666, and 671 herein.

674. Dr. Ofman testified in his deposition that "GRAIL's multi-cancer early detection test is a complement to, not a replacement for, the standard of care single-cancer screening tests." (PX7092 (Ofman (Grail) Dep. at 92)).

Response to Finding No. 674:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 660–61, 666, and 671 herein.

675. Dr. Ofman claimed at trial that he did not expect that Galleri would compete with companies developing single-cancer blood-based tests because "single-cancer screening tests" are "very different than doing a multicancer early detection test." (Ofman, (Grail)Tr. 3310-11). Instead, Galleri is "a complement to . . . single-cancer screening tests." (Ofman (Grail) Tr. 3308-09).

Response to Finding No. 675:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 660–61, 666, and 671 herein.

676. Dr. Ofman explained that Galleri "is not intended on any level to replace" the existing single-cancer screening tests. (Ofman (Grail) Tr. 3309).

Response to Finding No. 676:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 660–61, 666, and 671 herein.

677. Dr. Ofman testified, "if you have a negative Galleri test, you still want to encourage the individual to get their single-cancer screening tests." (Ofman (Grail) Tr. 3310).

Response to Finding No. 677:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 660–61, 666, and 671 herein.

678. Illumina's Dr. Aravanis testified at trial that Galleri is not intended to compete with single cancer tests because single-cancer screening tests "are to be used in current standard of care applications." (Aravanis (Illumina) Tr. 1921).

Response to Finding No. 678:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 660–61, 666, and 671 herein.

679. Grail documents show that Grail had originally planned on developing both single-cancer tests as well as an MCED test. (*See* PX2712 (Illumina) at 009 (Email from M. Nguyen, Illumina, to P. Scagnetti, Illumina, attaching Python: A Revolution in Early Cancer Detection, Dec. 3, 2019)). Grail explained that "[t]his strategy gives Python [Grail] the option to develop products aimed at augmenting and eventually replacing established screening modalities such as spiral CT for lung cancer and mammography for breast cancer while simultaneously driving transformation of the screening paradigm with a pan-cancer

product." (PX2712 (Illumina) at 009 (Email from M. Nguyen, Illumina, to P. Scagnetti, Illumina, attaching Python: A Revolution in Early Cancer Detection, Dec. 3, 2019)).

Response to Finding No. 679:

The proposed finding is incomplete and misleading to the extent it suggests that it is a viable option to convert from a single cancer screening test to a multi-cancer screening test. To the contrary, even once a company has developed a cancer screening test for a single cancer type, it does not become easier to add additional cancer types because "[t]he development of biomarkers for a particular cancer will not be adequate for other cancers" and "[w]hile there may be overlap, one still needs to go through all of the [development] steps," including "go[ing] through the case-control verification to determine whether or not the assay has the performance characteristics needed . . . for the new target cancer," and "go[ing] through a prospective trial depending on which cancer is being targeted." (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123; PFF ¶¶ 328–328.1.)

Dr. Aravanis testified that GRAIL considered developing a single cancer screening test as a route to a multicancer screening test but abandoned it because it would take far too long; building a multicancer test by developing single cancer tests seriatim could take four or five years for each cancer; to develop a 50-cancer test one cancer at a time, a developer would need to do a research study, discovery study and collect relevant samples, determine the right technology, go into a new test development phase and clinical trials for each new cancer; GRAIL was able to develop a test capable of detecting 50 cancer types simultaneously directly by undergoing a much more intensive process to develop a test for 50 cancer types at the same time. (Aravanis (Illumina) Tr. 1895–97.)

Respondents also note that Complaint Counsel chose not to discuss PX2712 at trial, (CC Exhibit Index at 29), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

680. Grail's former CEO—Mr. Bishop—testified that he does not expect Galleri to compete with either Freenome's or Guardant's colorectal cancer screening test. (Bishop (Grail) Tr. 1390-91; 1394).

Response to Finding No. 680:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 660–61, 666, and 671 herein.

681. Mr. Bishop explained that Galleri should not be used as a single-cancer blood-based screening test because "[i]t's being developed with a specific objective and optimized performance attributes to be a multicancer detection test to be used alongside single-cancer detection tests." (PX7069 (Bishop (Grail) IHT at 145)).

Response to Finding No. 681:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 660–61, 666, and 671 herein.

d) Industry Participants Testified That MCED Tests Will Complement Single-cancer Screening Tests

682. Grail's MCED test developer rivals also do not view NGS-based single-cancer early detection tests as directly competitive with MCED tests. (*See, e.g.*, PX7105 (Getty (Guardant) Dep. at 25-27) (testifying that "a multi-cancer test provides distinct value over a single cancer test"); PX7042 (Gao (Singlera) IHT at 120)).

Response to Finding No. 682:

The proposed finding is inaccurate and misleading to the extent it describes [redacted]

[redacted]

Respondents also note that, contrary to the statement in the finding that [redacted] The proposed finding also relies in part on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶¶ 660–61, 666, and 671 herein.

683. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 187 (*in camera*)).

Response to Finding No. 683:

The proposed finding is incomplete and misleading to the extent it suggests that Thrive's CancerSEEK test is a competitor to GRAIL's Galleri test because [redacted] In his deposition, Dr. Lengauer testified that [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 660–61, 666, 671, and 682 herein.

The proposed finding also relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

684. Guardant's William Getty testified, "if we can offer a physician a test that covers colorectal, breast, lung, pancreatic, you know, so on and so forth, with the check of a pen . . . that would have significant value to the patient to be screened for multiple cancers at one particular time, and also value for the physician who could do so in an efficient fashion." (PX7105 (Getty (Guardant) Dep. at 23)).

Response to Finding No. 684:

The proposed finding is incomplete and misleading insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–6) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note

that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

For example, [redacted]

685. Guardant's Mr. Sood testified, "[I]f I'm going to the doctor's office to give blood, you know, I want to be screened for as many cancers as possible. So I think eventually that's where the world will end [up]." (PX7090 (Sood (Guardant) Dep. at 106)).

Response to Finding No. 685:

The proposed finding is incomplete and misleading insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. Respondents also incorporate their responses to CCFF ¶ 684 herein.

686. [redacted] (PX7040 (Getty (Guardant) IHT at 151) (*in camera*)).

Response to Finding No. 686:

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) The proposed finding also relies on IH testimony which Respondents had no opportunity

to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶ 684 herein.

687. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 187) (*in camera*)).

Response to Finding No. 687:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶ 683 herein.

C. BROWN SHOE FACTORS SHOW THAT THE RELEVANT PRODUCT MARKET IS MCED TESTS

1. MCED Tests Will Have Distinct Pricing and Reimbursement from Other Oncology Tests

688. Guardant's Senior VP of Product, Nitin Sood, testified that "screening, to be widely adopted, must be economical, because it addresses such a large population. Whereas . . . tests that may address niches of people, . . . patient population, small groups of patient populations can be more expensive." (PX7090 (Sood (Guardant) Dep. at 110-11)).

Response to Finding No. 688:

Respondents have no specific response except to note that Complaint Counsel did not undertake any study concerning the price sensitivity of Galleri or any of the purported MCED tests in development. (RX6004 (Katz Trial Dep. at 20–23).) Respondents also note that during his deposition, Mr. Getty of Guardant added the caveat that "[i]n the context of the blood-based screening market, which is yet to evolve to its maturity, it would be very difficult to speculate about the relevancy of price". (PFF ¶ 748 (PX7105 (Getty (Guardant) Dep.) at 106–07).) Mr. Getty also testified that "price, in the context of healthcare, is really difficult to determine what happens. And the reasons I say that is because the typical sort of laws of economics do not often persist in healthcare because there's a third party paying for them." (PX7040 (Getty (Guardant)

IHT) at 127.) Respondents further note that [redacted] (*See* PFF ¶¶ 747–51.)

689. [redacted] (*See* PX7069 (Bishop (Grail) IHT at 149 (*in camera*)) [redacted]

Response to Finding No. 689:

Respondents have no specific response except to note that Complaint Counsel did not undertake any study concerning the price sensitivity of Galleri or any of the purported MCED tests in development. (RX6004 (Katz Trial Dep. at 20–23).) Respondents also note that Galleri is currently selling for $949 (PFF ¶ 747; Bishop (GRAIL) Tr. 1322), [redacted] Respondents note that payor adoption will depend on the development of extensive evidence to establish clinical utility of an MCED test. (RX3867 (Deverka Expert Report) ¶ 92.)

690. As Illumina's CEO Francis deSouza testified, [redacted] (PX7072 (deSouza (Illumina) IHT at 149) (*in camera*)).

Response to Finding No. 690:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 689 herein.

a) [redacted]

691. [redacted] (PX4079 (Grail) at 005 (A revolution in Early Cancer Detection, Jan. 16, 2020) (*in camera*)).

Response to Finding No. 691:

Respondents have no specific response except to note that Complaint Counsel did not undertake any study concerning the price sensitivity of Galleri or any of the purported MCED tests in development. (RX6004 (Katz Trial Dep. at 20–23).)

692. Grail internally performed its own analysis of [redacted] (PX4079 (Grail) at 007 (A revolution in Early Cancer Detection,, Jan. 16, 2020) (*in camera*)).

Response to Finding No. 692:

Respondents have no specific response except to note that Complaint Counsel did not undertake any study concerning the price sensitivity of Galleri or any of the purported MCED tests in development. (RX6004 (Katz Trial Dep. at 20–23).) Respondents also note that Galleri is currently selling for $949 (PFF ¶ 747; Bishop (GRAIL) Tr. 1322), [redacted] Respondents note that payor adoption will depend on the development of extensive evidence to establish clinical utility of an MCED test, because payors will evaluate clinical utility and other data when evaluating whether to provide reimbursement coverage for a new test. (RX3867 (Deverka Expert Report) ¶ 92.) Both Illumina and GRAIL witnesses testified that they believe Illumina's reacquisition of GRAIL can accelerate the process of developing clinical utility evidence, obtaining payor coverage and achieving widespread adoption of Galleri. (*See, e.g.*, Bishop (GRAIL) Tr. 1372; Ofman (GRAIL) Tr. 3320; Febbo (Illumina) Tr. 4326–27, 4337–38; *see also* RX6001 (Deverka Trial Dep.) at 61–64.)

693. [redacted]

[redacted] (PX4055 (Grail) at 009-010, 023-024 (A Revolution in Early Cancer Detection, Q3 '20 BoD Commercial slides) (*in camera*)).

Response to Finding No. 693:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 692 herein.

694. [redacted] (PX4450 (Grail) at 009 [redacted] (*in camera*)).

Response to Finding No. 694:

The proposed finding is incomplete and misleading. [redacted] Further, Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 49), and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. In addition, Complaint Counsel did not elicit testimony that would establish that this proposed finding accurately [redacted]

Respondents also note that Galleri is currently selling for $949 (PFF ¶ 747; Bishop (GRAIL) Tr. 1322), [redacted] Respondents note that payor adoption will depend on the development of extensive evidence to establish clinical utility of an MCED test, because payors will evaluate clinical utility and other

data when evaluating whether to provide reimbursement coverage for a new test. (RX3867 (Deverka Expert Report) ¶ 92.) Both Illumina and GRAIL witnesses testified that Illumina's reacquisition of GRAIL can accelerate the process of developing clinical utility evidence, obtaining payor coverage and achieving widespread adoption of Galleri. (*See, e.g.*, Bishop (GRAIL) Tr. 1372; Ofman (GRAIL) Tr. 3320; Febbo (Illumina) Tr. 4326–27, 4337–38; *see also* RX6001 (Deverka Trial Dep.) at 61–64.) Respondents also incorporate their responses to CCFF ¶ 692 herein.

695. [redacted] (PX4170 (Grail) at 009 [redacted] (*in camera*)).

Response to Finding No. 695:

The proposed finding is incomplete and misleading to the extent that it suggests that [redacted] GRAIL cannot actually monitor the pricing of nonexistent tests—as Mr. Getty of Guardant puts it: "[i]n the context of the blood-based screening market, which is yet to evolve to its maturity, it would be very difficult to speculate about the relevancy of price." (PFF ¶ 748; PX7105 (Getty (Guardant) Dep. at 106–07).)

The proposed finding is misleading to the extent it describes [redacted]

[redacted] (PFF ¶¶ 722–740.1), and most of the putative MCED developers identified by Complaint Counsel do not expect (and none can reasonably be expected) to launch a screening test for more than one cancer for many years (PFF ¶¶ 701–06).

Further, Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 39), and therefore should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

696. Grail [redacted] (PX4456 (Grail) at 013 [redacted] (*in camera*)). [redacted] PX4456 (Grail) at 013 [redacted] (*in camera*)).

Response to Finding No. 696:

The proposed finding is incomplete and misleading. Hans Bishop, GRAIL's CEO at the time, testified that PX4456 [redacted]

[redacted] (Bishop (GRAIL) Tr. 1496.) Accordingly, the cited document is entitled to little weight.

Furthermore, [redacted] (PFF ¶ 884 (RX6000 (Carlton Trial Dep.) at 30–31).) The only evidence presented at trial regarding projected future NGS costs came from Illumina's [redacted] In addition, Dr. Aravanis explained that "Illumina [] is [] going to lower the cost of sequencing over time," as will "[o]ther sequencing providers", which will "compound the overall reduction in sequencing costs as a fraction of the test." (Aravanis (Illumina) Tr. 1925.)

697. [redacted] (PX4075 (Grail) at 043 (Email from A. Aravanis, Grail, to M. Young, Grail, regarding "follow up on competition", Sept. 7, 2019, attaching a PowerPoint presentation titled "Competitive Intelligence," Aug. 14, 2019) (*in camera*)).

Response to Finding No. 697:

The proposed finding is incomplete and misleading insofar as it suggests that Singlera and Helio are [redacted] There is no testimony in the record to support Complaint Counsel's characterization that [redacted] Further, the cited document is nearly three years old. Since that time, Helio has abandoned its efforts to develop its multi-cancer screening test called IvyGene. (PFF ¶ 501.1.)

[redacted] Complaint Counsel's own witness, Dr. Lengauer of Thrive, [redacted] (Lengauer (Exact/Thrive) Tr. 206.)

Similarly, Galleri does not compete with [redacted] which is very different from Galleri. [redacted] (RX3115 (Chen, *et. al.,* 2020) at 4); [redacted] Indeed, Singlera is "far, far away from launching its PanSeer test" (PX7102) (Gao (Singlera) Dep. at 119) and does not currently have a price for the product. (Gao (Singlera) Tr. 2893.)

Finally, as Dr. Katz testified, [redacted] (RRFF ¶ 773 (RX6004) (Katz Trial Dep. at 105) (emphasis added).) Respondents further incorporate their responses to CCFF ¶¶ 454–57 and 773–76 herein.

b) MCED Test Developers Also Anticipate Pricing-Based MCED Competition

698. Freenome CEO Mr. Nolan testified that [redacted] (Nolan (Freenome) Tr. 2774-75 (*in camera*)).

Response to Finding No. 698:

The proposed finding is incomplete and misleading insofar as it suggests that Freenome is [redacted]

First, Mr. Nolan's characterization notwithstanding, Freenome's expectations are [redacted]

[redacted]

Respondents also incorporate their responses to CCFF ¶¶ 2353–2400 herein.

699. Guardant expects that primary care physicians will choose among MCED test providers based on multiple factors. (Getty (Guardant) Tr. 2670).

Response to Finding No. 699:

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. Mr. Getty is not a physician and has no knowledge as to how primary care physicians will choose among putative MCED test providers. The proposed finding also relies on improper lay opinion testimony and, accordingly, should be given no weight. (*See* Resps.' Motion *in limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents also note that Mr. Getty cited a number of factors other than price. [redacted]

700. [redacted] (Getty (Guardant) Tr. 2671; *see* PX7105 (Getty (Guardant) Dep. at 181) (explaining that its goal is "to have a test that has strong access, so low out-of-pocket cost for patients"); PX7051 (Lengauer (Third Rock Ventures) IHT at 178-80) (*in camera*) [redacted] PX7042 (Gao (Singlera) IHT at 99) (explaining that the price of the MCED test should be less than $1,000 for market acceptance in the United States)).

Response to Finding No. 700:

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. Mr. Getty is not a physician and has no knowledge as to how primary care physicians will choose among putative MCED test providers. The proposed finding also relies on improper lay opinion testimony and, accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding is also incomplete and misleading. [redacted]

The remaining testimony cited by Complaint Counsel is simply conjectural. [redacted] and Dr. Gao's statement that an MCED test should be less than $1,000 for market acceptance does not show that all "MCED tests" will have similar prices. Currently, there is no MCED test market to speak of, such that the significance of price is unknown.

Further, [redacted] (PFF ¶ 750.) Singlera has said that it [redacted] (PFF ¶ 750.1 (PX7042 (Gao (Singlera) IHT at 99)).) [redacted]

[redacted]

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

701. In addition to price, Mr. Getty testified that primary care physicians choosing among multiple screening tests will consider how easy it is for their staff to conduct the test, the performance characteristics of the test, and the number of cancers for which the test screens. (Getty (Guardant) Tr. 2671-72).

Response to Finding No. 701:

Respondents have no specific response except to note that the proposed finding is evidence that factors ***other than price*** are likely to differentiate MCED tests in the future.

702. Singlera also expects to compete with Grail's Galleri on multiple metrics, including price. (PX7042 (Gao (Singlera) IHT at 99-100)).

Response to Finding No. 702:

The proposed finding is incomplete and misleading to the extent it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future.

Singlera has said that it "couldn't know right now" at what price Singlera plans to market PanSeer. (PFF ¶ 750.1 (PX7042 (Gao (Singlera) IHT at 99)).) [redacted]

[redacted]

[redacted] (PFF ¶ 530 (RX3869 (Cote Expert Report) at ¶ 238; Cote Tr. 3869).)

703. [redacted] (PX7110 (Conroy (Exact) Dep. at 247-248) (*in camera*); PX7058 (Conroy (Exact) IHT at 111-113) (*in camera*)).

Response to Finding No. 703:

Respondents have no specific response except to note that [redacted] Any other analysis of CancerSEEK's characteristics, such as the number of cancers detected, its sensitivity or specificity, is premature, as Exact is going back to the drawing board with the test and "combining the Exact Sciences and Thrive approaches in one test." (PFF ¶ 726.6.) Exact/Thrive also admitted that, based on the DETECT-A trial, "[a]t present, we cannot be certain that the DETECT-A blood test"—the CancerSEEK test—"helped any participant." (RX3419 at 11.)

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

704. [redacted] (PX7077 (Chahine (Helio) Dep. at 83-84) (*in camera*)); *see* PX8654 (Helio) (Email exchange between J. Li, Helio, D.

Taggart, Helio, et al., Mar. 9, 2021) (discussing Grail's announcement of a $600-900 target price)).

Response to Finding No. 704:

The proposed finding is incomplete and misleading insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future.

[redacted]

2. MCED Tests Target Distinct Customers from Other Oncology Tests

705. [redacted] (Della Porta (Grail) Tr. 514 (*in camera*)).

Response to Finding No. 705:

The proposed finding is not supported by the cited evidence. In the cited testimony, Mr. Della Porta agreed that [redacted] (Della Porta (Grail) Tr. 514.)

706. Patients that would use MCED tests are different from patients that use therapy selection tests. (Getty (Guardant) Tr. 2502). There are about 700,000 to one million patients that have advanced-stage disease who might use a therapy selection test, compared to 100 to 120 million patients who could use an MCED test. (Getty (Guardant) Tr. 2501-02).

Response to Finding No. 706:

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including [redacted] do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–06) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

707. [redacted] (Rabinowitz (Natera) Tr. 353-54 (*in camera*)).

Response to Finding No. 707:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 706 herein.

708. Average-risk patients are generally defined as "45 and up." (PX7105, Getty (Guardant) Dep. at 18).

Response to Finding No. 708:

Respondents have no specific response except to note that Galleri is recommended for use in asymptomatic adults aged 50 and older. (PFF ¶ 727.)

709. [redacted] (PX7040 (Getty (Guardant) IHT at 31-32)); *see also* (PX4082 (Grail) at 008-009 (Email attaching "Grail S-1_A #1 As Filed," Sept. 17, 2020)); PX7051 (Lengauer (Third Rock Ventures) IHT at 28-29) (*in camera*)); PX7100 (Chudova (Guardant) Dep. at 15-16)); PX7094 (Nolan (Freenome) Dep. at 252-53) (*in camera*)).

Response to Finding No. 709:

The proposed finding is not supported by the cited evidence. *First*, Mr. Getty's testimony about [redacted] (PX7040 (Getty (Guardant) IHT at 31-32) was in response to a question about all liquid biopsy screening tests, not just putative MCED tests. (PX7040) (Getty (Guardant) IHT at 29 ("Q. Going back to something you said, how would liquid biopsy help improve compliance for screening of -- existing cancer screening methods?").) *Second*, the cited portion of GRAIL's S-1 does not discuss "MCED tests" broadly as the proposed finding suggests, but only that GRAIL intends for Galleri to be used at an annual physical. *Third*, nowhere in the cited portions of Dr. Chudova's testimony (or anywhere in the deposition) does she testify that MCED tests are to be used at annual routine appointments. (PX7100) (Chudova (Guardant) Dep. at 15-16.)

[redacted]

Respondents also note that the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Respondents also incorporate their responses to CCFF ¶¶ 381 and 2224 herein.

710. Because MCED tests are targeted towards patients who do not have symptoms of, and have not been treated for, cancer, [redacted] (PX7058 (Conroy (Exact) IHT at 103-04) (*in camera*)).

Response to Finding No. 710:

The proposed finding is misleading and contrary to the weight of the evidence. [redacted] Mr. Getty also testified that in the future, Guardant may market to OB/GYNs for female patients, "healthcare customers like employers", and "health systems". (Getty (Guardant) Tr. 2502–03; *see also* CCFF ¶ 2288.)

The proposed finding is also incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–06), and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Further, the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Respondents also incorporate their responses to CCFF ¶¶ 381–82 and 2224 herein.

711. [redacted] (PX4267 (Grail) at 008 [redacted] (*in camera*)). (PX4133 (Grail) at 016 (Email from H. Bishop, Grail, to F. deSouza, Illumina, attaching "Early Cancer Detection Investor Presentation," Aug. 2020) (explaining "Galleri is designed to be easy to use in primary care")); PX2712 (Illumina) at 019 (Email from P. Scagnetti, Illumina, to M. Nguyen, Illumina, attaching Python A Revolution in Early Cancer Detection, Dec. 3, 2019) ("While the oncology community will be critical to impressions of the utility and accuracy of our test, it is the general practitioner who orders routine screening tests like PSA and mammograms.")).

Response to Finding No. 711:

Respondents have no specific response except to note that certain of the putative MCED developers Complaint Counsel has identified intent to market their putative tests to other customers: [redacted] (CCFF ¶ 2219), and both Guardant and Freenome [redacted] (CCFF ¶¶ 2288 and 2389.) Respondents also incorporate their responses to CCFF ¶ 2224 herein.

712. [redacted] (PX4475 (Grail) at 033 [redacted] (*in camera*)).

Response to Finding No. 712:

The proposed finding is incomplete and misleading. PX4475 is titled [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶ 79 herein. Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 49), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

713. [redacted] (Ofman (Grail) Tr. 3417 (*in camera*)).

Response to Finding No. 713:

The proposed finding is incomplete and misleading. [redacted] Respondents also incorporate their responses to CCFF ¶ 79 herein.

714. [redacted] (Bishop (Grail) Tr. 1322; *see* Lengauer (Third Rock Ventures) Tr. 190 (*in camera*) (testifying that [redacted]; PX7091 (Lengauer (Third Rock Ventures) Dep. at 148-50) (*in camera*) [redacted]).

Response to Finding No. 714:

The proposed finding is not supported by the cited evidence. Mr. Bishop [redacted] (Bishop (Grail) Tr. 1322.) Dr. Lengauer testified that [redacted]

715. [redacted] (PX4075 (Grail) at 026 (Email from A. Aravanis, Grail, to M Young, Grail, et al., attaching Competitive Intelligence An Overview, Aug. 14, 2019) (*in camera*)) [redacted] (PX4075 (Grail) at 027 (Email from A. Aravanis, Grail, to M Young, Grail, et al., attaching Competitive Intelligence An Overview, Aug. 14, 2019) (*in camera*)).

Response to Finding No. 715:

The proposed fact is incomplete and misleading. PX4075 was created in 2019, and is significantly out of date. For example, Hans Bishop, GRAIL's CEO at the time of trial, testified that [redacted]

[redacted] (Bishop (GRAIL) Tr. 1496.) Accordingly, this cited document is entitled to little to no weight, and Complaint Counsels should not be permitted to rely on inferences from this document. Respondents also incorporate their responses to CCFF ¶ 2244 herein.

716. For example, Guardant anticipates that the primary customer for MCED tests would be primary care physicians. (Getty (Guardant) Tr. 2502).

Response to Finding No. 716:

Respondents have no specific response, except to note that Mr. Getty identified other potential customers in the future, including OB/GYNs for female patients, "healthcare customers like employers", and "health systems". (Getty (Guardant) Tr. 2502–03; *see also* CCFF ¶ 2288.) Respondents also incorporate their responses to CCFF ¶¶ 382,710, and 2244 herein.

717. [redacted] (Nolan (Freenome) Tr. 2769-70) (*in camera*)).

Response to Finding No. 717:

Respondents have no specific response [redacted] Respondents also incorporate their responses to CCFF ¶¶ 382, 710, and 2244 herein.

3. Both Blood-Based and Non-Blood Based Single-Cancer Screening Tests Have Different Customers

718. As set forth above in Sections III.B.1. (USPSTF Cancer Screening Methods are Complementary to MCED Tests) and III.B.2. (Other Non-USPSTF Single-Cancer Blood-Based Tests are Not Close Substitutes for MCED Tests), the existing single-cancer screening framework complements MCED tests, resulting in different customer bases.

Response to Finding No. 718:

To the extent Complaint Counsel relies on its Proposed Findings in CCFF Section III.B.1 and Section III.B.2 (¶¶ 635–687), Respondents incorporate their responses to those Proposed Findings herein.

719. Current screening tests are recommended for a different subset of the population than MCED tests will be. (*Compare* PX4303 (Grail) (Project Galileo Industry Report Pre-Read Presentation, May 7, 2018) (explaining the USPSTF guidelines) (*in camera*) *with* PX4082 (Grail) at 008-009 (Email attaching Grail 2020 S-1/Amended, Sept. 2020) (explaining that the Galleri test will be targeted for asymptomatic patients at their annual check-up)).

Response to Finding No. 719:

Respondents have no specific response except to note that this proposed finding provides support for the proposition that Galleri will be a complement to single cancer screening tests, including those that are available as the standard of care today, as well as complementary to screening tests for a handful of cancer types that many purported MCED test developers are pursuing. (*See* PFF ¶ 358 (RX0744 (GRAIL) at 76–90; [redacted] RX0867 (Clinical Overview Deck) at 15; PX7086 (Cance (ACS) Dep. at 50–53); [redacted]; RX3869 (Cote Expert Report) ¶ 136).) Respondents also note that [redacted] For example, [redacted]

720. "The Galleri test is intended to be complementary to, and not a replacement of, U.S. guideline-recommended cancer screening." (PX0063 at 001 (Grail's Galleri website)).

Response to Finding No. 720:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 719 herein.

721. MCED tests target customers who want to test for a multitude of cancers versus single-cancer tests that focuses on customers who want to test for a particular type of cancer. (Ofman Tr. 3312) ("[W]hen you order Galleri as a physician, you're not suspecting any particular type of cancer. That's why you order Galleri.").

Response to Finding No. 721:

The proposed finding is misleading because the cited source was only testifying about Galleri and not about the putative MCED test developers cited by Complaint Counsel. The proposed finding is also incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–06), and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

722. [redacted] (PX4303 (Grail) (Project Galileo Industry Report Pre-Read Presentation, May 7, 2018) (*in camera*)).

Response to Finding No. 722:

Respondents have no specific response.

723. [redacted]

[redacted] (PX4303 (Grail) (Project Galileo Industry Report Pre-Read Presentation, May 7, 2018) (*in camera*)).

Response to Finding No. 723:

Respondents have no specific response.

724. [redacted] (PX4303 (Grail) (Project Galileo Industry Report Pre-Read Presentation, May 7, 2018) (*in camera*)).

Response to Finding No. 724:

Respondents have no specific response.

725. [redacted] ((PX4303 (Grail) (Project Galileo Industry Report Pre-Read Presentation, May 7, 2018) (*in camera*)).

Response to Finding No. 725:

Respondents have no specific response.

4. DAC, Therapy Selection, and MRD Have Different Customers

726. DAC tests, in contrast, are intended for "symptomatic patients with a suspicion of cancer." (PX4082 (Grail) at 013 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 726:

Respondents have no specific response.

727. DAC tests will be "targeted "to oncologists and specialists." (PX4116 (Grail) (Email from M. Podoll, Morgan Stanley, to A. Freidin, Grail et al., attaching IPO Roadshow Video Outline: Project Galileo, Aug. 2020)).

Response to Finding No. 727:

Respondents have no specific response.

728. Patients that would use MCED tests are also different from patients that use therapy selection tests. (Getty (Guardant) Tr. 2502).

Response to Finding No. 728:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 721 herein.

729. [redacted] (*See* Getty (Guardant) Tr. 2503; *see also* PX7080 (Silvis (Tempus) Dep. at 31-33); PX8474 (Guardant) at 007 [redacted] (*in camera*); PX7040 (Getty (Guardant) IHT at 68-69); PX7068 (Perettie (FMI-Roche) IHT at 32 (*in camera*)).

Response to Finding No. 729:

Respondents have no specific response, except to note that the proposed finding relies in part on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

730. [redacted] (*See* PX7068 (Perettie (FMI-Roche) IHT at 32 (*in camera*)).

Response to Finding No. 730:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

731. [redacted] (*See* PX7121 (Otte (Freenome) Dep. at 181-82 (*in camera*) [redacted]; PX8474 (Guardant) at 007 [redacted] (*in camera*)).

Response to Finding No. 731:

Respondents have no specific response.

5. The Parties Recognize That MCED Testing Is Its Own Relevant Market

a) Illumina and Grail Refer to the MCED Industry, MCED Segment, and MCED Space

732. Grail publicly describes Galleri as an MCED test. (Bishop (Grail) Tr. 1319).

Response to Finding No. 732:

Respondents have no specific response.

733. Grail refers to its Galleri test as an MCED test on its corporate website. (Bishop (Grail) Tr. 1319).

Response to Finding No. 733:

Respondents have no specific response.

734. As shown in PX0063, Grail's website prominently refers to Galleri as a "Multi-cancer early detection test." (PX0063 at 001 (Grail, Galleri, Apr. 29, 2021)).

Response to Finding No. 734:

Respondents have no specific response.

735. [redacted] (PX4015 (Grail) at 053 (Grail, Board of Directors Meeting, September 10, 2020) (*in camera*)).

Response to Finding No. 735:

Respondents have no specific response.

736. Grail identifies itself in its documents as [redacted] (PX4048 (Grail) at 003-004 [redacted] (*in camera*) [redacted] ; PX4037 (Grail) at 008 [redacted] (*in camera*) [redacted] PX4075 (Grail) at 005 (Grail, Competitive Intelligence, Aug. 14, 2019) (*in camera*) [redacted]) Dep. at 92); PX7083 (Bishop (Grail) Dep. at 23-24); PX7103 (Jamshidi (Grail) Dep. at 38-39)).

Response to Finding No. 736:

The proposed finding is misleading and incomplete with respect to Complaint Counsel's characterization of PX4048. (PX4048 (Grail) at 003-004) [redacted] (PX4048 (Grail) at 004); *see also* (Della Porta (GRAIL) Tr. 512.) Respondents also incorporate their responses to CCFF ¶ 719 herein.

737. A May 2018 Grail document analyzes [redacted] **(**PX4295 (Grail) at 004 (Project Galileo – industry report, May 7, 2018) (*in camera*)).

Response to Finding No. 737:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 43), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to

rely on any inferences from it. Respondents also note that PX4295 is a four-year-old document that [redacted]

738. Jeff Huber's—Grail's former CEO—reaction to Thrive's launch was that it was "good to have a 'market' instead of a single company, and now we have a market. It'll also mean there will be others pushing the rock up the hill for reimbursement – which is a very good thing." (PX4121 (Grail) at 001 (Email from Jeff Huber to the Grail Board of Directors, May 30, 2018)).

Response to Finding No. 738:

The proposed finding is incomplete and misleading as well as contradicted by the weight of the evidence. In particular, the use of the term "market" in this context is vague and ambiguous, and improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding is also incomplete and misleading insofar as it suggests that Exact/Thrive is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. To the contrary, [redacted] Respondents further note that PX4121 also observes that it "looks like they're [Thrive] shooting for 8-12 cancers" and that "they will be relatively low cost since it's PCR+proteins/antigens." Further, Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 37), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

739. Hans Bishop—Grail's former CEO—also acknowledged that Exact is also in the "multicancer early detection space." (PX7069 (Bishop (Grail) IHT at 153)).

Response to Finding No. 739:

Respondents have no specific response except to note that in the cited testimony, Mr. Bishop was discussing Exact's acquisition of Thrive, and noted that Thrive has only "early technology." (PX7069 (Bishop (GRAIL) IHT at 154.)) [redacted]

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

740. Mr. Bishop expects that "other multicancer early detection tests will eventually [be] launched in the market." (PX7069 (Bishop (Grail) IHT at 163)).

Response to Finding No. 740:

The proposed finding is incomplete and misleading. [redacted]

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

741. Grail's [redacted] (PX4456 (Grail) at 013 [redacted] (*in camera*)).

Response to Finding No. 741:

The proposed finding is incomplete and misleading. Hans Bishop, GRAIL's CEO at the time, testified at trial that PX4456 [redacted] (Bishop (GRAIL) Tr. 1496). Accordingly, this proposed finding is entitled to little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

742. [redacted] (PX4284 (Grail) at 020 (Email from J. Ayers to M. Burns regarding GRAIL: First draft corporate communications plan attaching "GRAIL Corporate Comms Plan 5 19 2020 FINAL) (*in camera*)).

Response to Finding No. 742:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 43), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

743. [redacted] (PX4615 (Grail) at 070 [redacted] (*in camera*)).

Response to Finding No. 743:

Respondents have no specific response except to note that Complaint Counsel was unable to lay a foundation for any witness to discuss this document, and it is therefore entitled to little weight and Complaint Counsel should not be permitted to rely on any inferences from it. (Ofman (GRAIL) Tr. 3428). Respondents additionally note that [redacted]

744. Illumina documents presented to its Board of Directors regarding this transaction also discuss a market for MCED tests. [redacted] (PX5030 (Illumina) at 006 [redacted] (*in camera*)); *see* (PX7059, Scagnetti (Illumina) IHT at 63-64 (*in camera*) [redacted] (PX5030 (Illumina) at 009 [redacted] (*in camera*)).

Response to Finding No. 744:

The proposed finding is incomplete and misleading. Complaint Counsel omits that Dr. Aravanis provided additional context when shown PX5030 at trial:

[redacted]

[redacted]

(Aravanis (Illumina) Tr. 1806–07.)

745. Illumina's 2021-2025 Strategic Plan [redacted] (PX2169 (Illumina) at 048 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*)).

Response to Finding No. 745:

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including [redacted] do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–06), and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Respondents also note that [redacted]

(PX2169 (Illumina) at 048.)

b) [redacted]

746. [redacted]

Response to Finding No. 746:

To the extent Complaint Counsel relies on its proposed findings in Section VII.A (¶¶ 2607–3078), Respondents incorporate their responses to those proposed findings herein.

747. [redacted] (Berry (Illumina) Tr. 751-53) (*in camera*). [redacted] (Berry (Illumina) Tr. 753) (*in camera*).

Response to Finding No. 747:

Respondents have no specific response except to note that the cited testimony [redacted]

748. [redacted] (Berry (Illumina) Tr. 938 (*in camera*)). [redacted] (Berry (Illumina) Tr. 938 (*in camera*)).

Response to Finding No. 748:

The proposed finding is incomplete and misleading. [redacted]

749. [redacted] (Berry (Illumina) Tr. 753-54) (*in camera*).

Response to Finding No. 749:

Respondents have no specific response except to note that the cited testimony confirms that the purpose of the outreach was to assure customers that the Transaction would have no impact on their supply relationship with Illumina.

750. [redacted] (Bishop (Grail) Tr. 1497-98 (*in camera*); PX4063 (Grail) at 001 (Email from Megan Hall, Grail, to Executive Team, Grail, et al., Feb. 2, 2021)).

Response to Finding No. 750:

The proposed finding is incomplete and misleading. Mr. Bishop testified that he was [redacted] (Bishop (GRAIL) Tr. at 1498.)

751. [redacted] (Bishop (Grail) Tr. 1498-99 (*in camera*); PX4063 (Grail) at 001 (Email from Megan Hall, Grail, to Executive Team, Grail, et al., Feb. 2, 2021)).

Response to Finding No. 751:

The proposed finding is incomplete and misleading. Mr. Bishop testified that [redacted] (Bishop (Grail) Tr. 1499).

The proposed finding is also incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including [redacted] do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–06) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable. Respondents further note that [redacted]

752. [redacted]

Response to Finding No. 752:

To the extent Complaint Counsel relies on its proposed findings in Section VII.B.3 (¶¶ 3189–3507), Respondents incorporate their responses to those proposed findings herein.

The proposed fact is inaccurate and misleading. Complaint Counsel cites no evidence in support of this purported fact, and therefore it should be disregarded entirely. Respondents further note that Mr. Della Porta testified that [redacted] Outside of Galleri, there are currently no other MCED tests on the market. (*See* PFF ¶¶ 340-573.)

753. [redacted]

[redacted] (PX4259 (Grail) at 001 (Email from C. Della Porta, Grail, to J. Ofman, Grail, copying A. Aravanis, Grail, H. Bishop, Grail, J. Owens, Grail, and V. Demas, Grail, Jul. 22, 2019) (*in camera*)).

Response to Finding No. 753:

The proposed finding is incomplete and misleading. As explained in the immediately preceding sentence in the cited source, [redacted]

754. [redacted] (Della Porta (Grail) Tr. 477-78 (*in camera*)); PX4145 (Grail) at 006 (Grail, "Competitive Intelligence," Aug. 14, 2019) (*in camera*)).

Response to Finding No. 754:

The proposed finding is incomplete and misleading. [redacted] Respondents also incorporate their responses to CCFF ¶ 754 herein.

755. [redacted] (PX4145 (Grail) at 006 (Grail, "Competitive Intelligence," Aug. 14, 2019) (*in camera*) [redacted]).

Response to Finding No. 755:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

756. [redacted] (PX4145 (Grail) at 009 (Grail, "Competitive Intelligence," Aug. 14, 2019) (*in camera*)).

Response to Finding No. 756:

The proposed finding is incomplete and misleading. Respondents also incorporate their responses to CCFF ¶¶ 755–56 herein.

757. [redacted] (PX4287 (Grail) at 002 [redacted], 015-25 [redacted], 029-38 [redacted] (*in camera*). *See also,* PX4190 (Grail) at 013-15 [redacted] (*in camera*) ([redacted]).

Response to Finding No. 757:

The proposed finding is incomplete and misleading. [redacted] Dr. Ofman testified at trial that GRAIL does not conduct research and development in response to any test developer's work. (Ofman (GRAIL) Tr. 3304-05.)

A GRAIL conference report notes [redacted] Further, [redacted] Respondents also incorporate their responses to CCFF ¶¶ 3231–33 herein.

Complaint Counsel chose not to discuss PX4287 or PX4190 at trial, (CC Exhibit Index at 40, 43), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

758. [redacted] (Della Porta (Grail) Tr. 483 (*in camera*)).

Response to Finding No. 758:

Respondents have no specific response.

759. [redacted] (Aravanis (Illumina) Tr. 1802-1804 (*in camera*) (referencing PX4075 (Grail))).

Response to Finding No. 759:

The proposed finding is incomplete and misleading. [redacted] Respondents also incorporate their responses to CCFF ¶¶ 755–56 herein.

760. [redacted] (Aravanis (Illumina) Tr. 1802-1804) (*in camera*)).

Response to Finding No. 760:

The proposed finding is incomplete and misleading. [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 755–56 herein.

761. [redacted] (PX4250 (Grail) at 003, 009 [redacted] (*in camera*)).

Response to Finding No. 761:

The proposed finding is incomplete and misleading. [redacted]

Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 41), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

Respondents also incorporate their responses to CCFF ¶ 413 herein.

762. [redacted] (PX2588 (Illumina) at 008 (Illumina PowerPoint titled "Project: GRAIL", March 2020) (*in camera*)).

Response to Finding No. 762:

The proposed finding is incomplete and misleading. Contrary to the subsection's heading, nothing in the cited slide suggests that Illumina identified [redacted]

Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 25) and did not discuss this particular slide with the only witness who was shown this document in any deposition (*see* PX7099 (Febbo (Illumina) Dep. at 166–75), and should not be entitled to

rely on it to establish that the slide suggests Illumina views [redacted]

[redacted]

c) Illumina and Grail Track Research and Development Efforts of MCED Test Developers

763. Illumina tracks investment activity in MCED testing companies. (deSouza (Illumina) Tr. 2392).

Response to Finding No. 763:

Respondents have no specific response except to note that, contrary to the subsection's heading, nothing in the cited testimony suggests that Illumina tracks the research and development efforts of putative MCED test developers. Mr. deSouza only notes that after the announcement of the Illumina/GRAIL transaction, investment in the space "significantly ramped up". (deSouza (Illumina) Tr. 2392.)

764. Grail's R&D team tracks the research and development efforts of other companies that are developing MCED tests. (Della Porta (Grail) Tr. 583). [redacted] (PX4037 (Grail) at 008-10 [redacted] (*in camera*)).

Response to Finding No. 764:

The proposed finding is not supported by the cited evidence. Mr. Della Porta testified that [redacted] (Della Porta (Grail) Tr. 583). PX4037 demonstrates that [redacted] (PX4037 (Grail) at 008–10)

Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 35), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

765. [redacted] (PX4075 (Grail) at 009 (Email attaching Competitive Intelligence: An Overview, Aug. 14, 2019) (*in camera*)).

Response to Finding No. 765:

The proposed finding is incomplete and misleading. Respondents incorporate their responses to CCFF ¶ 759 herein.

766. [redacted] (PX4287 (Grail) at 013-14 (*in camera*)). [redacted] (PX4287 (Grail) at 022-042, 045-049 [redacted] (*in camera*)).

Response to Finding No. 766:

The proposed finding is incomplete and misleading. [redacted]

Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 43), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

767. In Grail's AACR Conference Report, dated May 5, 2021, Grail's Medical Affairs and R&D and Bioinformatics teams wrote: "MCED evolving into highly competitive landscape,

though many seem to be starting with one cancer type, with intent to add more." (PX4616 (Grail) at 017 (Grail, AACR Conference Report, May 5, 2021)).

Response to Finding No. 767:

The proposed finding is incorrect. Dr. Ofman testified that PX4616 was [redacted]

[redacted]

(Ofman (GRAIL) Tr. 3422). There is no evidence in the record regarding who wrote the sentence quoted in the proposed finding.

The proposed finding is also misleading to the extent it suggests that it is a viable option to convert from a single cancer screening test to a multi-cancer screening test. To the contrary, even once a company has developed a cancer screening test for a single cancer type, it does not become easier to add additional cancer types, because "[t]he development of biomarkers for a particular cancer will not be adequate for other cancers" and "[w]hile there may be overlap, one still needs to go through all of the [development] steps," including "go[ing] through the case-control verification to determine whether or not the assay has the performance characteristics needed . . . for the new target cancer," and "go[ing] through a prospective trial depending on which cancer is being targeted." (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123; PFF ¶¶ 328–328.1.)

Dr. Aravanis testified that GRAIL considered developing a single cancer screening test as a route to a multicancer screening test but abandoned it because it would take far too long; building a multicancer test by developing single cancer tests seriatim could take four or five years for each cancer; to develop a 50-cancer test one cancer at a time, a developer would need to do a research study, discovery study and collect relevant samples, determine the right technology, go into a new test development phase and clinical trials for each new cancer; GRAIL was able to develop a test capable of detecting 50 cancer types simultaneously directly by

undergoing a much more intensive process to develop a test for 50 cancer types at the same time.

(Aravanis (Illumina) Tr. 1895–97.)

768. The same Grail AACR Conference Report identifies Exact/Thrive as Grail's "most significant competitor in MCED space." PX4616 (Grail) at 030 (Grail, AACR Conference Report, May 5, 2021)).

Response to Finding No. 768:

The proposed finding is incorrect and Respondents incorporate their responses to CCFF ¶ 757 herein. Respondents further note that PX4616 notes [redacted]

769. [redacted] (Ofman (Grail) Tr. 3421-22 (*in camera*)).

Response to Finding No. 769:

Respondents have no specific response.

770. Grail's 2021 AACR Conference Report (PX4616) credits 27 Grail employees: 17 members of Grail's Medical Affairs team and ten members of Grail's bioinformatics and R&D teams. (PX4616 (Grail) at 135 (Grail, AACR Conference Report, May 5, 2021)).

Response to Finding No. 770:

Respondents have no specific response.

771. [redacted] (PX4037 (Grail) at 008-010 [redacted] (*in camera*)).

Response to Finding No. 771:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶ 754 herein.

772. [redacted] (PX4266 (Grail) at 013 [redacted] (*in camera*)).

Response to Finding No. 772:

Respondents note that the [redacted]

773. Dr. Katz, Respondents' expert, agreed that Grail has a process in place "that identi[fies] technologies and competitors whose approaches are worth evaluating for future iterations of Grail's product." (RX6004 (Katz Trial Dep. at 105).

Response to Finding No. 773:

The proposed finding mischaracterizes the cited testimony, and is incomplete and misleading. In response to this question from Complaint Counsel, Dr. Katz specifically [redacted]

[redacted]

(RX6004 (Katz Trial Dep. at 105) (emphasis added.)

774. Specifically, Dr. Katz, testified that firms that are developing MCED tests have identified other MCED developers as competitors. (RX6004 (Katz Trial Dep. at 104)).

Response to Finding No. 774:

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Dr. Katz testified that [redacted] (RX6004 (Katz Trial Dep.) at 21.) And, contrary to the proposed finding, Complaint Counsel's own witness Dr. Lengauer testified [redacted] (Lengauer (Third Rock) Tr. 205–06.)

Most of the putative MCED developers identified by Complaint Counsel, including [redacted] do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–06), and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Respondents incorporate their responses to CCFF ¶¶ 775–76 herein.

775. Dr. Katz also testified that firms developing MCED tests have assessed their rivals' product features for their MCED tests. (RX6004 (Katz Trial Dep. at 104).

Response to Finding No. 775:

Dr. Katz also testified that "these companies don't know exactly where their tests are going to turn out in terms of the various characteristics, and the companies have aspirations and have some expectations, but there's still a high degree of uncertainty there. So, you know, it may well be they think of these firms as their competitor or prospectively so, but that's not really enough I think to reliably tell us what the market boundaries are going to be." (RX6004 (Katz Trial Dep.) at 21-22).)

Respondents incorporate their responses to CCFF ¶¶ 774 and 776 herein.

776. Dr. Katz understood that firms in the MCED industry track the science of other firms developing MCED tests. (RX6004 (Katz Trial Dep. at 105).

Response to Finding No. 776:

The proposed finding is incomplete and misleading. Dr. Katz testified that [redacted] (RX6004 (Katz Trial Dep. at 105.)

Respondents incorporate their responses to CCFF ¶¶ 774–75 herein.

6. Industry Participants View MCED Tests as Its Own Relevant Market

777. As captured below and in Section VI., [redacted] (*See, e.g.*, Nolan (Freenome) Tr. 2773-4 (*in camera*) [redacted]; PX8392 (Exact) at 002 (*in camera*) [redacted] PX7042 (Gao (Singlera) IHT at 102-103) (testifying that Singlera's PanSeer test is in the pan-cancer market, competing against companies like Grail, Exact, Freenome, and Thrive); PX7053 (Fesko (Natera) IHT at 84) (*in camera*) [redacted]).

Response to Finding No. 777:

The proposed finding is inaccurate, incomplete, misleading and contrary to the weight of the evidence insofar as it suggests that [redacted]

First, as Dr. Katz testified, statements by competitors "are not going to answer these questions about the trade-offs or . . . the degree of differentiation or how consumers are going to really behave." (RRFF ¶ 774 (RX6004 (Katz Trial Dep.) at 21).)

Second, observations of the industry participants are less probative where they have no personal knowledge about the features and functions of these tests. As Dr. Katz explained: "these companies don't know exactly where their tests are going to turn out in terms of the various characteristics, and the companies have aspirations and have some expectations, but there's still a high degree of uncertainty there. So, you know, it may well be they think of these firms as their competitor or prospectively so, but that's not really enough I think to reliably tell us what the market boundaries are going to be." (RRFF ¶ 775 (RX6004 (Katz Trial Dep.) at 21-22).)

This is consistent with some of the testimony cited in the proposed finding. [redacted]

Third, the available industry or public information about the putative MCED tests in development does not suggest that these tests belong in the same product market as Galleri. Instead, they make clear that they are all very different from Galleri. (*See* PFF ¶¶ 716–721.4.)

Analyst reports from investment banks that cover the broader biotechnology space recognize that Galleri is very different. (*See* PFF ¶¶ 717.1–717.2.) [redacted] (*See* PFF ¶¶ 718–718.1.) While the features and functions of Galleri are described in detail in several peer-reviewed publications and GRAIL has multiple clinical trials listed at clinicialtrials.gov, most other putative MCED tests in development do not even have published articles or initiated clinical trials relating to cancer screening at all. (*See* PFF ¶¶ 719–20.)

In addition, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Further, Complaint Counsel chose not to discuss PX8392 at trial, (CC Exhibit Index at 61), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

778. At trial, MCED test developers referred to their tests as MCED tests. (*See, e.g.*, (Lengauer, Tr. 158-59) (describing CancerSEEK as "a multicancer blood test for the . . . early detection of cancer"); (Chahine (Helio) Tr. 1000) (differentiating Helio's liver cancer test from its "multicancer test"); (Nolan (Freenome) Tr. 2709) (discussing Freenome's "multicancer program")).

Response to Finding No. 778:

The proposed finding is inaccurate, incomplete and misleading. Respondents incorporate their responses to CCFF ¶ 777 herein.

779. [redacted] (*See, e.g.*, PX8392 (Exact) at 002 (*in camera*); RX0545 (Guardant) at 010 (*in camera*) [redacted]); PX8324 (Roche) at 003 [redacted] (*in camera*)).

Response to Finding No. 779:

The proposed finding is inaccurate, incomplete and misleading. Respondents incorporate their responses to CCFF ¶ 777 herein. Further, Complaint Counsel chose not to discuss PX8324 or PX8392 at trial, (CC Exhibit Index at 59, 61), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

a) [redacted]

780. [redacted] (Chahine (Helio) Tr. 1066 (*in camera*)).

Response to Finding No. 780:

The proposed finding is incomplete and misleading insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. Respondents note that Helio has [redacted] (Chahine (Helio) Tr. 1090, 1092–93.) Further, Dr. Chahine testified that [redacted] Accordingly, there is no indication based on [redacted]

[redacted]

(PFF ¶ 498.) Respondents also incorporate their responses to CCFF ¶¶ 454–60, 774–75 and 777 herein.

781. [redacted] (Chahine (Helio) Tr. 1066-67 (*in camera*)).

Response to Finding No. 781:

The proposed finding is incomplete and misleading insofar as it suggests that [redacted] and Respondents incorporate their responses to CCFF ¶ 780 herein.

782. For example, [redacted] (PX8655 (Helio) at 029 (*in camera*)).

Response to Finding No. 782:

The proposed finding is incomplete and misleading to the extent it suggests that [redacted] Further, Respondents incorporate their responses to CCFF ¶ 780 herein.

[redacted]

783. [redacted] (Chahine (Helio) Tr. 1067 (*in camera*)).

Response to Finding No. 783:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 782 herein.

784. [redacted] (Chahine (Helio) Tr. 1067 (*in camera*)).

Response to Finding No. 784:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 782 herein.

b) [redacted]

785. When describing the CancerSEEK test, former Chief Innovation Officer and Co-Founder of Thrive, Dr. Lengauer, explained that "we call it a multicancer test. That's in stark contrast to single organs test that only look for one particular organ." (Lengauer (Third Rock Ventures) Tr.159-60).

Response to Finding No. 785:

The proposed finding is incomplete and misleading insofar as it suggests that [redacted] Galleri detects more than 50 cancer types (PFF ¶ 61), [redacted] (Lengauer (Exact/Thrive) Tr. 245; RX3869 (Cote Expert Report) ¶ 177; PFF ¶¶ 429–430.1.) [redacted] By contrast, [redacted] (PFF ¶¶ 419 (RX3869 (Cote Expert Report) ¶ 174), 684.2 (Lengauer (Exact/Thrive) Tr. 246–48).) Dr. Lengauer also observes that the [redacted] (PFF ¶ 429 (Lengauer (Exact/Thrive) Tr. 245; RX3869 (Cote Expert Report) ¶ 177).) Dr. Lengauer also testified that [redacted] (PFF ¶¶ 725 (RX3409 (Klein et al., 2021) at 5; RX3419 (Lennon et al., 2020) at 7; RX3115 (Chen et al., 2020) at 4).) Thus, [redacted] and little evidence to indicate that [redacted] (PFF ¶ 421.) Respondents also incorporate their responses to CCFF ¶ 414 herein.

786. Mr. Conroy testified that there is now a nascent market—as Mr. Conroy uses the term as a layperson—in MCED testing since Galleri became available. (Conroy (Exact) Tr. 1738).

Response to Finding No. 786:

Respondents have no specific response except to note that Mr. Conroy's use of the term as a layperson provides no basis to determine the relevant product market, which requires a legal conclusion. Respondents also incorporate their responses to CCFF ¶ 785 herein.

787. [redacted] (Lengauer (Third Rock Ventures) Tr. 194-95 (*in camera*)).

Response to Finding No. 787:

Respondents have no specific response except to note [redacted] (Lengauer (Exact/Thrive) Tr. 205–06.) Respondents also incorporate their responses to CCFF ¶ 785 herein.

788. [redacted] (Conroy (Exact) Tr. 1652 (*in camera*)).

Response to Finding No. 788:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 785 herein.

789. [redacted] (PX8572 (Exact) at 048 (Exact Sciences Innovation & Technology Committee)) (*in camera*) [redacted]).

Response to Finding No. 789:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 774–75 and 785 herein.

790. [redacted] (PX8572 (Exact) at 092 (Exact Sciences Innovation & Technology Committee) (*in camera*)).

Response to Finding No. 790:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 774–75 and 785 herein.

791. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 177-78) (*in camera*)).

Response to Finding No. 791:

Respondents have no specific response except to note that [redacted]

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

c) [redacted]

792. [redacted]
(Rabinowitz (Natera) Tr. 359 (*in camera*)).

Response to Finding No. 792:

The proposed finding is incomplete and misleading insofar as it suggests that Natera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future.

Although [redacted] (PFF ¶¶ 508–09.) [redacted] and that Natera is unlikely to accelerate the development of a cancer screening test for multiple cancer types or to add a new cancer type to an existing screening test, [redacted]. (PFF ¶ 511 (RX3869 (Cote Expert Report) ¶ 227; [redacted].) Respondents also incorporate their responses to CCFF ¶¶ 774–75 and 794 herein.

793. [redacted]
(Rabinowitz (Natera) Tr. 359 (*in camera*)).

Response to Finding No. 793:

The proposed finding is incomplete and misleading insofar as it suggests that Natera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future.

Respondents also note that the cited testimony deserves little weight, because [redacted] Respondents also incorporate their responses to CCFF ¶ 792 herein.

794. [redacted] (Rabinowitz (Natera) Tr. 360 (*in camera*)).

Response to Finding No. 794:

The proposed finding is incomplete and misleading insofar as it suggests that Natera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future.

Respondents also note that [redacted] Respondents also incorporate their responses to CCFF ¶ 792 herein.

795. [redacted] (Rabinowitz (Natera) Tr. 360 (*in camera*)).

Response to Finding No. 795:

The proposed finding is incomplete and misleading insofar as it suggests that Natera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future.

Contrary to the cited testimony, [redacted] (RX0521 (Natera) at 3); *see also* (PX7113 (Rabinowitz (Natera) Dep. at 298–303).) [redacted] (*See generally* RX0521 (Natera).) Respondents also incorporate their responses to CCFF ¶ 792 herein.

d) Guardant Has Identified MCED Test Developers as Competitors in Its Market

796. Guardant estimates the potential size of the MCED market in terms of revenue as over $50 billion. (Getty (Guardant) Tr. 2503).

Response to Finding No. 796:

Respondents have no specific response, except to note that [redacted]

797. Guardant monitors Grail because of its funding and the advanced state of its technology. (Getty (Guardant) Tr. 2504).

Response to Finding No. 797:

The proposed finding is incomplete and misleading insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future.

Accordingly, while Guardant may "monitor[] GRAIL", there is no evidence that Guardant will launch in the foreseeable future a cancer screening test that is a close substitute to the Galleri test. (PFF ¶¶ 476–92.)

798. Guardant is "really focused" on Grail as a competitor. (Getty (Guardant) Tr. 2505).

Response to Finding No. 798:

The proposed finding is incomplete and misleading insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future.

The proposed finding relates to irrelevant subject matter because Guardant's characterization of its own competitors says nothing about whether Guardant is, in fact, a credible rival of GRAIL. Accordingly, there is no indication based on Guardant's work to date that [redacted]

[redacted]

[redacted]).) Respondents further incorporate their responses to CCFF ¶¶ 426–438 and 2257–2352 herein.

799. Guardant monitors Exact as a competitor because of Exact's funding and the advanced state of its technology. (Getty (Guardant) Tr. 2504).

Response to Finding No. 799:

The proposed finding relates to irrelevant subject matter because Guardant's characterization of its own competitors says nothing about whether Guardant is, in fact, a credible rival of GRAIL. Accordingly, there is no indication based on Guardant's work to date that [redacted]

[redacted]).) Respondents further incorporate their responses to CCFF ¶¶ 426–438 and 2257–2352 herein.

800. Guardant also views Grail, Natera, Exact, and Freenome as competitors in MCED test development. (Getty (Guardant) Tr. 2687-88) (referring to PX0060 (Guardant) at 014 (Guardant 10-K for fiscal year ending Dec. 31, 2020)).

Response to Finding No. 800:

The proposed finding is misleading and contrary to the weight of the evidence. There is no indication based on Guardant's work to date that [redacted]

[redacted] (PFF ¶ 475 [redacted]).)

Further, the reference to Guardant's 10-K is misleading and does not support the proposed finding. The quoted portions of Guardant's 10-K say that Grail, Natera, Exact, and Freenome are "competitors in minimal residual disease testing and early screening testing" (PX0060 (Guardant) at 14) and do not mention "MCED" or "multicancer". Respondents further incorporate their responses to CCFF ¶¶ 426–438 and 2257–2352 herein.

e) Freenome Has Identified MCED Test Developers as Competitors in Its Market

801. [redacted] (PX7050, Nolan (Freenome) IHT at 137, 251-52 (*in camera*)).

Response to Finding No. 801:

The proposed finding is incomplete and misleading insofar as it suggests that [redacted]

Notwithstanding Freenome's stated view of itself, Mr. Nolan testified that Freenome is [redacted] (PX7094 (Nolan (Freenome) Dep. at 307).) [redacted] (PFF ¶¶ 459-70.) [redacted]

[redacted] (PFF ¶ 458 (Cote Tr. 3846, 3849–50; RX3869 (Cote Expert Report) ¶ 193).)

Respondents further incorporate their responses to CCFF ¶¶ 439–446 and 2353–2400 herein.

802. Freenome CEO, Michael Nolan, testified at trial that [redacted] (Nolan (Freenome) Tr. 2774 (*in camera*)).

Response to Finding No. 802:

The proposed finding is incomplete and misleading insofar as it suggests that [redacted]

Respondents also note that [redacted] Respondents further incorporate their responses to CCFF ¶¶ 439–446, 801 and 2353–2400 herein.

803. [redacted] (Nolan (Freenome) Tr. 2772-73 (*in camera*)).

Response to Finding No. 803:

The proposed finding is incomplete and misleading insofar as it suggests that [redacted]

Respondents also note that [redacted] Respondents further incorporate their responses to CCFF ¶¶ 439–446, 801–02 and 2353–2400.

804. Freenome views Grail as a competitor in offering MCED tests. (Nolan (Freenome) Tr. 2727).

Response to Finding No. 804:

The proposed finding is incomplete and misleading insofar as it suggests that [redacted]

Respondents also note that the proposed finding is incomplete and misleading to the extent it implies that Mr. Nolan's testimony is representative of Freenome's views writ large. In

fact, [redacted] Respondents further incorporate their responses to CCFF ¶¶ 439–446 and 2353–2400.

805. Freenome CEO, Michael Nolan, testified that because Grail's MCED test is [redacted] (Nolan (Freenome) Tr. 2774 (*in camera*)).

Response to Finding No. 805:

Respondents have no specific response.

806. Mr. Nolan testified that [redacted] (Nolan (Freenome) Tr. 2774-75 (*in camera*)).

Response to Finding No. 806:

The proposed finding is incomplete and misleading insofar as it suggests that [redacted]

Respondents also note that [redacted] Respondents further incorporate their responses to CCFF ¶¶ 439–446 and 2353–2400.

f) [redacted]

807. [redacted] (PX8324 (Roche) at 003 (*in camera*))).

Response to Finding No. 807:

The proposed finding is incomplete and misleading insofar as it suggests that [redacted]

Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 59), or in any deposition, and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

808. Cindy Perettie from Foundation Medicine is aware that Grail, Thrive, Exact Sciences, Freenome, and Natera are "developing NGS-based early cancer detection tests." (PX7068 (Perettie IHT at 54-55)).

Response to Finding No. 808:

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–06), and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698).

Respondents also note that the proposed finding does not demonstrate that all "MCED tests" as Complaint Counsel defines the term are reasonably interchangeable with each other and properly considered in a single relevant product market. In fact, Ms. Perettie does not even use the term "multi-cancer early detection" in referring to tests from GRAIL, Thrive, Exact Sciences, Freenome or Natera.

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

7. Legislators, Regulators, and Others Discuss an MCED Market

809. The U.S. House of Representatives and Senate introduced the Medicare Multi-Cancer Early Detection Screening Coverage Act of 2020, which states that MCED tests "can complement the covered early detection tests," rather than replace them. (H.R. 8845 (116th Congress, 2d Session), Sec. 2(a)(7)). (RX2588 (Illumina) (Reps. Sewell, Arrington, Ruiz, and Hudson Introduce Bipartisan Legislation to Remove Barriers to Innovative Multi-Cancer Screening Technology for Medicare Beneficiaries, Dec. 3, 2020, https://sewell.house.gov/media-center/press-releases/reps-sewell-arrington-ruiz-and-hudson-introduce-bipartisan-legislation, last visited Apr. 6, 2022) (stating "these new tools will complement, not replace, existing screenings")).

Response to Finding No. 809:

Respondents have no specific response except to note that the proposed finding does not demonstrate that all "MCED tests" as Complaint Counsel defines the term are reasonably interchangeable with each other and properly considered in a single relevant product market. To the extent Complaint Counsel relies on its proposed findings in CCFF ¶¶ 810–17, Respondents incorporate their responses to those proposed findings herein.

810. [redacted] (RX2588 (Illumina) (Reps. Sewell, Arrington, Ruiz, and Hudson Introduce Bipartisan Legislation to Remove Barriers to Innovative Multi-Cancer Screening Technology for Medicare Beneficiaries, Dec. 3, 2020, https://sewell.house.gov/media-center/press-releases/reps-sewell-arrington-ruiz-and-hudson-introduce-bipartisan-legislation, last visited Apr. 6, 2022) (stating "these new tools will complement, not replace, existing screenings")). *See also* (Bishop (Grail) Tr. 1323-24); (Ofman (Grail) Tr. 3356 (*in camera*)).

Response to Finding No. 810:

Respondents have no specific response.

811. [redacted] (Ofman (Grail) Tr. 3353 (*in camera*)).

Response to Finding No. 811:

Respondents have no specific response.

812. [redacted] (Ofman (Grail) Tr. 3356 (*in camera*)).

Response to Finding No. 812:

Respondents have no specific response.

813. As noted above at Complaint Counsel's Proposed Findings of Fact ¶¶ 587, 590-591, Grail has lobbied Congress to pass legislation to enable Medicare's coverage MCED tests.

Response to Finding No. 813:

Respondents have no specific response.

814. The U.S. House of Representatives and Senate introduced the "Medicare Multi-Cancer Early Detection Screening Coverage Act of 2020," which states that MCED tests "can complement the covered early detection tests," rather than replace them. (H.R. 8845 (116th Congress, 2d Session), Sec. 2(a)(7)). (RX2588 (Illumina) (Reps. Sewell, Arrington, Ruiz, and Hudson Introduce Bipartisan Legislation to Remove Barriers to Innovative Multi-Cancer Screening Technology for Medicare Beneficiaries, Dec. 3, 2020, https://sewell.house.gov/media-center/press-releases/reps-sewell-arrington-ruiz-and-hudson-introduce-bipartisan-legislation, last visited Apr. 6, 2022) (stating "these new tools will complement, not replace, existing screenings")).

Response to Finding No. 814:

Respondents have no specific response.

815. The Press Release announcing the legislation specifies tests that "detect multiple types of cancer before systems develop." (RX2588 (Illumina) (Reps. Sewell, Arrington, Ruiz, and Hudson Introduce Bipartisan Legislation to Remove Barriers to Innovative Multi-Cancer Screening Technology for Medicare Beneficiaries, Dec. 3, 2020, https://sewell.house.gov/media-center/press-releases/reps-sewell-arrington-ruiz-and-hudson-introduce-bipartisan-legislation, last visited Apr. 6, 2022) ("The bipartisan legislation recognizes emerging advances in our nation's fight against cancer by ensuring Medicare coverage for new, innovative tests that detect multiple types of cancer before symptoms develop.")).

Response to Finding No. 815:

Respondents have no specific response.

816. The text of the "Medicare Multi-Cancer Early Detection Screening Coverage Act of 2020" defines "Multi-Cancer Early Detection Screening Tests" as "any of the following tests, approved or cleared by the Food and Drug Administration, furnished to an individual for the purpose of early detection of cancer across many cancer types (as categories in the Annual Report to the Nation on the Status of Cancer issued by the National Cancer Institute): (1) A genomic sequencing blood or blood product test that includes the analysis of cell-free nucleic acids. (2) Such other equivalent tests (which are based on urine or other sample of biological material) as the Secretary determine appropriate." (RX3602 (H.R.1946 - To Amend Title XVIII of the Social Security Act to Provide for Medicare Coverage of Multi-Cancer Early Detection Screening Tests)).

Response to Finding No. 816:

Respondents have no specific response.

817. The "Purpose" section of the "Medicare Multi-Cancer Early Detection Screening Coverage Act of 2020" says that "Several innovative private and academic efforts are engaged in research, including advanced clinical trial to develop multi-cancer early detection blood-based tests. Published data indicate that these tests can screen for many cancers at the same time, including rare cancers, with one example currently able to screen for more than 50 cancers." ((RX3602 (H.R.1946 - To Amend Title XVIII of the Social Security Act to Provide for Medicare Coverage of Multi-Cancer Early Detection Screening Tests)).

Response to Finding No. 817:

Respondents have no specific response except to note that the draft legislation notes that Galleri is able to screen for more than 50 cancer types. (RX3602.)

818. Guardant's Mr. Getty testified at trial that "there are benchmarks that are out there that suggest" the uses for which third-party payers will cover MCED tests. (Getty (Guardant) Tr. 2662-63).

Response to Finding No. 818:

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and, accordingly, should be given no weight. (*See* Resps.' Motion *in limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) The proposed finding is also vague as to what the "benchmarks" and "uses" are "for which third-party payers will cover MCED tests." Further, to the extent that such benchmarks do exist, the proposed finding is further evidence that Dr. Scott Morton's application of the hypothetical monopolist test in support of Complaint Counsel's proposed relevant market was insufficient, as she did not consider said "benchmarks" in performing her analysis and did not attempt to analyze substitution from the perspective of payors, despite acknowledging that payor choices will drive adoption of different screening tests. (PFF ¶ 767.)

819. [redacted] (Strom (Morgan Stanley) Tr. at 3567 (*in camera*)).

Response to Finding No. 819:

Respondents have no specific response except to note [redacted]

820. Cowen—a financial services firm—identified multi-cancer screening tests target at asymptomatic patients as its own market and assessed that it would have approximately a $5 to $50 billion target addressable market in its report on liquid biopsy. (PX2752 (Illumina) at 007 ("The Liquid Biopsy Report: Early Detection of a Huge Opportunity). Cowen's market assessment separately addressed single cancer tests, tests targeting high risk patients, and tests with a non-screening function. (PX2752 (Illumina) ("The Liquid Biopsy Report: Early Detection of a Huge Opportunity").

Response to Finding No. 820:

Respondents have no specific response except to note that the same report notes that: GRAIL has "conducted systematic clinical studies" and that Galleri "has been shown to be capable of identifying >50 types of cancers by scanning methylation patterns"; the only other entity it recognizes as pursuing a multicancer screening test is Thrive. By contrast, the cited report notes that Freenome and Guardant are among the companies in a separate market segment pursuing *single-cancer screening tests to detect colorectal cancer* (PX2022 (Cowen) at 30–31 (emphasis added)), while it lists Singlera in passing under the heading "[s]ome [o]thers" following its summary of the colorectal cancer screening market (PX2022 (Cowen) at 33), and considers Helio in a separate segment for "High Risk Cancer Detection" for its liver cancer screening test. The cited report does not even recognize [redacted] as pursuing early cancer detection at all: it notes [redacted] as a participant in the recurrence monitoring/MRD and "liquid biopsy for biopharma" (*i.e.*, companion diagnostic) segments (PX2022 (Cowen) at 46–

53), and [redacted] in the therapy selection and "liquid biopsy for biopharma" market segments. (PFF ¶¶ 717.1–717.1.3.)

For clarity, Respondents note that Respondents cited a different exhibit that contains the same Cowen report in Respondents' Proposed Findings of Fact ¶ 717.1. (*Compare* PX2022 (Illumina) at 2-59 *with* PX2752 (Illumina) at 2-59.)

821. Investors have also identified an MCED market and noted that Galleri test competes with other MCED test developers. (PX2138 (Illumina) at 008 (JPMorgan Investor Report "Searching for the (Un) Holy Grail: Deal Brings More Dilution than Test Sensitivity . . . Downgrading to Neutral, PT to $280") ("To address concerns around potential cannibalization into ILMN's existing customers that compete with Grail (GH. Freenome, Thrive, etc.)"); PX2138 (Illumina) at 025 (Wolfe Research "Betting The Farm) (recognizing that Guardant Health, Freenome, Exact, and Thrive are all posed to compete with GRAIL)).

Response to Finding No. 821:

The proposed finding is incomplete and misleading. The JPMorgan investor report refers to "the early detection market" and does not mention "multicancer" or "MCED". (PX2138 (Illumina) at 8.) The Wolfe Research report does not mention "multicancer" or "MCED" either; it says that "GRAIL is in the mix with early detection players". (PX2138 (Illumina) at 25.)

D. THE HYPOTHETICAL MONOPOLIST TESTS SHOWS MCED TESTS ARE A RELEVANT PRODUCT MARKET

822. Dr. Scott Morton concluded that the relevant product market is MCED tests. (PX7138 (Scott Morton Trial Dep. at 38)).

Response to Finding No. 822:

The proposed finding is incorrect. Complaint Counsel has the burden to prove the relevant market (RCoL ¶ 11), and has not done so (PFF ¶¶ 679–772). In proposing a relevant product market of "MCED tests" Complaint Counsel failed to conduct any analysis to show that all tests that detect multiple cancers simultaneously through a blood draw should be in a single product market. (PFF ¶ 689.) By defining the market to include tests that cannot be shown to be

substitutes for Galleri or each other, Complaint Counsel's proposed market violates the narrowest market rule. (PFF ¶ 690.1; RCoL ¶ 19.) To the extent Complaint Counsel relies on its proposed findings in CCFF ¶¶ 823–29, Respondents incorporate their responses to those proposed findings herein.

823. [redacted] (PX7138 (Scott Morton Trial Dep. at 40-43); PX6090 (Scott Morton Report) ¶ 149 (*in camera*)).

Response to Finding No. 823:

The proposed finding is incorrect. [redacted] Respondents also note that [redacted] (PFF ¶ 770.)

824. As described more fully in her expert report, Dr. Scott Morton found that "a hypothetical monopolist of all MCED products would likely be able to profitably impose a SSNIP above the MCED price that would prevail if there were multiple MCED rivals or profitably implement a significant reduction in product quality or availability." (PX7138 (Scott Morton Trial Dep. At 40-43); PX6090 (Scott Morton Report) ¶ 149 (*in camera*)).

Response to Finding No. 824:

The proposed finding is incorrect and Respondents incorporate their responses to CCFF ¶¶ 823 and 825–29 herein.

825. [redacted] (PX6090 (Scott Morton Report) ¶ 146 (*in camera*)).

Response to Finding No. 825:

Respondents do not dispute that [redacted] (PFF ¶ 770.) Dr. Scott Morton failed to assess how the possible characteristics of the MCED tests in development might impact the likelihood of switching within her defined market. (PFF ¶ 768.) In addition, Dr. Scott Morton lacks any foundation to opine on the behavior of doctors and patients, as she did not consider any information about the preferences and likely switching behavior of clinicians, patients and payors related to the products she includes and excludes from her proposed MCED market. (PFF ¶ 767.)

826. [redacted] (PX6090 (Scott Morton Report) ¶ 146 (*in camera*)).

Response to Finding No. 826:

Respondents do not dispute that [redacted] (PFF ¶ 770.) Dr. Scott Morton failed to assess how the possible characteristics of the MCED tests in development might impact the likelihood of switching within her defined market. (PFF ¶ 768.) In addition, Dr. Scott Morton lacks any foundation to opine on the behavior of doctors and patients, as she did not consider any information about the preferences and likely switching behavior of clinicians, patients and payors related to the products she includes and excludes from her proposed MCED market. (PFF ¶ 767.)

827. Dr. Scott Morton testified that a quantitative hypothetical monopolist test is not required to define a product market. (PX7138 (Scott Morton Trial Dep. at 42-43)).

Response to Finding No. 827:

Respondents have no specific response except to note that the proposed finding is improper because it consists entirely of a legal conclusion.

828. Respondents' economic expert admits that switching data and customer survey data is not necessary to define a relevant product market. (RX6004 (Katz Trial Dep. 99); *see also* PX0338 at 011-012, (*Horizontal Merger Guidelines* § 4.1.3, dated Aug. 19, 2010) ("Even when the evidence necessary to perform the hypothetical monopolist test quantitatively is not available, the conceptual framework of the test provides a useful methodological tool for gathering and analyzing evidence pertinent to customer substitution and to market definition. The Agencies follow the hypothetical monopolist test to the extent possible given the available evidence, bearing in mind that the ultimate goal of market definition is to help determine whether the merger may substantially lessen competition.")).

Response to Finding No. 828:

The proposed finding is incomplete and misleading to the extent it suggests that Dr. Katz believes that any such analysis was not necessary to conduct market definition analysis here. In fact, Dr. Katz testified that "because we don't have the actual switching behavior to study . . . there's an information gap" and Dr. Scott Morton didn't attempt to fill those information gaps by conducting a survey of "clinicians or payers to understand what they would think about . . . various alternatives and how close they would view those to be substitutes and then try to infer from that what that would mean for their switching behavior." (RX6004 (Katz Trial Dep.) at 19–20.) Nor did she consider any evidence about how "consumers weigh the different characteristics [of putative MCED tests] against each other . . . or what do they do if maybe one test looks better than the other in certain technical respects". (RX6004 (Katz Trial Dep.) at 20–21.)

829. [redacted]

[redacted] (*See* PX6090 (Scott Morton Report) ¶ 139 (*in camera*)).

Response to Finding No. 829:

The proposed finding is incorrect. [redacted]

Dr. Katz explained why Dr. Scott Morton's approach was insufficient. "First, the characteristics of the tests that we're going to end up seeing are uncertain now. I mean, both, if you think about specific tests, it's uncertain because we'll have to see how R&D and other issues, you know, play out by the companies, but also there's, you know, some uncertainty about, given what dimensions of differentiation among tests are going to really matter, which characteristics are going to most drive substitution." (RX6004 (Katz Trial Dep. at 20).)

In addition, relying solely on peculiar characteristics and uses "doesn't answer the question of . . . how [] consumers weigh the different characteristics against each other" or "what do they do if maybe one test looks better than the other in certain technical respects, but it also is more expensive. And just looking at the peculiar characteristics in isolation can't answer that question if . . . you have this other gap which you haven't really been able to collect information on the preferences of [clinicians, patients and payors]." (RX6004 (Katz Trial Dep. at 20-21).)

Further, Dr. Scott Morton applied the hypothetical monopolist test to the wrong set of products and relied on "practical indicia" to distinguish MCED tests from single-cancer screening tests and other blood-based cancer tests like DAC, MRD or Therapy Selection tests.

Dr. Scott Morton's analysis also ignores how the possible characteristics of the MCED tests in development might impact the likelihood of switching within her defined market. (PFF ¶ 768.) Because of this failure, her proposed market would include any test that screens for two or more cancer types, even though that would necessarily group together screening tests that detect distinct cancer types in different populations. (PFF ¶ 689.) As Dr. Katz testified: "suppose we have two tests, one of which covers testicular cancer and prostate cancer . . . and then we have another one that does uterine cancer and ovarian cancer. It's really difficult for me to see how those could be substitutes for one another. I believe they're not. And I think that shows a fundamental defect in [Complaint Counsel's proposed] market." (PFF ¶ 690.)

830. [redacted] (*See* RX3865 (Guerin-Calvert Rebuttal Report) (*in camera*); PX6105 (Katz Rebuttal Report) (*in camera*); RX3870 (Rock Rebuttal Report) (*in camera*); RX3867 (Deverka Rebuttal Report) (*in camera*); RX3864 (Carlton Rebuttal Report) (*in camera*); RX3869 (Cote Rebuttal Report) (*in camera*); PX6097 (Abrams Rebuttal Report) (*in camera*)).

Response to Finding No. 830:

Respondents have no specific response except to note that Complaint Counsel, not Respondents, has the burden to prove the relevant market. (RCoL ¶ 11.) To the extent the proposed finding is intended to suggest that Dr. Scott Morton's market definition analysis went unrebutted, nothing could be further from the truth. Many of Respondents' experts opined on the insufficiency of Dr. Scott Morton's market definition analysis. Dr. Carlton opined that Professor Scott Morton's market was not defined based on any empirical examination of demand. (PFF ¶ 1941.) Drs. Willig and Katz opined that Dr. Scott Morton failed to define the relevant market reliably. (PFF ¶¶ 2009–13, 2044–48.) [redacted]

[redacted]

(PX6097 (Abrams Expert Report) ¶ 47).

IV. THE UNITED STATES IS THE RELEVANT GEOGRAPHIC MARKET

A. THE UNITED STATES HAS UNIQUE REGULATORY REQUIREMENTS FOR MCED TESTS

831. In the United States, the Food and Drug Administration ("FDA") and Centers for Medicare & Medicaid Services ("CMS") (via the Clinical Laboratory Improvement Amendments of 1988 ("CLIA")) regulate MCED tests. (PX0043 (Grail) at 115, 132 (Grail 2020 Form S-1)).

Response to Finding No. 831:

Respondents have no specific response except to note that the College of American Pathologists ("CAP") also regulates laboratories. (PX0043 (Grail) at 43.) Illumina's laboratory that provides human whole-genome sequencing services is CLIA-certified and CAP-accredited. (PX0043 (Grail) at 43); *see also* PFF ¶ 27).

832. Dr. Chudova testified that the U.S. regulatory framework requires that the technology underlying an NGS platform be available for use in the U.S. for Guardant to commercialize its cancer screening test using that NGS platform:

> We have -- so we are working as a lab under two potential regulatory landscapes. We either work as a lab-developed test in -- under the CLIA regulations, or we're working under the FDA approval for a test that we can run in our internal lab. None of these configurations assume that you can -- you can -- you can use a technology that's not available in the U.S., as far as I can tell from regulatory sort of constraints around this.

(PX7045 (Chudova (Guardant) IHT at 52-53)).

Response to Finding No. 832:

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony.

(*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021)).

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76).

833. Dr. Chahine explained at trial that there are "two major options for bringing a diagnostic test to market" in the United States. (Chahine (Helio) Tr. 1027-28). "The first is to go through [the] FDA process … [and] the second way you can launch a product in the United States … is under … CLIA … the Clinical Laboratory Improvement Act [which is] run by a different government agency." (Chahine (Helio) Tr. 1028).

Response to Finding No. 833:

Respondents have no specific response, except to note that the "different government agency" to which Dr. Chahine is referring is the Centers for Medicare and Medicaid Services ("CMS").

834. [redacted] (Rabinowitz (Natera) Tr. 382 (*in camera*)).

Response to Finding No. 834:

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1. Centers for Medicare & Medicaid Services Oversees Laboratory Developed Tests

835. A laboratory-developed test ("LDT") must meet Clinical Laboratory Improvement Amendments ("CLIA") and College of American Pathologists ("CAP") guidelines, which are clinical lab guidelines. (Goswami (Illumina) Tr. 3185-86).

Response to Finding No. 835:

Respondents have no specific response.

836. An MCED test may be sold in the United States as a laboratory-developed test ("LDT") before the test has received Premarket Approval from the FDA if it is developed pursuant to CLIA/CAP guidelines (Goswami (Illumina) Tr. 3222).

Response to Finding No. 836:

Respondents have no specific response.

837. To be offered to U.S. patients, LDTs must be performed in CLIA-certified labs. (Febbo (Illumina) Tr. 4320).

Response to Finding No. 837:

Respondents have no specific response.

838. Grail described CLIA requirements to its investors explaining "CLIA is a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis prevention, or treatment of disease …." (PX0043 (Grail) at 043 (Grail 2020 Form S-1)).

Response to Finding No. 838:

Respondents have no specific response.

839. Grail represented to investors that CLIA certification requires laboratories to "mandate specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, test management, and quality assurance." (PX0043 (Grail) at 043 (Grail 2020 Form S-1)).

Response to Finding No. 839:

Respondents have no specific response.

840. Grail represented to investors that failure of Grail or its partners to comply with CLIA regulations could result in "prevent[ion] from performing our tests or …. disruption[] to our business." (PX0043 (Grail) at 043 (Grail 2020 Form S-1)).

Response to Finding No. 840:

Respondents have no specific response.

841. The Centers for Medicare & Medicaid Services ("CMS") certifies laboratory compliance with CLIA. (Ofman (Grail) Tr. 3317-18).

Response to Finding No. 841:

Respondents have no specific response.

842. Dr. Chahine explained that CLIA evaluates and set standards for laboratory developed tests that ensures the "laboratory quality, robustness, and accuracy of the test." (Chahine (Helio) Tr. 1029).

Response to Finding No. 842:

Respondents have no specific response.

843. Dr. Ofman testified that an LDT is also subject to FDA oversight of the representations that company makes about the LDT test stating a company offering an LDT "still need[s] to follow all the major guidances from the FDA about supportable claims and having evidence to support your claims …." (Ofman (Grail) Tr. 3317-18).

Response to Finding No. 843:

Respondents have no specific response.

2. The FDA Will Classify MCED Tests as Class III Medical Devices Requiring Pre-Market Approval

844. Grail represented to investors that it anticipates that the FDA will classify Galleri as a Class III device and require a PMA approval. (PX0043 (Grail) at 129 (Grail 2020 Form S-1)). Grail represented to investors that generally Class III medical devices require PMA approval by the FDA before they can be marketed. (PX4082 (Grail) at 135 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 844:

Respondents have no specific response.

845. Grail represented to investors that the FDA looks at a product's intended use when classifying, reviewing, and approving a Class III device, and the "FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s)." (PX4082 (Grail) at 135 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 845:

Respondents have no specific response.

846. Grail represented to investors that obtaining PMA approval involves "complete analytical and clinical performance data and also information about the device and its components

regarding, among other things, device design, manufacturing and labeling." (PX4082 (Grail) at 135 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 846:

Respondents have no specific response.

847. Dr. Ofman testified that Grail anticipates the FDA will require MCED tests to obtain Premarket Approval ("PMA") for FDA approval. (Ofman (Grail) Tr. 3319).

Response to Finding No. 847:

Respondents have no specific response.

848. Illumina's Dr. Febbo testified that Illumina anticipates that the FDA will classify MCED tests as Class III (high-risk) medical devices. (Febbo (Illumina) Tr. 4445); PX7099 (Febbo (Illumina) Dep. at 83-84)).

Response to Finding No. 848:

Respondents have no specific response.

849. Dr. Rabinowitz testified that Natera anticipates that the FDA is likely to require a PMA approval for any cancer test for people who are asymptomatic. (Rabinowitz (Natera) Tr. 302-03).

Response to Finding No. 849:

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021)).

850. Dr. Gao testified that based upon a meeting with the FDA, the FDA classifies MCED tests as a Class III high risk device and will require MCED tests to obtain a PMA for FDA approval. (Gao (Singlera) Tr. 2872-73).

Response to Finding No. 850:

Respondents have no specific response, except to note that the proposed finding is based on hearsay testimony, and accordingly, should be given no weight.

B. COMMERCIALIZATION OF AN MCED TEST IN THE UNITED STATES WILL REQUIRE FDA APPROVAL BECAUSE OF U.S. PAYER REQUIREMENTS

1. CMS Will Not Reimburse for an MCED Test Without FDA Approval

851. Illumina's CEO Francis DeSouza testified that FDA approval is necessary for federal CMS coverage. (DeSouza (Illumina) Tr. 2414).

Response to Finding No. 851:

Respondents have no specific response

852. Dr. Ofman testified that "in the U.S. … we don't expect that we'll be able to get Medicare reimbursement without FDA approval. …" (Ofman (Grail) Tr. 3319-20).

Response to Finding No. 852:

Respondents have no specific response

853. Dr. Ofman testified that Grail's "assumption[] and our plan is that get broad Medicare coverage, we will need a PMA approval." (PX7092 (Ofman (Grail) Dep. at 175)).

Response to Finding No. 853:

Respondents have no specific response

854. Dr. Chahine testified that CMS issued guidance "stating that it would require FDA approval for reimbursement under CMS" for early cancer detection. (Chahine (Helio) Tr. 1029).

Response to Finding No. 854:

The proposed finding lacks foundation because it relies on the testimony of a third party without citing any specific statement or guidance from CMS. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021)).

855. Mr. Conroy testified that FDA approval is necessary to obtain CMS payment for Medicare patients. (Conroy (Exact) Tr. 1734).

Response to Finding No. 855:

The proposed finding lacks foundation because it relies on the testimony of a third party without citing any specific statement or guidance from CMS. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021)).

856. [redacted] (Conroy (Exact) Tr. 1560-61) (*in camera*); PX7058 (Conroy (Exact/Thrive) IHT at 87) (*in camera*)).

Response to Finding No. 856:

The proposed finding lacks foundation because it relies on the testimony of a third party without citing any specific statement or guidance from CMS. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021)). The proposed finding also relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine. This testimony should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76).

857. [redacted] (PX4172 (Grail) at 059 (Grail, Board of Directors Meeting, Nov. 21, 2019) (*in camera*)).

Response to Finding No. 857:

Respondents have no specific response.

858. Illumina admits that "it is unlikely that Galleri will obtain Medicare coverage without FDA premarket approval." (PX6060 (Illumina) 023 (Illumina's Responses & Objections to FTC's First Set of Interrogatories).

Response to Finding No. 858:

The proposed finding is incomplete and misleading. Complaint Counsel's interrogatory had asked Respondents to identify all efficiencies Respondents alleged would result from this

Transaction. (PX6060 (Illumina) 021). Subject to and without waiving any of their objections, Respondents responded that, amongst other efficiencies, Illumina would accelerate GRAIL's ability to obtain a single-site PMA, accelerating Medicare coverage. (PX6060 (Illumina) 022–23). Illumina would also leverage its capabilities and relationships to accelerate obtaining coverage for GRAIL's tests from private insurers and adoption of GRAIL's tests by health systems. (PX6060 (Illumina) 023). Respondents incorporate PFF ¶¶ 1131–1135 and their objections to FTC's Interrogatory No. 3.

859. An investor report about liquid biopsy markets states that it "is clear that CMS reimbursement [for asymptomatic cancer screening tests] will require FDA approval . …" PX2752 (Illumina) at 020 ("The Liquid Biopsy Report: Early Detection of a Huge Opportunity.")).

Response to Finding No. 859:

Respondents have no specific response.

860. Medicare coverage will be particularly important for MCED test reimbursement because "many other U.S. payors look to the Medicare policies as a benchmark and model for their own." (PX0043 at 139 (Grail 2020 Form S-1); *see also* PX9090 (Roche) at 019 (Cowen, "The Liquid Biopsy Report: Early Detection of a Huge Opportunity", Sep. 18, 2020) ("[P]ractically speaking, FDA approval is (at a minimum) very important to driving reimbursement – both from CMS . . . and commercial payers")); PX4035 (Grail) at 039 (PiperJaffray, The 2015 Liquid Biopsy Report) (stating that "our payer diligence suggests the community does view FDA approval as an incremental supportive layer for payment" for liquid biopsy tests)).

Response to Finding No. 860:

Respondents have no specific response.

2. FDA Approval Is Also Important to Obtaining Broad Commercial Reimbursement in the United States

861. Grail's CEO agreed in trial testimony that FDA approval will likely be a prerequisite for getting broad-based reimbursement for Galleri. (Bishop (Grail) Tr. 1343-44).

Response to Finding No. 861:

Respondents have no specific response.

862. Dr. Ofman testified that Grail "does not expect that large U.S. payers are going to provide coverage for the test without FDA approval." (Ofman (Grail) Tr. 3319-20).

Response to Finding No. 862:

Respondents have no specific response.

863. Illumina's Dr. Aravanis testified that "FDA approval will help [Grail] with reimbursement and adoption of [Galleri]." (Aravanis Illumina) Tr. 1894).

Response to Finding No. 863:

Respondents have no specific response.

864. [redacted] (PX4004 (Grail) at 001 (Email from R. Currie, Illumina, to Executive Leadership Team, Illumina, Aug. 27, 2020) (*in camera*)).

Response to Finding No. 864:

Respondents have no specific response.

865. Grail represented to investors in its Form S-1 that Medicare coverage through CMS is important not only in its own right, but also because "many other U.S. payors look to the Medicare policies as a benchmark and model for their own." (PX0043 (Grail) at 139 (Grail 2020 Form S-1)).

Response to Finding No. 865:

Respondents have no specific response.

866. Exact Sciences Mr. Conroy testified that obtaining coverage from commercial payers without FDA approval is improbable. (Conroy (Exact) Tr. 1734).

Response to Finding No. 866:

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021)).

867. Mr. Conroy testified [redacted]

[redacted] (PX7058 (Conroy (Exact) IHT at 140-41) (*in camera*)).

Response to Finding No. 867:

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021)).

868. [redacted] (PX7058 (Conroy (Exact) IHT at 88) (*in camera*)).

Response to Finding No. 868:

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021)).

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76).

869. [redacted] (Getty Guardant) Tr. 2530 (*in camera*)).

Response to Finding No. 869:

Respondents have no specific response except to note that Mr. Getty also testified that [redacted] (Getty (Guardant) Tr. 2531.)

870. [redacted] (PX7055 (Otte (Freenome) IHT at 35) (*in camera*)).

Response to Finding No. 870:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76).

3. Obtaining FDA Approval and U.S. Payer Coverage Is Critical for Commercial Adoption of MCEDs in the United States

871. Grail's CEO testified at trial that FDA approval is "very necessary for getting American citizens access to our test." (Bishop (Grail) Tr. 1368).

Response to Finding No. 871:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 883 herein.

872. Grail represented to investors in its Form S-1, "Medicare is the single largest healthcare payor in the United States, and a particularly significant payor for many cancer-related laboratory services given the demographics of the Medicare population, a large portion of which includes elderly individuals." (PX0043 at 139 (Grail 2020 Form S-1)).

Response to Finding No. 872:

Respondents have no specific response.

873. Dr. Ofman testified that "getting PMA approval is going to be critically important for Galleri to get the kind of broad-based coverage and reimbursement that we ultimately want if we really want to make a dent in public health's cancer crisis." (PX7092 (Ofman (Grail) Dep. at 176)).

Response to Finding No. 873:

Respondents have no specific response.

874. [redacted] (PX5024 (Illumina) at 024 (Board of Directors M&A Landscape, Apr. 28, 2020) (*in camera*)).

Response to Finding No. 874:

Respondents have no specific response.

875. Illumina admits that "[t]o make Galleri broadly available in the U.S., it is essential that Galleri obtain coverage from both Medicare and private insurers." (PX6060 (Illumina Responses & Objections to FTC First Set of Interrogatories) at 023 (Interrogatory No. 3)).

Response to Finding No. 875:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 858 herein.

876. An investor report about liquid biopsy markets states that "practically speaking, FDA approval is (at a minimum) very important to driving reimbursement – both from CMS (the biggest payer given many people targeted are Medicare covered) and commercial payers." (PX2752 (Illumina) at 020 ("The Liquid Biopsy Report: Early Detection of a Huge Opportunity", Sept. 18, 2020)).

Response to Finding No. 876:

Respondents have no specific response.

877. [redacted] (RX3864 (Carlton Rebuttal Report) ¶¶ 13, 115 (*in camera*)).

Response to Finding No. 877:

Respondents have no specific response.

C. RESPONDENTS RECOGNIZE THE UNITED STATES AS A DISTINCT MARKET

878. Grail's Form S-1 filing references a United States-specific "early detection market." (PX0043 at 005-007 (Grail 2020 Form S-1)).

Response to Finding No. 878:

The proposed finding is incomplete and misleading. In the cited source, GRAIL uses the term "market" to refer to the customers of early detection cancer tests, not a market of purported MCED tests of which there exists only GRAIL's Galleri test. (*See* PFF ¶¶ 697-712; PX0043 at 005-007 (Grail 2020 Form S-1) ("We believe that we have an unprecedented opportunity to

transform cancer care and establish a market leading position for Galleri. Initially, we plan to target the following key channels in the United States: large, self-insured employers; physician-directed channels, including concierge practices and executive health programs; and progressive, integrated health systems. *These channels represent a significant segment of the overall early detection market of 107 million individuals between the ages of 50-79 in the United States.*") (emphasis added)).

The proposed finding is also incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including [redacted] do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701, 706) and Galleri is the only multi-cancer early detection test testing for anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

879. [redacted] (PX5027 (Illumina) at 015 [redacted] (*in camera*)).

Response to Finding No. 879:

Respondents have no specific response except to note that the cited source also observes that [redacted] (PX5027 (Illumina) at 015

(Project Valor, Aug. 4, 2020) (*in camera*)). Further, the cited source observes that Illumina will [redacted] (PX5027 (Illumina) at 015 (Project Valor, Aug. 4, 2020) (*in camera*)).

880. Illumina admits that requirements to commercialize medical devices in various "international markets" are distinct from the United States and require a "country-by-country process of commercializing" medical devices in previous court filings related to the transaction. (PX6060 (Illumina Responses & Objections to FTC First Set of Interrogatories) at 030-31 (Interrogatory No. 3)).

Response to Finding No. 880:

Respondents have no specific response except to note that the cited source also observes that "Illumina's experience will be invaluable to GRAIL as it undertakes the country-by-country process of commercializing its tests, including with obtaining foreign regulatory authorizations." (PX6060 (Illumina Responses & Objections to FTC First Set of Interrogatories) at 031 (Interrogatory No. 3)). Further, the cited source states that "[t]he breadth and depth of Illumina's international expertise stands in marked contrast to GRAIL", that "international acceleration is likely to further accelerate U.S. adoption and improvement of GRAIL's tests", and that "[a]bsent the Proposed Transaction, Illumina would have less incentive to provide such support for GRAIL's international regulatory and expansion efforts, and GRAIL would not have an incentive or desire to share with Illumina the data that Illumina would need to provide such support." (PX6060 (Illumina Responses & Objections to FTC First Set of Interrogatories) at 031-32 (Interrogatory No. 3)). The cited source therefore also provides support for the proposition that the reunion of Illumina and GRAIL will accelerate the international expansion of Galleri. (*See* PFF ¶¶ 1168–1173.3).

881. [redacted] (*See* PX2553 (Illumina) at 145 (Liquid Biopsy Market Landscape Analysis, Oct. 27, 2016) (*in camera*)).

Response to Finding No. 881:

Respondents have no specific response except to note that the cited source [redacted] (*See* PX2553 (Illumina) at 145 (Liquid Biopsy Market Landscape Analysis, Oct. 27, 2016) (*in camera*)). Accordingly, the cited source therefore also provides support of the breadth and depth of Illumina's international expertise, which will accelerate the international expansion of Galleri. (*See* PFF ¶¶ 1168-1173.3).

882. [redacted] (*See* PX2553 (Illumina) at 148 (Liquid Biopsy Market Landscape Analysis, Oct. 27, 2016) (*in camera*)).

Response to Finding No. 882:

Respondents have no specific response.

883. Grail's CEO, Hans Bishop, testified that "PMA approval with [the] FDA . . . [provides] American citizens access to our test" and that Grail will "have to go through equivalent processes all around the world to get patients outside of the United States access to our technology." (Bishop (Grail) Tr. 1368).

Response to Finding No. 883:

Respondents have no specific response except to note that Mr. Bishop testified that GRAIL intends to seek a PMA approval from the FDA, that seeking a PMA approval is a long and complicated process, and that PMA approval is a prerequisite to getting payor and insurance coverage for Galleri. (PFF ¶ 1587 (Bishop (GRAIL) Tr. 1368, 1370, 1403)). Mr. Bishop also testified that GRAIL will need to obtain regulatory approvals outside of the United States and that Illumina's commercial experience and relationships around the world will help GRAIL reach those customers faster. (PFF ¶ 1593 (Bishop (GRAIL) Tr. 1368, 1372, 1406–07). Respondents also note that Mr. Bishop testified that Illumina's acquisition of GRAIL will result

in numerous efficiencies including accelerating market access to Galleri (Bishop (GRAIL) Tr. 1368–72, 1403).

884. [redacted] (PX6090 (Scott Morton Report) ¶ 150 (*in camera*)).

Response to Finding No. 884:

The proposed finding is inaccurate and misleading because Dr. Scott Morton did not conduct a SSNIP analysis based on quantitative purchase data to identify the relevant geographic or product market. [redacted]

885. Respondent's economic expert, Dr. Carlton, does not dispute Dr. Scott Morton's opinion that the United States is the relevant geographic market to analyze the proposed transaction. (PX7134 (Carlton Dep. at 112-114)).

Response to Finding No. 885:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 884 herein.

V. ILLUMINA NGS IS A NECESSARY INPUT TO MCED TESTS

A. NEXT GENERATION SEQUENCING OVERVIEW

1. Next Generation Sequencing Determines the Order of Nucleotides in DNA Molecules

886. Next-generation sequencing ("NGS") is a method of DNA sequencing, the process of determining the order of nucleotides (A, C, G, or T) in a DNA molecule. (RX3333 at 007 (Illumina 2020 Form 10-K)).

Response to Finding No. 886:

Complaint Counsel did not present the exhibit RX3333 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (Resps. Exhibit Index at 160), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

Respondents note that the cited source also states that NGS sequencing platforms are used only for DNA sequencing but for many other purposes, including performing whole-genome, de novo, exome and RNA sequencing, and targeted resequencing of specific gene regions and genes. (RX3333 (Illumina 2020 Form 10-K) at 007.)

887. Illumina's website summarizes the NGS process: "The basic next-generation sequencing process involves fragmenting DNA/RNA into multiple pieces, adding adapters, sequencing the libraries, and reassembling them to form a genomic sequence. In principle, the concept is similar to capillary electrophoresis. The critical difference is that NGS sequences millions of fragments in a massively parallel fashion, improving speed and accuracy while reducing the cost of sequencing." (PX0113 at 002 (A Beginner's Guide to NGS)).

Response to Finding No. 887:

Complaint Counsel did not present the exhibit PX0113 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 2), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

Respondents note that the cited source also discloses that "[t]he cost of NGS has declined dramatically in recent years". (PX0113 (A Beginner's Guide to NGS) at 003.)

888. "The way [DNA sequencing] works at a high level is you prepare the DNA," and perform library preparations "where you take the DNA that you've extracted from the sample" and prepare it. (Rabinowitz (Natera) Tr. 304, 307-08).

Response to Finding No. 888:

Respondents have no specific response except to note that even test developers that are using the Illumina platform for sequencing do not use Illumina technology for library preparation. (Berry (Illumina) Tr. 815-16 (stating that the library preparation step "is very unique and specific to the particular test provider's sort of approach of methodology" and that there are "hundreds and hundreds of library preparation methods" and "potentially hundreds of providers of library preparation technology or kits").)

889. "[O]nce the DNA is hybridized onto the flow cell, a process is then undertaken called sequencing by synthesis, where you will add a particular nucleotide to the reaction, and the DNA that's attached onto the flow cell will be built up next to a matching fragment of DNA where the nucleotide that is added matches the nucleotide that is on that fragment that is attached to the substrate." (Rabinowitz (Natera) Tr. 307).

Response to Finding No. 889:

The proposed finding is inaccurate and misleading to the extent it suggests that all types of DNA sequencing require sequencing-by-synthesis, which is practiced by Illumina, BGI, Thermo Fisher, [redacted], Singular, Element and Omniome. (RX3869 (Cote Expert Report) ¶¶ 272, 281, 286, 301, [redacted], 314, 318; PFF ¶¶ 575, 578.1, 588, 605, [redacted], 632, 639, 641.) However, Oxford Nanopore's NGS platforms sequence DNA by measuring the minute charge in electrical conductance across biological nanopores. (PFF ¶ 598; RX3538 (ONT); RX3166 (Deamer et al., 2016).) [redacted]

[redacted]

890. The DNA is prepared for sequencing by attaching sequencing adapters onto the ends of the DNA fragments to allow the DNA to work with a particular sequencer. (Rabinowitz (Natera) Tr. 307-08).

Response to Finding No. 890:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 888 herein.

891. "Sequencing is a way of taking many fragments of DNA and telling you exactly what those fragments are made of, in other words, what nucleotides, A, C, T, or G, go into those fragments." (Rabinowitz (Natera) Tr. 304).

Response to Finding No. 891:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 886 and 888 herein.

892. NGS allowed sequencers to complete a sequencing project that would have cost billions of dollars and take over a decade to complete without NGS in a single day for under a thousand dollars. (*See* PX0124 at 006-007 (Jon Gertner, *New York Times*, "Genome Sequencing and COVID-19 – How Scientists Are Tracking the Virus," Mar. 25, 2021)).

Response to Finding No. 892:

Respondents have no specific response except note that the cited reference confirms that several of Illumina's NGS competitors, including BGI, have indicated that they will soon achieve a $100 genome; Illumina achieved the $1,000 genome in 2014, Illumina NovaSeq 6000 could sequence a whole human genome for $600 and the path to a $100 genome would not entail a breakthrough, just incremental technical improvements. (PX0124 (Jon Gertner, New York Times, "Genome Sequencing and COVID-19 – How Scientists Are Tracking the Virus," Mar. 25, 2021) at 006–007.)

2. Short-Read Versus Long-Read Sequencing

893. The two categories of NGS platforms are (1) short read and (2) long read. (PX8399 (Henry (PacBio) Decl. ¶ 3)).

Response to Finding No. 893:

The proposed finding is inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that all traditional "long-read" platforms have the same capabilities. Historically, platforms using sequencing-by-synthesis technology like Illumina, BGI and Thermo Fisher, were limited in the length of nucleotide fragments that they could read (*see*, *e.g.*, RX3869 (Cote Expert Report) ¶¶ 277, 282, 287; PFF ¶¶ 575, 579, 590), which made such traditionally "short-read" platforms better suited to sequencing for certain applications. By contrast, platforms using other sequencing technologies, such as nanopore technology, could read much longer fragments and were referred to as "long-read" platforms. (*See*, *e.g.*, RX3869 (Cote Expert Report) ¶ 294; PFF ¶ 599.)

For example, technology has been developed to conjoin (concatenate) short fragments of DNA into very, very long strands of DNA, allowing for efficient, high throughput sequencing of cell-free DNA using Oxford Nanopore's sequencers. (Cote Tr. 3754–56.) [redacted] Pacific Biosciences, a provider of traditional "long-read" platform, acquired Omniome, a developer of "short-read", sequencing-by-binding sequencers, in 2021 to specifically target the cancer screening market, as well as other oncology applications. (PFF ¶¶ 639–641 (RX3533 (Omniome); RX3947 (Clinical OMICs) at 1–3.)

Respondents incorporate their responses to CCFF ¶ 971 herein. Respondents also note that Complaint Counsel chose not to discuss PX8399 at trial, or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

894. [redacted] (PX7045 (Chudova (Guardant) IHT at 44-47) (*in camera*); PX8399 (Henry (PacBio) Decl. ¶¶ 3-4)).

Response to Finding No. 894:

The proposed finding is inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that all so-called "long-read" platforms have the same capabilities. Respondents incorporate their responses to CCFF ¶ 893 herein.

The proposed finding relies in part on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

To the extent that the proposed finding relies on testimony from Dr. Chudova, the proposed finding is also based in part on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies in part on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents also note that the cited testimony states that [redacted] (PX7045 (Chudova (Guardant) IHT at 44–47.)

Respondents also note that Complaint Counsel chose not to discuss PX8399 at trial, or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

895. [redacted] (PX8399 (Henry (PacBio) Decl. ¶¶ 3-5) (*in camera*); PX7045 (Chudova (Guardant) IHT at 83-84) (*in camera*)). Illumina's NGS platforms are considered short-read sequencers. (Berry (Illumina) Tr. 823-24).

Response to Finding No. 895:

Respondents have no specific response except to note that many NGS platforms on the market and in development offer short-read NGS, including Illumina, Thermo Fisher, BGI, Singular, [redacted] Element and Omniome. (*See*, *e.g.*, RX3869 (Cote Expert Report) ¶¶ 277, 282, 287, 303, [redacted] 319; PFF ¶¶ 575, 579, 590, 609–609.6, [redacted], 642–642.2.) Respondents incorporate their responses to CCFF ¶¶ 888 and 893–894 herein.

Respondents also note that technology has been developed to conjoin (concatenate) short fragments of DNA into very, very long strands of DNA, allowing for efficient, high throughput sequencing of cell-free DNA using Oxford Nanopore's sequencers. (Cote Tr. 3754–56.)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Respondents also note that Complaint Counsel chose not to discuss PX8399 at trial, or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

896. [redacted] (*See* PX7042 (Gao (Singlera) IHT at 65); PX7043 (Gunn (Roche) IHT at 83-84) (*in camera*); PX7045 (Chudova (Guardant) IHT at 44-45); PX7046 (George (Invitae) IHT at 77) (*in camera*)).

Response to Finding No. 896:

The proposed finding is inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore and PacBio sequencing technologies have the same capabilities. Respondents incorporate their responses to CCFF ¶¶ 893–895, 904 and 970 herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

To the extent that the proposed finding relies on testimony from Dr. Chudova, Dr. Gao and Mr. George, the proposed finding is also based in part on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies in part on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

897. [redacted] (PX7043 (Gunn (Roche) IHT at 72) (*in camera*)).

Response to Finding No. 897:

The proposed finding is incomplete and misleading because [redacted] (*See*, *e.g.*, RX3869 (Cote Expert Report) ¶ 294.)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

898. [redacted] (PX7055 (Otte (Freenome) IHT at 64-65) (*in camera*)).

Response to Finding No. 898:

The proposed finding is inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore

and PacBio sequencing technologies have the same capabilities. In particular, technology has been developed to conjoin (concatenate) short fragments of DNA into very, very long strands of DNA, allowing for efficient, high throughput sequencing of cell-free DNA using Oxford Nanopore's sequencers. (Cote Tr. 3754–56.)

Respondents also note that the cited testimony states that [redacted] (PX7055 (Otte (Freenome) IHT at 64–66.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding also relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

899. Former Illumina CFO/COO and current PacBio CEO Christian Henry declared that short-read sequencing provides high read count and low cost per read relative to long-read sequencing. (*See, e.g.*, PX8399 (Henry (PacBio) Decl. ¶¶ 3-4)).

Response to Finding No. 899:

The proposed finding is inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore and PacBio sequencing technologies have the same capabilities. Oxford Nanopore's PromethION sequencer has sequencing costs of as low as $2.55 per gigabase, which is lower

than the per gigabase sequencing costs using Illumina's NovaSeq 6000. (*See* PFF ¶¶ 603–603.3.)

Furthermore, the evidence shows that [redacted] (PFF ¶ 884 (RX6000 (Carlton Trial Dep.) at 30–31).)

Respondents also incorporate their responses to CCFF ¶¶ 893, 898, and 904 herein.

Respondents also note that Complaint Counsel chose not to discuss PX8399 at trial, or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

900. Former Illumina CFO/COO and current PacBio CEO Christian Henry declared, "[b]ecause [ctDNA fragments] are typically fewer than 350 base pairs long, Illumina's short-read NGS platforms are capable of analyzing many ctDNA fragments in their entirety." (PX8399 (Henry (PacBio) Decl. ¶ 5)).

Response to Finding No. 900:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 893 herein.

901. [redacted] (PX8399 (Henry (PacBio) Decl. ¶¶ 5, 9–11 (*in camera*)).

Response to Finding No. 901:

The proposed finding is inaccurate. PacBio, along with recently-acquired Omniome, has publicly stated that they would specifically target the cancer screening market, as well as other oncology applications, including a general interest in companies developing blood-based early cancer screening tests. (RX3947 (Clinical OMICs) at 3; PX7096 (Song (Omniome) Dep. at 59–63, 66; [redacted]

[redacted] (PX7096 (Song (Omniome) Dep. at 82, 100–01); [redacted] Ultimately, Omniome has stated that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72)**;** [redacted] In addition, the proposed finding is contradicted by the testimony of Complaint Counsel's own witnesses. For example, [redacted]

The proposed finding is also inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore and PacBio sequencing technologies have the same capabilities. Contrary to Complaint Counsel's unproven contention, Oxford Nanopore's sequencing technology is suitable for multi-cancer screening and has been used by test developers for that purpose. (*See* PFF ¶¶ 598–604.1.) Oxford Nanopore "believe[s] that nanopore-based sequencing can provide rich biological insights that include the ability to directly characterise variants that are relevant in cancer, including methylation, structural variants, repeats and phasing. . . . Shorter fragments can be sequenced, in the case of circulating tumour DNA, or ultra-long fragments for other cancer related analyses." (RX3939 (Oxford Nanopore Registration Document), at 41, 56, 65–66.) Respondents also incorporate their responses to CCFF ¶ 904 herein.

Respondents also note that Complaint Counsel chose not to discuss PX8399 at trial, or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

902. [redacted] (*See* PX8399 (Henry (PacBio) Decl. ¶ 4; PX7045 (Chudova (Guardant) IHT at 44-47) (*in camera*)).

Response to Finding No. 902:

The proposed finding is irrelevant and it is also misleading to the extent that it suggests that a particular number of read counts is required for particular applications, such as MCED test development. The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893 and 904, which Respondents incorporate herein.

The proposed finding also relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

To the extent that the proposed finding relies on testimony from Dr. Chudova, the proposed finding is also based in part on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies in part on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents also note that Complaint Counsel chose not to discuss PX8399 at trial, or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

903. [redacted] (*See, e.g.*, PX7045 (Chudova (Guardant) IHT at 45-48) (*in camera*)).

Response to Finding No. 903:

The proposed finding is irrelevant and it is also misleading to the extent that it suggests that the capability of long-read sequencers to read [redacted]

renders them unsuitable for use in MCED test development. The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 902, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

904. MCED developers do not view the long-read NGS platforms of PacBio or Oxford Nanopore as viable alternatives to Illumina's short-read NGS platform due to their lower read counts, lower accuracy, and higher costs. (*See infra* Section V.E.3. ("Extremely Inefficient" Long-Read NGS Is Not an Option for MCED).

Response to Finding No. 904:

The proposed finding is inaccurate, incomplete, and misleading. Recent improvements have made Oxford Nanopore long-read sequencing more suitable for multi-cancer screening. (PFF ¶¶ 600–600.5.) Researchers have demonstrated that Oxford Nanopore sequencers are capable of short-read sequencing. (PFF ¶¶ 601–601.4 (RX3446 (Martignano et al., 2021); RX3737 (Wei & Williams 2016); RX3744 (Wilson et al., 2019); RX3441 (Marcozzi A et al., 2020)).) Technology has been developed to conjoin (concatenate) short fragments of DNA into very, very long strands of DNA, allowing for efficient, high throughput sequencing of cell-free DNA using Oxford Nanopore's sequencers. (Cote Tr. 3754–56.) Oxford Nanopore "believe[s] that nanopore-based sequencing can provide rich biological insights that include the ability to directly characterise variants that are relevant in cancer, including methylation, structural

variants, repeats and phasing. . . . Shorter fragments can be sequenced, in the case of circulating tumour DNA, or ultra-long fragments for other cancer related analyses." (RX3939 (Oxford Nanopore Registration Document), at 41, 56, 65–66.) Oxford Nanopore has also announced its intent to support the liquid biopsy market. (PFF ¶ 602 (RX3470 (Nanopore); RX3521 (NCM) at 50–52; RX3167 (Nanopore); RX3520 (NCM) at 6, 9–10)).)

Oxford Nanopore sequencers have a per-gigabase cost comparable to Illumina's NGS sequencers. (PFF ¶¶ 603.1-603.3.) Methods have been developed to obtain consensus sequences from homogenous DNA samples by genome assembly, resulting in accuracies of more than 99.999% (Q50). (RX3541 (ONT) at 1; RX3535 (ONT); RX3536 (ONT).) Oxford Nanopore has also announced that its single-molecule modal accuracy is now >99.3% (Q20) using its "Q20+" chemistry, and also developed a new approach termed "Duplex" sequencing, which enables the sequencing of both template and complementary strands and accuracy "trending towards 99.9% (Q30)". (RX3541 (ONT) at 1; RX3535 (ONT) at 1.)

[redacted]

Dr. Cote also explained that Oxford Nanopore's platform "is capable of sequencing up to 10 Terabase pairs ('Tb') per run and may be used to detect methylation and other epigenomic

changes directly. While Oxford Nanopore historically faced lower accuracy, the latest improvements in chemistry and bioinformatics enable the platform's accuracy to the Q50 range. This platform is already being used by developers of potential cancer screening tests." (RX3869 (Cote Expert Report) ¶ 19.)

In addition, because it does not require PCR amplification, Oxford Nanopore's long-read sequencing eliminates amplification bias while preserving base modifications, making it useful for epigenomic analysis such as methylation profiling. (PFF ¶ 600.1 (RX3439 (Mantere 2019) at 2; *see also* RX3236 (Folkard).) Oxford Nanopore's nanopore sequencing technology is capable of directly detecting methylation and other epigenomic markers on DNA or RNA, without the bisulfite conversion step used by other sequencing technologies (*e.g.*, for Illumina's sequencing technology) that can cause sample degradation, and that can complicate data analysis. (PFF ¶ 600.2 (RX3869 (Cote Expert Report) ¶ 295).) Using Oxford Nanopore's nanopore sequencing, researchers have directly identified epigenomic modifications at nucleotide resolution, including DNA methylation, with detection of other epigenomic modifications possible through training base-calling algorithms. (PFF ¶ 600.2 (RX3539 (ONT)).)

Furthermore, Respondents also note that PacBio, with its recently-acquired Omniome, has publicly stated that they would specifically target the cancer screening market, as well as other oncology applications, including a general interest in companies developing blood-based early cancer screening tests. (RX3947 (Clinical OMICs) at 3; PX7096 (Song (Omniome) Dep. at 59–63, 66; [redacted] In addition, the proposed finding is contradicted by the testimony of Complaint Counsel's own witnesses. For example, [redacted]

Respondents also incorporate their responses to CCFF ¶¶ 893, 898–899, 901, 913, 970 and 1346 herein. To the extent Complaint Counsel relies on its Proposed Findings in Section V.E.3 (CCFF ¶¶ 1346–98), Respondents incorporate their responses to those Proposed Findings herein.

905. [redacted] (Chudova (Guardant) Tr. 1221-22) (*in camera*).

Response to Finding No. 905:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 904, which Respondents incorporate herein. Further, contrary to Complaint Counsel's unproven contention, [redacted]

(Chudova (Guardant) Tr. 1221–23.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

906. [redacted] (PX7045 (Chudova (Guardant) IHT at 47-48) (*in camera*)).

Response to Finding No. 906:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 904, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

907. Christian Henry, President and CEO of PacBio, a provider of long-read sequencing platforms, declared that "[g]iven the relatively short length of many ctDNA fragments, long-read sequencing does not often present the same technical benefits over short-read sequencing as it does for other sequencing applications" and stated that [redacted] (PX8399 (Henry (PacBio) Decl. ¶ 5) (*in camera*)).

Response to Finding No. 907:

The proposed finding relies on hearsay and is incomplete and misleading. In July 2021, Pacific Biosciences of California ("PacBio") announced it had acquired Omniome for $800M. (RX3947 (Clinical OMICs).) PacBio stated that it believes Omniome's data accuracy should help the combined company target oncology applications like cancer screening. RX3947 (Clinical OMICs) at 3.) Omniome has stated that, at launch, its NGS sequencer will have accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. PX7096 (Song (Omniome) Dep. at 43, 58); [redacted] RX3869 (Cote Expert Report) ¶ 319.)

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 904, which Respondents incorporate herein.

In addition, the proposed finding is contradicted by the testimony of Complaint Counsel's own witnesses. For example, [redacted]

[redacted]

Respondents also note that Complaint Counsel chose not to discuss PX8399 at trial, or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

908. Dr. Vogelstein testified that long-read sequencing technologies "are not applicable to the analysis of plasma DNA," and he elaborated "the reason is simple to understand: Plasma DNA is not long. Plasma DNA, the average size in a normal individual is 167 base pairs. And in cancers, it's a bit shorter." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 73-74)).

Response to Finding No. 908:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 904, which Respondents incorporate herein.

909. [redacted] (PX7045 (Chudova (Guardant) IHT at 44-47, 48-49) (*in camera*); *see* PX7042 (Gao (Singlera) IHT at 65) (Long-read sequencing would "cost tens of thousands [of] dollar[s] to do the same job" as a short-read sequencer, so long-read sequencers "are not a viable option for screening test[s].")).

Response to Finding No. 909:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 904, and 927, which Respondents incorporate herein.

The proposed finding also relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony

and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

910. Illumina CEO, Francis deSouza, explained in an investor call that in looking at circulating tumor DNA fragments, "the ability to do very long-read doesn't offer any incremental value and certainly isn't worth paying a significant premium in terms of the cost per base." (PX2544 (Illumina) at 027 (Email from T. Peterson, JP Morgan, to F. deSouza, Illumina, attaching "JP Morgan Life Sciences CEO Conference Call Series" transcript, Sept. 5, 2019)).

Response to Finding No. 910:

The proposed finding is incomplete and misleading. The proposed finding relates to irrelevant subject matter because the facts that "the ability to do very long-read doesn't offer any incremental value" over Illumina's short-read sequencers and that it "isn't worth paying a significant premium in terms of the cost per base" do not mean that Oxford Nanopore's long-read sequencers may not be used for some of the same applications as Illumina's short-read sequencers, including MCED test development.

Oxford Nanopore's PromethION sequencer has sequencing costs of as low as $2.55 per gigabase, while [redacted] (*See* PFF ¶¶ 577.4, 598–604.1.) Respondents also incorporate their responses to CCFF ¶ 904 herein.

911. Dr. Felton does not view long-read NGS platforms such as PacBio or Oxford Nanopore as competitors for oncology applications because the throughput of long-read NGS sequencing is inadequate to meet the needs of oncology testing. (Felton (Thermo Fisher) Tr. 1997-99).

Response to Finding No. 911:

The proposed finding is inaccurate, incomplete and misleading. Oxford Nanopore's PromethION has total throughput per run of up to 10 Tb, much higher than the up to 50 Gb per run generated by Thermo Fisher's Ion GeneStudio S5. (*See* PFF ¶¶ 579, 598–604.1.) Dr. Felton

did not consider the new technology of using concatenation to read cfDNA fragments using nanopore sequencing. (Felton (Thermo Fisher) Tr. 1996–97; Cote Tr. 3754–56.) Respondents also incorporate their responses to CCFF ¶ 904 herein.

912. Illumina CEO, Francis deSouza, explained to investors that short-read NGS platforms are much more suitable for detecting ctDNA fragments than long-read platforms:

> The way we see it is that there are applications that are very well suited for long-read technology, that frankly short-read technology don't [sic] address and vice versa it's true as well. But there are markets, our core markets where short-read technologies work exceptionally well and long-read don't offer any additional values. So let me give you some specifics. If you look at some of our core markets, for example, in NIPT the fragments we're looking at are 150-ish base pairs. So somewhere between 130 base pairs and maybe up to 200 base pairs long. And so the ability to sequence fragments that are a million base pairs long or a hundred thousand base pairs long is frankly irrelevant, because the fragments are nowhere near that long. And so what customers are looking for is a high-volume sequencer that's able to cost effectively and accurately read those short fragments. That's true in circulating tumor DNA fragments in the oncology space as well. And so if you look at the number of our core markets, the ability to do very long-read doesn't offer any incremental value and certainly isn't worth paying a significant premium in terms of the cost per base.

(PX2544 (Illumina) at 026-027 (Email from T. Peterson, JP Morgan, to F. deSouza, Illumina, attaching "JP Morgan Life Sciences CEO Conference Call Series" transcript, Sept. 5, 2019)).

Response to Finding No. 912:

The proposed finding is incomplete and misleading. Although the cited source is from September 2019, the proposed finding appears to suggest that, even today, more than three years later, that only traditional short-read platforms like those marketed and in development by Illumina, BGI, Thermo Fisher, Singular, Element, [redacted] and Omniome are suitable for sequencing circulating tumor DNA fragments. To the contrary, however, platforms such as Oxford Nanopore have progressed substantially since 2019. (*See*, *e.g.*, PFF ¶¶ 601–601.4 (RX3446 (Martignano et al., 2021); RX3737 (Wei & Williams 2016); RX3744 (Wilson et al., 2019); RX3441 (Marcozzi A et al., 2020)).) In particular, technology has been developed to

conjoin (concatenate) short fragments of DNA into very, very long strands of DNA, allowing for efficient, high throughput sequencing of cell-free DNA on Oxford Nanopore's sequencers. (Cote Tr. 3754–56.) Respondents incorporate their responses to CCFF ¶¶ 893 and 904 herein.

913. Dr. Vogelstein testified that long-read sequencing is not suitable for analyzing plasma DNA molecules because "the error rates of long-read sequencers are much too high to effectively analyze the molecules and plasma for [ ] early cancer detection with the number of artifactual mutations outnumbering the expected number of real mutations by many fold." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 65-66)).

Response to Finding No. 913:

The proposed finding is incomplete and misleading. Contrary to Complaint Counsel's unproven contention, Oxford Nanopore's sequencing technology is suitable for multi-cancer screening and has been used by test developers for that purpose. (*See* PFF ¶¶ 598–604.1.) Methods have been developed to obtain consensus sequences from homogenous DNA samples by genome assembly, resulting in accuracies of more than 99.999% (Q50). (RX3541 (ONT) at 1; RX3535 (ONT); RX3536 (ONT).) Oxford Nanopore has also announced that its single-molecule modal accuracy is now >99.3% (Q20) using its "Q20+" chemistry, and also developed a new approach termed "Duplex" sequencing, which enables the sequencing of both template and complementary strands and accuracy "trending towards 99.9% (Q30)". (RX3541 (ONT) at 1; RX3535 (ONT) at 1; *see also* PFF ¶¶ 604–604.1.) Respondents incorporate their responses to CCFF ¶ 904 herein.

914. Dr. Vogelstein testified that "[l]ong-read sequencers are [ ] unsuited for early detection cfDNA biopsy testing" because "the throughput of long-read sequencers are much lower than the throughput of short-read sequencers." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 65-66)).

Response to Finding No. 914:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 904, which Respondents incorporate herein.

B. MCED PRESENTS ENORMOUS SCIENTIFIC AND TECHNICAL CHALLENGES

915. The presence of a cancer signal in an individual's blood at an early stage is "very subtle." (PX7042 (Gao (Singlera) IHT at 39-40)).

Response to Finding No. 915:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

916. [redacted] (PX4032 (Grail) at 006 ("A Revolution in Early Cancer Detection," Feb. 10, 2020) (*in camera*)).

Response to Finding No. 916:

Complaint Counsel did not present the exhibit PX4032 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 35), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

Respondents note that the cited reference further explains that [redacted] (PX4032 (GRAIL) ("A Revolution in Early Cancer Detection," Feb. 10, 2020) at 006.)

917. [redacted] (PX2013 (Illumina) at 009 ("Cancer Screening," Apr. 28, 2020) (*in camera*)).

Response to Finding No. 917:

Complaint Counsel did not present the exhibit PX2013 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 5), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

Respondents note that the cited reference further notes that [redacted]

(PX2013 (Illumina) ("Cancer Screening," Apr. 28, 2020) at 009 (emphasis original).)

918. Thrive's Dr. Lengauer analogized finding cancer cells in a person's blood as looking for the "proverbial needle in the haystack . . . ." (Lengauer (Third Rock Ventures) Tr. 163).

Response to Finding No. 918:

The proposed finding is inaccurate, incomplete and misleading. Dr. Lengauer's testimony was regarding finding "cancer cell DNA in a blood sample", not "finding cancer cells in a person's blood" as Complaint Counsel proposed. (Lengauer (Exact/Thrive) Tr. 163.)

919. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 41-42) (*in camera*)).

Response to Finding No. 919:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

920. MCED tests require the ability to detect one molecule of DNA in ten milliliters of blood. (Lengauer (Third Rock Ventures) Tr. 163).

Response to Finding No. 920:

The proposed finding is not supported by the cited evidence. In the cited testimony, Dr. Lengauer merely commented on the ability for current technologies to "detect one molecule of DNA in ten milliliter of blood", which "becomes stochastic, because the ten next milliliters might not contain any cancer molecules." (Lengauer (Exact/Thrive) Tr. 162–63.) Dr. Lengauer did not testify that only NGS can detect one molecule of DNA in ten milliliters of blood or what specific techniques are so sensitive that can detect one molecule of DNA in ten milliliters of blood. (Lengauer (Exact/Thrive) Tr. 162–63.) For example, PCR is highly sensitive and

requires only minimal amount of sample for detection and amplification of specific sequences. (*See* PFF ¶¶ 158–162.) Respondents also incorporate their responses to CCFF ¶ 345 herein.

921. [redacted]
(PX7077 (Chahine (Helio) Dep. at 23) (*in camera*)).

Response to Finding No. 921:

The proposed finding is inaccurate, incomplete and misleading. Mr. Chahine's testimony was regarding [redacted]

(PX7077 (Chahine (Helio) Dep. at 23.)

922. [redacted]
(PX7045 (Chudova (Guardant) IHT at 53) (*in camera*)).

Response to Finding No. 922:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

923. [redacted]
(PX7045 (Chudova (Guardant) IHT at 30-31) (*in camera*)).

Response to Finding No. 923:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

924. Dr. Vogelstein testified that Illumina's NGS sequencers allow his lab to "evaluate the majority of DNA template molecules in a small amount of plasma," which is "critical because there are only a small, very small, number of molecules in plasma that come from [a] tumor" including as "little as 1 in 10,000 molecules or 1 in 100,000 molecules." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 58)).

Response to Finding No. 924:

Respondents have no specific response except note that Dr. Vogelstein did not testify that only Illumina's NGS technology can detect one molecule of DNA in 10,000 molecules or 100,000 molecules or what specific techniques are so sensitive. (PX7101 (Vogelstein (Johns Hopkins University) Dep.) at 58.) For example, PCR is highly sensitive and requires only minimal amount of sample for detection and amplification of specific sequences. (*See* PFF ¶¶ 158–162.)

C. MCED TESTS REQUIRE HIGH-THROUGHPUT, HIGHLY ACCURATE, LOW-COST NGS PLATFORMS

925. [redacted] (PX7121 (Otte (Freenome) Dep. at 48-50) (*in camera*) [redacted].

Response to Finding No. 925:

The proposed finding is vague and ambiguous. Mr. Otte fails to define any particular threshold for [redacted] Mr. Otte's former company, Freenome, has published data only relating to a single cancer, colorectal, and has commenced additional clinical trials only relating to colorectal cancer screening. (RX3869 (Cote Expert Report) ¶ 192; [redacted] Mr. Otte testified that Freenome is developing a "multiomics cancer screening assay" and is currently "in the process of assessing

the clinical performance of the CRC [*i.e.*, colorectal] portion of that test." (PX7121 (Otte (Freenome) Dep. at 16).) As such, this proposed finding is entitled to no weight.

Respondents also incorporate their responses to CCFF ¶¶ 893, 904, 928 and 1293 herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

926. Deep sequencing drives the performance of cancer screening tests because it "[i]mproves signal-to-noise, making small amounts of ctDNA detectable" and it "[c]over[s] more genes and mutations" which drive sensitivity and specificity. (PX2005 (Illumina) at 006-007 (ScreenCo – Early Cancer Detection on a Global Scale)).

Response to Finding No. 926:

The proposed finding is incomplete and misleading. PX2005 is an Illumina presentation dated 2015. It does not discuss MCED tests generally, but rather discusses GRAIL/ "ScreenCo" as a new venture. (PX2005 (Illumina) at 004–05, 009 (ScreenCo – Early Cancer Detection on a Global Scale Presentation, 2015).)

The proposed finding also appears to suggest that MCED testing today requires "deep sequencing", which is wrong. For example, GRAIL's Galleri test does not use "deep sequencing", but relies on targeted methylation for cancer signal detection and localization. (*See*, *e.g.*, PFF ¶¶ 56, 345, 384, 1289.)

Respondents also note that Complaint Counsel chose not to discuss PX2005 at trial (CC Exhibit Index at 4), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

927. [redacted]

[redacted] (Chudova (Guardant) Tr. 1208-09) (*in camera*).

Response to Finding No. 927:

The proposed finding is inaccurate, incomplete and misleading to the extent it suggests that only Illumina's NovaSeq instrument is suitable for supporting Guardant's putative MCED test. [redacted] Dr. Chudova also stated that Guardant could use alternative sequencing platforms for its LUNAR-2 screening test in development that meet the throughput, error, time, and sequencing cost requirements. (PX7045 (Chudova (Guardant) IHT at 44–47.) [redacted]; RX3869 (Cote Expert Report) ¶ 287; [redacted]**.)** BGI also recently won a jury verdict that held three of Illumina's patents to be invalid meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022). BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.) Mr. Getty also admitted that Thermo Fisher Scientific Inc., and other companies developing next-generation sequencing platforms also provide NGS platforms that could be used for liquid biopsy testing. (Getty (Guardant) Tr. 2642.) Respondents also incorporate their responses to CCFF ¶¶ 927, 1115 and 1118 herein.

The proposed finding is also incomplete and misleading insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future.

Respondents further note that [redacted]

Accordingly, there is no indication based on Guardant's work to date that [redacted] PFF ¶ 475 [redacted] RX3869 (Cote Expert Report) ¶ 202).)

[redacted]

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents further incorporate their responses to CCFF ¶¶ 426–438 and 2257–2352 herein.

928. Natera's Fesko testified that [redacted] (PX7111 (Fesko (Natera) Dep. at 50-52) (*in camera*)).

Response to Finding No. 928:

The proposed finding is inaccurate, incomplete and misleading with respect to the statement that [redacted] Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.)

For example, Natera and BGI Genomics formed a partnership to commercialize Natera's Signatera NGS-based cancer monitoring test on BGI's DNBSEQ platform in China, and has now launched a version of the Signatera test in China "that incorporates MGI sequencing platforms." [redacted]; RX3062 (BGI) at 1.)

The Record Shows Availability of NGS Alternatives in the United States. BGI already has a commercially available NGS platform. (PFF ¶¶ 777–777.5.) BGI also markets its NGS technology in many other countries and is expected to enter the U.S. market in the near future. [redacted]; RX3869 (Cote Expert Report) ¶ 287; [redacted]**.)** BGI also recently won a jury verdict that held three of Illumina's patents to be invalid meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022). BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.) [redacted]. (PFF ¶¶ 778–778.2; 2085.) Thermo Fisher's Ion Torrent sequencers are suitable for certain MCED tests. (RX3869 (Cote Expert Report) ¶ 285.) Thermo Fisher has confirmed that its sequencers are capable of being used for MCED tests and researchers are successfully developing new ways to use Thermo Fisher products for early cancer screening applications. (PX7097 (Felton (Thermo Fisher) Dep. at 66-69.) [redacted]

[redacted]

Oxford Nanopore is also a viable alternative for MCED test developers. (RX3521 (NCM) at 50-51; RX3869 (Cote Expert Report) ¶¶ 293, 295-98.) Oxford Nanopore's instruments reportedly will compete with Illumina on throughput, accuracy and cost. Oxford Nanopore states that its highest throughput instrument, PromethION, has a higher throughput than the highest performance instrument and flow cell currently offered by Illumina, the NovaSeq 6000 with the S4 flow cell. (RX3543 (ONT); RX1205 (Illumina): RX3869 (Cote Expert Report) ¶ 294.) Oxford Nanopore states that its instruments have similar accuracy to Illumina. (*Compare* RX3541 (ONT) at 1 *with* RX3368 (Illumina).) [redacted]

Singular commercially launched the G4 NGS sequencer at the end of 2021 and will begin shipping the G4 NGS systems in the first half of 2022. (PFF ¶ 607; Velarde (Singular) Tr. 4515–16, 4522; *see also* PX8561 (Singular) at 1–2; PX7117 (Velarde (Singular) Dep. at [redacted]–31).) Singular Genomics's G4 sequencer is reportedly [redacted]

[redacted] (PFF ¶ 609-609.6.)

[redacted]

Respondents also note that several other sequencers that are capable of supporting MCED development are arriving in the near future. [redacted]

[redacted]

Omniome, which was acquired by PacBio for $800 million in July 2021, is developing a NGS sequencer. (PFF ¶ 787 (RX3533 (Omniome)).) Omniome has stated that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72)**;** [redacted]

Roche has stated that it expects to bring to market an NGS nanopore sequencer by the 2024 time frame. (PFF ¶ 625 (RX3614 (Roche)).) [redacted]

Test Developers Agree That There are NGS Alternatives. Dr. Aravanis testified that GRAIL considered BGI, Thermo Fisher, Oxford Nanopore and Genapsys NGS sequencers for GRAIL's Galleri test, and determined that many of them would be a viable alternative. (PFF ¶ 1311 (Aravanis (Illumina) Tr. 1862–63).) Dr. Aravanis also testified that BGI's systems are used for liquid biopsy applications; BGI has an NGS sequencing product that could be used for multicancer screening; BGI competes with Illumina for liquid biopsy applications in the countries in which it operates; BGI markets its NGS offerings as an alternative to Illumina. (PFF ¶ 1306 (Aravanis (Illumina) Tr. 1852–54).)

Dr. Aravanis also testified that Thermo Fisher's Ion Torrent can be us as an alternative for many Illumina applications; that the Ion Torrent platform is adequate in terms of the type of sequencing data it produces, the accuracy and the cost and that Thermo Fisher markets the Ion Torrent as an alternative to Illumina. (PFF ¶ 1305 (Aravanis (Illumina) Tr. 1848–52).)

Dr. Aravanis further testified that it is possible to do short-read sequencing on Oxford Nanopore's platforms at very low cost; the Oxford Nanopore platform is a very high-output sequencing platform; the amount of data and cost per data is comparable to the high-end Illumina systems; Oxford Nanopore's NGS sequencing product can be used and have been for liquid biopsy oncology testing; Oxford Nanopore markets its NGS offering as an alternative to Illumina and Illumina views Oxford Nanopore as a competitor in NGS sequencing. (PFF ¶ 1308 (Aravanis (Illumina) Tr. 1856–59).) (*See also* PFF ¶¶ 1304–1310.)

Purported MCED test developers treat these NGS platforms as viable substitutes for Illumina's NGS platform. (PFF ¶ 780.) Dr. Vogelstein, a founder of Thrive, stated, [redacted]

[redacted] Dr. Gao of Singlera testified that the PanSeer test can be run using Thermo Fisher equipment. (PFF ¶ 780.4.) [redacted] (PFF ¶ 780.5.) Dr. Chudova also stated that Guardant could use alternative sequencing platforms for its LUNAR-2 screening test in development that meet the throughput, error, time, and sequencing cost requirements. (PX7045 (Chudova (Guardant) IHT at 44–52.) Mr. Getty also admitted that Thermo Fisher Scientific Inc., and other companies developing next-generation sequencing platforms also provide NGS platforms that could be used for liquid biopsy testing. (Getty (Guardant) Tr. 2642.) [redacted] (*See also* PFF ¶¶ 578–644, 1305–10 for further analysis of alternatives to Illumina's NGS platforms.)

Mr. Stahl of Invitae also recognized that Thermo Fisher (along with Oxford Nanopore, BGI, and PacBio) is a participant in the NGS field and that there would be "no way to predict" which NGS company would be successful over the next five or ten years. (PX7075 (Stahl

(Invitae) Dep. at 42–43).) Mr. Stahl also testified that BGI's and Illumina's technologies are "very similar". (PX7075 (Stahl (Invitae) Dep. at 75.)

Natera Development Status. The proposed finding is also incomplete and misleading insofar as it suggests that Natera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future.

[redacted] (PFF ¶¶ 508–09.) [redacted] and that Natera is unlikely to accelerate the development of a cancer screening test for multiple cancer types or to add a new cancer type to an existing screening test, [redacted] There is no evidence based on [redacted] (PFF ¶ 511 (RX3869 (Cote Expert Report) ¶ 227; [redacted]).) Respondents also incorporate their responses to CCFF ¶¶ 341, 774–775 and 794 herein.

Lack of Foundation/Improper Lay Witness Testimony. The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

929. [redacted] (Conroy (Exact Sciences) Tr. 1580; 1582 (*in camera*)).

Response to Finding No. 929:

The proposed finding is also incomplete and misleading with respect to Exact/Thrive's purported reliance on Illumina's NGS systems. [redacted]

Further, Dr. Vogelstein, the founder of Thrive stated, [redacted]

[redacted] The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 1293 and 2833, which Respondents incorporate herein.

The proposed finding is incomplete and misleading insofar as it suggests that Exact is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future for the reasons explained in Respondents' responses to CCFF ¶¶ 414, 418, 905 and 1912, which Respondents incorporate herein.

[redacted] Exact/Thrive also admitted that, based on the DETECT-A trial, "[a]t present, we cannot be certain that the DETECT-A blood test"—the CancerSEEK test—"helped any participant." (RX3419 at 11.)

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper

Lay Witness Opinion Testimony (Aug. 5, 2021).) In particular, Mr. Conroy was not involved in the development of CancerSEEK, Exact Sciences does not have any tests that use NGS technology and Exact Sciences was not an Illumina customer until its acquisition of Thrive. (*See* Conroy (Exact Sciences) Tr. 1542–43, [redacted].)

930. Illumina's Mr. Naclerio testified that "Illumina has really competed on primarily three parameters since the beginning, cost, throughput, and quality or accuracy. And [] at this time, we believed we were still the leaders in all three of those parameters." (PX7060 (Naclerio (Illumina) IHT at 76)).

Response to Finding No. 930:

Respondents note that Illumina anticipates additional NGS platforms launching in the near future, as is reflected in Illumina's ordinary course strategy documents. [redacted]

Respondents also note that Mr. Naclerio was testifying with respect to PX2270, which was a Board Presentation Mr. Naclerio prepared in October 2012. Mr. Naclerio noted in 2012 that "Complete Genomics Acquisition by BGI poses a threat to Illumina and our largest customers" and "BGI strategic rational believed to include – Expand commercial footprint in US". (PX2270 (Illumina) at 003, 020.)

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1. MCED Tests Need High-Throughput NGS Machines to Sample an Extremely High Number of cfDNA Fragments from Each Blood Sample

931. [redacted] (deSouza (Illumina) Tr. 2265 (*in camera*)).

Response to Finding No. 931:

Respondents have no specific response.

932. [redacted] (Conroy (Exact Sciences) Tr. 1580-81).

Response to Finding No. 932:

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 929, which Respondents incorporate herein.

933. "Reads per run" is a measurement of throughput and means the number of DNA library molecules an instrument can sequence on each run of the instrument. (PX0114 at 002, Illumina Sequencing Platforms, https://www.illumina.com/systems/sequencing-platforms.html (last visited Apr. 6, 2022)); *see* PX0035 at 002 (An Introduction to Next-Generation Sequencing Technology, https://www.illumina.com/Documents/products/Illumina_Sequencing_Introduction.pdf (last visited Apr. 6, 2022)); PX7044 (Stahl (Invitae) IHT at 87 ("Q. When you say 'throughput,' is that another way of talking about the depth of read that we were just talking about or is that a different attribute of the machine? A. It is that attribute, so how many millions of reads are you getting."); PX7070 (Felton (Thermo Fisher) IHT at 30-31 ("Q Can you explain the unit of measurement that you used to describe throughput, the reads per run? A. Sure. So read, as I've described earlier in the deposition, is a single contiguous length of DNA sequence from, in our case, a chip. So each well on a chip can generate a read, and we typically generate those reads in the range of 200 to 400 base pairs per sequence. So we're generating 60 to 80 million 200 to 400 base-pair sequencers per run.")).

Response to Finding No. 933:

The proposed finding is inaccurate and misleading to the extent it suggests that all types of DNA sequencing use the same types of metrics to measure throughput. While "reads per run" is an appropriate metric for throughput for traditional short-read sequencers, [redacted] Respondents incorporate their responses to CCFF ¶ 904 herein.

Respondents also note that Complaint Counsel chose not to discuss PX0114 and PX0035 at trial (CC Exhibit Index at 1, 2), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

934. Multiplying the number of reads per run by the length of each read calculates the instrument's output in terms of gigabases per run. (PX7044 (Stahl (Invitae) IHT at 80); PX7070 (Felton (Thermo Fisher) IHT at 31) (Gigabases is "how much overall sequence information is provided. The overall sequencing information and gigabases is a combination of the number of reads times the length of the read.")).

Response to Finding No. 934:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 933, which Respondents incorporate herein.

935. [redacted] (Chudova (Guardant) Tr. 1222-23) (*in camera*)).

Response to Finding No. 935:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927 and 933, which Respondents incorporate herein.

936. In defining the term throughput in the context of cancer screening, Natera's Dr. Rabinowitz testified:

[redacted]

(PX7054 (Rabinowitz (Natera) IHT at 47) (*in camera*)).

Response to Finding No. 936:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 933, 1099 and 1293, which Respondents incorporate herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

937. [redacted] (Chudova (Guardant) Tr. 1210) (*in camera*)).

Response to Finding No. 937:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 927, which Respondents incorporate herein.

938. [redacted] (Chudova (Guardant) Tr. 1211) (*in camera*)).

Response to Finding No. 938:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 927, which Respondents incorporate herein.

The proposed finding also undermines Complaint Counsel's theory that multicancer tests require more or different sequencing than single cancer tests. *See, e.g.*, CC Post Trial Br. at 73-74 (arguing that Thermo Fisher sequencers are insufficient for MCED tests). [redacted]

939. [redacted] (deSouza (Illumina), Tr. 2265-66 (*in camera*)).

Response to Finding No. 939:

Respondents have no specific response.

940. [redacted] (PX7100 (Chudova (Guardant) Dep. at 60-61) (*in camera*)).

Response to Finding No. 940:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 928, 1115 and 1293, which Respondents incorporate herein.

The proposed finding is also incomplete and misleading to the extent it suggests that only Illumina's NovaSeq instrument is suitable for supporting Guardant's putative MCED test. [redacted] Dr. Chudova also stated that Guardant could use alternative sequencing platforms for its LUNAR-2 screening test in development that meet the throughput, error, time, and sequencing cost requirements. (PX7045 (Chudova (Guardant) IHT at 44–52.)

941. [redacted] (PX7100 (Chudova (Guardant) Dep. at 60-61) (*in camera*)).

Response to Finding No. 941:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927–928, 940, 1115 and 1293, which Respondents incorporate herein.

942. [redacted]

(PX7100 (Chudova (Guardant) Dep. at 61-62) (*in camera*)).

Response to Finding No. 942:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927–28 and 940, which Respondents incorporate herein.

[redacted]

943. [redacted]

(PX7045 (Chudova (Guardant) IHT at 50) (*in camera*)).

Response to Finding No. 943:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927–28, 940 and 942, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

944. [redacted] (Chudova (Guardant) Tr. 1207-08 (*in camera*)).

Response to Finding No. 944:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927–28, 940 and 942, which Respondents incorporate herein.

945. Freenome CEO, Michael Nolan testified at trial that the high throughput of Illumina's sequencer also enables Freenome to "keep []costs in a position with proper ratios." (Nolan (Freenome) Tr. 2716).

Response to Finding No. 945:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928 and 1293, which Respondents incorporate herein. It is also contradicted by the weight of the evidence. In particular, [redacted] BGI also markets its NGS technology in many other countries and is expected to enter the U.S. market in the near future. [redacted] RX3869 (Cote Expert Report) ¶ 287; [redacted]**.)** BGI also recently won a jury verdict that held three of Illumina's patents to be invalid meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022). BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.)

The proposed finding is also inaccurate and misleading to the extent it suggests that only Illumina's NGS is cost effective for Freenome's putative test in development. *First*, Freenome is

still at the very early stages of developing a putative MCED test. Mr. Nolan testified that

[redacted] (PFF ¶¶ 459-70.)

Mr. Otte, Freenome's former CEO, also testified that [redacted]

[redacted]

Accordingly, there is no indication based on Freenome's work to date that [redacted] (PFF ¶ 458 ([redacted]; RX3869 (Cote Expert Report) ¶ 193).)

Second, the evidence shows that [redacted] (PFF ¶ 884 (RX6000 (Carlton Trial Dep.) at 30–31).) Respondents also incorporate their responses to CCFF ¶¶ 439–446, 696, 698, 801 and 2353–2400 herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

946. Freenome CEO, Michael Nolan testified at trial that the high throughput of Illumina's NGS sequencer will enable "performing billions of tests a year." (Nolan (Freenome) Tr. 2715).

Response to Finding No. 946:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 945 and 1293, which Respondents incorporate herein. In particular, [redacted]

[redacted]

The proposed finding also lacks any evidentiary basis. Dr. Carlton estimated that, assuming no acceleration from the Transaction, GRAIL would sell about 0.1 million tests in 2022 and would only sell a total of 29.9 million tests from 2022-2030. (RX3864 (Carlton Expert Report) ¶ 119.)

947. Mr. Nolan further testified that the high throughput of Illumina's sequencer also enables Freenome to achieve "operational efficiency." (Nolan (Freenome) Tr. 2716).

Response to Finding No. 947:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 945 and 1293, which Respondents incorporate herein. In particular, [redacted]

948. Freenome's Nolan also explained at trial that "there's probably no higher priority" than the ability of an NGS sequencer to scale, because, "even with a relatively small share of [the] market," Freenome will be performing "millions of tests a year." (Nolan (Freenome) Tr. 2720).

Response to Finding No. 948:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 945 and 1293, which Respondents incorporate herein. In particular, [redacted]

949. In discussing potential alternatives to Illumina's NGS sequencers for Freenome's cancer screening test, Mr. Nolan testified, [redacted]

[redacted] (PX7094 (Nolan (Freenome) Dep. at 221-223) (*in camera*)).

Response to Finding No. 949:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 945 and 1293, which Respondents incorporate herein. In particular, [redacted]

950. Freenome's Otte testified that, for example, [redacted] (PX7055 (Otte (Freenome) IHT at 17-19) (*in camera*)).

Response to Finding No. 950:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 945 and 1293, which Respondents incorporate herein. In particular, [redacted] Further, the evidence shows that [redacted] (PFF ¶ 884 (RX6000 (Carlton Trial Dep.) at 30–31).) Respondents also incorporate their responses to CCFF ¶¶ 439–446, 696, 698, 801 and 2353–2400 herein.

The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

951. [redacted] (PX7111 (Fesko (Natera) Dep. at 52) (*in camera*)).

Response to Finding No. 951:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 1264 and 1293, which Respondents incorporate herein.

952. According to Thermo Fisher's Dr. Felton, MCED tests require a "high throughput platform such that you could screen through many thousands of patient samples per day or per week or tens of thousands per week because population screening for early cancer is likely to be a very sample-intensive solution." (PX7070 (Felton (Thermo Fisher) IHT at 52)).

Response to Finding No. 952:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928 and 1293, which Respondents incorporate herein.

[redacted]

[redacted]

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Respondents also incorporate their responses to CCFF ¶¶ 1212–68 herein.

953. Dr. Felton testified that multi-cancer early detection is an application suited for high-throughput NGS sequencers because "[t]he collection of samples from a wide area of the population is inherently easier if it's funneled into a central facility . . . and then running those samples on a high throughput platform would reduce the amount of labor time involved in the processing of said samples." (Felton (Thermo Fisher) Tr. 2002).

Response to Finding No. 953:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 952 and 1293, which Respondents incorporate herein.

954. Dr. Felton testified that a sequencing platform would have to be able to produce "a large number of reads" per run to be used for MCED tests because "we would expect there to be a high number of samples, and, therefore, a system with a high throughput capability would be much preferable to one with a small output that you would have to run multiple times." (Felton (Thermo Fisher) Tr. 1990-1991).

Response to Finding No. 954:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 952 and 1293, which Respondents incorporate herein.

2. MCED Tests Need NGS with High Accuracy and Low Error Rates to Correctly Identify ctDNA and Increase Sensitivity and Specificity

955. [redacted] (Conroy (Exact) Tr. 1581).

Response to Finding No. 955:

Respondents have no specific response except to note that to the extent the proposed finding suggests that platforms other than Illumina NGS platforms are not accurate enough to support putative MCED tests, this is inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 971, which Respondents incorporate herein.

956. [redacted] (deSouza (Illumina) Tr. 2266 (*in camera*)).

Response to Finding No. 956:

Respondents have no specific response except to note that to the extent the proposed finding suggests that platforms other than Illumina NGS platforms are not accurate enough to

support putative MCED tests, this is inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 971, which Respondents incorporate herein.

957. Dr. Lengauer testified that for Thrive's CancerSEEK test, [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 66-67 (*in camera*)).

Response to Finding No. 957:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.). To the extent the proposed finding suggests that platforms other than Illumina NGS platforms are not accurate enough to support putative MCED tests, this is inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 971, which Respondents incorporate herein.

958. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 70 (*in camera*)).

Response to Finding No. 958:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.). To the extent the proposed finding suggests that platforms other than Illumina NGS platforms are not accurate enough to support putative MCED tests, this is inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 971, which Respondents incorporate herein.

959. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 69) (*in camera*)).

Response to Finding No. 959:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.). To the extent the proposed finding suggests that platforms other than Illumina NGS platforms are not accurate enough to support putative MCED tests, this is inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 971, which Respondents incorporate herein.

960. [redacted] (Chudova (Guardant) Tr. 1208) (*in camera*)).

Response to Finding No. 960:

Respondents have no specific response except to note that Dr. Chudova testified that even Illumina's sequencing technology has error rates: "[T]hrough the history of working with Illumina platforms and NextSeq platforms in particular, we learned about specific error modes that the platform generates in addition to sort of .3/.1 generic random error that we discussed, right. There are certain places in the genome where the technology is more prone to errors, and we have mitigations in our algorithmic analysis for these error modes." (PX7045 (Chudova (Guardant) IHT at 34.) To the extent the proposed finding suggests that platforms other than Illumina NGS platforms are not accurate enough to support putative MCED tests, this is inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 971, which Respondents incorporate herein.

961. Guardant's Dr. Chudova explained how accuracy affects sequencing costs, "to correct the error rate inherent in the sequencing technology, we oversequence, which means we read each molecule more than once to try to minimize the error." ((PX7045 (Chudova (Guardant) IHT at 28-31)).

Response to Finding No. 961:

Respondents have no specific response except incorporate their responses to CCFF ¶ 960 herein. Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) To the extent the proposed finding suggests that platforms other than Illumina NGS platforms are not accurate enough to support putative MCED tests, this is inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 971, which Respondents incorporate herein.

962. Dr. Chudova explained that an NGS platform's accuracy influences sequencing costs because: "you can trade off throughput for error, so that means if you all of a sudden want to tolerate, instead of .3 percent, let's say .5 percent error rate, you need to sequence that molecule more times and you need to have higher throughput." (PX7045 (Chudova (Guardant) IHT at 31-34).

Response to Finding No. 962:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 960 herein. Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.). To the extent the proposed finding suggests that platforms other than Illumina NGS platforms are not accurate enough to support putative MCED tests, this is inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 971, which Respondents incorporate herein.

963. Dr. Rabinowitz testified that a "sequencer has to be very accurate in saying what series of nucleotides constitute each fragment, and the sequencer needs to be stable. In other words, [Natera] need[s] to model the noise of the sequencer very precisely so that [Natera] can calibrate out that noise[.]" (Rabinowitz (Natera) Tr. 310).

Response to Finding No. 963:

Respondents have no specific response except to note that to the extent the proposed finding suggests that platforms other than Illumina NGS platforms are not accurate enough to support putative MCED tests, this is inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 971, which Respondents incorporate herein.

964. "If the sequencer is accurate sometimes, not accurate [other times], and has a variable noise model or run-to-run instability, that creates major issues." (Rabinowitz (Natera) Tr. 310).

Response to Finding No. 964:

Respondents have no specific response except to note that to the extent the proposed finding suggests that platforms other than Illumina NGS platforms are not accurate enough to support putative MCED tests, this is inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 971, which Respondents incorporate herein.

965. [redacted] (Rabinowitz (Natera) Tr. 362 (*in camera*)).

Response to Finding No. 965:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928 and 1293, which Respondents incorporate herein. To the extent the proposed finding suggests that platforms other than Illumina NGS platforms are not accurate enough to support putative MCED tests, this is inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 971, which Respondents incorporate herein.

[redacted]

[redacted]

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

966. Low NGS platform accuracy increases costs to run a cancer screening test because low accuracy requires more "sequencing . . . to tell mutation from error." (PX7042 (Gao (Singlera) IHT at 46)).

Response to Finding No. 966:

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.). To the extent the proposed finding suggests that platforms other than Illumina NGS platforms are not accurate enough to support putative MCED tests, this is inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 971, which Respondents incorporate herein.

967. Dr. Gao elaborated that if the accuracy is low you need to resequence, but "[w]ith Illumina you need less sequencing" or "coverage" so "if you look at the . . . raw sequencing reagent cost, [a less accurate NGS sequencer] may be a little bit cheaper. However if you look at the required amount of sequencing needed to tell mutation from error, you end up paying more[.]" (PX7042 (Gao (Singlera) IHT at 46-47)).

Response to Finding No. 967:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 960, 971 and 1293, which Respondents incorporate herein. Dr. Gao of Singlera testified that the PanSeer test can be run using Thermo Fisher equipment (Gao (Singlera) Tr. 2928.) [redacted] To the extent the proposed finding suggests that platforms other than Illumina NGS platforms are not accurate enough to support putative MCED tests, this is inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 971, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

968. Freenome CEO, Michael Nolan, testified at trial that the accuracy of an NGS sequencer "an important parameter overall for [an MCED] test, and it's of course important for [Freenome] in [its] research and product development to have accuracy." (Nolan (Freenome) Tr. 2720).

Response to Finding No. 968:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 945 and 1293, which Respondents incorporate herein. To the extent the proposed finding suggests that platforms other than Illumina NGS platforms are not accurate enough to support putative MCED tests, this is inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 971, which Respondents incorporate herein.

969. [redacted] (PX4140 (Grail) at 007, 010 ("R&D Portfolio Planning – Part B: Sequencing Technology," last modified Apr. 14, 2019) (*in camera*)).

Response to Finding No. 969:

The proposed finding is incomplete and misleading. [redacted]

Dr. Aravanis identified a number of sequencing platforms on the market today and in development that would be viable platforms for an MCED test such as Galleri. (Aravanis (Illumina) Tr. 1848–63.) Respondents also incorporate their responses to CCFF ¶¶ 1074 and 1088 herein.

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 971 and 1293, which Respondents incorporate herein. To the extent the proposed finding suggests that platforms other than Illumina NGS platforms are not accurate enough to support putative MCED tests, this is inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 971, which Respondents incorporate herein.

Respondents also note that Complaint Counsel chose not to discuss PX4140 at trial (CC Exhibit Index at 38), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

970. Illumina's Mr. Aravanis testified "the one area [] where Illumina is superior in a meaningful way is around data accuracy, so the accuracy of the Oxford Nanopore reads is not as good as the Illumina reads." (PX7065 (Aravanis (Illumina) IHT at 158)).

Response to Finding No. 970:

The proposed finding is incomplete and misleading. [redacted]

Dr. Cote also explained that Oxford Nanopore's platform "is capable of sequencing up to 10 Terabase pairs ('Tb') per run and may be used to detect methylation and other epigenomic changes directly. While Oxford Nanopore historically faced lower accuracy, the latest improvements in chemistry and bioinformatics enable the platform's accuracy to the Q50 range. This platform is already being used by developers of potential cancer screening tests." (RX3869 (Cote Expert Report) ¶ 19.)

In addition, Oxford Nanopore states that its instruments have similar accuracy to Illumina. (*Compare* RX3541 (ONT) at 1; RX3535 (ONT) at 1 *with* RX3368 (Illumina).)

Methods have been developed to obtain consensus sequences from homogenous DNA samples by genome assembly, resulting in accuracies of more than 99.999% (Q50). (RX3541 (ONT) at 1; RX3535 (ONT); RX3536 (ONT).) Oxford Nanopore has also announced that its single-molecule modal accuracy is now >99.3% (Q20) using its "Q20+" chemistry, and also developed a new approach termed "Duplex" sequencing, which enables the sequencing of both template and complementary strands and accuracy "trending towards 99.9% (Q30)". (RX3541 (ONT) at 1; RX3535 (ONT) at 1; *see also* PFF ¶¶ 604–604.1.)

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 904, which Respondents incorporate herein.

971. Dr. Vogelstein testified that the accuracy of Illumina's NGS sequencers "approaches about one error in several thousand bases" which he explained is "absolutely essential to get the specificity that you need for an earlier detection test" because "[o]therwise, you'll get too many false positives." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 58-59)).

Response to Finding No. 971:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which it is not. Dr. Vogelstein only testified that the accuracy of "about one error in several thousand bases [] is absolutely essential to get the specificity that you need for an earlier detection test." (PX7101 (Vogelstein (Johns Hopkins University) Dep.) at 58–59.) As Dr. Vogelstein has stated, there are other viable NGS platforms on the market that compare to Illumina's level of accuracy. BGI's DNBSEQ sequencer's reported accuracy is comparable to that of Illumina's sequencers, and guarantees over 99.9% accuracy (>80% of bases >Q30). (PFF ¶ 591 (RX3465 (MGI Tech); RX3067 (BGI)).) Specifically, Dr. Vogelstein stated, [redacted]

[redacted]

Oxford Nanopore states that its instruments have similar accuracy to Illumina. (*Compare* RX3541 (ONT) at 1; RX3535 (ONT) at 1 *with* RX3368 (Illumina).)

Singular Genomics' G4 System's reported performance characteristics are comparable to those of Illumina's NextSeq and NovaSeq systems, with high accuracy of 99.7% on 150 base reads. (PX8561 (Singular) at 4-5; [redacted]

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928 and 1293, which Respondents incorporate herein.

972. To deliver sufficiently accurate results, MCED test developers must use sequencing technology with low error rates. ((PX7075 (Stahl (Invitae) Dep. at 71-74) (describing how some NGS platforms' error rates are prohibitively high for Invitae's applications)).

Response to Finding No. 972:

The proposed finding is based on speculation. [redacted] PX7075 (Stahl (Invitae) Dep. at

22, 44, 77–78) The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 904, 928 and 1293, which Respondents incorporate herein. To the extent the proposed finding suggests that platforms other than Illumina NGS platforms are not accurate enough to support putative MCED tests, this is inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 971, which Respondents incorporate herein.

973. In an internal presentation to Illumina's Science & Technology Committee, Illumina executives recognized that [redacted] (PX2013 (Illumina) at 003 (Cancer Screening, Apr. 28, 2020) (*in camera*)).

Response to Finding No. 973:

The proposed finding is misleading. The cited language refers to cancer screening generally, not MCED tests. Respondents also note that Complaint Counsel chose not to discuss PX2013 at trial (CC Exhibit Index at 5), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

974. An internal presentation made to Illumina's Science & Technology Committee recognizes that [redacted] (PX2013 (Illumina) at 003 (Cancer Screening, Apr. 28, 2020) (*in camera*)).

Response to Finding No. 974:

The proposed finding is misleading. The cited language refers to cancer screening generally, not MCED tests. The full sentence reads [redacted] (PX2013 (Illumina) at 003 (Cancer Screening, Apr. 28, 2020) (*in camera*) (emphasis added)).

The proposed finding is incomplete and misleading insofar as it suggests that Guardant and Freenome are actual competitors to GRAIL today or will be competitors to GRAIL in the foreseeable future. Respondents also incorporate their responses to CCFF ¶¶ 927 (Guardant) and 945 (Freenome) herein.

Respondents also note that Complaint Counsel chose not to discuss PX2013 at trial (CC Exhibit Index at 5), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

975. Illumina's CEO Mr. deSouza testified that Illumina's expertise is "try[ing] [to] continue to move the accuracy of the reads of our sequencers using machine learning." (PX7072 (deSouza (Illumina) IHT at 187)).

Response to Finding No. 975:

Respondents have no specific response.

3. MCED Tests Need Low-Cost Sequencing to Screen the General Population

976. Because MCED test developers ultimately seek to regularly test most of the adult population in the United States, low costs are important to the success of an MCED test. (*See supra* Sections II.C.6. (MCED Tests Seek to Detect Multiple Cancers Simultaneously in Asymptomatic Individuals) and III.C.1. (MCED Tests Will Have Distinct Pricing and Reimbursement from Other Oncology Tests)).

Response to Finding No. 976:

The proposed finding is improper because it treats Complaint Counsel's inaccurate, misleading and argumentative headers as purported facts. To the extent Complaint Counsel relies on its Proposed Findings in Sections II.C.6 and III.C.1 (CCFF ¶¶ 375–475, 688–704), Respondents incorporate their responses to those Proposed Findings herein.

977. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 127-28) (*in camera*)).

Response to Finding No. 977:

The proposed finding is misleading. [redacted]

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

978. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 68-69) (*in camera*); PX7102 (Gao (Singlera) Dep. at 27); PX7045 (Chudova (Guardant) IHT at 43-44) (*in camera*); Nolan (Freenome) Tr. 2723; Ofman (Grail) Tr. 3302.

Response to Finding No. 978:

The proposed finding is vague and misleading. It is not clear which witnesses would be considered "MCED witnesses". The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. [redacted] (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

The proposed finding is misleading to the extent it describes [redacted] (RX3869 (Cote Expert Report ¶¶ 174 (Exact/Thrive), 193 (Freenome), 202 (Guardant), 238 (Singlera)).) [redacted] (PFF

¶¶ 722–740.1), and [redacted] (PFF ¶¶ 701–706).

979. Thrive's Lengauer testified that [redacted]

[redacted]

(PX7051 (Lengauer (Third Rock Ventures) IHT at 68-69) (*in camera*)).

Response to Finding No. 979:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 977 herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

980. Freenome's Otte testified that, for example, [redacted] (PX7055 (Otte (Freenome) IHT at 17-19) (*in camera*)).

Response to Finding No. 980:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 950 and 1293, which Respondents incorporate herein. Additionally, contrary to the cited testimony, putative MCED test developers *do* use Illumina's lower throughput NextSeq and MiSeq instruments. For example, the Singlera's

PanSeer test only requires approximately 2 million sequencing reads per sample, and is compatible with both Illumina's MiSeq or NextSeq systems and Thermo Fisher's Ion Torrent S5 systems, though it appears to primarily use the NextSeq 550Dx system from Illumina. (PFF ¶ 533 (RX3115 (Chen et al., 2020) at 7; RX3637 (Singlera) at 1–6; Gao (Singlera) Tr. 2875, 2894, 2928–29; PX7102 (Gao (Singlera) Dep. at 78); RX3869 (Cote Expert Report) ¶ 239).) Helio currently uses Illumina's MiSeq sequencer for its Helio Liver test. (Chahine (Helio) Tr. 1010-12). Dr. Chahine testified Helio uses the MiSeq because "a smaller machine is more efficient" as a "company in its early stage" prior to "ramp[ing] up." (Chahine (Helio) Tr. 1012).

[redacted] (Rabinowitz (Natera) Tr. 361) (*in camera*)). Respondents also incorporate their responses to CCFF ¶ 1115 herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

981. Dr. Gao explained that Singlera chooses to run its cancer screening test on Illumina's NGS platform in part because "it's very cost economic" in terms of the number of reads per run. (PX7102 (Gao (Singlera) Dep. at 27)).

Response to Finding No. 981:

Respondents incorporate their responses to CCFF ¶¶ 928, 967, 980 and 1293 herein.

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony

and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Furthermore, the evidence shows that [redacted] (PFF ¶ 884 (RX6000 (Carlton Trial Dep.) at 30–31).) Respondents also incorporate their responses to CCFF ¶¶ 439–446, 696, 698, 801 and 2353–2400 herein.

982. Singlera's Gao explained that a cancer "screen[ing] test has to be very cheap," "unlike [a] confirmation test" in order to be commercially viable. (PX7042 (Gao (Singlera) IHT at 50-51)).

Response to Finding No. 982:

Respondents incorporate their responses to CCFF ¶¶ 928, 967, 980 and 1293 herein.

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Furthermore, the evidence shows that [redacted] (PFF ¶ 884 (RX6000 (Carlton Trial Dep.) at 30–31).) Respondents also incorporate their responses to CCFF ¶¶ 439–446, 696, 698, 801 and 2353–2400 herein.

983. [redacted] (PX7045 (Chudova (Guardant) IHT at 43-44) (*in camera*)).

Response to Finding No. 983:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 928 and 1293, which Respondents incorporate herein.

984. Mr. Nolan indicated at trial that keeping the cost of NGS sequencing and the related consumables low is important to Freenome because they are the "majority of [the] cost of goods today in [Freenome's] different prototypes." (Nolan (Freenome), Tr. 2723).

Response to Finding No. 984:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 945, which Respondents incorporate herein.

The proposed finding is also irrelevant as it does not relate to MCED tests in particular, and it is misleading because Illumina is not the only provider of sequencing instruments and core consumables, nor is it the only provider of other consumables used in the testing workflow, such as sample collection consumables or library preparation consumables. *See, e.g.,* (Bishop (GRAIL) Tr. 1381–82. (GRAIL uses a variety of reagents and consumables and not all of these inputs are from Illumina).

For example, liquid biopsy test developers do not use Illumina technology for blood or other fluid sample collection from the patient. (*See* Berry (Illumina) Tr. 814 ("Illumina does not participate specifically in this space" of "isolating the genetic material to be sequenced from [a blood] sample").) Similarly, most liquid biopsy test developers do not use Illumina technology for library preparation. (Berry (Illumina) Tr. 815–16 (stating that the library preparation step "is very unique and specific to the particular test provider's sort of approach of methodology" and that there are "hundreds and hundreds of library preparation methods" and "potentially hundreds of providers of library preparation technology or kits").) [redacted]

[redacted]

Furthermore, the evidence shows that [redacted] (PFF ¶ 884 (RX6000 (Carlton Trial Dep.) at 30–31).) In addition, Dr. Aravanis explained that "Illumina is [ ] going to lower the cost of sequencing over time," as will "other sequencing providers", which will "compound the overall reduction in sequencing costs as a fraction of the test." (Aravanis (Illumina) Tr. 1924–25.)

985. Dr. Chahine testified at trial that the R&D process to develop a screening test is "extremely expensive," and the two major costs are "acquiring the actual samples" to conduct the analysis and the sequencing the samples. (Chahine (Helio) Tr. 1035-36).

Response to Finding No. 985:

Respondents have no specific response.

986. [redacted] (PX7077 (Chahine (Helio) Dep. at 30 (*in camera*)).

Response to Finding No. 986:

The proposed finding is irrelevant as it is does not relate to MCED tests and is directed to [redacted]

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 984 and 1293, which Respondents incorporate herein.

987. Dr. Rabinowitz testified that "uniformity" of coverage across regions of the genome being screened is a key factor for the cost of sequencing—for Natera "all the regions of DNA that [Natera] want[s] to look at should have a similar amount of sequencing." (Rabinowitz (Natera) Tr. 310-11).

Response to Finding No. 987:

The proposed finding is irrelevant as it is not specific to MCED tests or Illumina's sequencers. Respondents also incorporate their responses to CCFF ¶¶ 696, 928, 984 and 1293 herein.

988. Dr. Rabinowitz explained the significance of a sequencer's lack of uniformity:

> If you have lack of uniformity in the sequencer, you'll get a lot of information about one region of the chromosome and much less information about another region, and the result of that is you have to do a whole lot more sequencing, because you want to get a minimum amount of coverage and the coverage is largely the richness of the data that you can get about what's going on at that particular region of the chromosome.

(Rabinowitz (Natera) Tr. 311).

Response to Finding No. 988:

The proposed finding is irrelevant as it is not specific to MCED tests or Illumina's sequencers. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 987 and 1293, which Respondents incorporate herein.

989. Dr. Rabinowitz further testified that "especially for the oncology tests, you want to do as much sequencing as your costs will allow, because the more sequencing you do, the broader the things that you can look at, the better you are at capturing single molecules, and the better the sensitivity and specificity of your test." (Rabinowitz (Natera) Tr. 311).

Response to Finding No. 989:

The proposed finding is irrelevant as it is not specific to MCED tests or Illumina's sequencers. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 987 and 1293, which Respondents incorporate herein.

990. Dr. Rabinowitz explained that the sequencing data generated connects directly with test performance: "[T]he more sequencing that one can do, the better performance of the test,

especially in the oncology context, where you want to go down to sort of single-molecule detection levels." (Rabinowitz (Natera) Tr. 311-12).

Response to Finding No. 990:

The proposed finding is irrelevant as it is not specific to MCED tests or Illumina's sequencers. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 987 and 1293, which Respondents incorporate herein.

991. [redacted] (PX8354 (Roche) at 004 (Monitoring and Screening Markets, Jan. 29, 2021) (*in camera*)).

Response to Finding No. 991:

The proposed finding is incomplete and misleading. PX8354 at 004 [redacted] Respondents also note that Complaint Counsel chose not to discuss PX8354 at trial (CC Exhibit Index at 60), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

Respondents further note that [redacted]

[redacted]

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928 and 984, which Respondents incorporate herein.

992. Customers requiring the sequencing of a large number of samples require sequencers with a low price per sample. (Felton (Thermo Fisher) Tr. 2000-01).

Response to Finding No. 992:

The proposed finding is irrelevant as it is not specific to MCED tests or Illumina's sequencers. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 952, which Respondents incorporate herein.

993. Thermo Fisher's Felton acknowledged that NGS instruments with a "low cost per sample [are] likely to be the major requirement" for MCED tests. (PX7070 (Felton (Thermo Fisher) IHT at 52)).

Response to Finding No. 993:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 952, which Respondents incorporate herein.

994. Dr. Vogelstein testified that "the sequencing component of the test is the most expensive part of" the research performed at his lab. (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 69)).

Response to Finding No. 994:

The proposed finding is irrelevant because it does not relate to costs for an MCED test. Dr. Vogelstein's lab does its own laboratory work to "discover improved ways to carry out experiments." PX7101(Vogelstein (Johns Hopkins University) Dep. at 38). Dr. Vogelstein testified that in his capacity as a consultant for Thrive, he "specifically said to them that I know nothing about business and did not want to discuss it because I was not a source of information." PX7101(Vogelstein (Johns Hopkins University) Dep. at 30)). Respondents also note that Dr. Vogelstein also testified that Illumina's cost of sequencing per giga-base has gone down over time. (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 62.)

Respondents also incorporate their responses to CCFF ¶ 977 herein.

995. Dr. Vogelstein testified that his "lab's goal is to ultimately create tests that are affordable for all" and "[t]herefore, the cost and the throughput of the sequencing are key." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 68)).

Response to Finding No. 995:

The proposed finding is irrelevant for the reasons explained in Respondents' responses to CCFF ¶ 994, which Respondents incorporate herein.

996. Dr. Vogelstein testified that "[r]esearchers in the field are acutely aware of Illumina's sequencing because sequencing is a major cost in the analysis of CF DNA" and "[t]he cost of sequencing is therefore a major factor that drives the cost of creating a test for the public that could become part of the battery of relatively routine tests associated with an annual physical." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 67-68)).

Response to Finding No. 996:

The proposed finding is irrelevant for the reasons explained in Respondents' responses to CCFF ¶ 994, which Respondents incorporate herein.

997. [redacted]

[redacted] (PX8399 (Henry (PacBio) Decl. ¶ 5) (*in camera*)).

Response to Finding No. 997:

The proposed finding relies on hearsay and is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 907, which Respondents incorporate herein.

998. Grail's Aaron Freidin explained, [redacted] (PX7066 (Freidin (Grail) IHT at 216-17) (*in camera*)).

Response to Finding No. 998:

Respondents have no specific response.

999. Grail witnesses also testified at trial that NGS sequencing needs to be low cost, including Grail's CEO Hans Bishop who testified that it is "a very high priority [in] reducing the cost of our test." (Bishop (Grail), Tr. 1368).

Response to Finding No. 999:

Respondents have no specific response.

1000. [redacted] (Bishop (Grail) Tr. 1446 (*in camera*)).

Response to Finding No. 1000:

Respondents have no specific response.

1001. Grail's Dr. Ofman testified that "we need to get the cost of the [MCED] test down" "to achieve [Grail's] mission of providing access to this type of technology to adults worldwide to . . . dramatically improve the cancer detection rate." (Ofman (Grail) Tr. 3302).

Response to Finding No. 1001:

Respondents have no specific response.

1002. Grail's ordinary course documents state, "Illumina represents >50% of GRAIL V2 Product Cost of goods sold." (PX4079 (Grail) at 004 (ILMN/Grail, Jan. 16, 2020) (listing total Illumina COGS at 56% and non-royalty COGS at 50%); *see* (PX4040 (Grail) at 005 (Email from K. Martin, Grail, to A. Freidin, Grail, Feb. 12, 2020) (listing a range of Illumina COGS from 32% to 54% depending on sales volumes and Galleri version number)).

Response to Finding No. 1002:

The proposed finding is incomplete and misleading. [redacted] Mr. deSouza also testified that "today sequencing costs represent about 10 percent of the price of Galleri" and "[b]y 2025, we project that sequencing costs will be less than 4 percent of the price of GRAIL's Galleri test." (deSouza (Illumina) Tr. 2388.) (*See also* [redacted].)

4. An MCED Developer Planning to Sell a Kitted MCED Test Requires an FDA-Cleared NGS Platform

1003. A distributed kit (or "kitted") in-vitro diagnostic test is where the test developer generates a version of the test that can then be distributed to third-party CLIA/CAP-certified labs to be processed. (Goswami (Illumina) Tr. 3185-87).

Response to Finding No. 1003:

Respondents have no specific response.

1004. A kitted IVD is an IVD test that has received pre-market approval from the FDA permitting analysis by independent testing providers. (Goswami (Illumina) Tr. 3186-87).

Response to Finding No. 1004:

Respondents have no specific response.

1005. The distributed kit IVD test developer has "responsibility for quality control and quality analysis" of the distributed kit IVD test. (Goswami (Illumina) Tr. 3187).

Response to Finding No. 1005:

Respondents have no specific response.

1006. An NGS-based kitted IVD test uses dedicated "DX" versions of Illumina's NGS platforms, which have obtained 510(k) clearance from the FDA. (Goswami (Illumina) Tr. 3188-89; *see* PX6056 (Illumina) at 051 (Illumina, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*) [redacted]).

Response to Finding No. 1006:

Respondents have no specific response.

1007. It is Illumina's responsibility to get FDA clearance for "the box that runs the test, and supply the core consumables that go along with the box" for a test developer developing a test on an Illumina's Dx platform. (Goswami (Illumina) Tr. 3188-89).

Response to Finding No. 1007:

Respondents have no specific response.

1008. Illumina then provides a device master file to the FDA when a kitted IVD test developer is seeking FDA approval for its test. (Goswami (Illumina) Tr. 3224).

Response to Finding No. 1008:

Respondents have no specific response.

1009. A distributed kit IVD test developer must follow FDA guidelines and submit to regular FDA audits following PMA approval of a distributed kit IVD. (Goswami (Illumina) Tr. 3187).

Response to Finding No. 1009:

Respondents have no specific response.

1010. An executive from Invitae, an Illumina oncology customer though not an MCED test developer, testified that, in order to offer a cancer screening test as "a distributed IVD, the FDA mandates that the next-generation sequencer be cleared, so it has to have a 510(k) clearance. That clearance then must be part of the companion diagnostic device." (PX7044 (Stahl (Invitae) IHT at 51-52)).

Response to Finding No. 1010:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. At 275–76.) The proposed finding is based on testimony for which the witnesses lack personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1011. Singlera's Dr. Gao testified that Singlera plans to commercially launch its screening test as an "IVD kit[ted test.]" (PX7102 (Gao (Singlera) Dep. at 45-46)).

Response to Finding No. 1011:

Respondents have no specific response except to note that Singlera is many years from launching its putative MCED test. Dr. Gao testified Singlera testified that it is "far [a]way" from starting clinical trials in the United States, and that is it is "still not in the really starting clinical trial state." (Gao (Singlera) Tr. 2926; PX7102 (Gao (Singlera) Dep. at 113–14, 81–82; PFF ¶¶ 527–542.) Specifically, Singlera's PanSeer test is in its extreme infancy and will not reach the market in any realistic near-term time span. Dr. Gao testified that PanSeer test is at least eight to ten years away from potential launch in the United States (Gao (Singlera) Tr. 2919, 2924–26; RX3869 (Cote Expert Report) ¶ 242.) As of now, PanSeer can only detect five cancers and Singlera is a long way from starting clinical trials for PanSeer—Singlera has not even had discussions with the FDA regarding PanSeer, begun developing a clinical trial plan for PanSeer, or engaged FDA consultants for FDA submissions related to PanSeer. (Gao (Singlera) Tr. 2914–15, 2917; 2917–18; 2926–27, 2942–43, 2949.) Even when clinical trials for PanSeer are undertaken, Dr. Gao believes that, to generate sufficient data for FDA approval, Singlera will need to undertake a ten-year, 100,000 person study. (Gao (Singlera) Tr. 2919, 2924, 2926.) Dr.

Gao testified it could take 50 years before it was able to develop a MCED test that could detect 50 cancer types (Gao (Singlera) Tr. 2883.) Respondents also incorporate their responses to CCFF ¶¶ 546–547 herein.

The proposed finding is also misleading to the extent it implies that a distributed IVD model will be part of the plan for any putative MCED test. Several features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (PFF ¶ 675; RX3869 (Cote Expert Report) ¶ 359.) The test developer's decision whether to proceed with an IVD kit as opposed to a centralized model is an economic decision driven by test-specific factors. (Goswami (Illumina) Tr. 3197.) IVD kits are most suitable for tests that have precious samples, that present shipping challenges and require fast turnaround times. (Goswami (Illumina) Tr. 3196–3200; *see also* RX3869 (Cote Expert Report) § XI, ¶¶ 360–63.)

1012. When asked why Singlera chose to use Illumina's NGS platform for its cancer screening test, Dr. Gao testified, "the first reason is the NextSeqDx is FDA 510K cleared." (PX7102 (Gao (Singlera) Dep. at 27)).

Response to Finding No. 1012:

Respondents have no specific response except to note that this proposed finding undermines Complaint Counsel's assertion that the NovaSeq sequencer is a requirement for MCED test development. Respondents also incorporate their responses to CCFF ¶ 1011 herein.

1013. Dr. Gao explained that Singlera "had to use a sure [sic] FDA cleared device, so we choose [Illumina's] NextSeqDx, even though NovaSeq/HiSeq will also do the job, even cheaper. But because they are not FDA cleared, we do not want to run the risk." (PX7102 (Gao (Singlera) Dep. at 27)).

Response to Finding No. 1013:

Respondents have no specific response except to note that this proposed finding undermines Complaint Counsel's assertion that the NovaSeq sequencer is a requirement for MCED test development. Respondents also incorporate their responses to CCFF ¶ 1011 herein.

1014. In discussing the prospect of Singlera running its cancer screening test on a sequencing platform that has not secured FDA clearance, Dr. Gao indicated, "[i]t's the – we call it's the no deal kind of a situation. If you don't have FDA clearance, we cannot go with you." (PX7042 (Gao (Singlera) IHT at 53)).

Response to Finding No. 1014:

Respondents have no specific response except to note that [redacted] Respondents also incorporate their responses to CCFF ¶¶ 928, 1011 and 1293 herein.

1015. [redacted]

Response to Finding No. 1015:

To the extent Complaint Counsel relies on its Proposed Findings in Section VII.A.2.d.1 (CCFF ¶¶ 2945–54), Respondents incorporate their responses to those Proposed Findings herein.

Respondents note that features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (PFF ¶¶ 675–678.5 (RX3869 (Cote Expert Report) ¶¶ 359–363; Goswami (Illumina) Tr. 3188–92, 3194–95).)

The proposed finding is also incomplete and misleading to the extent that it suggests that [redacted] (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

The proposed finding is misleading to the extent it describes [redacted] (RX3869 (Cote Expert Report ¶¶ 174 (Exact/Thrive), 184 (FMI/Roche), 193 (Freenome), 202 (Guardant), 217 (Helio), 227 (Natera), 238 (Singlera)).) [redacted] (PFF ¶¶ 722–740.1), and most of the putative MCED developers identified by Complaint Counsel do not expect (and none can reasonably be expected) to launch a screening test for more than one cancer for many years (PFF ¶¶ 701–706).

1016. [redacted]

Response to Finding No. 1016:

Respondents have no specific response.

1017. [redacted]

Response to Finding No. 1017:

Respondents have no specific response.

1018. Invitae's Stahl explained why Illumina's NGS platform is the only option for an oncology customer, like Invitae, or any MCED test developer, to sell a cancer screening test as a distributed IVD kit:

> It comes down to FDA regulation. So for a distributed IVD, the FDA mandates that the next-generation sequencer be cleared, so it has to have a 510(k) clearance. That clearance then must be part of the companion diagnostic device. . . . So unless you have an agreement with Illumina to agree when the FDA request it to send them their sequencing package, you have no way to get approval. Therefore, without them, it – I mean, right now, it's actually – it's impossible. You can't do it.

(PX7044 (Stahl (Invitae) IHT 51-52)).

Response to Finding No. 1018:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1010, which Respondents incorporate herein.

The proposed finding is also incomplete and misleading. Mr. Stahl testified that BGI's and Illumina's technologies are "very similar". (PX7075 (Stahl (Invitae) Dep. at 74–75.) Moreover, Dr. Felton explained how the PGM Dx platform, a fully FDA-approved system, is used in oncology applications. (Felton (Thermo Fisher) Tr. 1983–87.) [redacted] Respondents also incorporate their responses to CCFF ¶¶ 928 and 1293 herein.

D. ONLY ILLUMINA NGS PLATFORMS MEET THE REQUIREMENTS OF MCED TESTS

1019. As shown below, every MCED test developer testified that they need and rely on Illumina NGS as the sole NGS provider that meets their tests' needs. (*See* Section V.D.2).

Response to Finding No. 1019:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1025, which Respondents incorporate herein.

To the extent Complaint Counsel relies on its Proposed Findings in Section V.D.2 (CCFF ¶¶ 1053–1200), Respondents incorporate their responses to those Proposed Findings herein.

The proposed finding is also incomplete and misleading, including because it appears to suggest that Illumina's NGS sequencer is required for MCED tests. Respondents incorporate their responses to CCFF ¶¶ 341, 928 and 1293 herein.

1020. According to Illumina, more than 90% of the world's sequencing data is generated using Illumina NGS technology: "Leaders turn to Illumina technology for the high-quality sequencing data our instruments produce. They've done so for decades. With more than 90% of the world's sequencing data generated by Illumina sequencing by synthesis (SBS) chemistry, and > 17,000 active Illumina sequencers deployed globally, our solutions enable our customers to make discoveries that were unimaginable even a few years ago." (PX0121, Illumina, Choosing an NGS Company, https://www.illumina.com/science/technology/next-generation-sequencing/choose-ngs-company.html (last visited Apr. 6, 2022)).

Response to Finding No. 1020:

Respondents have no specific response.

1. Illumina's Industry Leading NGS Technology

a) Instruments

1021. Illumina's identifies three categories of "production-scale sequencers": the "NextSeq 550 Series," the "NextSeq 1000 & 2000," and the "NovaSeq 6000." (PX0114, Illumina, Sequencing Platforms, https://www.illumina.com/systems/sequencing-platforms.html (last visited Apr. 6, 2022)).

Response to Finding No. 1021:

Respondents have no specific response.

1022. [redacted] (PX2032 (Illumina) at 014 (Illumina, AMR 2021 Revenue Forecast, Oct. 9, 2020) (*in camera*)).

Response to Finding No. 1022:

Complaint Counsel did not present the exhibit PX2032 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 5), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

(1) NovaSeq

1023. The NovaSeq is Illumina's "high-throughput platform." (Goswami (Illumina) Tr. 3191-92).

Response to Finding No. 1023:

Respondents have no specific response.

1024. The NovaSeq is the only sequencer for which Illumina identifies "cell-free sequencing & liquid biopsy analysis" and "methylation sequencing" as "key applications." (PX0114, Sequencing Platforms, https://www.illumina.com/systems/sequencing-platforms.html (last visited Apr. 6, 2022)).

Response to Finding No. 1024:

The proposed finding is incomplete and misleading to the extent that it suggests that out of Illumina's platforms, only Illumina's NovaSeq may be used for cell-free sequencing, liquid biopsy analysis or methylation sequencing. To the contrary, as described in Respondents responses to CCFF ¶ 980, incorporated herein, putative MCED test developers are also pursuing test development using the NextSeq and MiSeq instruments.

1025. A "flow cell" is a surface onto which a prepared library of DNA molecules is attached for the purpose of sequencing. (PX7104 Aravanis (Illumina) Dep. at 117)).

Response to Finding No. 1025:

Respondents have no specific response.

1026. "Reads" are the strings of nucleotide bases in each library molecule being sequenced. (PX0035 at 002, Illumina, An Introduction to Next-Generation Sequencing Technology, https://www.illumina.com/Documents/products/Illumina_Sequencing_Introduction.pdf (last visited Apr. 6, 2022)).

Response to Finding No. 1026:

Respondents have no specific response.

1027. [redacted] (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 15-16 (RFA No. 17) (*in camera*)).

Response to Finding No. 1027:

The proposed finding is inaccurate, incomplete, and misleading to the extent it suggests that [redacted] Respondents also incorporate their responses to CCFF ¶¶ 341, 928, 1275 and 1293 herein.

Respondents further note that BGI's highest throughput instrument has a higher reported throughput than the highest performance instrument and flow cell currently offered by Illumina, the NovaSeq 6000 with the S4 flow cell (up to 6 Tb/run) (*see* PFF ¶ 592), and that BGI may enter the U.S. market by August 2022. (PFF ¶ 588.2.) Similarly, [redacted]

1028. [redacted] (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 16 (RFA No. 18) (*in camera*)).

Response to Finding No. 1028:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1027, which Respondents incorporate herein.

(2) NextSeq Series

1029. The NextSeq is Illumina's "medium or mid-throughput platform." (Goswami (Illumina) Tr. 3191).

Response to Finding No. 1029:

Respondents have no specific response.

1030. Illumina identifies the NextSeq as a "production-scale sequencer." (PX0114, Sequencing Platforms, https://www.illumina.com/systems/sequencing-platforms.html (last visited Apr. 6, 2022)).

Response to Finding No. 1030:

Respondents have no specific response.

1031. Illumina identifies the NextSeq as capable of "cell-free sequencing & liquid biopsy analysis" and "methylation sequencing." (PX0114, Illumina, Sequencing Platforms, https://www.illumina.com/systems/sequencing-platforms.html (last visited Apr. 6, 2022)).

Response to Finding No. 1031:

Respondents have no specific response.

1032. "Cell-free sequencing & liquid biopsy analysis" and "methylation sequencing" are not identified as "key applications" for NextSeq sequencers. (PX0114, Illumina, Sequencing Platforms, https://www.illumina.com/systems/sequencing-platforms.html (last visited Apr. 6, 2022)).

Response to Finding No. 1032:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1024, which Respondents incorporate herein.

(3) Illumina's Other Platforms

1033. Illumina offers a number of other benchtop sequencers that are not designated as "production-scale sequencers," including the iSeq 100, the MiniSeq, and the MiSeq series. (PX0114, Illumina, Sequencing Platforms, https://www.illumina.com/systems/sequencing-platforms.html (last visited Apr. 6, 2022)).

Response to Finding No. 1033:

Respondents have no specific response except to note that Dr. Gao of Singlera admitted that the PanSeer test only needs over 5 million reads and was being developed in part with Illumina's MiSeq. (Gao (Singlera) Tr. At 2893, 2928–31.)

1034. Illumina's MiSeq is a "low-throughput platform." (Goswami (Illumina) Tr. 3191). That means it "can run tests that have a low number of reads per test, so something like NIPT or an infectious disease test or a small oncology panel." (Goswami (Illumina) Tr. 3192).

Response to Finding No. 1034:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1033 herein.

1035. Generally, a low-throughput instrument will be used for an application with low reads or if the lab does not process many samples (i.e., ten to twenty samples at a time). (Goswami (Illumina) Tr. 3193).

Response to Finding No. 1035:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1033 herein.

(4) Illumina's Proactive Performance Monitoring System

1036. [redacted] (PX7076 (Berry (Illumina) Dep. at 27-30, 35-36); PX6056 (Illumina) at 047 (Illumina, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 1036:

The proposed finding is incomplete and misleading. Mr. deSouza was unequivocal in testifying that customers could run their sequencers with an "airgap"—that is, they can

"completely just run it on their own and don't have any connection to the Internet at all." (deSouza (Illumina) Tr. 2383–84.) The Proactive monitoring service and the cloud storage services are both voluntary, opt-in programs for customers. (*See also* PX7076 (Berry (Illumina) Dep. at 30.) Respondents also note that it is "an important bright line" for Illumina to "never access or look at or review any customer's genomic data", which customers do not provide to Illumina even if they are connected to the Proactive service. (deSouza (Illumina) Tr. 2385.) Respondents also incorporate their responses to CCFF ¶¶ 1038, 2612, 2673 and 2678 herein.

1037. Proactive provides customers with access to improved service. (PX7076 (Berry (Illumina) Dep. at 36-37)).

Response to Finding No. 1037:

The proposed finding is incomplete and misleading. The extent of the "improved service" that a customer receives from using Proactive is the Proactive service itself. Proactive "allows Illumina to have visibility into specific instrument sort of physical states to try to understand when an instrument is likely to requires service." (Berry (Illumina) Tr. 850–852.) The only added service benefit to the Proactive user is a notice from Illumina that its machines are likely to require service. Respondents also note that it is "an important bright line" for Illumina to "never access or look at or review any customer's genomic data", which customers do not provide to Illumina even if they are connected to the Proactive service. (deSouza (Illumina) Tr. 2385.) Respondents also incorporate their responses to CCFF ¶¶ 1038, 2676 and 2678 herein.

The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2612 and 2673, which Respondents incorporate herein.

1038. [redacted]

[redacted] (PX6056 (Illumina) at 047 (Illumina, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 1038:

The proposed finding is inaccurate, incomplete and misleading, including for the reasons described in Respondents' responses to CCFF ¶¶ 1036–37, which Respondents incorporate herein.

In any event, any information collected in connection with servicing is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—such as order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.)

Illumina also takes extensive precautions to protect the confidentiality of information it receives from developers including: (1) setting up confidentiality agreements with partners, (2) training staff and requiring them to sign confidentiality agreements, (3) separating teams who might work on similar products, (4) using document control processes and (5) providing legal guidance if individuals request access to protected documents. (PFF ¶¶ 1040–1040.5; Goswami (Illumina) Tr. 3227–30.) These practices are standard in the industry and generally accepted by companies that serve multiple clients in the same industry. (PFF ¶ 1040.8; Goswami (Illumina) Tr. 3228–29.)

The Open Offer, which Illumina made available after the submission of PX6056, requires Illumina not to share any customer confidential information with GRAIL or its subsidiaries or employees, or with Illumina employees who work with GRAIL. (*See* PFF ¶¶ 1038–1038.1.)

The Open Offer requires that to the extent that Illumina has access to customer confidential information, Illumina shall not share such information with GRAIL, any GRAIL

subsidiary or any employee who works within GRAIL. (PFF ¶ 1038; [redacted]; Berry (Illumina) Tr. 916–17; PX0064 (Illumina) at 9.)

Under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (PFF ¶ 1039; [redacted] deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted].)

1039. Proactive provides Illumina with "the ability to monitor instrument use, specifically as it relates to run metrics" and grants Illumina access to information on the number of runs a customer performs on each instrument, as well as the type of flow cell in use on each instrument. (PX7076 (Berry (Illumina) Dep. at 27-30, 39-40)).

Response to Finding No. 1039:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1036–38, which Respondents incorporate herein.

(5) [redacted]

(a) Technical Improvements/Updates – Process to Market

1040. Illumina continuously makes improvements and updates to the performance and feature set of its existing platforms:

> JUDGE CHAPPELL: Do you know if there are frequent – I'm not sure of the terminology – but software updates or something that would need to be added to make the machine perform properly?
>
> THE WITNESS [Nicole Berry, Illumina SVP and General Manager of the Americas Commercial Region]: Sure. So we are continuously seeking to improve performance and, you know, the feature set of our instruments and user friendliness as it relates to things like software. So, yes, software updates are something that we would typically provide and make part of our continuous sort of update and improvement process.
>
> Those oftentimes could be actually administered remotely. If the customer opted into sort of, you know, a remote connectivity, we could potentially just push an update to the customer's instrument without having to actually go into

> the lab and, you know, sit at it and put disks in a hard drive, you know, the old-fashioned way.

(Berry (Illumina) Tr. 675-76).

Response to Finding No. 1040:

Respondents have no specific response.

1041. Illumina's Ms. Berry testified about Illumina's "track record in terms of our technology innovation and new product introduction process," stating that Illumina has introduced new instrument platforms and new chemistries within instrument platforms "on a very regular basis." (Berry (Illumina) Tr. 714-15).

Response to Finding No. 1041:

Respondents have no specific response.

(b) [redacted]

1042. [redacted] (deSouza (Illumina) Tr. 2278 (*in camera*)).

Response to Finding No. 1042:

Respondents have no specific response.

1043. [redacted] (deSouza (Illumina) Tr. 2278 (*in camera*)).

Response to Finding No. 1043:

Respondents have no specific response.

(c) [redacted]

1044. [redacted] (Aravanis (Illumina) Tr. 1794 (*in camera*); deSouza (Illumina) Tr. 2271 (*in camera*); PX2169 (Illumina) at 022, 025 (Illumina Strategic Plan 2021-2025, Oct. 23, 2020) (*in camera*); PX5026 (Illumina) at 009 (FY20-25 Strategic Plan Initial Revenue Discussion, Jun. 4, 2020 (*in camera*))).

Response to Finding No. 1044:

Complaint Counsel did not present the exhibit PX5026 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 54), and

therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1045. [redacted] (RX1254 (Illumina) at 009 [redacted] (*in camera*)).

Response to Finding No. 1045:

Respondents have no specific response except to note that BGI's highest throughput instrument, the DNBSEQ-T10, has a higher reported throughput (20 Tb per day) than the highest performance instrument and flow cell currently offered by Illumina, the NovaSeq 6000 with the S4 flow cell (up to 6 Tb/run), [redacted] (PFF ¶ 592; *compare* RX4004 (MGI Tech) at 1–2 *with* RX3357 (Illumina) at 7; [redacted]

Complaint Counsel did not present the exhibit RX1254 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (RC Exhibit Index at 64), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1046. [redacted] (Aravanis (Illumina) Tr. 1797; PX6056 (Illumina) at 017 (Illumina, Narrative Response to the Second Request, Mar. 1, 2021) (*in camera*) [redacted] ; RX1254 (Illumina) at 010 [redacted] (*in camera*) [redacted] ; PX2169 (Illumina) at 025 (Illumina Strategic Plan 2021-2025, Oct. 23, 2020) [redacted]

Response to Finding No. 1046:

Respondents have no specific response except to note that [redacted] (deSouza (Illumina) Tr. 2301 (in camera)). Furthermore, BGI's highest throughput instrument is claimed to have a higher throughput than the highest performance instrument and flow cell currently offered by Illumina, the NovaSeq 6000 with the S4 flow cell (up to 6 Tb/run), [redacted]; Cote Tr. 3743–44; RX3869 (Cote Expert Report) ¶ 287.)

Respondents also note that BGI announced that its DNBSEQ-T10×4RS sequencers can generate $100 genomes, making it per Gb cost only $1.00. (PFF ¶ 594.2; RX4004 (MGI); *see also* deSouza (Illumina) Tr. 2331 ("Last year, BGI announced its hundred-dollar genome and has talked about its T-10 being ready to be deployed around the world").

Complaint Counsel did not present the exhibit RX1254 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (RC Exhibit Index at 64), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also incorporate their responses to CCFF ¶¶ 1044–46 herein.

b) Illumina Consumables

1047. Illumina sells multiple versions of flow cells (SP, S1, S2, and S4): "the main difference between these flow cells is that they have different outputs," with the S4 providing the highest output of data in a single run of the sequencer. (PX7104 (Aravanis (Illumina) Dep. at 117-122)).

Response to Finding No. 1047:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1115 herein.

1048. The S4 flow cell for the NovaSeq can load 10 billion DNA library fragments, yielding 10 billion single-end reads (or 20 billion paired-end reads if each fragment is read both forward and backward). (PX0085 at 001, Illumina, NovaSeq 6000 System Specifications, https://www.illumina.com/systems/sequencing-platforms/novaseq/specifications.html (last visited Apr. 6, 2022)).

Response to Finding No. 1048:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1115 herein.

1049. The NovaSeq is capable of processing two flow cells simultaneously, and thus is capable of reading 20 billion library fragments, yielding 20 billion single-end reads (or 40 billion paired end reads), in a single 44-hour run of the instrument. (PX0085 at 001-002, Illumina, NovaSeq 6000 System Specifications, https://www.illumina.com/systems/sequencing-platforms/novaseq/specifications.html (last visited Apr. 6, 2022)).

Response to Finding No. 1049:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1115 herein.

1050. Many of Illumina's consumables are off-the-shelf products for use in a variety of sequencing applications. (Berry (Illumina) Tr. 827).

Response to Finding No. 1050:

Respondents have no specific response.

1051. Ms. Berry admitted at trial that Illumina also sells custom library prep kits to its NGS sequencing customers. (Berry (Illumina) Tr. at 928; PX7063 (Berry (Illumina) IHT at 33).

Response to Finding No. 1051:

Respondents have no specific response.

1052. In 2020, Illumina's consumable sales accounted for 71 percent of Illumina's total revenue. (PX0061 at 007 (Illumina 2020 Form 10-K)).

Response to Finding No. 1052:

Respondents have no specific response.

2. MCED Test Developers Testified That They Need and Rely on Illumina NGS as Their Only NGS Option

1053. Illumina sells NGS equipment to Grail, Exact, Natera, Guardant, Freenome, Singlera, and Foundation Medicine. (*See* Berry (Illumina) Tr. 650-51).

Response to Finding No. 1053:

Respondents have no specific response.

a) Grail

1054. Grail's Galleri test relies on Illumina's NGS instruments and reagents. (PX0043 at 011 (Grail 2020 Form S-1); PX7069 (Bishop (Grail) IHT at 208-10)).

Response to Finding No. 1054:

Complaint Counsel did not present the exhibit PX0043 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 1), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1055. [redacted] (Jamshidi (Grail) Tr. 4029 (*in camera*); (Bishop (Grail) Tr. 1336-37; 1381)).

Response to Finding No. 1055:

Respondents have no specific response except to note that [redacted]. (Jamshidi (GRAIL) Tr. 4029–30. (*in camera*))

1056. [redacted] (Jamshidi (Grail) Tr. 4029 (*in camera*)).

Response to Finding No. 1056:

The proposed finding is misleading to the extent that it suggests that [redacted] To the contrary, Mr. Bishop (GRAIL's CEO at the time of trial) testified that, while GRAIL uses the Illumina NovaSeq, the choice to use it relates mainly to the fact that it was used when Illumina founded GRAIL; GRAIL uses a variety of reagents and

consumables and not all of these inputs are from Illumina; and Illumina has no role in running the Galleri test. (PFF ¶ 1560; Bishop (GRAIL) Tr. 1381–82.) Respondents also incorporate their responses to CCFF ¶¶ 341, 928, 969 and 1293 herein.

Respondents also note that Dr. Aravanis identified a number of sequencing platforms on the market today and in development that would be viable platforms for an MCED test such as Galleri. (Aravanis (Illumina) Tr. 1848–63.) In particular, Dr. Aravanis testified that when he was at GRAIL, GRAIL considered using BGI, Thermo Fisher and Oxford Nanopore; GRAIL evaluated these platforms and determined that many of them would be a viable alternative. (PFF ¶ 1311; Aravanis (Illumina) Tr. 1863.) Dr. Aravanis also testified that "as a matter of good business, we did want to have contingencies. We – excuse me – evaluated the platforms that I mentioned and determined that many of them would be a viable alternative." (Aravanis (Illumina) Tr. 1863.)

1057. [redacted]
(Jamshidi (Grail) Tr. 4029 (*in camera*)).

Response to Finding No. 1057:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶ 1056, which Respondents incorporate herein. Respondents also note that [redacted] (Jamshidi (GRAIL) Tr. 4029 (emphasis added) (*in camera*).)

1058. [redacted]

[redacted]

Response to Finding No. 1058:

Respondents have no specific response.

1059. [redacted] (PX4140 (Grail) at 007, 010 (R&D Portfolio Planning – Part B: Sequencing Technology) (*in camera*)).

Response to Finding No. 1059:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 969, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶¶ 341, 928, 1056 and 1293.

1060. [redacted] (Freidin (Grail) Tr. 3066 (*in camera*)).

Response to Finding No. 1060:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1056, which Respondents incorporate herein. Respondents also note that Dr. Aravanis identified a number of sequencing platforms on the market today and in development that would be viable platforms for an MCED test such as Galleri. (Aravanis (Illumina) Tr. 1848–63.) In particular, Dr. Aravanis testified that when he was at GRAIL, GRAIL considered using BGI, Thermo Fisher and Oxford Nanopore; GRAIL evaluated these platforms and determined that many of them would be a viable alternative. (PFF

¶ 1311; Aravanis (Illumina) Tr. 1863.) Dr. Aravanis also testified that "as a matter of good business, we did want to have contingencies. We – excuse me – evaluated the platforms that I mentioned and determined that many of them would be a viable alternative." (Aravanis (Illumina) Tr. 1863.)

1061. [redacted] (PX7066 (Freidin (Grail) IHT at 133) (*in camera*)).

Response to Finding No. 1061:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1056 and 1060, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. At 275–76.)

1062. [redacted] (PX7066 (Freidin (Grail) IHT at 126) (*in camera*)).

Response to Finding No. 1062:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is inaccurate, incomplete, and misleading for the

reasons explained in Respondents' responses to CCFF ¶¶ 1056 and 1060, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. At 275–76.)

1063. [redacted] (PX6049 (Grail) at 023 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 1063:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1056 and 1060, which Respondents incorporate herein.

1064. [redacted] (PX4140 (Grail) at 003 (R&D Portfolio Planning – Part B: Sequencing Technology) (*in camera*)).

Response to Finding No. 1064:

Complaint Counsel did not present the exhibit PX4140 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 38), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1065. [redacted] (PX4140 (Grail) at 003, 009-010 (R&D Portfolio Planning – Part B: Sequencing Technology) (*in camera*)).

Response to Finding No. 1065:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 969, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶¶ 341, 928, 1056 and 1293.

1066. Grail has never physically performed technical evaluations of non-Illumina sequencers. (PX7103 (Jamshidi (Grail) Dep. at 33)).

Response to Finding No. 1066:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1056 and 1060, which Respondents incorporate herein.

1067. In Grail's Form S-1 filed with the Securities and Exchange Commission, Grail detailed in the "Risk Factors" section, "[w]e rely on Illumina, Inc. as a sole supplier for our next-generation sequencers and associated reagents. . . ." (PX0043 at 011 (Grail 2020 Form S-1)).

Response to Finding No. 1067:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1056 and 1060, which Respondents incorporate herein.

Respondents also note that Dr. Aravanis identified a number of sequencing platforms on the market today and in development that would be viable platforms for an MCED test such as Galleri. (Aravanis (Illumina) Tr. 1848–63.) In particular, Dr. Aravanis testified that when he was at GRAIL, GRAIL considered using BGI, Thermo Fisher and Oxford Nanopore; GRAIL

evaluated these platforms and determined that many of them would be a viable alternative. (PFF ¶ 1311; Aravanis (Illumina) Tr. 1863.) Dr. Aravanis also testified that "as a matter of good business, we did want to have contingencies. We – excuse me – evaluated the platforms that I mentioned and determined that many of them would be a viable alternative." (Aravanis (Illumina) Tr. 1863.)

Complaint Counsel did not present the exhibit PX0043 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 1), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1068. In an internal email, Grail's Board Chair, Cathy Friedman, referred to "Illumina's position as a 'necessary tax' on the entire genomics industry . . . ." (PX4375 (Grail) at 001 (Email from G. Golumbeski, Grail, to C. Friedman, Grail, Oct. 10, 2018) (referring to a quote from Guardant's S-1, which states, "We rely on Illumina as the sole supplier of the sequencers, and as the sole provider of maintenance and repair services for these sequencers.")).

Response to Finding No. 1068:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1056 and 1060, which Respondents incorporate herein.

Complaint Counsel did not present the exhibit PX4375 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 46), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1069. [redacted] (PX7066 (Freidin (Grail) IHT at 212-13; PX6049 (Grail) at 023 (Grail, Narrative Response to Second Request, Mar. 1, 2021)) (*in camera*).

Response to Finding No. 1069:

The proposed finding is misleading to the extent that it suggests that [redacted] To the contrary, Mr. Bishop (GRAIL's CEO at the time of trial) testified that, while GRAIL uses the Illumina NovaSeq, the choice to use it relates mainly to the fact that it was used when Illumina founded GRAIL; GRAIL uses a variety of reagents and consumables and not all of these inputs are from Illumina; and Illumina has no role in running the Galleri test. (PFF ¶ 1560; Bishop (GRAIL) Tr. 1381–82.) The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1056 and 1060, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. At 275–76.)

1070. [redacted] (Freidin (Grail) Tr. 3065 (*in camera*)); *see* (Bishop (Grail) Tr. 1381) (explaining that Grail's earlier research was conducted on Illumina's NGS)).

Response to Finding No. 1070:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1056 and 1060, which Respondents incorporate herein.

1071. [redacted]

[redacted] (Freidin (Grail) Tr. 3066 (*in camera*)).

Response to Finding No. 1071:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1056 and 1060, which Respondents incorporate herein.

1072. Grail's former CEO Mr. Bishop testified at trial that Grail has stayed with Illumina NGS because it is the "technology we know and that works." (Bishop (Grail) Tr. 1381).

Response to Finding No. 1072:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1056 and 1060, which Respondents incorporate herein.

1073. Galleri has been validated for use on only an Illumina NGS sequencer. (Bishop (Grail) Tr. 1337).

Response to Finding No. 1073:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1056 and 1060, which Respondents incorporate herein.

1074. Grail does not have a validated alternative to Illumina's NGS platforms for Galleri. (Bishop (Grail) Tr. 1337-38).

Response to Finding No. 1074:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1056 and 1060, which Respondents incorporate herein.

Respondents also note that Dr. Aravanis identified a number of sequencing platforms on the market today and in development that would be viable platforms for an MCED test such as Galleri. (Aravanis (Illumina) Tr. 1848–63.) In particular, Dr. Aravanis testified that when he was at GRAIL, GRAIL considered using BGI, Thermo Fisher and Oxford Nanopore; GRAIL evaluated these platforms and determined that many of them would be a viable alternative. (PFF ¶ 1311; Aravanis (Illumina) Tr. 1863.) Dr. Aravanis also testified that "as a matter of good business, we did want to have contingencies. We – excuse me – evaluated the platforms that I mentioned and determined that many of them would be a viable alternative." (Aravanis (Illumina) Tr. 1863.)

The proposed finding is also misleading to the extent that it suggests that GRAIL could not switch to an alternative platform from the Illumina NovaSeq platform. Dr. Aravanis noted that that customers switch from one Illumina NGS platform to another every few years; in order to switch from an Illumina NGS platform to another NGS platform, GRAIL would need to do an analytical bridging study to demonstrate that the test performs similarly on an alternative sequencing platform, there might be other steps where minor modifications to some of the library prep or analysis would also be required; an alternative NGS platform would not need FDA approval before it could be used for development or commercialization of an MCED test like

Galleri; if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch, and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (PFF ¶ 1312; Aravanis (Illumina) Tr. 1861–65.)

Respondents also note that GRAIL has used both Illumina's HiSeq platform and NovaSeq platform with S2 and S4 flow cells (Cote Tr. 3739–40; PX7104 (Aravanis (Illumina) Dep.) at 168–69; RX3773 (Supplement Information to Klein 2021) at 11, 13, 15–16), and [redacted]

1075. Grail's former CEO, Hans Bishop, testified that Illumina is Grail's "only [supplier of NGS instruments and reagents] that we validated with our technology, so if they're not available to us, we don't have a validated alternative." (PX7069 (Bishop (Grail) IHT at 210)).

Response to Finding No. 1075:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1074, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶¶ 1056 and 1060.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. At 275–76.)

1076. Mr. Bishop explained that Illumina's status as Grail's only validated sequencer, "means that all the analytical validation and regulatory compliance documents that we've done that you're required to do to show our tests work is done, again, with all the different suppliers on that list, and if we had to substitute one, we would have to do that work again." (PX7069 (Bishop (Grail) IHT at 210)).

Response to Finding No. 1076:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1056 and 1074, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. At 275–76.)

1077. [redacted] (PX4085 (Grail) at 011 (Grail, "Critical Materials Landscape, Dec. 5, 2018) (*in camera*)).

Response to Finding No. 1077:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1056 and 1060, which Respondents incorporate herein.

1078. [redacted] (PX6049 (Grail) at 023 (Grail, Narrative Response to Second Request) (*in camera*)).

Response to Finding No. 1078:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is inaccurate, incomplete, and misleading for the

reasons explained in Respondents' responses to CCFF ¶¶ 1056 and 1060, which Respondents incorporate herein.

1079. [redacted] (Freidin (Grail) Tr. 3065-66 (*in camera*); PX7066 (Freidin (Grail) IHT at 133) (*in camera*)).

Response to Finding No. 1079:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1056 and 1060, which Respondents incorporate herein.

Respondents also note that Dr. Aravanis identified a number of sequencing platforms on the market today and in development that would be viable platforms for an MCED test such as Galleri. (Aravanis (Illumina) Tr. 1848–63.) In particular, Dr. Aravanis testified that when he was at GRAIL, GRAIL considered using BGI, Thermo Fisher and Oxford Nanopore; GRAIL evaluated these platforms and determined that many of them would be a viable alternative. (PFF ¶ 1311; Aravanis (Illumina) Tr. 1863.) Dr. Aravanis also testified that "as a matter of good business, we did want to have contingencies. We – excuse me – evaluated the platforms that I mentioned and determined that many of them would be a viable alternative." (Aravanis (Illumina) Tr. 1863.)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. At 275–76.)

1080. [redacted] (PX6049 (Grail) at 023 (Grail, Narrative Response to Second Request) (*in camera*)).

Response to Finding No. 1080:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1056 and 1060, which Respondents incorporate herein.

1081. [redacted] (PX6082 (Grail) at 009 (Grail Response to Request for Admission) (*in camera*)).

Response to Finding No. 1081:

The proposed finding is misleading to the extent that it suggests that [redacted] To the contrary, Mr. Bishop (GRAIL's CEO at the time of trial) testified that, while GRAIL uses the Illumina NovaSeq, the choice to use it relates mainly to the fact that it was used when Illumina founded GRAIL; GRAIL uses a variety of reagents and consumables and not all of these inputs are from Illumina; and Illumina has no role in running the Galleri test. (PFF ¶ 1560; Bishop (GRAIL) Tr. 1381–82.) The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1056 and 1060, which Respondents incorporate herein.

Complaint Counsel did not present the exhibit PX6082 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 56), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1082. [redacted] (PX7066 (Freidin (Grail) IHT at 212-13) (*in camera*)).

Response to Finding No. 1082:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1056 and 1060, which Respondents incorporate herein.

[redacted]

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1083. Grail's Form S-1—a filing submitted to the Securities and Exchange Commission—warns that a qualitative substitute for Illumina "may not be available at all":

> In the case of attempting to obtain an alternative supplier for Illumina, Streck, or Twist, replacement instruments and associated reagents, tubes, and panels that meet our quality control and performance requirements may not be available at all, or may not be available on reasonable terms or in a timely manner.

(PX4082 (Grail) at 034 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 1083:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1056 and 1060, which Respondents incorporate herein.

Respondents also note that Dr. Aravanis identified a number of sequencing platforms on the market today and in development that would be viable platforms for an MCED test such as Galleri. (Aravanis (Illumina) Tr. 1848–63.) In particular, Dr. Aravanis testified that when he was at GRAIL, GRAIL considered using BGI, Thermo Fisher and Oxford Nanopore; GRAIL evaluated these platforms and determined that many of them would be a viable alternative. (PFF ¶ 1311; Aravanis (Illumina) Tr. 1863.) Dr. Aravanis also testified that "as a matter of good business, we did want to have contingencies. We – excuse me – evaluated the platforms that I

mentioned and determined that many of them would be a viable alternative." (Aravanis (Illumina) Tr. 1863.)

b) [redacted]

1084. [redacted]

Response to Finding No. 1084:

The proposed finding is also incomplete and misleading with respect to Exact/Thrive's purported reliance on Illumina's NGS systems. [redacted]

Further, Dr. Vogelstein, the founder of Thrive stated, [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 341, 928, 1293 and 2833 herein.

The proposed finding is incomplete and misleading insofar as it suggests that Exact is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future for the reasons explained in Respondents' responses to CCFF ¶¶ 414, 418, 929, 1905, 1911, 1912, 1935 and 2023, which Respondents incorporate herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) In particular, Mr. Conroy was not involved in the development of CancerSEEK, Exact Sciences does not have any tests that use NGS technology and Exact Sciences was not an Illumina customer until its acquisition of Thrive. (*See* Conroy (Exact Sciences) Tr. 1542–43.)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. At 275–76.)

1085. [redacted]

Response to Finding No. 1085:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1084, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1086. [redacted]

Response to Finding No. 1086:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1084, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶ 1089 herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1087. [redacted]

Response to Finding No. 1087:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1084, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1088. [redacted]

Response to Finding No. 1088:

The proposed finding is not supported by the cited evidence. Dr. Lengauer testified that [redacted]. (Lengauer (Exact/Thrive) Tr. 185–186. (*in camera*)) The cited testimony also supports Respondents' proposition that switching between platforms will have no impact on any putative test development. [redacted] Further, neither Complaint Counsel nor Dr. Scott Morton offered any empirical assessment of the *incremental* cost of switching from an Illumina

platform to a third-party platform as compared to the switching cost that would be incurred by a test developer that seeks to upgrade to Illumina's next generation system. (PFF ¶ 948.2; RX3871 (Willig Expert Report) ¶¶ 46, 48.)

1089. [redacted]

Response to Finding No. 1089:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1084, which Respondents incorporate herein. [redacted]

[redacted]

[redacted]

1090. [redacted]

Response to Finding No. 1090:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1084 and 1089, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1091. [redacted]

Response to Finding No. 1091:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in

Respondents' responses to CCFF ¶ 929, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶¶ 341, 928 and 1293 herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

Respondents also note that Dr. Vogelstein, a founder of Thrive, stated, [redacted]

1092. [redacted]

Response to Finding No. 1092:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929 and 1091, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

Respondents also note that during the cited testimony, Dr. Lengauer confirmed that: [redacted]

[redacted]

[redacted]

[redacted]

[redacted]" (Lengauer (Exact/Thrive) Tr. 238–39.)

1093. [redacted]

Response to Finding No. 1093:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929 and 1091–92, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1094. [redacted]

Response to Finding No. 1094:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 904, 929 and 1091–92, which Respondents incorporate

herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1095. [redacted]

Response to Finding No. 1095:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929 and 1091–92, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. At 275–76.)

c) [redacted]

1096. [redacted]

Response to Finding No. 1096:

The proposed finding is misleading to the extent it suggests that Natera uses only Illumina platforms for its commercial testing. For example, Natera and BGI Genomics formed a partnership to commercialize Natera's Signatera NGS-based cancer monitoring test on BGI's DNBSEQ platform in China, and has now launched a version of the Signatera test in China "that incorporates MGI sequencing platforms." ([redacted]; RX3062 (BGI) at 1.)

1097. [redacted]

Response to Finding No. 1097:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928 and 1293, which Respondents incorporate herein. . The proposed finding is also misleading to the extent it suggests that Natera uses only Illumina platforms for its tests. For example, Natera and BGI Genomics formed a partnership to commercialize Natera's Signatera NGS-based cancer monitoring test on BGI's DNBSEQ platform in China, and has now launched a version of the Signatera test in China "that incorporates MGI sequencing platforms." [redacted] RX3062 (BGI) at 1.)

1098. [redacted]

Response to Finding No. 1098:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 965 and 1293, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1099. [redacted]

Response to Finding No. 1099:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

The proposed finding is also inaccurate, incomplete and misleading, including because it appears to suggest that [redacted] which is not true. [redacted] (PX8532 (Natera) at

001 (*in camera*).) [redacted] (PX8532 (Natera) at 007 (*in camera*).) [redacted] As Complaint Counsel has contended in multiple of its proposed findings and in its post-trial brief, MRD tests are not the same as MCED tests. (*See* CCFF ¶¶ 155, 624–628, 731; CC Br. at 51–52, 54–55.)

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to ¶¶ 928, 965, 1264 and 1293, which Respondents incorporate herein.

1100. [redacted]

Response to Finding No. 1100:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 965 and 1293, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1101. [redacted]

Response to Finding No. 1101:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 965, 1264 and 1293, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1102. [redacted]

Response to Finding No. 1102:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 965, 1264 and 1293, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1103. [redacted]

[redacted]

Response to Finding No. 1103:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 965, 1264 and 1293 herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1104. [redacted]

Response to Finding No. 1104:

The proposed finding is inaccurate, incomplete and misleading, including because it appears to suggest that [redacted] Respondents incorporate their responses to CCFF ¶¶ 904 and 913 herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1105. [redacted]

Response to Finding No. 1105:

The proposed finding is irrelevant because it does not relate to MCED tests. The proposed finding is also misleading to the extent it suggests that Natera uses only Illumina platforms for its tests. For example, Natera and BGI Genomics formed a partnership to commercialize Natera's Signatera NGS-based cancer monitoring test on BGI's DNBSEQ platform in China, and has now launched a version of the Signatera test in China "that incorporates MGI sequencing platforms." [redacted]; RX3062 (BGI) at 1.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

Complaint Counsel did not present the exhibit PX0155 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 2), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928 and 1293, which Respondents incorporate herein.

d) Guardant

1106. [redacted] (Chudova (Guardant) Tr. 1196) (*in camera*)).

Response to Finding No. 1106:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 341, 927, 928, 940, 960, 971 and 1293, which Respondents incorporate herein. (*See also* PFF ¶¶ 473–492.) Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1107. [redacted] (Chudova (Guardant) Tr. 1300 (*in camera*)).

Response to Finding No. 1107:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 341, 927, 928, 940, 960, 971 and 1293, which Respondents incorporate herein. (*See also* PFF ¶¶ 473–492.) For example, [redacted]

[redacted] (PFF ¶ 780.5.) Dr. Chudova also stated that Guardant could use alternative sequencing platforms for its LUNAR-2 screening test in development that meet the throughput, error, time, and sequencing cost requirements. (PX7045 (Chudova (Guardant) IHT at 43–47.)

1108. [redacted] (Chudova (Guardant) Tr. 1212 (*in camera*); *see also* PX7045 (Chudova (Guardant) IHT at 22-23; 39-40) (*in camera*)).

Response to Finding No. 1108:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 341, 927, 928, 940, 960, 971 and 1293, which Respondents incorporate herein. (*See also* PFF ¶¶ 473–492.) Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1109. [redacted] (Chudova (Guardant) Tr. 1207 (*in camera*)).

Response to Finding No. 1109:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 341, 927, 928, 940, 960, 971 and 1293, which Respondents incorporate herein. (*See also* PFF ¶¶ 473–492.) Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1110. [redacted] (Chudova (Guardant) Tr. 1208 (*in camera*)); PX7045 (Chudova (Guardant) IHT at 40-41) (*in camera*)).

Response to Finding No. 1110:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 341, 927, 928, 940, 960, 971 and 1293, which Respondents incorporate herein. (*See also* PFF ¶¶ 473–492.) Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1111. [redacted] (Chudova (Guardant) Tr. 1212 (*in camera*)).

Response to Finding No. 1111:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 341, 927, 928, 940, 960, 971 and 1293, which Respondents incorporate herein. (*See also* PFF ¶¶ 473–492.) Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1112. [redacted] (Chudova (Guardant) Tr. at 1212-13 (*in camera*)).

Response to Finding No. 1112:

Respondents have no specific response.

1113. [redacted] (Chudova (Guardant) Tr. 1212-13 (*in camera*)).

Response to Finding No. 1113:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1115 herein.

1114. [redacted] (Chudova (Guardant) Tr. 1213 (*in camera*)).

Response to Finding No. 1114:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1115 herein.

1115. [redacted] (Chudova (Guardant) Tr. 1213 (*in camera*)).

Response to Finding No. 1115:

The proposed finding is inaccurate, incomplete, and misleading to the extent it suggests that only Illumina's NovaSeq may be used for MCED test development. Respondents further note that BGI's highest throughput instrument has a higher reported throughput than the highest performance instrument and flow cell currently offered by Illumina, the NovaSeq 6000 with the S4 flow cell (up to 6 Tb/run) (*see* PFF ¶ 592), and that BGI may enter the U.S. market by August 2022. (PFF ¶ 588.2.) BGI's second highest throughput instrument, the DNBSEQ-T7, is reported to simultaneously sequence 20 billion DNA fragments in less than 24 hours, which is less than the 45 hours required for the NovaSeq to sequence the same number of fragments. (PFF ¶ 590.) BGI's highest throughput instrument, the DNBSEQ-T10, is reported to simultaneously sequence 80 billion DNA fragments in less than 24 hours. (PFF ¶ 590.)

Respondents also note that many customers outside of China have successfully built a relationship with BGI, [redacted]

[redacted] (PX7053 (Fesko (Natera) IHT at 50–51); RX3473 (Natera) at 1; *see also* RX3062 (Natera); [redacted].

Oxford Nanopore's highest throughput instrument, the PromethION, has a throughput of 10 Tb in less than 72 hours (PFF ¶ 599 (RX3536 (ONT); RX3869 (Cote Expert Report) ¶ 293)), which is equivalent to about 6.25 Tb in the 45 hours required for a NovaSeq run. (PFF ¶ 575.)

Similarly, [redacted]

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 341, 927, 928, 940, 960, 971, 1275 and 1293, which Respondents incorporate herein. (*See also* PFF ¶¶ 473–492.)

1116. [redacted] (Chudova (Guardant) Tr. 1224 (*in camera*)).

Response to Finding No. 1116:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1115, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms,

there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1117. [redacted] (Chudova (Guardant) Tr. 1224 (*in camera*)).

Response to Finding No. 1117:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1115, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1118. [redacted] (Chudova (Guardant) Tr. 1214 (*in camera*)).

Response to Finding No. 1118:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1115, which Respondents incorporate herein.

Specifically, for BGI's DNBSEQ-T7, [redacted]

[redacted]

For BGI's highest throughput instrument, the DNBSEQ-T10 that reportedly generates 20 Tb in 24 hours (PFF ¶ 590 (RX3465 (MGI Tech); RX4004 (MGI Tech))), [redacted]

Similarly, using Oxford Nanopore's PromethION with a reported throughput of 10 Tb in up to 72 hours (PFF ¶ 599 (RX3536 (ONT); RX3869 (Cote Expert Report) ¶ 293)), [redacted]

1119. [redacted]
(Chudova (Guardant) Tr. 1214 (*in camera*)).

Response to Finding No. 1119:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1115 and 1118, which Respondents incorporate herein.

1120. [redacted] (Chudova (Guardant) Tr. 1215 (*in camera*)).

Response to Finding No. 1120:

The proposed finding is inaccurate and misleading because [redacted]

1121. [redacted] (Chudova (Guardant) Tr. 1215 (*in camera*)).

Response to Finding No. 1121:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1115 and 1118, which Respondents incorporate herein. (*See also* PFF ¶¶ 473–492.)

1122. [redacted] (Chudova (Guardant) Tr. 1215 (*in camera*)).

Response to Finding No. 1122:

The proposed finding is inaccurate and misleading because it does not address the discounts that Guardant receives under its supply agreement. [redacted]

Respondents also note that [redacted]

1123. [redacted] (Chudova (Guardant) Tr. 1215-16 (*in camera*)).

Response to Finding No. 1123:

The proposed finding is inaccurate and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1122, which Respondents incorporate herein.

1124. [redacted] (Chudova (Guardant) Tr. 1216 (*in camera*)).

Response to Finding No. 1124:

The proposed finding is inaccurate and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927 and 1122, which Respondents incorporate herein.

1125. [redacted] (Chudova (Guardant) Tr. 1216 (*in camera*)).

Response to Finding No. 1125:

The proposed finding is inaccurate and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927 and 1122, which Respondents incorporate herein.

1126. Guardant's Chudova testified, "Illumina sequencers . . . are the only game in town. There are other sequencers on the market, but ultimately they don't perform similarly. And [Guardant's cancer screening] test has been optimized to work in an Illumina environment." (PX7105 (Chudova (Guardant) Dep. at 239-40)).

Response to Finding No. 1126:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not.

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1115 and 1118, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1127. Guardant's Chudova explained that [redacted] (PX7045 (Chudova (Guardant) IHT at 40-41) (*in camera*))

Response to Finding No. 1127:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1115 and 1118, which Respondents incorporate herein. The proposed finding is also incomplete and misleading to the extent that it suggests that [redacted] To the contrary, as described in Respondents responses to CCFF ¶ 980, incorporated herein, putative MCED test developers are also pursuing test development using the NextSeq and MiSeq instruments. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1128. Dr. Chudova testified that Next Generation Sequencing is a requirement for Guardant's multicancer early detection test because it "need[s] parallel digital readout of every fragment in a highly, highly multiplex format, which means you need to run and read millions of molecules at a time or hundreds of millions of molecules at a time, and that is kind of the definition of what next-generation sequencing allows you to do." (Chudova (Guardant) Tr. 1177).

Response to Finding No. 1128:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1115 and 1118, which Respondents incorporate herein.

The proposed finding is also inaccurate, incomplete and misleading, including because it appears to suggest that an NGS platform is required for Guardant's putative development of cancer screening tests. Respondents incorporate their responses to CCFF ¶ 344 herein.

1129. Referring to Illumina, Guardant's Getty explained, [redacted] (Getty (Guardant) Tr. 2546 (*in camera*)).

Response to Finding No. 1129:

The proposed finding is irrelevant because it is not related to MCED tests.

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1115, 1118 and 1128, which Respondents incorporate herein.

The proposed finding is also inaccurate and misleading to the extent that it suggests that [redacted]

[redacted] (Chudova (Guardant) Tr. 1299–1301.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

To the extent that the proposed finding suggests that it is not viable to switch between an Illumina platform and another sequencing platform, this is also inaccurate and misleading. Respondents also note that Dr. Aravanis noted that that customers switch from one Illumina NGS platform to another every few years; in order to switch from an Illumina NGS platform to another NGS platform, the test developer would need to do an analytical bridging study to demonstrate that the test performs similarly on an alternative sequencing platform, there might be other steps where minor modifications to some of the library prep or analysis would also be required; an alternative NGS platform would not need FDA approval before it could be used for development or commercialization of an MCED test; if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (PFF ¶ 1312; Aravanis (Illumina) Tr. 1861–65.) Respondents also incorporate their responses to CCFF ¶¶ 1074, 1088, 1115 and 1118 herein.

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1130. "Guardant wouldn't exist without access to Illumina's products." (Getty (Guardant) Tr. 2510).

Response to Finding No. 1130:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927–28, 1115, 1118 and 1129, which Respondents incorporate herein.

Respondents also note that Guardant (whose founders previously were employed by Illumina) stole a significant amount of confidential technical information and materials from Illumina relating to cancer testing at Guardant's founding. *See*, *e.g.*, *Illumina, Inc. v. Guardant Health, Inc. et al.*, Civ. No. 1:22-cv-00334-VAC, D.I. 1, at 6–7 (D. Del. Mar. 17, 2022).

1131. Guardant cannot operate its assays without Illumina, its sole supplier for NGS. (Getty (Guardant) Tr. 2510).

Response to Finding No. 1131:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927–928, 1115, 1118 and 1129, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1132. Guardant has no opportunity to move away from Illumina as its NGS provider. (Getty (Guardant) Tr. 2510).

Response to Finding No. 1132:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927–928, 1115, 1118 and 1129, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1133. Guardant could not switch to another NGS system. (Getty (Guardant) Tr. 2510).

Response to Finding No. 1133:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927–928, 1115, 1118 and 1129, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1134. Guardant's Mr. Getty testified that nothing is comparable to Illumina's NGS platforms. (Getty (Guardant) Tr. 2510).

Response to Finding No. 1134:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927–928, 1115, 1118 and 1129, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1135. For both PacBio and Oxford Nanopore the "throughput is substantially less than what [Guardant] would require even for the smallest Guardant360 test." (PX7045 (Chudova (Guardant) IHT at 45; *see* PX7045 (Chudova (Guardant) IHT at 45) (*in camera*) [redacted]

Response to Finding No. 1135:

The proposed finding is inaccurate, incomplete and misleading to the extent it suggests that PacBio's and Oxford Nanopore's respective systems are not suitable for use with oncology tests. Respondents also incorporate their responses to CCFF ¶ 904 herein.

The proposed finding is also irrelevant because it relates to the requirements for the Guardant360 test, which is an 80-gene panel therapy selection test, and does not relate to an MCED test. (PFF ¶¶ 491–92; (RX3219 (Guardant)*;* RX3295 (Guardant); (RX3869 (Cote Expert Report) ¶¶ 214–15.))

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1136. "[T]here's a symbiotic relationship between Guardant Health and our activity and Illumina's activities in terms of making sure we're maximizing the value of the products they have delivered to us." (Getty (Guardant) Tr. 2509).

Response to Finding No. 1136:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927–928, 1115, 1118 and 1129, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1137. Guardant's SVP of Commercial, Cancer Screening Core, William Getty, testified, "[w]ithout [Illumina], Guardant doesn't exist." (PX7040 (Getty (Guardant) IHT at 190)).

Response to Finding No. 1137:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927–928, 1115, 1118 and 1129, which Respondents incorporate herein.

Respondents also note that Guardant (whose founders previously were employed by Illumina) stole a significant amount of confidential technical information and materials from Illumina relating to cancer testing at Guardant's founding. *See*, *e.g.*, *Illumina, Inc. v. Guardant Health, Inc. et al.*, Civ. No. 1:22-cv-00334-VAC, D.I. 1, at 6–7 (D. Del. Mar. 17, 2022).

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1138. In Guardant's 2020 Form 10-K filed with the Securities and Exchange Commission, Guardant explained,

> We rely on Illumina as the sole supplier of . . . sequencers and as the sole provider of maintenance and repair services for these sequencers. Any disruption in operations of Illumina . . . or termination or suspension of our relationships with them could materially and adversely impact our supply chain and laboratory operations . . . and thus our ability to conduct our business and generate revenue.

(PX0153 at 047 (Guardant, 2020 Form 10-K, Feb. 25, 2021)).

Response to Finding No. 1138:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1115, 1118, 1129 and 1139, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1139. Guardant has "[v]ery little" leverage in negotiating with Illumina. (PX7105 (Getty (Guardant) Dep. at 66)).

Response to Finding No. 1139:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1115, 1118 and 1129, which Respondents incorporate herein. Further, the actual circumstances of Guardant's negotiations with Illumina

are starkly different from Mr. Getty's self-serving explanation of Guardant's relationship with Illumina purportedly described in this proposed finding, therefore, the proposed finding is contradicted by the weight of the evidence.

Contrary to Mr. Getty's testimony, [redacted] (*See* Berry (Illumina) Tr. 938–43.) [redacted]. (Berry (Illumina) Tr. 938.) [redacted] This would not have been the case if Guardant had very little leverage in negotiating with Illumina.

[redacted]

[redacted] Guardant attached the amended supply agreement to its 2020 10–K because the amended agreement represented a material and important contract for Guardant. (PFF ¶ 1075.4; Getty (Guardant) Tr. 2668–69; PX0060 (Guardant) at 151.)

Finally, the public availability of the Open Offer increases Guardant's (and other customers') negotiating power, which, as outlined above, was already significant. As economist and the President and Senior Managing Director of FTI Consulting's Center for Healthcare Economics and Policy, Margaret Guerin-Calvert explained, [redacted]

[redacted] (RX3865 (Guerin-Calvert Expert Report) ¶ 44.)

e) Freenome

1140. Freenome CEO, Michael Nolan, testified that Illumina's sequencing technology is "really foundational" and a "pillar" in Freenome's product development efforts. (Nolan (Freenome) Tr. 2714).

Response to Finding No. 1140:

The proposed finding is irrelevant because it does not relate to MCED tests.

The proposed finding is also contradicted by the weight of the evidence. For example, [redacted] BGI also markets its NGS technology in many other countries and is expected to enter the U.S. market in the near future. [redacted] RX3869 (Cote Expert Report) ¶ 287; [redacted].) BGI also recently won a jury verdict that held three of Illumina's patents to be invalid meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022). BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.) Respondents also incorporate their responses to CCFF ¶¶ 928, 945 and 1293 herein.

The proposed finding is also inaccurate and misleading to the extent it suggests that [redacted]

[redacted] (PFF ¶¶ 459-70.)

Mr. Otte, Freenome's former CEO, also testified that [redacted]

Accordingly, there is no indication based on Freenome's work to date that [redacted] (PFF ¶ 458 ([redacted]; RX3869 (Cote Expert Report) ¶ 193).)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 341, 928, 945, 971, 1115, 1118 and 1293 which Respondents incorporate herein.

1141. Freenome uses Illumina's NovaSeq sequencer for its multiomics platform. (Nolan (Freenome) Tr. 2714-15).

Response to Finding No. 1141:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not.

The proposed finding is vague and ambiguous because it refers to a undefined "multiomics platform". The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1140, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1142. [redacted] PX7050 (Nolan (Freenome) IHT at 89-90 (*in camera*)); PX7055 (Otte (Freenome) IHT at 94-95 (*in camera*))).

Response to Finding No. 1142:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is vague and ambiguous because it refers to [redacted] Freenome is a pre-commercial company that does not have any [redacted]. (Nolan (Freenome) Tr. 2724.) The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1140, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1143. [redacted] (PX7094 (Nolan (Freenome) Dep. at 142-44) (*in camera*)).

Response to Finding No. 1143:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945 and 1140, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1144. Mr. Nolan testified that Freenome uses NGS in its multiomics platform as opposed to other technologies because it "gives [Freenome] great stability to detect the cancer in its – in the early stages. It's a really foundational or – or pillar in overall product development efforts. . . . [I]t is really I would say the anchor tenant." (Nolan (Freenome) Tr. 2713-14).

Response to Finding No. 1144:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945 and 1140, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS

platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.The proposed finding is also misleading to the extent that it suggests that only NGS is suitable for use in developing putative MCED tests. Respondents also incorporate their responses to CCFF ¶ 344 herein.

1145. Mr. Nolan testified that "anchor tenant" means "really foundational… [Freenome] get[s] a majority of the signal from next-generation sequencing [which is then] complemented by some of the other omics to be able to get better performance than [Freenome] would without it." (Nolan (Freenome) Tr. 2714).

Response to Finding No. 1145:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945 and 1144, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1146. In other words, "anchor tenant" is like the Macy's in a shopping mall; it's the "headliner, the major part of the model is next-generation sequencing." (Nolan (Freenome) Tr. 2714).

Response to Finding No. 1146:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in

Respondents' responses to CCFF ¶¶ 945 and 1144, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1147. Freenome purchases NGS consumables from Illumina. (Nolan (Freenome) Tr. 2718).

Response to Finding No. 1147:

Respondents have no specific response.

1148. Freenome purchases NGS sequencer servicing from Illumina. (Nolan (Freenome) Tr. 2718).

Response to Finding No. 1148:

Respondents have no specific response.

1149. Mr. Nolan further explained, [redacted] (Nolan (Freenome) Tr. 2759-60 (*in camera*)).

Response to Finding No. 1149:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945 and 1140, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1150. In discussing potential alternatives to Illumina's NGS sequencers for Freenome's cancer screening test, Mr. Nolan testified, [redacted]

[redacted] (PX7094 (Nolan (Freenome) Dep. at 221-223) (*in camera*)).

Response to Finding No. 1150:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945 and 1140, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1151. [redacted] (PX7094 (Nolan (Freenome) Dep. at 142-44) (*in camera*); PX7050 (Nolan (Freenome) IHT at 113) (*in camera*) [redacted]).

Response to Finding No. 1151:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. At 275–76.)

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945 and 1140, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in

development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1152. In discussing the requirements to run Freenome's cancer screening test, Mr. Nolan indicated that Freenome [redacted] (PX7094 (Nolan (Freenome) Dep. at 221-223) (*in camera*)).

Response to Finding No. 1152:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945 and 1140, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1153. [redacted] (PX8378 (Freenome) at 002 (Email from M. Nolan, Freenome, to A. Welland, Illumina, Feb. 26, 2021) (*in camera*)).

Response to Finding No. 1153:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945 and 1140, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in

development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1154. Freenome's Nolan listed reasons why alternatives to Illumina's sequencers were not viable options to run Freenome's cancer screening test: [redacted] (PX7094 (Nolan (Freenome) Dep. at 222-223) (*in camera*)).

Response to Finding No. 1154:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945 and 1140, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

The proposed finding is also inaccurate to the extent it suggests that MCED tests require sequencing at "depth". For example, GRAIL's Galleri test does not use "ultra-deep sequencing", but relies on targeted methylation for cancer signal detection and localization. *(See, e.g.*, PFF ¶¶ 56, 345, 384, 981, 1289.)

1155. Freenome CEO, Michael Nolan, testified at trial that Freenome cannot switch away from Illumina's NGS platform because Freenome "just [does not] have . . . a suitable substitute to meet [Freenome's] highest-level requirements." (Nolan (Freenome) Tr. 2729).

Response to Finding No. 1155:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in

Respondents' responses to CCFF ¶¶ 945 and 1140, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1156. In discussing the viability of using alternatives to Illumina's NGS platform, Freenome's Otte testified, [redacted] (PX7055 (Otte (Freenome) IHT at 69) (*in camera*)).

Response to Finding No. 1156:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1140, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1157. Freenome's former CEO Gabe Otte testified that [redacted] (PX7055 (Otte (Freenome) IHT at 64-66) (*in camera*)).

Response to Finding No. 1157:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not.

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1140, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1158. [redacted] (PX7121 (Otte (Freenome) Dep. at 48-50) (*in camera*) [redacted]

Response to Finding No. 1158:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1140 and 1154, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1159. [redacted] (PX7055 (Otte (Freenome) IHT at 17-18) (*in camera*)).

Response to Finding No. 1159:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1140 which Respondents incorporate herein. The proposed finding is also incomplete and misleading to the extent that it suggests that only the NovaSeq may be used for MCED test development. To the contrary, as described in Respondents responses to CCFF ¶ 980, incorporated herein, putative MCED test developers are also pursuing test development using the NextSeq and MiSeq instruments.

1160. Mr. Otte testified that [redacted] (PX7055 (Otte (Freenome) IHT at 72) (*in camera*)).

Response to Finding No. 1160:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 945 which Respondents incorporate herein. The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is inaccurate, incomplete and misleading to the extent it suggests that Oxford Nanopore's systems are not suitable for use with oncology tests. Respondents also incorporate their responses to CCFF ¶¶ 901, 904 and 1140 herein.

1161. [redacted] (PX7055 (Otte (Freenome) IHT at 73-74) (*in camera*)).

Response to Finding No. 1161:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1144 which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1162. [redacted] (Nolan (Freenome) Tr. 2756-57 (*in camera*)).

Response to Finding No. 1162:

Respondents have no specific response.

1163. Freenome CEO, Michael Nolan, testified at trial that [redacted] (Nolan (Freenome) Tr. 2759 (*in camera*)).

Response to Finding No. 1163:

Respondents have no specific response.

1164. At trial, Mr. Nolan, explained that Freenome [redacted] (Nolan (Freenome) Tr. 2759-60 (*in camera*)).

Response to Finding No. 1164:

Respondents have no specific response.

f) Singlera

1165. Dr. Gao testified at trial that Singlera does not have another viable alternative to Illumina's NGS sequencers for the PanSeer test. (Gao (Singlera) Tr. 2901).

Response to Finding No. 1165:

The proposed finding is incomplete and misleading, including because it appears to suggest that Illumina's NGS platform is required for Singlera's development of its PanSeer test. Respondents incorporate their responses to CCFF ¶¶ 341, 928, 940, 981–82, 971, 1011, 1115, 1118 and 1293 herein.

The proposed finding is inaccurate, incomplete and misleading. Dr. Gao of Singlera testified that the PanSeer test only needs over 5 million reads (Gao (Singlera) Tr. at 2893) and can be run using alternative NGS instruments such as Illumina's MiSeq and Thermo Fisher equipment. (*See* Gao (Singlera) Tr. at 2928–31; PFF ¶¶ 780–780.6.) [redacted] (PFF ¶¶ 778–778.2; 2085.) Thermo Fisher's Ion Torrent sequencers are suitable for certain MCED tests. (RX3869 (Cote Expert Report) ¶ 285.) [redacted]

[redacted]

1166. Singlera's PanSeer test relies on Illumina's NextSeqDx NGS platform. (Gao (Singlera) Tr. 2875; PX7102 (Gao (Singlera) Dep. at 26)).

Response to Finding No. 1166:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1165 which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1167. Singlera also uses Illumina's MiSeq sequencer as part of its efforts to develop the PanSeer test. (Gao (Singlera) Tr. 2929).

Response to Finding No. 1167:

Respondents have no specific response.

1168. Singlera's Co-founder, Gary Gao, testified at trial that Singlera's use of Illumina's sequencer is "an essential step" in the PanSeer test. (Gao (Singlera) Tr. 2892-93).

Response to Finding No. 1168:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1165 which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms,

there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1169. Dr. Gao testified that Singlera uses Illumina's sequencer because "[i]t's very cost-effective, first, and very eas[y to] use, and they are very reliable, and it's performing in the market." (Gao (Singlera) Tr. 2894).

Response to Finding No. 1169:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1165 which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1170. Dr. Gao explained that Singlera runs its cancer screening test on Illumina's NGS sequencing platform, in part, because it is "easy to use, very accurate, easy to maintain, and cost effective." (PX7102 (Gao (Singlera) Dep. at 27-28)).

Response to Finding No. 1170:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1165 which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development.

(PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1171. Dr. Gao testified that Singlera runs the PanSeer test on Illumina's NextSeq Dx sequencer "[b]ecause NextSeq is FDA-cleared, and we have to use FDA-cleared device for FDA trial." (Gao (Singlera) Tr. 2930-31).

Response to Finding No. 1171:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1011, 1014 and 1165 which Respondents incorporate herein.

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Dr. Gao does not have the required expertise as an expert on FDA regulations. (PX7102 (Gao (Singlera) Dep. at 41–42.)

An NGS sequencer with FDA clearance is not required for development of a cancer screening test. GRAIL has used both Illumina's HiSeq platform and NovaSeq platform with S2 and S4 flow cells (Cote Tr. 3739–40; PX7104 (Aravanis (Illumina) Dep.) at 168–69; RX3773 (Supplement Information to Klein 2021) at 11, 13, 15–16), and [redacted] (PX7103 (Jamshidi (GRAIL) Dep. at 189–90.)

1172. Singlera's Dr. Gao explained that Singlera chose to use Illumina's NextSeqDx NGS sequencer to develop its cancer screening test because "the NextSeqDx is FDA cleared, and it's very cost economic" in terms of the number of reads per run. (PX7102 (Gao (Singlera) Dep. at 27)).

Response to Finding No. 1172:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not.

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1171 which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1173. Singlera's Dr. Gao testified that, "Illumina has the highest throughput[.]" (PX7042 (Gao (Singlera) IHT at 43)).

Response to Finding No. 1173:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1165 which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is inaccurate, misleading, and based on testimony for which the witness lacks personal knowledge or foundation. BGI's DNBSEQT10×4RS / DNBSEQ-Tx and Oxford Nanopore's PromethION NGS sequencers both have reported higher throughputs than Illumina's NGS sequencers. (*Compare* PFF ¶¶ 575, 590 and 599.)

1174. Dr. Gao described Singlera's relationship with Illumina as like being a "prisoner of war." (PX7042 (Gao (Singlera) IHT at 88)).

Response to Finding No. 1174:

The proposed finding is incomplete and misleading, and contradicted by the weight of the evidence. In the portion of his IH cited here, Dr. Gao testified to facts that indicate that his characterization of Singlera's relationship with Illumina has no basis. For example, Dr. Gao testified that once Singlera seriously began pursuing a supply agreement with Illumina, Illumina

"quickly turn[ed] around a draft proposal of [a] supply agreement", which was a "standard boilerplate" agreement. (PX7042 (Gao (Singlera) IHT at 74–75).) Dr. Gao testified that Singlera was "happy" to receive a standardized agreement because Singlera's "only request [was] to have a standard supply agreement". (PX7042 (Gao (Singlera) IHT at 75).) Finally, Dr. Gao admitted that Illumina "provided us with [a draft supply agreement], expect[ed] us to negotiate I'm sure, but we never went back" to negotiate with Illumina. (PX7042 (Gao (Singlera) IHT at 87).) Thus, Dr. Gao's testimony shows that, after Singlera proposed entering a supply agreement with Illumina, Illumina sent a boilerplate agreement, which was exactly what Singlera wanted, and yet Singlera refused to even engage with Illumina on the draft agreement.

Further, even though Singlera stopped engaging with Illumina on a supply agreement, Illumina extended the Open Offer to Singlera (as well as all U.S. oncology customers). (*See* PX0064 (Illumina) at 1, 3.) The Open Offer specifically addresses the concerns identified in the portion of Dr. Gao's IH in which he discussed Singlera's desire for a supply agreement. In his IH, Dr. Gao identified two primary reasons why Singlera sought a supply agreement with Illumina: (1) to ensure that "Illumina will [not] discontinue the product line" that Singlera uses and (2) to ensure that Illumina does not increase the costs of sequencing equipment for Singlera. (PX7042 (Gao (Singlera) IHT at 71–72).) The Open Offer addresses each of these concerns. *First*, Illumina is prohibited from discontinuing products that any oncology customer has purchased in the prior year. (PFF ¶ 1011; [redacted] Berry (Illumina) Tr. 883; PX0064 (Illumina) at 6; [redacted].) *Second*, the Open Offer expressly forbids Illumina from raising prices over the entire 12-year term and affirmatively requires Illumina to lower the price of sequencing by at least 43% by 2025. (PFF ¶ ¶ 1021 –23; [redacted]; Berry (Illumina) Tr. 899, 901 –04; Conroy

(Exact/Thrive) Tr. 1731 –32; deSouza (Illumina) Tr. 2403; PX0064 (Illumina) at 7; [redacted] [redacted] Even though Dr. Gao claimed these concerns drove Singlera's requests for a supply agreement, Dr. Gao testified at trial that he was "*not even aware of the first open – open offer* until [his] lawyer told [him]", let alone the amended version, which provides even greater protections. (Gao (Singlera) Tr. 2952 (emphasis added).)

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1175. Dr. Gao testified that Oxford Nanopore's long-read sequencer is not a viable option for Singlera's Panseer test. (PX7042 (Gao (Singlera) IHT at 66)).

Response to Finding No. 1175:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 904 which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶ 1165 herein.

1176. Singlera plans to run the PanSeer test on Illumina's NovaSeq sequencer when the sequencer obtains FDA clearance. (Gao (Singlera) Tr. 2930).

Response to Finding No. 1176:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1171 herein. Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

g) Helio

1177. Dr. Chahine testified at trial that the Illumina platform is "by far [ ] the preferred one that's used even at third-party shops" and the "leading one for many different [ ] reasons." (Chahine (Helio) Tr. 1044).

Response to Finding No. 1177:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928 and 1293, which Respondents incorporate herein. Contrary to the proposed finding, [redacted]

[redacted]; RX3869 (Cote Expert Report) ¶ 287; [redacted].) BGI also recently won a jury verdict that held three of Illumina's patents to be invalid meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022). BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.) Respondents also incorporate their responses to CCFF ¶ 1293 herein.

The proposed finding is also based entirely on inadmissible hearsay testimony because Dr. Chahine refers to "the preferred one that's used even at third-party shops", which is not based on Dr. Chahine's own experience, therefore, it should be accorded little weight. The proposed finding is also irrelevant because it doesn't appear to relate to MCED tests.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Specifically, Dr. Chahine testified that [redacted] (Chahine (Helio) Tr. 1090, 1092–93.) Further, Dr. Chahine testified that [redacted]

[redacted]

Accordingly, there is no indication based on Helio Health's work to date that [redacted] (PFF ¶ 498.) Respondents also incorporate their responses to CCFF ¶ 454 herein.

1178. [redacted] (Chahine (Helio) Tr. 1114-15 (*in camera*)).

Response to Finding No. 1178:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1177, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶¶ 940, 971, 980, 1115 and 1118 herein.

Furthermore, [redacted] (PFF ¶ 884 (RX6000 (Carlton Trial Dep.) at 30–31).) Respondents also incorporate their responses to CCFF ¶¶ 439–446, 696, 698, 801 and 2353–2400 herein.

1179. Dr. Chahine testified at trial that Illumina is the preferred NGS platform because "from a business standpoint [ ] it is just considered the top technology with respect to its ability to sequence [ ] accurately . . . at larger scales" that create "some [very useful] economies of scale." (Chahine (Helio) Tr. 1044).

Response to Finding No. 1179:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1178, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1180. Dr. Chahine testified at trial that Illumina's suite of NGS sequencers is "designed to sort of scale with the company" and "almost everyone would likely start off with a smaller machine for some of the research but then eventually[,] if it was successful and there was enough volume, would move up to the NovaSeq." (Chahine (Helio) Tr. 1022).

Response to Finding No. 1180:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1178, which Respondents incorporate herein. Additionally, contrary to the cited testimony, putative MCED test developers *do* use Illumina's lower throughput NextSeq and MiSeq instruments. (*See* RRFF ¶ 980).

1181. In comparing Illumina's MiSeq to its NovaSeq sequencer, Dr. Chahine testified at trial that "quite simply on a NovaSeq you would be able to in a single run test the DNA of many more individuals than you would for a MiSeq [ ] at least more robustly." (Chahine (Helio) Tr. 1022). He elaborated that "[i]t's almost like using a more powerful computer for computing." (Chahine (Helio) Tr. 1022).

Response to Finding No. 1181:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 980 herein.

1182. Helio currently uses Illumina's MiSeq sequencer for its Helio Liver test. (Chahine (Helio) Tr. 1010-12). Dr. Chahine testified Helio uses the MiSeq because "a smaller machine is more efficient" as a "company in its early stage" prior to "ramp[ing] up." (Chahine (Helio) Tr. 1012).

Response to Finding No. 1182:

Respondents have no specific response.

1183. Dr. Chahine testified at trial that "almost everyone would likely start off with a smaller machine for some of the research but then eventually, you know, if it was successful and there was enough volume, would move up to a NovaSeq." (Chahine (Helio) Tr. 1022.)

Response to Finding No. 1183:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1178, which Respondents incorporate herein. Additionally, contrary to the cited testimony, putative MCED test developers *do* use Illumina's lower throughput NextSeq and MiSeq instruments. (*See* RRFF ¶ 980).

1184. Dr. Chahine testified at trial that Illumina's NovaSeq sequencer "provides economies of scale that are advantageous" because of its capacity to sequence more samples at once. (Chahine (Helio) Tr. 1022-23).

Response to Finding No. 1184:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1178, which Respondents incorporate herein. Furthermore, [redacted] (PFF ¶ 884 (RX6000 (Carlton Trial Dep.) at 30–31).) Additionally, contrary to the cited testimony, putative MCED test developers *do* use Illumina's lower throughput NextSeq and MiSeq instruments. (*See* RRFF ¶ 980).

1185. Helio has not seriously considered switching from Illumina's NGS platform to an NGS platform sold by another vendor. (Chahine (Helio) Tr. 1043-44).

Response to Finding No. 1185:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1178, which Respondents incorporate herein. Contrary to the proposed finding, [redacted]

Respondents also note that Dr. Aravanis noted that that customers switch from one Illumina NGS platform to another every few years; in order to switch from an Illumina NGS platform to another NGS platform, GRAIL would need to do an analytical bridging study to demonstrate that the test performs similarly on an alternative sequencing platform, there might be other steps where minor modifications to some of the library prep or analysis would also be required; an alternative NGS platform would not need FDA approval before it could be used for development or commercialization of an MCED test like Galleri; if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (PFF ¶ 1312; Aravanis (Illumina) Tr. 1861–65.) Respondents also incorporate their responses to CCFF ¶¶ 1074, 1088, 1115 and 1118 herein.

1186. Helio also purchases NGS sequencers and reagents from Illumina. (Chahine (Helio) Tr. 1024).

Response to Finding No. 1186:

Respondents have no specific response.

1187. Helio cannot buy reagents from another company for use on Illumina's NGS sequencers. (Chahine (Helio) Tr. 1024).

Response to Finding No. 1187:

Respondents have no specific response.

1188. Dr. Chahine testified at trial that Illumina's NGS sequencers and its reagents are a "razor-razorblade model" and the Illumina reagents that Helio purchases "are specific to Illumina." (Chahine (Helio) Tr. 1024).

Response to Finding No. 1188:

Respondents have no specific response.

1189. Dr. Chahine testified that Helio has "looked at different providers. I don't want to say technically we couldn't, but the truth is that the entire category uses Illumina. We're very familiar with Illumina. … The cost is much lower. … [T]here are just a number of … technical advantages and just performance." (PX7077 (Chahine (Helio) Dep. at 26)).

Response to Finding No. 1189:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1178, which Respondents incorporate herein. Contrary to the proposed finding, [redacted] The proposed finding also relies on inadmissible hearsay to the extent it refers to "the entire category [using] Illumina" and should be accorded little weight.

h) [redacted]

1190. [redacted]

Response to Finding No. 1190:

The proposed finding is inaccurate and misleading to the extent it suggests that [redacted]

The proposed finding is also inaccurate, incomplete and misleading, including because it appears to suggest that [redacted] (*See* PFF ¶¶ 444–455, 705, 734 (Fiedler (FMI) Tr. 4476).)

Dr. Fielder testified that [redacted]

1191. [redacted]

Response to Finding No. 1191:

The proposed finding is irrelevant because it does not relate to MCED tests.

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 341, 928, 940, 971, 980, 1115 1118 and 1293 which Respondents incorporate herein.

Respondents note that Dr. Fiedler, FMI's current COO, testified that since 2019, FMI has purchased well over a hundred million, probably $140 million, in NGS products from Illumina; and during the time that FMI has been an Illumina customer FMI has had no issues or problems with Illumina servicing the Illumina instruments that FMI uses. (Fiedler (FMI) Tr. 4470.) Dr. Fiedler has never known Illumina to delay providing services or replacement parts to FMI; Illumina has acted in good faith with respect to its obligations under the 2013 supply agreement; Illumina has never "monkeyed with supply"; Illumina has never interrupted supply to FMI because it claimed FMI had infringed on Illumina's intellectual property; Illumina has never reneged on a commitment it made to FMI; FMI is a satisfied customer and FMI trusts Illumina to abide by its commitments. (Fiedler (FMI) Tr. 4471–72.)

[redacted]

[redacted]

1192. [redacted]

Response to Finding No. 1192:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1190–91, which Respondents incorporate herein. [redacted]

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1193. [redacted]

Response to Finding No. 1193:

The proposed finding is irrelevant because it does not relate to MCED tests.

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1190–91, which Respondents incorporate herein. [redacted]

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1194. [redacted]

Response to Finding No. 1194:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is irrelevant because it does not relate to MCED tests. [redacted]

[redacted]

Dr. Fiedler also testified that: [redacted] (Fiedler (FMI) Tr. 4471–72.) Further, Respondents incorporate their responses to CCFF ¶ 904 and 1190–91 herein, and refer to Section IV of PFF (PFF ¶¶ 574–678.5), which sets out the extensive upstream competition facing Illumina.

1195. [redacted]

Response to Finding No. 1195:

The proposed finding is irrelevant because it does not relate to MCED tests. Respondents also incorporate their responses to CCFF ¶¶ 1190–91 herein.

1196. [redacted]

Response to Finding No. 1196:

The proposed finding is irrelevant because it does not relate to MCED tests. The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not.

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1190–91, which Respondents incorporate herein. [redacted]

Respondents also note that [redacted] (Fiedler (FMI) Tr. 4497–98.)

1197. [redacted]

Response to Finding No. 1197:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1196, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1198. [redacted]

Response to Finding No. 1198:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1196, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1199. [redacted]

Response to Finding No. 1199:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not.

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1196, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1200. [redacted]

Response to Finding No. 1200:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1196, which Respondents incorporate herein. [redacted]

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3. Illumina Understands That Its NGS Platforms Far Surpass Other Platforms on High Throughput, High Accuracy, and Low Cost

1201. When speaking to investors about the Grail acquisition announcement, Mr. deSouza said, "This [acquisition] is about accessing the largest opportunity in clinical genomics… we have enabled this market, and now we are moving more firmly into the application layer." (PX2575 (Illumina) at 019 (Illumina, Investor Call Transcript, Sept. 21, 2020)).

Response to Finding No. 1201:

Respondents have no specific response.

1202. [redacted] (PX6069 (Illumina) at 15-16 (RFA No. 17) (Illumina Responses & Objections to FTC Requests for Admissions)).

Response to Finding No. 1202:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1027, which Respondents incorporate herein.

Complaint Counsel did not present the exhibit PX6069 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 56), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1203. [redacted] (PX6069 (Illumina) at 16 (RFA No. 18) (Illumina Responses & Objections to FTC Requests for Admissions (*in camera*))).

Response to Finding No. 1203:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1027, which Respondents incorporate herein.

Counsel did not present the exhibit PX6069 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 56), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1204. Respondents' expert, Dr. Carlton notes in his report, [redacted] (RX3864 (Carlton Rebuttal Report) ¶ 24 (*in camera*) (citing PX6090 (Scott Morton Report) ¶ 152 (*in camera*)).

Response to Finding No. 1204:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 940, 971, 980, 1115, 1118 and 1293, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1205. [redacted] (PX2169 (Illumina) at 016 (Illumina, Strategic Plan 2021-2025, Oct. 23, 2020 (*in camera*))).

[redacted]

Response to Finding No. 1205:

Respondents have no specific response except to note that Illumina's ordinary course documents, including the cited source, refers to [redacted] Dr. Aravanis also testified that the Illumina patents that are currently blocking BGI from entering the U.S. will expire no later than 2023; Illumina projects BGI will enter the U.S. no later than 2023. (PFF ¶ 1306 (Aravanis (Illumina) Tr. 1852–54).) Respondents also note that BGI may enter the United States market as soon as August 2022, after certain Illumina patents expire. (PFF ¶¶ 777-777.3.) BGI also recently won a jury verdict that held three of Illumina's patents to be invalid meaning that these patents do not prevent BGI from launching its sequencing instruments and

related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022).

Respondents also note that Illumina expects there will be intensifying competition in the NGS space in the near future both from incumbent players and new entrants. (PFF ¶ 38 (deSouza (Illumina) Tr. 2318–20).)

1206. [redacted] (PX2169 (Illumina) at 020 (Illumina, Strategic Plan 2021-2025, Oct. 23, 2020 (*in camera*))).

Response to Finding No. 1206:

The proposed finding is irrelevant as it does not relate to MCED testing.

Respondents also incorporate their responses to CCFF ¶¶ 928, 1205 and 1293 herein.

1207. [redacted] (PX5026 (Illumina) at 005 (FY20-25 Strategic Plan Initial Revenue Discussion, Jun 4, 2020 (*in camera*)).

Response to Finding No. 1207:

The proposed finding is irrelevant as it does not relate to MCED testing.

Respondents also incorporate their responses to CCFF ¶¶ 928, 1205 and 1293 herein.

Complaint Counsel did not present the exhibit PX5026 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 54), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

4. Other Industry Participants Recognize that Illumina NGS Platforms Are the Only Viable Option for MCED Testing

1208. Dr. Vogelstein testified that "[t]he only technology available for short-read sequencing that is at a throughput and cost that would enable liquid biopsy to be analyzed is sold by Illumina." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 67)).

Response to Finding No. 1208:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 971, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶¶ 928–29, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1209. The Illumina NGS sequencer is the only sequencer that can be used for applications that demand "high accuracy for low frequency events" such as multi-cancer early detection. (PX7075 (Stahl (Invitae) Dep. at 71)).

Response to Finding No. 1209:

The proposed finding is based on speculation. [redacted] The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding is also incomplete and misleading. Mr. Stahl testified that BGI's and Illumina's technologies are "very similar". (PX7075 (Stahl (Invitae) Dep. at 75.)

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 341, 904, 928, 940, 971, 980, 1115, 1118 and 1293, which Respondents incorporate herein.

1210. Invitae represented to investors in its Form 10-Q filed with the Securities and Exchange Commission that "[w]e rely on Illumina as the sole supplier of next generation sequencers and associated reagents" and "[i]n the case of an alternative supplier for Illumina, we cannot assure you that replacement sequencers and associated reagents will be available or will meet our quality control and performance requirements for our laboratory operations." (PX0158 at 51-52 (Invitae Form 10-Q, Nov. 5, 2020)).

Response to Finding No. 1210:

The proposed finding is irrelevant because Invitae/ArcherDx is not developing an MCED test.

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1209, which Respondents incorporate herein.

1211. Invitae represented to investors in its Form 10-Q filed with the Securities and Exchange Commission that:

> ArcherDX's product customers are required to use Illumina sequencers and reagents …. ArcherDX's failure to maintain a continued supply of the sequencers and reagents … would adversely impact its business, financial condition, and results of operations. In particular, while ArcherDX is seeking to validate its tests on additional sequencing platforms, it has not, to date, validated any alternative sequencing platform on which its testing could be run in a commercially viable manner.

(PX0158 at 70 (Invitae Form 10-Q, Nov. 5, 2020)).

Response to Finding No. 1211:

The proposed finding is irrelevant because Invitae/ArcherDx is not developing an MCED test.

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1209, which Respondents incorporate herein.

E. NON-ILLUMINA NGS PLATFORMS DO NOT MEET THE REQUIREMENTS OF MCED TESTS

1. Thermo Fisher Is Not an Option for MCED Test Developers

a) Thermo Fisher Recognizes That Its NGS Platform Does Not Meet the Requirements of MCED Tests

1212. Thermo Fisher Vice President of Product Management, Dr. Andrew Felton, testified at trial that Thermo Fisher sequencers are not currently being used for MCED tests. (Felton (Thermo Fisher) Tr. 1987).

Response to Finding No. 1212:

The proposed finding is vague, speculative, and misleading. *First*, the phrase "used for MCED tests" is unclear. *Second*, [redacted] In fact, [redacted] and Singlera have already confirmed that their tests can be used on Thermo Fisher equipment, [redacted] (Gao (Singlera) Tr. 2928; [redacted]

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 952 and 1293, which Respondents incorporate herein.

1213. Dr. Felton testified that Illumina's NGS sequencers are better suited than Thermo Fisher's NGS sequencers for "any application that requires a very large number of samples … like early cancer detection." (Felton (Thermo Fisher) Tr. 2001).

Response to Finding No. 1213:

The proposed finding is vague and misleading. [redacted] (Felton (Thermo Fisher) Tr. 2021–23; PX7097 (Felton (Thermo Fisher) Dep. at 65–68).) [redacted]

[redacted] (Felton (Thermo Fisher) Tr. 2021–23; PX7097 (Felton (Thermo Fisher) Dep. at 65–68).) Dr. Cote has also determined that Thermo Fisher's systems are suitable for certain MCED tests. (RX3869 (Cote Expert Report) ¶ 285.) This capability is not merely theoretical—Singlera and [redacted] have confirmed their tests' interoperability with Thermo Fisher systems. (Gao (Singlera) Tr. 2928; [redacted]

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 952 and 1293, which Respondents incorporate herein.

1214. According to Dr. Felton, Illumina's NovaSeq platform has much higher output than any of Thermo Fisher's NGS sequencers. (Felton (Thermo Fisher) Tr. 2000).

Response to Finding No. 1214:

Respondents have no specific response except to note that [redacted]

Respondents also incorporate their responses to CCFF ¶¶ 928, 952 and 1293 herein.

1215. Thermo Fisher's highest throughput sequencer, the GeneStudio S5, has a maximum output of 130 million reads per run. (Felton (Thermo Fisher) Tr. 1983-84).

Response to Finding No. 1215:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1214 herein.

1216. According to Dr. Felton, the total work flow time for the GeneStudio to achieve 130 million reads per run is 24 to 48 hours. (Felton (Thermo Fisher) Tr. 1985).

Response to Finding No. 1216:

The proposed finding is inaccurate. [redacted]

1217. Dr. Felton testified that even Thermo Fisher's highest throughput sequencer, the GeneStudio, is not an option for MCED developers because "a platform with considerable more out-put per run than 130 million reads would be . . . preferred. . . . In general, the system isn't well suited to a kind of test that needs a very large number of samples . . . running through it very quickly." (Felton (Thermo Fisher) Tr. 1987-89).

Response to Finding No. 1217:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 940, 952,1115, 1118, 1212–13 and 1293 which Respondents incorporate herein. The proposed finding is also inaccurate, incomplete and misleading to the extent it suggests that only Illumina's NovaSeq platform could be used for putative MCED test development. To the contrary, as described in Respondents responses to CCFF ¶ 980, incorporated herein, putative MCED test developers are also pursuing test development using the NextSeq and MiSeq instruments, as well as Thermo Fisher's Ion Torrent S5 instrument.

1218. No other NGS platform available in the United States, other than Illumina's sequencers, can read more than 130 million fragments per run. (Felton (Thermo Fisher) Tr. 1985).

Response to Finding No. 1218:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1217 and 1293 which Respondents incorporate herein.

Respondents also note that [redacted] It is "undisputed that . . . BGI's technology is substitutable for Illumina's NGS technology in throughput, accuracy, turnaround time, and cost. (RX3869 (Cote Expert Report)

¶ 287.) Specifically, BGI's NGS sequencers use an SBS technology that is similar to Illumina's NGS sequencing technology. (PFF ¶ 588; RX3869 (Cote Expert Report) ¶ 286.) BGI currently markets five sequencers.

Singular commercially launched the G4 NGS sequencer at the end of 2021 and will begin shipping the G4 NGS systems in the first half of 2022. (PFF ¶ 607; Velarde (Singular) Tr. 4515–16, 4522; *see also* PX8561 (Singular) at 1–2; PX7117 (Velarde (Singular) Dep. at 30–31).) Singular Genomics' G4 sequencer, which is [redacted] (PFF ¶ 609–609.6.)

1219. The cost per read of Thermo Fisher's GeneStudio is higher than the cost per read of the NovaSeq. (Felton (Thermo Fisher) Tr. 2000).

Response to Finding No. 1219:

The proposed finding is misleading. [redacted]

1220. [redacted] (Felton (Thermo Fisher) Tr. 2008) (*in camera*)).

Response to Finding No. 1220:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1217 which Respondents incorporate herein.

Additionally, [redacted]

[redacted]

Respondents also note that Thermo Fisher has confirmed that its sequencers are capable of being used for multi-cancer screening tests. (Felton (Thermo Fisher) Tr. 2021–23; PX7097 (Felton (Thermo Fisher) Dep. at 65–68).) [redacted] (Felton (Thermo Fisher) Tr. 2021–23; PX7097 (Felton (Thermo Fisher) Dep. at 65–68).) Dr. Cote has also determined that Thermo Fisher's systems are suitable for certain MCED tests. (RX3869 (Cote Expert Report) ¶ 285.) This capability is not merely theoretical—Singlera and [redacted] have confirmed their tests' interoperability with Thermo Fisher systems. (Gao (Singlera) Tr. 2928; [redacted]

1221. [redacted] (Felton (Thermo Fisher) Tr. 2006) (*in camera*)).

Response to Finding No. 1221:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1217 and 1220, which Respondents incorporate herein.

1222. [redacted] (PX7097 (Felton (Thermo Fisher) Dep. at 29) (*in camera*)).

Response to Finding No. 1222:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1217 and 1220, which Respondents incorporate herein.

1223. [redacted] (PX7097 (Felton (Thermo Fisher) Dep. at 34-35) (*in camera*)).

Response to Finding No. 1223:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1217 and 1220, which Respondents incorporate herein.

1224. [redacted] (PX7097 (Felton (Thermo Fisher) Dep. at 42-43) (*in camera*)).

Response to Finding No. 1224:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1217 and 1220, which Respondents incorporate herein.

As of the time of trial, [redacted]

Indeed, Singlera and [redacted] have confirmed their tests' interoperability with Thermo Fisher systems. (Gao (Singlera) Tr. 2928; [redacted] Singlera even notes on its website that its PanSeer assay is "compatible with the two leading next-generation sequencing platforms on the market (systems from Illumina such as the MiSeq or NextSeq as well as from Thermo Fisher Scientific including the Ion Torrent S5) any laboratory familiar with NGS library construction can quickly implement this method". (RX3637 (Singlera) at 5.)

1225. Dr. Felton, admitted that Thermo Fisher's NGS platforms are not used for MCED tests because "the implementation of such a test is likely favored to a very high throughput system in a centralized facility, and our systems are generally suited to . . . smaller amounts of patient samples." (PX7070 (Felton (Thermo Fisher) IHT at 52-53)).

Response to Finding No. 1225:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1217 and 1220, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1226. Mr. Felton explained, "the systems that [Thermo Fisher's] Ion Torrent provides are generally much better suited to the population of patients who's progressed to a late-stage cancer setting, so the number of patients is much smaller relative to the number of patients you are screening in a population-screening experiment or study." (PX7070 (Felton (Thermo Fisher) IHT at 52-53)).

Response to Finding No. 1226:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF¶¶ 1217 and 1220, which Respondents incorporate herein.

Respondents also note that the proposed finding also relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1227. Mr. Felton maintained that [redacted] (PX7070 (Felton (Thermo Fisher) IHT at 69) (*in camera*)).

Response to Finding No. 1227:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1217 and 1220, which Respondents incorporate herein.

The proposed finding is misleading to the extent it suggests that [redacted] (Felton (Thermo Fisher) Tr. 2021–23; PX7097 (Felton (Thermo Fisher) Dep. at 65–68).) [redacted] (Felton (Thermo Fisher) Tr. 2021–23; PX7097 (Felton (Thermo Fisher) Dep. at 65–68).) Dr. Cote has also determined that Thermo Fisher's systems are suitable for certain MCED tests. (RX3869 (Cote Expert Report) ¶ 285.) Singlera and [redacted] have confirmed their tests' interoperability with Thermo Fisher systems. (Gao (Singlera) Tr. 2928; [redacted]

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1228. Mr. Felton stated further, "we are playing in the late-stage cancer setting. The GRAIL Illumina combination would be playing in the early cancer" setting. (PX7070 (Felton (Thermo Fisher) IHT at 69)).

Response to Finding No. 1228:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1217 and 1220, which Respondents incorporate herein.

Singlera and [redacted] have confirmed their tests' interoperability with Thermo Fisher systems. (Gao (Singlera) Tr. 2928; [redacted]

Respondents also note that the proposed finding also relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

b) [redacted]

1229. [redacted] (Chudova (Guardant) Tr. 1218-19) (*in camera*)

Response to Finding No. 1229:

The proposed finding is misleading and vague. [redacted]

[redacted]

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) [redacted]

Respondents also incorporate their responses to CCFF ¶¶ 927, 952 and 1212–28 herein.

1230. [redacted] (Chudova (Guardant) Tr. 1218-19) (*in camera*)).

Response to Finding No. 1230:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1220 and 1229, which Respondents incorporate herein.

[redacted] (Felton (Thermo Fisher) Tr. 2021–23; PX7097 (Felton (Thermo Fisher) Dep. at 65–68).)

1231. [redacted] (Chudova (Guardant) Tr. 1219-20) (*in camera*)).

Response to Finding No. 1231:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1220 and 1229, which Respondents incorporate herein. [redacted]

1232. [redacted] (Chudova (Guardant) Tr. 1218-19) (*in camera*)).

Response to Finding No. 1232:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1218, 1220 and 1229, which Respondents incorporate herein.

1233. [redacted] (Chudova (Guardant) Tr. 1220) (*in camera*)).

Response to Finding No. 1233:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1220 and 1229, which Respondents incorporate herein.

[redacted] (Felton (Thermo Fisher) Tr. 2021–23; PX7097 (Felton (Thermo Fisher) Dep. at 65–68).)

1234. [redacted] (Chudova (Guardant) Tr. 1220) (*in camera*)).

Response to Finding No. 1234:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1220 and 1229, which Respondents incorporate herein. [redacted]

1235. [redacted]

(PX7045 (Chudova (Guardant) IHT at 49-50) (*in camera*)).

Response to Finding No. 1235:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1220, 1229 and 1234, which Respondents incorporate herein. Additionally, [redacted]

1236. Guardant's Mr. Getty testified at trial that Guardant cannot run its MCED test on a Thermo Fisher sequencer. (Getty (Guardant) Tr. 2688).

Response to Finding No. 1236:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1220, 1229 and 1234, which Respondents incorporate herein. [redacted] (Felton (Thermo Fisher) Tr. 2021–23; PX7097 (Felton (Thermo Fisher) Dep. at 65–68).)

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Mr. Getty's testimony also [redacted]

1237. Freenome evaluated Illumina's sequencer against Thermo Fisher's S5 sequencer. (Nolan (Freenome) Tr. 2715-18).

Response to Finding No. 1237:

The proposed finding relies on hearsay and is incomplete and misleading. Mr. Nolan admitted at trial that that "[Freenome] hadn't evaluated anything" since he has been at Freenome "with regard to an actual head-to-head evaluation," and he "was aware high level that [Freenome had] looked at the S5. That was really the extent of it." (Nolan (Freenome) Tr. 2737.)

1238. Mr. Nolan testified that Illumina's sequencer "did a better job with [sequence] variant calling" and "did a better job of detecting [colorectal cancer]" than Thermo Fisher's S5 sequencer in Freenome's evaluation. (Nolan (Freenome) Tr. 2715-16).

Response to Finding No. 1238:

The proposed finding relies on hearsay and is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1220 and 1237, which Respondents incorporate herein. The proposed finding is vague and misleading. It is unclear what "better job" means in Mr. Nolan's context and whether such a "better job" has any significance for multiple cancer screening tests. [redacted] (Felton (Thermo Fisher) Tr. 2021–23; PX7097 (Felton (Thermo Fisher) Dep. at 65–68).) [redacted] (Felton (Thermo Fisher) Tr. 2021–23; PX7097 (Felton (Thermo Fisher) Dep. at 65–68).) Dr. Cote has also determined that Thermo Fisher's systems are suitable for certain MCED tests. (RX3869 (Cote Expert Report) ¶ 285.)

Singlera and [redacted] have confirmed their tests' interoperability with Thermo Fisher systems. (Gao (Singlera) Tr. 2928; [redacted]

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents also incorporate their responses to CCFF ¶¶ 952 and 1212–28 herein.

1239. Freenome's Nolan testified that [redacted] (PX7094 (Nolan (Freenome) Dep. at 222-223) (*in camera*)).

Response to Finding No. 1239:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1220, 1237 and 1238, which Respondents incorporate herein. [redacted] (Felton (Thermo Fisher) Tr. 2021–23; PX7097 (Felton (Thermo Fisher) Dep. at 65–68).)

1240. Freenome's Nolan testified that [redacted] (PX7050 (Nolan (Freenome) IHT at 100-01) (*in camera*)).

Response to Finding No. 1240:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to ¶¶ 1220, 1237 and 1238, which Respondents incorporate herein. [redacted] (Felton (Thermo Fisher) Tr. 2021–23; PX7097 (Felton (Thermo Fisher) Dep. at 65–68).) [redacted]

[redacted]

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1241. Freenome's Otte testified that [redacted]

(PX7055 (Otte (Freenome) IHT at 65-66) (*in camera*)).

Response to Finding No. 1241:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1220 and 1238, which Respondents incorporate herein. In addition, Mr. Otte appears to [redacted] For instance, Respondents note that Thermo Fisher has a paired-end sequencing protocol for its sequencer. (RX3869 (Cote Expert Report) ¶ 333.) [redacted] (Felton (Thermo Fisher) Tr. 2021–23; PX7097 (Felton (Thermo Fisher) Dep. at 65–68).)

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1242. Freenome's Otte testified, [redacted] (PX7055 (Otte (Freenome), IHT at 66) (*in camera*)).

Response to Finding No. 1242:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1220 and 1238, which Respondents incorporate herein.

Respondents also note that [redacted] Respondents also incorporate their responses CCFF ¶ 1217 herein. [redacted]

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1243. Thermo Fisher's Dr. Felton testified that [redacted] (Felton (Thermo Fisher) Tr. 2006-2007 (*in camera*)).

Response to Finding No. 1243:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945 , 1217, 1220 and 1238, which Respondents incorporate herein.

The proposed finding is based on inadmissible hearsay, speculative, and misleading.

[redacted]

Respondents additionally note that [redacted] (Felton (Thermo Fisher) Tr. 2021–23; PX7097 (Felton (Thermo Fisher) Dep. at 65–68).) [redacted] (Felton (Thermo Fisher) Tr. 2021–23; PX7097 (Felton (Thermo Fisher) Dep. at 65–68).) Dr. Cote has also determined that Thermo Fisher's systems are suitable for certain MCED tests. (RX3869 (Cote Expert Report) ¶ 285.) This capability is not merely theoretical—Singlera and [redacted] have confirmed their tests' interoperability with Thermo Fisher systems. (Gao (Singlera) Tr. 2928; [redacted]

[redacted]

1244. Dr. Felton explained [redacted] *in camera*)).

Response to Finding No. 1244:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1220 and 1243, which Respondents incorporate herein.

[redacted]

Respondents also note that the proposed finding also relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1245. Singlera Co-founder, Gary Gao, testified that Thermo Fisher is one of the alternatives to Illumina that Singlera has evaluated. (Gao (Singlera) Tr. 2894).

Response to Finding No. 1245:

Respondents have no specific response.

1246. Dr. Gao testified at trial that Thermo Fisher is "not going to be a viable alternative" for its PanSeer test and it has no plans to switch to Thermo Fisher's NGS platform. (Gao (Singlera) Tr. 2894).

Response to Finding No. 1246:

The proposed finding is inaccurate and misleading. Contrary to the proposed finding, Dr. Gao has admitted that Singlera's PanSeer test is interoperable with Thermo Fisher's systems, including the Ion Torrent S5. (Gao (Singlera) Tr. 2928.) **Singlera even notes on its website** that its PanSeer assay is "compatible with the two leading next-generation sequencing platforms on the market (systems from Illumina such as the MiSeq or NextSeq as well as from Thermo Fisher Scientific including the Ion Torrent S5) any laboratory familiar with NGS library construction can quickly implement this method". (RX3637 (Singlera) at 5.) Dr. Gao also confirmed that a switch to Thermo Fisher's systems would take about six months to a year. (Gao (Singlera) Tr. 2942–43.) The switch would not disrupt any ongoing clinical work for PanSeer and Singlera would not even need to run any bridging study to revalidate any PanSeer trial results. (Gao (Singlera) Tr. 2942–43.)

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents also incorporate their responses to CCFF ¶¶ 952 and 1212–28 herein.

1247. Singlera's Dr. Gao testified that Thermo Fisher's platforms are "not cost-effective," "not an easy workflow," and "not basically a viable alternative to Illumina['s] platform." (PX7042 (Gao (Singlera) IHT at 42-43)).

Response to Finding No. 1247:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1220 and 1246, which Respondents incorporate herein.

Furthermore, the proposed finding also relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents additionally note that [redacted]

1248. Dr. Gao indicated that the throughput of Illumina's NextSeqDx instrument is higher than the Thermo Proton instrument: "[A] NextSeqDx will produce you about a -- I think between 100 to 300 million read per run while the Thermo Proton is more like 40 million to 100 million, so it's about only one-third to one-fifth of what Illumina produce." (PX7042 (Gao (Singlera) IHT at 43)).

Response to Finding No. 1248:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1220 and 1246, which Respondents incorporate herein.

Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Respondents also note that [redacted]

1249. In characterizing Thermo Fisher's NGS platform, Singlera's Gao testified:

> [T]here are basically sequencing -- higher sequencing error and a sequencing bias with the Thermo technology. For example, the homopolymer problem is significant in the Ion platform from Thermo Fisher, but the Illumina doesn't have that shortcoming. And also the mutation, you know, the error, sequencing error rate is higher in the Proton system.

(PX7042 (Gao (Singlera) IHT at 44)).

Response to Finding No. 1249:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1220 and 1246, which Respondents incorporate herein.

Respondents also emphasize that Dr. Gao has admitted that Singlera's PanSeer test is interoperable with Thermo Fisher's systems, including the Ion Torrent S5. (Gao (Singlera) Tr. 2928.)

Furthermore, the proposed finding also relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1250. In explaining why Illumina's FDA-cleared NextSeqDX NGS platform is suitable for Singlera's PanSEER test and Thermo Fisher's NGS platform is not, Dr. Gao testified:

> [T]he throughput is lower, and you know, it's only one-third, so you want a -- Illumina system can do three times more sample. For screening, your scale economy coming from you can do many more sample in one day. That will save you equipment cost, you know, your depreciation, your labor, your time, your competitive skill.

(PX7042 (Gao (Singlera) IHT at 53)).

Response to Finding No. 1250:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1220 and 1246, which Respondents incorporate herein.

Respondents also emphasize that Dr. Gao has admitted that Singlera's PanSeer test is interoperable with Thermo Fisher's systems, including the Ion Torrent S5. (Gao (Singlera) Tr. 2928.)

Furthermore, the proposed finding also relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1251. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 103-04) (*in camera*)).

Response to Finding No. 1251:

The proposed finding is ambiguous and misleading as discussed in Respondents' responses to CCFF ¶¶ 1220 and 1252, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1252. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 106) (*in camera*)).

Response to Finding No. 1252:

The proposed finding is ambiguous and misleading. [redacted]

[redacted]

[redacted] (Lengauer (Exact/Thrive) Tr. 238–39.)

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Respondents also incorporate their responses to CCFF ¶¶ 952 and 1212–28 herein.

1253. Dr. Lengauer explained that Thrive's CancerSeek technology [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 96) (*in camera*)).

Response to Finding No. 1253:

The proposed finding is ambiguous and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1252, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1254. Dr. Lengauer testified that [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 96) (*in camera*)).

Response to Finding No. 1254:

The proposed finding is ambiguous and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1252, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1255. Dr. Lengauer said [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 107-08) (*in camera*)).

Response to Finding No. 1255:

The proposed finding is ambiguous and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1252, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1256. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 107) (*in camera*)).

Response to Finding No. 1256:

The proposed finding is ambiguous and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1252, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1257. Dr. Lengauer described [redacted]

[redacted]

(PX7051 (Lengauer (Third Rock Ventures) IHT at 108-09) (*in camera*)).

Response to Finding No. 1257:

The proposed finding is ambiguous and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1252, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1258. Dr. Lengauer testified that [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 109) (*in camera*)).

Response to Finding No. 1258:

The proposed finding is ambiguous and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1252, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1259. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 109-10) (*in camera*)).

Response to Finding No. 1259:

The proposed finding is incomplete and misleading to the extent it seems to suggest that [redacted] 428, 431 ("In the DETECT-A study, CancerSEEK obtained [a] specificit[y] of 95.3% in its baseline blood test (that is, with a single blood test).").) [redacted]

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1212–14 and 1252, which Respondents incorporate herein.

Furthermore, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.).

1260. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 112) (*in camera*)).

Response to Finding No. 1260:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1252 and 1259, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1261. Kevin Conroy, CEO of Exact, testified that [redacted] (PX7110 (Conroy (Exact) Dep. at 70-71) (*in camera*)).

Response to Finding No. 1261:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1220, 1252 and 1259, which Respondents incorporate herein.

[redacted] Furthermore, Singlera and [redacted] have explicitly confirmed their tests' interoperability with Thermo Fisher systems. (Gao (Singlera) Tr. 2928; [redacted] Singlera even publicly notes on its website that its PanSeer assay is "compatible with the two leading next-generation sequencing platforms on the market (systems from Illumina such as the MiSeq or NextSeq as well as from Thermo Fisher Scientific including the Ion Torrent S5) any laboratory familiar with NGS library construction can quickly implement this method". (RX3637 (Singlera) at 5.) [redacted]

[redacted]

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Mr. Conroy was not involved in the development of CancerSEEK, Exact Sciences does not have any tests that use NGS technology and Exact Sciences was not an Illumina customer until its acquisition of Thrive. (*See* Conroy (Exact Sciences) Tr. 1542–43, [redacted]

1262. [redacted] (PX7058 (Conroy (Exact) IHT at 120-21) (*in camera*)).

Response to Finding No. 1262:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1261, which Respondents incorporate herein.

The proposed finding is also vague as to the [redacted] Furthermore, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1263. Mr. Conroy further testified that [redacted] (PX7058 (Conroy (Exact) IHT at 70) (*in camera*)).

Response to Finding No. 1263:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1220 and 1261, which Respondents incorporate herein.

[redacted]

Furthermore, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1264. [redacted] (PX7111 (Fesko (Natera) Dep. at 52-53) (*in camera*)).

Response to Finding No. 1264:

The proposed finding is misleading and vague, and irrelevant because it does not relate to MCED tests.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents also incorporate their responses to CCFF ¶¶ 952 and 1212–28 herein.

1265. [redacted] (PX7111 (Fesko (Natera) Dep. at 52-53) (*in camera*)).

Response to Finding No. 1265:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1264, which Respondents incorporate herein.

[redacted] Furthermore, Singlera and [redacted] have explicitly confirmed their tests' interoperability with Thermo Fisher systems. (Gao (Singlera) Tr. 2928; [redacted] Singlera even publicly notes on its website that its PanSeer assay is "compatible with the two leading next-generation sequencing platforms on the market (systems from Illumina such as the MiSeq or NextSeq as well as from Thermo Fisher Scientific including the Ion Torrent S5) any laboratory familiar with NGS library construction can quickly implement this method". (RX3637 (Singlera) at 5.) [redacted]

1266. Ms. Perettie explained that [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 60)).

Response to Finding No. 1266:

The proposed finding is misleading and vague for the reasons explained in Respondents' responses to CCFF ¶¶ 952, 1190 and 1212–28 which Respondents incorporate herein.

[redacted] Furthermore, Singlera and [redacted] have explicitly confirmed their tests' interoperability with Thermo Fisher systems. (Gao (Singlera) Tr. 2928; [redacted] Singlera even publicly notes on its website that its PanSeer assay is "compatible with the two leading next-generation sequencing platforms on the market (systems from Illumina such as the MiSeq or NextSeq as well as from

Thermo Fisher Scientific including the Ion Torrent S5) any laboratory familiar with NGS library construction can quickly implement this method". (RX3637 (Singlera) at 5.) [redacted]

Lastly, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1267. Invitae's Stahl testified that Thermo Fisher's "sequencer data quality is so far below what Illumina can do, [that] you do not have a viable product" if a cancer screening test is run on Thermo Fisher's NGS platform. (PX7044 (Stahl (Invitae) IHT at 51-53)).

Response to Finding No. 1267:

The proposed finding is based on speculation. [redacted] The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding is also misleading and vague. *First*, the cited testimony discusses NGS in the context of IVD tests in general, *not* NGS cancer screening tests, specifically. (PX7044 (Stahl (Invitae) IHT at 51-54) *Second*, [redacted]

[redacted] Furthermore, Singlera and [redacted] have explicitly confirmed their tests' interoperability with Thermo Fisher systems. (Gao (Singlera) Tr. 2928; [redacted]

Respondents also note that Mr. Stahl himself recognized that Thermo Fisher (along with Oxford Nanopore, BGI, and PacBio) is a participant in the NGS field and that there would be "no way to predict" which NGS company would be successful over the next five or ten years. (PX7075 (Stahl (Invitae) Dep. at 43.)

Lastly, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Respondents also incorporate their responses to CCFF ¶¶ 952 and 1212–28 herein.

1268. Mr. Stahl explained that Thermo Fisher's error rates are "very high" and "one mistake could mean cancer or not cancer." (PX7044 (Stahl (Invitae) IHT at 92-93)).

Response to Finding No. 1268:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1267, which Respondents incorporate herein.

Furthermore, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2. BGI Is Not an Option for MCED Test Developers

a) Illumina Sued BGI for Patent Infringement and Obtained an Injunction That Bars BGI from Beginning to Sell its NGS Platforms in the United States

1269. BGI is a Chinese genomics company that does next-generation sequencing. (deSouza (Illumina) Tr. 2226).

Response to Finding No. 1269:

Respondents have no specific response except to note that BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.) BGI acquired California-based sequencing company Complete Genomics in 2013 and launched its BGISEQ-500 NGS sequencer in 2015. (PFF ¶ 587; RX3063 (BGI).)

Respondents also note that many customers outside of China have successfully built a relationship with BGI, [redacted]; PFF ¶ 780.1.

1270. When Mr. deSouza spoke at the JPM Life Sciences CEO Conference Series and answered questions from investors, one question Mr. deSouza responded to was whether BGI may try to come to the United States that year. (deSouza (Illumina) Tr. 2223-2225; PX2544 (Illumina) at 024-025 (Transcript of JPM Life Sciences CEO Conference Call, Sept. 3, 2019)). Mr. deSouza responded, "We [Illumina] think that every player should be considering coming to the U.S. It's also an area where we [Illumina] have very strong IP protection. And so for BGI or anyone else to be successful in the U.S., they'll have to do so with the technology that they have the IP to run." (deSouza (Illumina) Tr. 2223-2225; PX2544 (Illumina) at 024-025 (Transcript of JPM Life Sciences CEO Conference Call, Sept. 3, 2019)).

Response to Finding No. 1270:

Respondents have no specific response except to note that BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.)

1271. As set forth below in Section V.E.2.c., MCED test developers testified that the uncertainty around BGI's freedom to operate in the United States is one reason BGI is not a viable NGS option for MCED test developers.

Response to Finding No. 1271:

Respondents have no specific response except to note that BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.)

1272. As Illumina's CEO admitted at trial, Illumina has filed multiple lawsuits against BGI alleging that it has infringed on Illumina's patents. (deSouza (Illumina) Tr. 2226).

Response to Finding No. 1272:

The proposed finding is misleading and irrelevant. Respondents also note that BGI may enter the United States market as soon as August 2022, after certain Illumina patents expire. (PFF ¶¶ 777-777.3.) BGI also recently won a jury verdict that held three of Illumina's patents to be invalid meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022).

1273. An Illumina board presentation states that it "has 11 active IP infringement suits against BGI." (PX2847 (Illumina) at 013 (Project Protego BoD Discussion, July 15, 2020)).

Response to Finding No. 1273:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1272, which Respondents incorporate herein.

Further, Complaint Counsel did not present the exhibit PX2847 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 33), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1274. In 2019 and 2020, Illumina successfully sued BGI in the Northern District of California alleging that "BGI's sequencers and reagents infringe Illumina owned patents. (PX0119

at 001 (Illumina Inc. Announces that U.S. Federal Court Issues Preliminary Injunction Against BGI Companies)).

Response to Finding No. 1274:

Respondents have no specific response except to note that BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.)

Complaint Counsel did not present the exhibit PX0119 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 2), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1275. Dr. Felton testified that Thermo Fisher and Illumina are the only two companies offering short-read NGS sequencers in the United States. (Felton (Thermo Fisher) Tr. 1996).

Response to Finding No. 1275:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 928 and 1293, which Respondents incorporate herein.

Respondents also note that recent research demonstrates that Oxford Nanopore's long-read sequencers also have short-read sequencing capabilities. (PFF ¶¶ 601-601.4.) Respondents also incorporate their responses to CCFF ¶ 904 herein.

b) Illumina is Already Seeking Additional Injunctive Relief Against BGI Based on U.S. Patents that Do Not Expire Until 2027 and May Assert Additional Patents Against BGI That Run Beyond 2027

1276. Illumina has already filed additional patent infringement claims against BGI. (PX9232 at 015, 025-027 (Answer and Counterclaim, *Complete Genomic, Inc. v. Illumina, Inc.*, Case 1:19-cv-00970-MN (D. Del.) (July 25, 2019)).

Response to Finding No. 1276:

The proposed finding is incomplete and misleading. In particular, BGI won a jury verdict in the case described in the proposed finding that held all three of Illumina's patents to be invalid meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022). Therefore, as previously noted, BGI can enter the United States market as early as August 2022. (PFF ¶¶ 777–777.3.)

In addition, Complaint Counsel presented no evidence regarding which products or services BGI would be enjoined from selling in the U.S. if Illumina's infringement claims are successful. (*See, e.g.*, (deSouza (Illumina) Tr. 2226–27) ("[BGI] can sell services here and has sequencing customers that use its service, but in terms of products, it has until 2023 that it can't sell here.").)

1277. Illumina filed claims against BGI in a Delaware Federal Court alleging that BGI infringed Illumina's U.S. Patent No. 9,303,290, U.S. Patent No. 9,217,178, and U.S. Patent No. 9,970,055. (deSouza (Illumina) Tr. 2226; PX9232 at 015, 025-027 (Answer and Counterclaim, *Complete Genomic, Inc. v. Illumina, Inc.*, Case 1:19-cv-00970-MN (D. Del.) (July 25, 2019)).

Response to Finding No. 1277:

The proposed finding is irrelevant, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1276, which Respondents incorporate herein. Respondents also note that BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777–777.3.)

1278. Illumina has sought an order preliminarily and permanently enjoining BGI from infringing on its U.S. Patent No. 9,303,290, U.S. Patent No. 9,217,178, and U.S. Patent No. 9,970,055. (PX9232 at 032 (Answer and Counterclaim, *Complete Genomic, Inc. v. Illumina, Inc.*, Case 1:19-cv-00970-MN (D. Del.) (July 25, 2019)).

Response to Finding No. 1278:

The proposed finding is irrelevant, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1276, which Respondents incorporate herein.

Respondents also note that BGI may enter the United States market as soon as August 2022.

(PFF ¶¶ 777–777.3.)

1279. The latest expiring of these patents, Illumina's U.S. Patent 9,217,178, does not expire until December 22, 2027. (PX9232 at 053 (Answer and Counterclaim, *Complete Genomic, Inc. v. Illumina, Inc.*, Case 1:19-cv-00970-MN (D. Del.) (July 25, 2019) (patent attached as exhibit showing the Patent Cooperation Treaty filing date of Dec. 13, 2005 and an extension of the twenty year patent term under 35 U.S.C. 154(b) by 739 days)).

Response to Finding No. 1279:

The proposed finding is irrelevant, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1276, which Respondents incorporate herein.

Respondents also note that BGI may enter the United States market as soon as August 2022.

(PFF ¶¶ 777–777.3.)

1280. Dr. Alex Aravanis, Illumina's Chief Technology Officer, spoke at an event titled "Baird Non-Deal Roadshow," a large group investor meeting on Monday, February 22, 2021. (deSouza (Illumina) Tr. 2229-2230; PX2822 (Illumina) at 001 (Baird Non-Deal Roadshow with Alex Aravanis, Feb. 19, 2021)).

Response to Finding No. 1280:

The proposed finding is irrelevant, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1276, which Respondents incorporate herein.

1281. One question Dr. Aravanis prepared a response to for the "Baird Non-Deal Roadshow" meeting was:

> I'd be really curious to hear about near-term patent expiration. I know there are 3 or 4 expiring in next 2-3 yrs. If we could dig into what those patents cover and how ILMN thinks about the impact of those patents expiring, that would be helpful.

(deSouza (Illumina) Tr. 2220-2231; PX2822 (Illumina) at 006 (Baird Non-Deal Roadshow with Alex Aravanis, Feb. 19, 2021)).

Response to Finding No. 1281:

The proposed finding is irrelevant, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1276, which Respondents incorporate herein. BGI may enter the U.S. market by August 2022. *Illumina, Inc. v. BGI Genomics, Co.*, 20-cv-01465-WHO (N.D. Cal. Mar. 27, 2022), ECF No. 665 at 48 ("If [BGI] make[s] offers to sell Accused Products in the U.S. before the expiration of the patents-in-suit—as they are permitted—they must include the following conspicuous written disclaimer: 'No sales will occur, and no purchase orders will be accepted, until after August 23, 2022.'"). (PFF ¶ 588.2.)

1282. Dr. Aravanis' prepared response to the question on near-term patent expiration at the Baird Non-Deal Roadshow notes that Illumina has alleged that BGI infringed patents that expire after 2023 and range from 2024 to 2027:

> Illumina also alleged infringement by BGI of a number of other patents in the U.S. and Europe with later expiration dates. These include patents directed to Illumina's proprietary imaging reagent, modified polymerase and fluorescent dyes, which have expiration dates ranging from 2024 to 2027 depending on the patent and country.

(deSouza (Illumina) Tr. 2231; PX2822 (Illumina) at 006 (Baird Non-Deal Roadshow with Alex Aravanis, Feb. 19, 2021)).

Response to Finding No. 1282:

The proposed finding is irrelevant, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1276, which Respondents incorporate herein. Respondents also note that BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777–777.3.)

1283. The patents Dr. Aravanis described at the Baird Non-Deal Roadshow include the patents that Illumina has alleged BGI has infringed in the counterclaims BGI filed in Delaware. (deSouza (Illumina) Tr. 2231; PX9232 at 032 (Answer and Counterclaim, *Complete Genomic, Inc. v. Illumina, Inc.*, Case 1:19-cv-00970-MN (D. Del.) (July 25, 2019)).

Response to Finding No. 1283:

The proposed finding is irrelevant, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1276, which Respondents incorporate herein.

Respondents also note that BGI may enter the United States market as soon as August 2022.

(PFF ¶¶ 777–777.3.)

1284. Dr. Aravanis' response further notes that "[a]s we learn more about BGI's products, additional patents may become relevant" and that Illumina has additional patents touching "every aspect of the sequencing workflow, including nucleotides, enzymes, reagent mixes, instruments, optics, analysis software, and bioinformatics, which result from Illumina's significant investments in research and development." (deSouza (Illumina) Tr. 2231-2232; PX2822 (Illumina) at 006-007 (Baird Non-Deal Roadshow with Alex Aravanis, Feb. 19, 2021)). According to Dr. Aravanis' response, these additional patents extend from 2023 to beyond 2030. (deSouza (Illumina) Tr. 2232; PX2822 (Illumina) at 006-007 (Baird Non-Deal Roadshow with Alex Aravanis, Feb. 19, 2021)).

Response to Finding No. 1284:

The proposed finding is irrelevant, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1276, which Respondents incorporate herein.

Respondents also note that BGI may enter the United States market as soon as August 2022.

(PFF ¶¶ 777–777.3.)

1285. Dr. Aravanis' notes that, as Illumina continues to innovate, Illumina intends to "broadly file patent applications covering these innovations, providing competitive advantages in our key technology areas." (deSouza (Illumina) Tr. 2232; PX2822 (Illumina) at 007 (Baird Non-Deal Roadshow with Alex Aravanis, Feb. 19, 2021)).

Response to Finding No. 1285:

The proposed finding is irrelevant, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1276, which Respondents incorporate herein.

Respondents also note that BGI may enter the United States market as soon as August 2022.

(PFF ¶¶ 777–777.3.)

c) Even if BGI Entered the U.S. Market, the Uncertainty Around BGI's Freedom to Operate in the United States in the Future Makes MCED Developers Unwilling to Switch to BGI

1286. Mr. Stahl testified that "Illumina has sued BGI for patent infringement. So the technologies are very similar. Due to the risk of that IP and them not being well intrenched [sic] in the US and also not having regulatory clearances in the US, we've decided not to pursue that instrument." (PX7075 (Stahl (Invitae) Dep. at 74-75)).

Response to Finding No. 1286:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1269 and 1276, which Respondents incorporate herein. Respondents also note that BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777–777.3.)

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Mr. Stahl is the President of Oncology at Invitae, a non-legal position completely focused on research and development efforts. (PX7075 (Stahl (Invitae) Dep. at 12-13.) His employment history similarly reveals no relevant patent-related expertise; he has always taken purely scientific and medical-related positions at his former and current employers. (PX7075 (Stahl (Invitae) Dep. at 10-13.)

The proposed finding is based on speculation. [redacted] (PX7075 (Stahl (Invitae) Dep. at 22, 44, 77–78) The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1287. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 59-60) (*in camera*)).

Response to Finding No. 1287:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1269 and 1276, which Respondents incorporate herein. Respondents also note that BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777–777.3.)

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Ms. Perettie is the CEO of FMI, a non-legal, purely business-related position. (PX7068 (Perettie (FMI-Roche) IHT at 14–17.) Her employment history similarly reveals no relevant patent-related expertise; she has always taken non-legal positions at his former and current employers and Ms. Perettie has no experience regarding patents or patent-related litigation. (PX7068 (Perettie (FMI-Roche) IHT at 11–14.) Accordingly, Ms. Perettie's analysis is not credible.

Respondents also note that [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶ 1190 herein.

Lastly, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1288. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 64) (*in camera*)).

Response to Finding No. 1288:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1269, 1276 and 1287, which Respondents incorporate herein. Respondents also note that BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777–777.3.)

1289. [redacted] (PX7074 (Perettie (FMI-Roche) Dep. at 158) (*in camera*)).

Response to Finding No. 1289:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1269, 1276 and 1287, which Respondents incorporate herein. Respondents also note that BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777–777.3.)

1290. Dr. Gao testified that using BGI for its PanSeer test is "out of the picture" because of the IP dispute involving its sequencers. (Gao (Singlera) Tr. 2895).

Response to Finding No. 1290:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1269, 1276 and 1318, which Respondents incorporate herein. Respondents also note that BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777–777.3.)

The proposed finding is also misleading and speculative. Dr. Gao apparently has minimal knowledge regarding BGI. He admitted that "[did] not have the facts" regarding switching to BGI systems and was "not sure" whether BGI actually has a dispute in China. (Gao (Singlera) Tr. 2895–97.) Dr. Gao also claimed that BGI had an injunction in Europe (Gao (Singlera) Tr. 2895) when, in actuality, [redacted]

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Dr. Gao held various research-related positions at Singlera and is currently Singlera's Research Advisor. (Gao (Singlera) Tr. 2870-72.) As Mr. Gao puts it, he is "heavily involved in the research part" and there is nothing in the record demonstrating Dr. Gao's knowledge or expertise regarding patents or patent-related litigation. (Gao (Singlera) Tr. 2870-72.) Accordingly, Mr. Gao's analysis is not credible.

1291. Dr. Gao explained the "BGI platform IP" would expose Singlera to "business risk from a legal point of view": If Singlera were to "develop a [cancer screening test] depending on BGI['s] . . . sequencer, we spend 40 to 60 million dollar[s] to get FDA approval. If they [BGI] were sued, we cannot use their machine." (PX7042 (Gao (Singlera) IHT at 63)).

Response to Finding No. 1291:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1269, 1276, 1290 and 1318, which Respondents incorporate herein. Respondents also note that BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777–777.3.)

The proposed finding is also misleading and speculative. Dr. Gao apparently has minimal knowledge regarding BGI. He admitted that "[did] not have the facts" regarding switching to BGI systems and was "not sure" whether BGI actually has a dispute in China. (Gao (Singlera) Tr. 2895–97.) Dr. Gao also claimed that BGI had an injunction in Europe (Gao (Singlera) Tr. 2895) when, in actuality, [redacted]

Furthermore, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1292. Dr. Gao identified the legal risk that Illumina patents would continue to block BGI as a reason why Singlera would not switch to BGI, stating, "[c]ommercially, [] we don't know whether [the] BGI machine will be able to continue. Or even if they decided they cannot just – they cannot continue their operation fully, then we are dead. . . . We cannot risk our future on other companies' legal potential and commercial potential." (PX7042 (Gao (Singlera) IHT at 63).

Response to Finding No. 1292:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1269, 1276, 1290 and 1318, which Respondents incorporate herein. Respondents also note that BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777–777.3.)

The proposed finding is also misleading and speculative. Dr. Gao apparently has minimal knowledge regarding BGI. He admitted that "[did] not have the facts" regarding switching to BGI systems and was "not sure" whether BGI actually has a dispute in China. (Gao (Singlera) Tr. 2895–97.) Dr. Gao also claimed that BGI had an injunction in Europe (Gao (Singlera) Tr. 2895) when, in actuality, [redacted]

Furthermore, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1293. [redacted] (Rabinowitz (Natera) Tr. 338-341 (*in camera*)).

Response to Finding No. 1293:

The proposed finding is compound due to it standing for five different propositions, each requiring individual analysis and support. It is also speculative, vague, consists of improper lay opinion, and is misleading.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) There is nothing in the record supporting Mr. Rabinowitz's ability to credibly speak about the relative strengths of the patents Illumina holds and Illumina's likelihood of success in their litigation. Dr. Rabinowitz is the executive chairman

of Natera and has an engineering/aeronautics educational background. (Rabinowitz (Natera) Tr. 284-85.) He has no background in patents, the law, or patent litigation. (Rabinowitz (Natera) Tr. 284-85.)

Intellectual Property. While BGI is currently enjoined in the United States, BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777–777.3.) *Illumina, Inc. v. BGI Genomics, Co.*, 20-cv-01465-WHO (N.D. Cal. Mar. 27, 2022), ECF No. 665 at 48 ("If [BGI] make[s] offers to sell Accused Products in the U.S. before the expiration of the patents-in-suit—as they are permitted—they must include the following conspicuous written disclaimer: 'No sales will occur, and no purchase orders will be accepted, until after August 23, 2022.'") BGI recently won a jury verdict that held three of Illumina's patents to be invalid meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022).

Performance. It is "undisputed that . . . BGI's technology is substitutable for Illumina's NGS technology in throughput, accuracy, turnaround time, and cost. (RX3869 (Cote Expert Report) ¶ 287.) Specifically, BGI's NGS sequencers use an SBS technology that is similar to Illumina's NGS sequencing technology. (PFF ¶ 588; RX3869 (Cote Expert Report) ¶ 286.) BGI currently markets five sequencers. The below chart shows each of the BGI instruments and their current throughput:

Instrument(s)	Throughput	Read Length	Run Time
DNBSEQ-G50	Simultaneous sequencing of ~ 100 to 500 million DNA fragments	50 to 2x150 nucleotides to generate outputs of up to ~ 150 Gb per run	10–66 hours
DNBSEQ-G400 FAST	Simultaneous sequencing of ~ 550 million DNA fragments	100 to 2x150 nucleotides to generate outputs of up to 330 Gb per run	13–37 hours

Instrument(s)	Throughput	Read Length	Run Time
DNBSEQ-G400	Simultaneous sequencing of ~ 1,500 to 1,800 million DNA fragments	50 to 2x200 nucleotides to generate outputs of up to 1,440 Gb (1.44 Tb) per run	13–37 hours
DNBSEQ-T7	Simultaneous sequencing of ~ 20 billion DNA fragments	100 to 2x150 nucleotides to generate outputs of up to 6,000 Gb (6 Tb) per run	<24 hours
DNBSEQ-T10×4RS / DNBSEQ-Tx[1]	Simultaneous sequencing of ~ 80 billion DNA fragments	100 to 2x150 nucleotides to generate outputs of up to 20 Tb per day	<24 hours

(PFF ¶ 590 (RX3465 (MGI Tech); RX4004 (MGI Tech)); RX3869 (Cote Expert Report) ¶ 287.)

BGI's DNBSEQ sequencer's reported accuracy is comparable to that of Illumina's sequencers, and guarantees more than 80% of bases with a quality score greater than Q30—which is over 99.9% accurate. (PFF ¶ 591; RX3465 (MGI Tech); RX3067 (BGI).) BGI's highest throughput instrument has a higher reported throughput than the highest performance instrument and flow cell currently offered by Illumina, the NovaSeq 6000 with the S4 flow cell (up to 6 Tb/run), [redacted]. (PFF ¶ 592; *Compare* RX4004 (MGI Tech) at 1–2 *with* RX3357 (Illumina) at 7; [redacted] BGI's reported sequencing costs for its DNBSEQ sequencers are lower than those for Illumina's NovaSeq instrument. (PFF ¶¶ 594–594.2).

Purported MCED test developers treat these NGS platforms as viable substitutes for Illumina's NGS platform. (PFF ¶ 780.) Dr. Vogelstein, the founder of Thrive stated, [redacted]

[1] MGI Tech, *MGI Introduces DNBSEQ-T10×4RS Genetic Sequencing System at the ICG-15*, Oct. 30, 2020, at https://en.mgi-tech.com/news/183/.

[redacted] Mr. Stahl also testified that BGI's and Illumina's technologies are "very similar". (PX7075 (Stahl (Invitae) Dep. at 75.)

Dr. Aravanis explained that BGI manufactures multiple sequencing instruments and consumables; they have an array of instruments very similar to Illumina's offerings in terms of the different categories of high throughput, mid throughput, low throughput; the instruments are comparable in terms of sequencing output; BGI's systems are used for liquid biopsy applications; BGI has an NGS sequencing product that could be used for multicancer screening; BGI competes with Illumina for liquid biopsy applications in the countries in which it operates; BGI markets its NGS offerings as an alternative to Illumina. (PFF ¶ 1306; Aravanis (Illumina) Tr. 1852–54.)

Other sequencing platform developers also observe the excellent performance of the BGI system. Specifically, [redacted]

Perception/Purportedly Limited Install Base. The proposed finding is speculative and vague as to the [redacted] Other NGS customers have successfully built a relationship with BGI, [redacted] In fact, Natera already uses BGI for its Signatera test in China. (PX7053 (Fesko (Natera) IHT at 50–51); RX3473 (Natera) at 1; *see also* RX3062 (Natera).) Natera's Signatera test was initially validated on Illumina's HiSeq 2500 NGS platform, showing that Natera has *already* switched between Illumina's platform and BGI's platform. (RX3499 (Natera) at 6.) Respondents also note that many customers outside of China have successfully built a relationship with BGI, [redacted]

[redacted]

Switching. Dr. Rabinowitz's statements with respect to switching are inaccurate and misleading. Switching between Illumina's platform and alternative platforms is feasible. (PFF ¶ 645; RX3869 (Cote Expert Report) ¶ 336.) Contrary to Dr. Rabinowitz's testimony, [redacted] (PX7111 (Fesko (Natera) Dep. at 251–52); RX3062 (BGI) at 1.) Natera's Signatera test was initially validated on Illumina's HiSeq 2500 NGS platform, showing that Natera has *already* switched between Illumina's platform and BGI's platform. (RX3499 (Natera) at 6.)

[redacted]

Dr. Aravanis noted that that customers switch from one Illumina NGS platform to another every few years; in order to switch from an Illumina NGS platform to another NGS

platform, the test developer would need to do an analytical bridging study to demonstrate that the test performs similarly on an alternative sequencing platform, there might be other steps where minor modifications to some of the library prep or analysis would also be required; an alternative NGS platform would not need FDA approval before it could be used for development or commercialization of an MCED test; if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (PFF ¶ 1312; Aravanis (Illumina) Tr. 1861–65.)

Lastly, Respondents also note that, based on [redacted]. (RX3869 (Cote Expert Report) ¶ 227; [redacted] the last time Natera mentioned anything related to early-detection appears to be 2017 ((RX3495 (Natera) at 7 (discussing exploring breast and ovarian cancer screening); RX3491 (Natera) at 18.) and Natera's CEO has publicly stated that "[Natera is] ***not focused on asymptomatic cancers strain or early detection.***" (RX3492 (Natera) at 6.) Respondents also incorporate their responses to CCFF ¶¶ 928, 965, 1099, 1269 and 1293 herein.

1294. [redacted]

[redacted] (Rabinowitz (Natera) Tr. 339 (*in camera*)).

Response to Finding No. 1294:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1269, 1276 and 1293, which Respondents incorporate herein.

1295. [redacted] (Rabinowitz (Natera) Tr. 338 (*in camera*)).

Response to Finding No. 1295:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1269, 1276 and 1293, which Respondents incorporate herein.

Additionally, Respondents emphasize that [redacted]

d) Even if BGI Entered the U.S. Market, U.S. Companies Are Unlikely to Use a Chinese Company Due to Data Privacy and Reputational Concerns

1296. BGI is a Chinese company affiliated with the Chinese government. (deSouza (Illumina) Tr. 2312).

Response to Finding No. 1296:

The proposed finding is irrelevant, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1269, which Respondents incorporate herein.

1297. [redacted] (PX5027 (Illumina) at 063 [redacted] (*in camera*)).

Response to Finding No. 1297:

The proposed finding is vague and irrelevant. [redacted]

1298. Illumina's Senior Director of Corporate Strategy circulated a "Sample of 2020 BGI Headlines" that includes, among other things, "IP violations" headlines and "Ethics issues" headlines such as "Chinese coronavirus test maker [BGI] agreed to build a Xinjiang gene bank," and "Commerce Department Adds Eleven Chinese Entities Implicated in Human Rights Abuses in Xinjiang to the Entity List." (PX2170 (Illumina) at 001-002 (Email from J. Andrew, Illumina, to E. Milsovic, Illumina, Nov. 2, 2020)).

Response to Finding No. 1298:

The proposed finding is irrelevant, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1269 and 1297, which Respondents incorporate herein.

Respondents also note that Complaint Counsel chose not to discuss PX2170 at trial (CC Exhibit Index at 10), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1299. [redacted] (PX2790 (Illumina) at 001 (Email from J. Andrew, Illumina, to J. Goswami, Illumina, Jan. 29, 2021) (*in camera*)).

Response to Finding No. 1299:

The proposed finding is irrelevant, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1269 and 1297, which Respondents incorporate herein.

[redacted]

Respondents also note that Complaint Counsel chose not to discuss PX2790 at trial (CC Exhibit Index at 32), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1300. [redacted] (PX2791 (Illumina) at 001 (Email from J. Andrew, Illumina, to F. deSouza et al., Illumina, Jan. 30, 2021) (*in camera*)).

Response to Finding No. 1300:

The proposed finding is irrelevant, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1269 and 1297, which Respondents incorporate herein.

1301. Dr. Aravanis testified that:

> [T]here have been some concerns raised about the privacy and data integrity of data produced on the BGI system and whether or not that data would be protected . . . for its customers . . . [such as] data from the instruments, you know, being sent to China, perhaps without customers' knowledge.

(PX7065 (Aravanis (Illumina) IHT at 156)).

Response to Finding No. 1301:

The proposed finding is irrelevant, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1269 and 1297, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.

1302. Mr. Stahl testified that there is a "broader macro question" about using BGI machines "in the sense that [BGI is] a Chinese company and US-China relations aren't the greatest, so to be determined." (PX7075 (Stahl (Invitae) Dep. at 99)).

Response to Finding No. 1302:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1269 and 1297, which Respondents incorporate herein.

The proposed finding is vague, irrelevant, speculative, and consists of an improper lay opinion. It is unclear what effects "US-China relations" will have on BGI and/or its entry into the United States market. Furthermore, given the enormity and complexity of nation-state relationships, any attempt to determine the potential impact (if any) of the US-China relationship on BGI is inherently speculative and deserves no credence.

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Mr. Stahl is the President of Oncology at Invitae, a position completely focused on research and development. (PX7075 (Stahl (Invitae) Dep. at 12-13.) He does not claim to possess, and his employment history reveals no, expertise on US-China relationships, its second-order impacts on NGS businesses, BGI's positioning within China, or United States assessments of BGI. (*See* (PX7075 (Stahl (Invitae) Dep. at 10-13.)

1303. [redacted] (PX7077 (Chahine (Helio) Dep. at 132) (*in camera*)).

Response to Finding No. 1303:

The proposed finding is misleading and speculative. [redacted]

Respondents also note that Dr. Chahine testified at trial that Helio has chosen to pursue a liver cancer screening test because Helio "has operations both in China and in the U.S." and "China has the largest number of liver cancer cases in the world." (Chahine (Helio) Tr. 1025.) [redacted] Helio has partnered with Chinese collaborators in the past as part of its work to validate its liver test, further undermining Complaint Counsel's argument that Chinese competitors such as BGI are off-limits to putative MCED developers. (RX3308 (Helio) at 1.) Complaint Counsel also concedes that [redacted]. (Chahine (Helio) Tr. 1062; CCFF ¶ 2537).

1304. [redacted] (Chahine (Helio) Tr. 1048 (*in camera*)).

Response to Finding No. 1304:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1303, which Respondents incorporate herein.

1305. [redacted] (Chahine (Helio) Tr. 1059-1060 (*in camera*)).

Response to Finding No. 1305:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1303, which Respondents incorporate herein.

1306. [redacted] (Chahine (Helio) Tr. 1110 (*in camera*)).

Response to Finding No. 1306:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1303, which Respondents incorporate herein.

1307. Helio's Chinese and United States operations share a "common interest and strategies," but the R&D is completely segregated between the two operations—all of the R&D work in China is done with Chinese samples, sequenced in China, and developed with an algorithm specific to China. (Chahine (Helio) Tr. 1026).

Response to Finding No. 1307:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1303, which Respondents incorporate herein.

1308. Dr. Chahine testified at trial that Helio has chosen to segregate the R&D between its United States and Chinese operations because of "specific laws" and because it "makes good business sense to completely segregate and not commingle any of those data" between the operations. (Chahine (Helio) Tr. 1026).

Response to Finding No. 1308:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1303, which Respondents incorporate herein.

1309. [redacted] (Chahine (Helio) Tr. 1048-49 (*in camera*)).

Response to Finding No. 1309:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1303 herein.

1310. [redacted] (Chahine (Helio) Tr. 1048-50 (*in camera*)).

Response to Finding No. 1310:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1303, which Respondents incorporate herein. Contrary to the proposed finding, [redacted] Respondents also incorporate their responses to CCFF ¶ 1177 herein.

1311. [redacted] (Chahine (Helio) Tr. 1048-49 (*in camera*)).

Response to Finding No. 1311:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1303, which Respondents incorporate herein. Further, [redacted]

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. Dr. Chahine testified at trial that he was no longer the CEO of Helio,

he terminated employment at Helio at the end of June 2021 and is currently at a start-up out of New York. (Chahine (Helio) Tr. 998–99.)

1312. [redacted] (Rabinowitz (Natera) Tr. 338-341 (*in camera*)).

Response to Finding No. 1312:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1293, which Respondents incorporate herein.

The proposed finding is inadmissible hearsay and misleading. [redacted] RX3473 (Natera) at 1; *see also* RX3062 (Natera).) [redacted]

1313. [redacted] (Rabinowitz (Natera) Tr. 338-41 (*in camera*)).

Response to Finding No. 1313:

The proposed finding is hearsay, irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1293 and 1312, which Respondents incorporate herein.

The proposed finding is vague, irrelevant, speculative, and consists of an improper lay opinion. It is unclear [redacted]

[redacted]

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Dr. Rabinowitz is the executive chairman of Natera and has an engineering/aeronautics educational background. (Rabinowitz (Natera) Tr. 284-85.) He does not claim to possess, and his employment history reveals no, expertise on US-China relationships, its second-order impacts on NGS businesses, BGI's positioning within China, or United States assessments of BGI. (Rabinowitz (Natera) Tr. 284-85.)

1314. [redacted] (Rabinowitz (Natera) Tr. 338-341 (*in camera*)).

Response to Finding No. 1314:

The proposed finding is hearsay, irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1293 and 1312, which Respondents incorporate herein.

Contrary to Complaint Counsel's unproven contention, [redacted]; RX3473 (Natera) at 1; *see also* RX3062 (Natera).) [redacted]

1315. [redacted] (PX7058 (Conroy (Exact) IHT at 122-123) (*in camera*)).

Response to Finding No. 1315:

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Mr. Conroy is the Chairman and CEO of Exact Sciences. (PFF ¶ 1689; Conroy (Exact/Thrive) Tr. 1526.) He does not claim to possess, and his employment history reveals no, expertise on US-China relationships, its second-order impacts on NGS businesses, BGI's positioning within China, or United States assessments of BGI. (Conroy (Exact/Thrive) Tr. 1526–27, 1530.)

Respondents also incorporate their responses to CCFF ¶ 1293 herein.

Furthermore, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1316. [redacted] (PX7058 (Conroy (Exact) IHT at 122-123) (*in camera*)).

Response to Finding No. 1316:

The proposed finding is hearsay, irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1293 and 1316, which Respondents incorporate herein.

Furthermore, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1317. [redacted] (PX7058 (Conroy (Exact) IHT at 122-123) (*in camera*)).

Response to Finding No. 1317:

The proposed finding is irrelevant because Cologuard uses PCR technology, not NGS, and is not an MCED test. Furthermore, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1318. Though both BGI and Singlera have Chinese offices, Dr. Gao testified that "may not be beneficial for [BGI] for [Singlera] to be Chinese, because we kind of know them better, you know, then in terms of business practice, reputation." (PX7042 (Gao (Singlera) IHT at 61-62)).

Response to Finding No. 1318:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1290 and 1293, which Respondents incorporate herein. Respondents also note that BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777–777.3.)

The proposed finding is also misleading and speculative. Dr. Gao apparently has minimal knowledge regarding BGI. He admitted that "[did] not have the facts" regarding switching to BGI systems and was "not sure" whether BGI actually has a dispute in China. (Gao (Singlera) Tr. 2895–97.) Dr. Gao also claimed that BGI had an injunction in Europe (Gao (Singlera) Tr. 2895) when, in actuality, [redacted]

[redacted]

Furthermore, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1319. Dr. Gao testified that BGI's reputation is "[n]ot great." (PX7042 (Gao (Singlera) IHT at 62)).

Response to Finding No. 1319:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1318, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶ 1293.

1320. [redacted] (PX5027 (Illumina) at 057 [redacted] (*in camera*)).

Response to Finding No. 1320:

The proposed finding is irrelevant. [redacted] Respondents also note that BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777–777.3.) Respondents also incorporate their responses to CCFF ¶ 1297 herein.

1321. [redacted]

[redacted] (PX5027 (Illumina) at 058 [redacted] (*in camera*)).

Response to Finding No. 1321:

The proposed finding is irrelevant for the reasons explained in Respondents' responses to CCFF ¶¶ 1269, 1297 and 1320, which Respondents incorporate herein.

1322. [redacted] PX5027 (Illumina) at 058 [redacted] (*in camera*)).

Response to Finding No. 1322:

The proposed finding is irrelevant for the reasons explained in Respondents' responses to CCFF ¶¶ 1269, 1297 and 1320, which Respondents incorporate herein.

1323. [redacted] (PX5027 (Illumina) at 058 [redacted] (*in camera*)).

Response to Finding No. 1323:

The proposed finding is irrelevant for the reasons explained in Respondents' responses to CCFF ¶¶ 1269, 1297 and 1320, which Respondents incorporate herein.

1324. [redacted] (PX5027 (Illumina) at 058 [redacted] (*in camera*)).

Response to Finding No. 1324:

The proposed finding is irrelevant for the reasons explained in Respondents' responses to CCFF ¶¶ 1269, 1297 and 1320, which Respondents incorporate herein. Respondents also note that BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.)

e) Even if BGI Entered the U.S. Market, MCED Test Developers Do Not Consider BGI an Alternative to Illumina

1325. [redacted] (Chahine (Helio) Tr. 1048 (*in camera*)).

Response to Finding No. 1325:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1293, which Respondents incorporate herein. In particular, it is [redacted] (RX3869 (Cote Expert Report) ¶ 287.) Further, Dr. Aravanis explained that BGI manufactures multiple sequencing instruments and consumables; they have an array of instruments very similar to Illumina's offerings in terms of the different categories of high throughput , mid throughput, low throughput; the instruments are comparable in terms of sequencing output; BGI's systems are used for liquid biopsy applications; BGI has an NGS sequencing product that could be used for multicancer screening; BGI competes with Illumina for liquid biopsy applications in the countries in which it operates; BGI markets its NGS offerings as an alternative to Illumina. (PFF ¶ 1306; Aravanis (Illumina) Tr. 1852–54.)

The proposed finding is also vague, misleading, and inaccurate. [redacted]

1326. [redacted] (PX7077 (Chahine (Helio) Dep. at 28) (*in camera*)).

Response to Finding No. 1326:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1325, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF 1293 herein. [redacted]

1327. [redacted] (Lengauer (Third Rock Ventures) Tr. 240 (*in camera*)).

Response to Finding No. 1327:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1293, which Respondents incorporate herein. [redacted] Specifically, [redacted] (RX0055 (Exact/Thrive) at

2.) [redacted]

1328. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 114) (*in camera*)).

Response to Finding No. 1328:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1293 and 1327, which Respondents incorporate herein.

[redacted]

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents additionally note that BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.)

1329. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 114) (*in camera*)).

Response to Finding No. 1329:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1293 and 1327, which Respondents incorporate herein.

[redacted]

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1330. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 113-115) (*in camera*)).

Response to Finding No. 1330:

The proposed finding is inaccurate, incomplete, and misleading with respect to the statement "BGI's lack of efficiency would limit Exact's ability to scale CancerSEEK" for the reasons explained in Respondents' responses to CCFF ¶¶ 1293 and 1327, which Respondents incorporate herein. [redacted]

1331. [redacted] (Rabinowitz (Natera) Tr. 341 (*in camera*)).

Response to Finding No. 1331:

Respondents have no specific response.

1332. [redacted] (Rabinowitz (Natera) Tr. 341 (*in camera*)).

Response to Finding No. 1332:

Respondents have no specific response.

1333. [redacted] (Rabinowitz (Natera) Tr. 337-338 (*in camera*)).

Response to Finding No. 1333:

Respondents have no specific response.

1334. [redacted] (Rabinowitz (Natera) Tr. 337-338 (*in camera*)).

Response to Finding No. 1334:

The proposed finding is misleading and is contradicted by the weight of the record evidence. For example, in June of 2021, BGI and Natera announced that, after two years of development alongside BGI, Natera was officially launching its Signatera MRD test in China, using BGI sequencers. (RX3473 (Natera) at 1.) [redacted] Respondents also incorporate their responses to CCFF ¶¶ 1293 and 1338 herein.

1335. [redacted] (Rabinowitz (Natera) Tr. 338-341 (*in camera*)).

Response to Finding No. 1335:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1293 and 1334, which Respondents incorporate herein. [redacted]

1336. [redacted] (Rabinowitz (Natera) Tr. 360-361 (*in camera*)).

Response to Finding No. 1336:

Respondents have no specific response.

1337. [redacted] (Rabinowitz (Natera) Tr. 342 (*in camera*)).

Response to Finding No. 1337:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1293, 1327 and 1338, which Respondents incorporate herein. [redacted]

1338. [redacted] (Rabinowitz (Natera) Tr. 342-343 (*in camera*)).

Response to Finding No. 1338:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1293 and 1327, which Respondents incorporate herein.

Contrary to Complaint Counsel's unproven contention, Respondents emphasize that Natera announced the launch of its *branded* Signatera MRD test in China, using BGI's sequencers. (RX3473 (Natera) at 1.)

(RX3473 (Natera) at 1.)

[redacted]

1339. [redacted] (Rabinowitz (Natera) Tr. 361 (*in camera*)).

Response to Finding No. 1339:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1293, 1327 and 1338, which Respondents incorporate herein. [redacted]

1340. [redacted] (Rabinowitz (Natera) Tr. 341-342 (*in camera*)).

Response to Finding No. 1340:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1293, 1327 and 1338, which Respondents incorporate herein. [redacted]

1341. [redacted] (Rabinowitz (Natera) Tr. 338-341 (*in camera*)).

Response to Finding No. 1341:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1293, 1327 and 1338, which Respondents incorporate herein. [redacted]

1342. Dr. Gao explained at trial that "[a]ll we hear is [that BGI's] platform [is] not very reliable. Breakdown may be frequently, and the service is not that good, so . . . [that is what] I hear from market." (Gao (Singlera) Tr. 2899).

Response to Finding No. 1342:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1293 and 1318, which Respondents incorporate herein. [redacted]

The proposed finding is also misleading and speculative. Dr. Gao apparently has minimal knowledge regarding BGI. He admitted that "[did] not have the facts" regarding switching to BGI systems and was "not sure" whether BGI actually has a dispute in China. (Gao (Singlera) Tr. 2895–97.) Dr. Gao also claimed that BGI had an injunction in Europe (Gao (Singlera) Tr. 2895) when, in actuality, [redacted]

1343. Dr. Gao testified that BGI has a reputation for being "spotty, not as good as Illumina." (Gao (Singlera) Tr. 2898).

Response to Finding No. 1343:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1293 and 1318, which Respondents incorporate herein.

[redacted]

The proposed finding is also misleading and speculative. Dr. Gao apparently has minimal knowledge regarding BGI. He admitted that "[did] not have the facts" regarding switching to BGI systems and was "not sure" whether BGI actually has a dispute in China. (Gao (Singlera) Tr. 2895–97.) Dr. Gao also claimed that BGI had an injunction in Europe (Gao (Singlera) Tr. 2895) when, in actuality, [redacted]

1344. Dr. Gao testified that BGI's poor reputation for reliability and service prevents Singlera from using BGI sequencers to run its PanSeer test. (Gao (Singlera) Tr. 2899).

Response to Finding No. 1344:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1293 and 1318, which Respondents incorporate herein.

[redacted]

The proposed finding is also misleading and speculative. Dr. Gao apparently has minimal knowledge regarding BGI. He admitted that "[did] not have the facts" regarding switching to BGI systems and was "not sure" whether BGI actually has a dispute in China. (Gao

(Singlera) Tr. 2895–97.) Dr. Gao also claimed that BGI had an injunction in Europe (Gao (Singlera) Tr. 2895) when, in actuality, [redacted]

1345. [redacted] (*in camera*)).

Response to Finding No. 1345:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1293, which Respondents incorporate herein. [redacted]

3. "Extremely Inefficient" Long-Read NGS Is Not an Option for MCED

a) Industry Participants and the Parties Recognize that Long-Read NGS is Not an Option for MCED

1346. Illumina's CEO, Mr. deSouza, stated on his JP Morgan investor call that long-read platforms such as PacBio will not expand into short read NGS for oncology applications. (See PX2544 (Illumina) at 027 (Email from T. Peterson, JP Morgan, to F. deSouza, Illumina, attaching "JPM Life Sciences CEO Conference Call Series" transcript, Sept. 5, 2019) ("And so if we look at how this industry plays out over the next decade, we expect to continue to see that dynamic play out where there are applications for long-read that will continue to scale. And as those vendors continue to drive the price points down as they expand their accuracy as PacBio has done, it'll catalyze the adoption and the expansion of those markets but it won't get them into the short-read technology of markets like NIPT or oncology that we expect to be competing into the next decade.").

Response to Finding No. 1346:

The proposed finding is incomplete and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore

and PacBio sequencing technologies have the same capabilities, as the cited testimony appears to only refer to PacBio. Respondents incorporate their responses to CCFF ¶ 904 herein.

The proposed finding is also incomplete, misleading and outdated. Although the cited source is from September 2019, the proposed finding appears to suggest that the same market dynamics exist today, nearly three years later. To the contrary, however, platforms such as Oxford Nanopore have progressed substantially since 2019. (*See*, *e.g.*, PFF ¶¶ 601–601.4 (RX3446 (Martignano et al., 2021); RX3737 (Wei & Williams 2016); RX3744 (Wilson et al., 2019); RX3441 (Marcozzi A et al., 2020)).) Recent improvements have made Oxford Nanopore long-read sequencing more suitable for multi-cancer screening. (PFF ¶¶ 600–600.5.)

1347. PacBio supplies long-read NGS platforms, and its 2020 annual revenue was approximately $79 million. (PX8399 (Henry (PacBio) Decl. ¶ 1)).

Response to Finding No. 1347:

Respondents note that Complaint Counsel chose not to discuss PX8399 at trial (CC Exhibit Index at 61), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1348. Long-read NGS platforms "can generate contiguous reads of up to 25,000 base pairs" in contrast to short-read NGS platforms like Illumina's that generate contiguous reads of only approximately 700 base pairs. (PX8399 (Henry (PacBio) Decl. ¶ 3)).

Response to Finding No. 1348:

The proposed finding is irrelevant and it is also misleading to the extent that it suggests that the length of contiguous reads suggests that Oxford Nanopore sequencers may not be used for MCED test development. The proposed finding is also inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore and PacBio sequencing technologies have the same capabilities, as the cited

testimony appears to only refer to PacBio. Respondents incorporate their responses to CCFF ¶ 904 herein.

In particular, researchers have demonstrated that Oxford Nanopore sequencers are capable of short-read sequencing. (PFF ¶¶ 601–601.4 (RX3446 (Martignano et al., 2021); RX3737 (Wei & Williams 2016); RX3744 (Wilson et al., 2019); RX3441 (Marcozzi A et al., 2020)).) Technology has been developed to conjoin (concatenate) short fragments of DNA into very, very long strands of DNA, allowing for efficient, high throughput sequencing of cell-free DNA using Oxford Nanopore's sequencers. (Cote Tr. 3754–56.) Oxford Nanopore "believe[s] that nanopore-based sequencing can provide rich biological insights that include the ability to directly characterise variants that are relevant in cancer, including methylation, structural variants, repeats and phasing. . . . Shorter fragments can be sequenced, in the case of circulating tumour DNA, or ultra-long fragments for other cancer related analyses." (RX3939 (Oxford Nanopore Registration Document), at 41, 56, 65–66.) Accordingly, Oxford Nanopore sequencers may be "a reliable alternative to Illumina sequencing, with the advantages of minute instrumentation costs and extremely short analysis time". (RX3446 (Martignano et al., 2021) at 1.)

Respondents note that Complaint Counsel chose not to discuss PX8399 at trial (CC Exhibit Index at 61), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1349. Former Illumina CFO/COO and current PacBio CEO Christian Henry explained: "To accomplish whole-genome sequencing, sequencing platforms must sequence longer genomes—such as the human genome—by piecing together many individual sequencing reads using bioinformatics software. This process is akin to putting together puzzle pieces to form a complete picture of a genome." (PX8399 (Henry (PacBio) Decl. ¶ 2)).

Response to Finding No. 1349:

The proposed finding is irrelevant because the cited testimony does not explain why Oxford Nanopore sequencers may not be used for MCED test development. The proposed finding is also inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore and PacBio sequencing technologies have the same capabilities, as the cited testimony appears to only refer to PacBio. Respondents incorporate their responses to CCFF ¶¶ 904, 1346 and 1348 herein. Respondents note that Complaint Counsel chose not to discuss PX8399 at trial (CC Exhibit Index at 61), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1350. Mr. Henry explained that long-read NGS platforms "are particularly beneficial for applications like whole-genome sequencing because it is easier to determine the entire genomic sequence by assembling fewer long sequence fragments than by assembling many short ones. Using the puzzle analogy, it is easier to piece together a puzzle with fewer larger pieces than many smaller ones." (PX8399 (Henry (PacBio) Decl. ¶ 3)).

Response to Finding No. 1350:

The proposed finding is irrelevant because the cited testimony does not explain why Oxford Nanopore sequencers may not be used for MCED test development. The proposed finding is also inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore and PacBio sequencing technologies have the same capabilities, as the cited testimony appears to only refer to PacBio. Respondents incorporate their responses to CCFF ¶¶ 904, 1346 and 1348 herein. Respondents note that Complaint Counsel chose not to discuss PX8399 at trial (CC Exhibit Index at 61), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1351. Mr. Henry declared that, "[b]ecause [ctDNA fragments] are typically fewer than 350 base pairs long, Illumina's short-read NGS platforms are capable of analyzing many ctDNA fragments in their entirety." (PX8399 (Henry (PacBio) Decl. ¶ 5)).

Response to Finding No. 1351:

The proposed finding is irrelevant because the cited testimony simply states that Illumina's NGS platform is capable of analyzing ctDNA fragments. Respondents also incorporate their responses to CCFF ¶¶ 893, 904, 1346 and 1348 herein.

Respondents note that Complaint Counsel chose not to discuss PX8399 at trial (CC Exhibit Index at 61), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1352. Mr. Henry indicated that, "[g]iven the relatively short length of many ctDNA fragments, long-read sequencing does not often present the same technical benefits over short-read sequencing as it does for other sequencing applications." (PX8399 (Henry (PacBio) Decl. ¶ 5)).

Response to Finding No. 1352:

The proposed finding is also irrelevant because the fact Oxford Nanopore sequencers may not "present the same technical benefits *over* short-read sequencing" does not show that Oxford Nanopore sequencers may not be used for MCED test development. Respondents also incorporate their responses to CCFF ¶¶ 893, 904, 1346 and 1348 herein.

Respondents also note that Complaint Counsel chose not to discuss PX8399 at trial (CC Exhibit Index at 61), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1353. [redacted]
(PX8399 (Henry (PacBio) Decl. ¶ 5) (*in camera*)).

Response to Finding No. 1353:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 1346 and 1348, which Respondents incorporate herein. The proposed finding is inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore and PacBio sequencing technologies have the same capabilities. Oxford Nanopore's PromethION sequencer has sequencing costs of as low as $2.55 per gigabase, which is lower than the per gigabase sequencing costs using Illumina's NovaSeq 6000. (*See* PFF ¶¶ 603–603.3.) Using Oxford Nanopore's PromethION with a throughput of 10 Tb in up to 72 hours (PFF ¶ 599 (RX3536 (ONT); RX3869 (Cote Expert Report) ¶ 293)), [redacted] Respondents also incorporate their responses to CCFF ¶ 1118 herein.

Respondents also note that Complaint Counsel chose not to discuss PX8399 at trial (CC Exhibit Index at 61), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1354. [redacted] (PX8399 (Henry (PacBio) Decl. ¶ 5) (*in camera*)).

Response to Finding No. 1354:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1353, which Respondents incorporate herein. Oxford

Nanopore's PromethION sequencer has sequencing costs of as low as $2.55 per gigabase, which is lower than the per gigabase sequencing costs using Illumina's NovaSeq 6000. (*See* PFF ¶¶ 603–603.3.) Using Oxford Nanopore's PromethION with a throughput of 10 Tb in up to 72 hours (PFF ¶ 599 (RX3536 (ONT); RX3869 (Cote Expert Report) ¶ 293)), [redacted] Respondents also incorporate their responses to CCFF ¶ 1118 herein.

1355. [redacted] (PX8399 (Henry (PacBio) Decl. ¶ 9) (*in camera*)).

Response to Finding No. 1355:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 904, 907 and 1353, which Respondents incorporate herein.

The proposed finding is inaccurate and outdated. PacBio, along with recently-acquired Omniome, has publicly stated that they would specifically target the cancer screening market, as well as other oncology applications, including a general interest in companies developing blood-based early cancer screening tests. (RX3947 (Clinical OMICs) at 3; PX7096 (Song (Omniome) Dep. at 59–63, 66; [redacted] (PX7096 (Song (Omniome) Dep. at 82, 100–01); [redacted]

[redacted]

Respondents note that Complaint Counsel chose not to discuss PX8399 at trial (CC Exhibit Index at 61), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1356. [redacted] (PX8399 (Henry (PacBio) Decl. ¶ 10) (*in camera*)).

Response to Finding No. 1356:

The proposed finding is outdated, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 907 and 1355, which Respondents incorporate herein. In July 2021, Pacific Biosciences of California ("PacBio") announced it had acquired Omniome for $800M. (RX3947 (Clinical OMICs).) PacBio stated that it believes Omniome's data accuracy should help the combined company target oncology applications like cancer screening. RX3947 (Clinical OMICs) at 3.) Omniome has stated that, at launch, its NGS sequencer will have accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. PX7096 (Song (Omniome) Dep. at 43, 58); [redacted] RX3869 (Cote Expert Report) ¶ 319.)

Respondents also note that Complaint Counsel chose not to discuss PX8399 at trial (CC Exhibit Index at 61), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1357. Illumina's CEO Francis deSouza explained in an investor call that in looking at circulating tumor DNA fragments, "the ability to do very long-read doesn't offer any incremental value and certainly isn't worth paying a significant premium in terms of the cost per base." (PX2544 (Illumina) at 026-027 (Email from T. Peterson, JP Morgan, to F. deSouza,

Illumina, attaching "JP Morgan Life Sciences CEO Conference Call Series" transcript, Sept. 5, 2019)).

Response to Finding No. 1357:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 910, 1346, 1348 and 1353, which Respondents incorporate herein.

1358. Illumina's Mr. deSouza, explained to investors that short-read NGS platforms are much more suitable for detecting ctDNA fragments than long-read platforms:

> The way we see it is that there are applications that are very well suited for long-read technology, that frankly short-read technology don't [sic] address and vice versa it's true as well. But there are markets, our core markets where short-read technologies work exceptionally well and long-read don't offer any additional values. So let me give you some specifics. If you look at some of our core markets, for example, in NIPT the fragments we're looking at are 150-ish base pairs. So somewhere between 130 base pairs and maybe up to 200 base pairs long. And so the ability to sequence fragments that are a million base pairs long or a hundred thousand base pairs long is frankly irrelevant, because the fragments are nowhere near that long. And so what customers are looking for is a high-volume sequencer that's able to cost effectively and accurately read those short fragments. That's true in circulating tumor DNA fragments in the oncology space as well. And so if you look at the number of our core markets, the ability to do very long-read doesn't offer any incremental value and certainly isn't worth paying a significant premium in terms of the cost per base.

(PX2544 (Illumina) at 026-027 (Email from T. Peterson, JP Morgan, to F. deSouza, Illumina, attaching "JP Morgan Life Sciences CEO Conference Call Series" transcript, Sept. 5, 2019)).

Response to Finding No. 1358:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 910, 1346, 1348 and 1353, which Respondents incorporate herein.

1359. Illumina's Mr. deSouza, explained to investors that long-read NGS platforms are not likely to impact Illumina's market position for liquid biopsy applications:

> Our thoughts on long read haven't really changed in the sense that … we believe long-read technologies … serve about 5% of the market where you're doing de novo sequencing for new species, for example. …[F]or the vast majority of the market, the 95% of the market, short reads are just simply the better technology in terms of accuracy, in terms of price performance. The price gap can be 10x between what you can do in short reads and what you can do in long reads. The raw accuracy is []higher on short reads. … [In markets like] liquid biopsy [] [y]ou're looking at fragments that are under 200 base pairs long. And so, you're not willing to make a trade-off in accuracy or cost just to be able to read 10,000 base pairs.

(PX2622 (Illumina) at 012 (Email from J. Cunningham, Illumina, to F. deSouza, Illumina, attaching "Edited Transcript, ILMN.OQ – Illumina Inc. at JPMorgan Healthcare Conference (Virtual) and Q&A Session," , Jan. 12, 2021)).

Response to Finding No. 1359:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF 893, 904, 910, 1346, 1348 and 1353, which Respondents incorporate herein.

Respondents also note that Complaint Counsel chose not to discuss PX2622 at trial (CC Exhibit Index at 26), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1360. In discussing Oxford Nanopore's long-read sequencing platform, Illumina Senior Vice President and Chief Technology Officer, Alex Aravanis, described Illumina as "superior in a meaningful way . . . around data accuracy, so the accuracy of the Oxford Nanopore reads is not as good as the Illumina reads." (PX7065 (Aravanis (Illumina) IHT at 157-59) (noting that MCED tests other than Grail are even more sensitive to NGS accuracy)).

Response to Finding No. 1360:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

Dr. Cote also explained that Oxford Nanopore's platform "is capable of sequencing up to 10 Terabase pairs ('Tb') per run and may be used to detect methylation and other epigenomic changes directly. While Oxford Nanopore historically faced lower accuracy, the latest improvements in chemistry and bioinformatics enable the platform's accuracy to the Q50 range. This platform is already being used by developers of potential cancer screening tests." (RX3869 (Cote Expert Report) ¶ 19.)

In addition, Oxford Nanopore states that its instruments have similar accuracy to Illumina. (*Compare* RX3541 (ONT) at 1; RX3535 (ONT) at 1 *with* RX3368 (Illumina).) Methods have been developed to obtain consensus sequences from homogenous DNA samples by genome assembly, resulting in accuracies of more than 99.999% (Q50). (RX3541 (ONT) at 1; RX3535 (ONT); RX3536 (ONT).) Oxford Nanopore has also announced that its single-molecule modal accuracy is now >99.3% (Q20) using its "Q20+" chemistry, and also developed a new approach termed "Duplex" sequencing, which enables the sequencing of both template and complementary strands and accuracy "trending towards 99.9% (Q30)". (RX3541 (ONT) at 1; RX3535 (ONT) at 1; *see also* PFF ¶¶ 604–604.1.)

The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 904, 970, 1346 and 1348, which Respondents incorporate herein.

Furthermore, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1361. Thermo Fisher Vice President of Product Management Andrew Felton testified that "it's highly inefficient to use a platform [for routine testing applications] that can generate and has to generate very long reads compared to a platform that's … primary utility is in the 200 to 600 base pair read length space." (Felton (Thermo Fisher) Tr. 1997-1998).

Response to Finding No. 1361:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904 and 911, which Respondents incorporate herein. Oxford Nanopore's PromethION has total throughput per run of up to 10 Tb, much higher than the up to 50 Gb per run generated by Thermo Fisher's Ion GeneStudio S5. (*See* PFF ¶¶ 579, 598–604.1.) Dr. Felton did not consider the new technology of using concatenation to read cfDNA fragments using nanopore sequencing.

[redacted]

1362. Mr. Felton explained that the cost of clinical oncology sequencing "would tend to be higher [for long read NGS instruments] because you typically have smaller numbers of reads of longer reads in the long-read technologies. (PX7070 (Felton (Thermo Fisher) IHT at 24-25)).

Response to Finding No. 1362:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 911 and 1361, which Respondents incorporate herein.

Furthermore, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1363. Mr. Felton testified that when short-read NGS instruments are used in clinical oncology, "your cost per read and naturally your cost per [gigabase] of sequence would tend to be much lower than for a long-read technology." (PX7070 (Felton (Thermo Fisher) IHT at 24-25)).

Response to Finding No. 1363:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 911 and 1361, which Respondents incorporate herein.

Furthermore, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1364. Dr. Bert Vogelstein of Johns Hopkins University testified that "[l]ong-read sequencers are [ ] unsuited for early detection [cfDNA] liquid biopsy testing" in part because "the throughput of long-read sequencers are much lower than the throughput of short-read sequencers" and "the error rates of long-read sequencers are much too high to effectively analyze the molecules and plasma". (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 65-66)).

Response to Finding No. 1364:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904 and 913, which Respondents incorporate herein.

Contrary to Complaint Counsel's unproven contention, Oxford Nanopore's sequencing technology is suitable for multi-cancer screening and has been used by test developers for that purpose. (*See* PFF ¶¶ 598–604.1.) Methods have been developed to obtain consensus sequences from homogenous DNA samples by genome assembly, resulting in accuracies of more than 99.999% (Q50). (RX3541 (ONT) at 1; RX3535 (ONT); RX3536 (ONT).) Oxford Nanopore has also announced that its single-molecule modal accuracy is now >99.3% (Q20) using its "Q20+" chemistry, and also developed a new approach termed "Duplex" sequencing, which enables the sequencing of both template and complementary strands and accuracy "trending towards 99.9% (Q30)". (RX3541 (ONT) at 1; RX3535 (ONT) at 1; *see also* PFF ¶¶ 604–604.1.) Oxford Nanopore claims its instruments have similar accuracy to Illumina. (*Compare* RX3541 (ONT) at 1; RX3535 (ONT) at 1 *with* RX3368 (Illumina).) Respondents incorporate their responses to CCFF ¶ 904 herein.

1365. Dr. Vogelstein testified that long-read sequencing technologies "are not applicable to the analysis of plasma DNA," and he elaborated "the reason is simple to understand: Plasma DNA is not long. Plasma DNA, the average size in a normal individual is 167 base pairs. And in cancers, it's a bit shorter." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 73-74)).

Response to Finding No. 1365:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 913 and 1364, which Respondents incorporate herein.

1366. Dr. Vogelstein testified that "long-read sequencing is not suitable for analyzing the plasma DNA molecules that" his lab tests in part because "the throughput of long-read sequencers are much lower than the throughput of short-read sequencers" and "[a]s a result, short-read sequencers can analyze the plasma DNA molecules much faster and in many more samples in a given time than can long-read sequencers". (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 65-66)).

Response to Finding No. 1366:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 913 and 1364, which Respondents incorporate herein.

1367. Dr. Vogelstein testified that long-read sequencing is not suitable for analyzing plasma DNA molecules in part because "the error rates of long-read sequencers are much too high to effectively analyze the molecules and plasma for [ ] early cancer detection with the number of artifactual mutations outnumbering the expected number of real mutations by many fold." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 65-66)).

Response to Finding No. 1367:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 913 and 1364, which Respondents incorporate herein.

1368. Dr. Vogelstein testified that PacBio's sequencers are not "applicable to a good assay for plasma." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 73-74)).

Response to Finding No. 1368:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904 and 1355, which Respondents incorporate herein.

Respondents also note that PacBio, along with its recently-acquired Omniome, has publicly stated that they would specifically target the cancer screening market, as well as other oncology applications, including a general interest in companies developing bllod-based early cancer screening tests. (RX3947 (Clinical OMICs) at 3; PX7096 (Song (Omniome) Dep. at 59–63, 66; [redacted] In addition, the proposed finding is contradicted by the testimony of Complaint Counsel's own witnesses. For example, [redacted]

[redacted]

1369. Dr. Vogelstein testified that "only short-read sequencing is suitable for the liquid biopsy sequencing" that his lab performs for the research it conducts. (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 65-66)).

Response to Finding No. 1369:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 913 and 1364, which Respondents incorporate herein.

b) MCED Test Developers Testified that Long-Read NGS Is Not an Alternative to Illumina NGS

1370. [redacted] (Chudova (Guardant) Tr. 1221-22) (*in camera*)).

Response to Finding No. 1370:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904 and 1346, which Respondents incorporate herein.

1371. [redacted]
(Chudova (Guardant) Tr. 1218-19) (*in camera*)).

Response to Finding No. 1371:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904 and 1346, which Respondents incorporate herein.

Recent improvements have made Oxford Nanopore long-read sequencing more suitable for multi-cancer screening. (PFF ¶¶ 600–600.5.) Researchers have demonstrated that Oxford Nanopore sequencers are capable of short-read sequencing. (PFF ¶¶ 601–601.4 (RX3446 (Martignano et al., 2021); RX3737 (Wei & Williams 2016); RX3744 (Wilson et al., 2019); RX3441 (Marcozzi A et al., 2020)).) Technology has been developed to conjoin (concatenate) short fragments of DNA into very, very long strands of DNA, allowing for efficient, high throughput sequencing of cell-free DNA using Oxford Nanopore's sequencers. (Cote Tr. 3754–56.) Oxford Nanopore "believe[s] that nanopore-based sequencing can provide rich biological insights that include the ability to directly characterise variants that are relevant in cancer, including methylation, structural variants, repeats and phasing. . . . Shorter fragments can be sequenced, in the case of circulating tumour DNA, or ultra-long fragments for other cancer related analyses." (RX3939 (Oxford Nanopore Registration Document), at 41, 56, 65–66.) Accordingly, Oxford Nanopore sequencers may be "a reliable alternative to Illumina sequencing, with the advantages of minute instrumentation costs and extremely short analysis time". (RX3446 (Martignano et al., 2021) at 1.) Dr. Chudova did not consider the new technology of using concatenation to read cfDNA fragments using nanopore sequencing.

Respondents also note that Omniome's (acquired by PacBio) in-development NGS sequencer reportedly has comparable throughput and run times to Illumina's NextSeq sequencers, but with up to 10-100x better accuracy. (PX7096 (Song (Omniome) Dep. at 82, 100–01); [redacted] Ultimately, Omniome has stated that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72)**;** [redacted]

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 927 and 2273, which Respondents incorporate herein.

1372. [redacted] (Chudova (Guardant)Tr. 1218-19) (*in camera*)).

Response to Finding No. 1372:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 927, 1346 and 1371, which Respondents incorporate herein.

Using Oxford Nanopore's PromethION with a throughput of 10 Tb in up to 72 hours (PFF ¶ 599 (RX3536 (ONT); RX3869 (Cote Expert Report) ¶ 293)), [redacted] —*a few more* samples in the same time frame. Respondents also incorporate their responses to CCFF ¶ 1118 herein.

1373. [redacted] (Chudova (Guardant) Tr. 1223-24) (*in camera*)).

Response to Finding No. 1373:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 927, 1355 and 1368, which Respondents incorporate herein.

Respondents also note that PacBio, along with its recently-acquired Omniome, has publicly stated that they would specifically target the cancer screening market, as well as other oncology applications, including a general interest in companies developing bllod-based early cancer screening tests. (RX3947 (Clinical OMICs) at 3; PX7096 (Song (Omniome) Dep. at 59–63, 66; [redacted] In addition, the proposed finding is contradicted by the testimony of Complaint Counsel's own witnesses. For example, [redacted]

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 927 and 2273, which Respondents incorporate herein.

1374. [redacted] (Chudova (Guardant) Tr. 1224 (*in camera*)).

Response to Finding No. 1374:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 927, 1346 and 1371, which Respondents incorporate herein.

Contrary to Complaint Counsel's unproven contention, Oxford Nanopore's sequencing technology is suitable for multi-cancer screening and has been used by test developers for that purpose. (*See* PFF ¶¶ 598–604.1.) Methods have been developed to obtain consensus sequences from homogenous DNA samples by genome assembly, resulting in accuracies of more than

99.999% (Q50). (RX3541 (ONT) at 1; RX3535 (ONT); RX3536 (ONT).) Oxford Nanopore has also announced that its single-molecule modal accuracy is now >99.3% (Q20) using its "Q20+" chemistry, and also developed a new approach termed "Duplex" sequencing, which enables the sequencing of both template and complementary strands and accuracy "trending towards 99.9% (Q30)". (RX3541 (ONT) at 1; RX3535 (ONT) at 1; *see also* PFF ¶¶ 604–604.1.) Oxford Nanopore claims its instruments have similar accuracy to Illumina. (*Compare* RX3541 (ONT) at 1; RX3535 (ONT) at 1 *with* RX3368 (Illumina).) Respondents incorporate their responses to CCFF ¶ 904 herein.

1375. Guardant Senior Vice President of Technology Dr. Darya Chudova explained that because ctDNA fragments are short in length, "mostly below 400 base pairs in length," and there is "nothing to read beyond the molecule itself … it's not useful to have long-read technology[]" for MCED tests. (PX7100 (Chudova (Guardant) Dep. at 73)).

Response to Finding No. 1375:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 927, 1346 and 1371, which Respondents incorporate herein.

1376. [redacted] (PX7045 (Chudova (Guardant) IHT at 44-47, 48-49) (i*n camera*)).

Response to Finding No. 1376:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904 and 927, which Respondents incorporate herein. Using Oxford Nanopore's PromethION with a throughput of 10 Tb in up to 72 hours (PFF ¶ 599 (RX3536 (ONT); RX3869 (Cote Expert Report) ¶ 293)), [redacted]

[redacted] Oxford Nanopore's PromethION sequencer has sequencing costs of as low as $2.55 per gigabase, which is lower than the per gigabase sequencing costs using Illumina's NovaSeq 6000. (*See* PFF ¶¶ 603–603.3.) Respondents also incorporate their responses to CCFF ¶ 1118 herein.

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 927 and 2273, which Respondents incorporate herein.

1377. [redacted]

(PX7045 (Chudova (Guardant) IHT at 47-48) (*in camera*)).

Response to Finding No. 1377:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 927, 1346 and 1371, which Respondents incorporate herein.

Using Oxford Nanopore's PromethION with a throughput of 10 Tb in up to 72 hours (PFF ¶ 599 (RX3536 (ONT); RX3869 (Cote Expert Report) ¶ 293)), [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶ 1118 herein.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1378. [redacted]

(PX7045 (Chudova (Guardant) IHT at 48-49) (*in camera*)).

Response to Finding No. 1378:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 927, 1355 and 1368, which Respondents incorporate herein.

Respondents also note that PacBio, along with its recently-acquired Omniome, has publicly stated that they would specifically target the cancer screening market, as well as other oncology applications, including a general interest in companies developing blood-based early cancer screening tests. (RX3947 (Clinical OMICs) at 3; PX7096 (Song (Omniome) Dep. at 59–

63, 66; [redacted] In addition, the proposed finding is contradicted by the testimony of Complaint Counsel's own witnesses. For example, [redacted]

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 927 and 2273, which Respondents incorporate herein.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. At 275–76.)

1379. [redacted] (Conroy (Exact) Tr. 1759) (*in camera*)).

Response to Finding No. 1379:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904 and 929, which Respondents incorporate herein.

The proposed finding is also incomplete and misleading including insofar as it suggests that Exact/Thrive is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. (*See* RRFF ¶ 929, incorporated herein). Respondents also incorporate their responses to CCFF ¶¶ 346 and 1348, herein.

1380. [redacted] (Conroy (Exact) Tr. 1759) (*in camera*)).

Response to Finding No. 1380:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893 and 904, which Respondents incorporate herein. The proposed finding is inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore and PacBio sequencing technologies have the same capabilities.

Contrary to Complaint Counsel's unproven contention regarding accuracy, Oxford Nanopore's sequencing technology is suitable for multi-cancer screening and has been used by test developers for that purpose. (*See* PFF ¶¶ 598–604.1.) Methods have been developed to obtain consensus sequences from homogenous DNA samples by genome assembly, resulting in accuracies of more than 99.999% (Q50). (RX3541 (ONT) at 1; RX3535 (ONT); RX3536 (ONT).) Oxford Nanopore has also announced that its single-molecule modal accuracy is now >99.3% (Q20) using its "Q20+" chemistry, and also developed a new approach termed "Duplex" sequencing, which enables the sequencing of both template and complementary strands and accuracy "trending towards 99.9% (Q30)". (RX3541 (ONT) at 1; RX3535 (ONT) at 1; *see also* PFF ¶¶ 604–604.1.) Oxford Nanopore claims its instruments have similar accuracy to Illumina. (*Compare* RX3541 (ONT) at 1; RX3535 (ONT) at 1 *with* RX3368 (Illumina).) Respondents incorporate their responses to CCFF ¶ 904 herein.\

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1381. [redacted]

[redacted]
(Lengauer (Third Rock Ventures) Tr. 180-81 (*in camera*)).

Response to Finding No. 1381:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 929, 1346 and 1348, which Respondents incorporate herein. The proposed finding is inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore and PacBio sequencing technologies have the same capabilities.

Recent improvements have made Oxford Nanopore long-read sequencing more suitable for multi-cancer screening.Researchers have demonstrated that Oxford Nanopore sequencers are capable of short-read sequencing. (PFF ¶¶ 601–601.4 (RX3446 (Martignano et al., 2021); RX3737 (Wei & Williams 2016); RX3744 (Wilson et al., 2019); RX3441 (Marcozzi A et al., 2020)).) Technology has been developed to conjoin (concatenate) short fragments of DNA into very, very long strands of DNA, allowing for efficient, high throughput sequencing of cell-free DNA using Oxford Nanopore's sequencers. (Cote Tr. 3754–56.) Oxford Nanopore "believe[s] that nanopore-based sequencing can provide rich biological insights that include the ability to directly characterise variants that are relevant in cancer, including methylation, structural variants, repeats and phasing. . . . Shorter fragments can be sequenced, in the case of circulating tumour DNA, or ultra-long fragments for other cancer related analyses." (RX3939 (Oxford Nanopore Registration Document), at 41, 56, 65–66.) Accordingly, Oxford Nanopore sequencers may be "a reliable alternative to Illumina sequencing, with the advantages of minute instrumentation costs and extremely short analysis time". (RX3446 (Martignano et al., 2021) at 1.) Dr. Lengauer did not consider the new technology of using concatenation to read cfDNA fragments using nanopore sequencing.

1382. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 117) (*in camera*)).

Response to Finding No. 1382:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 929, 1355 and 1368, which Respondents incorporate herein.

Respondents also note that PacBio, along with its recently-acquired Omniome, has publicly stated that they would specifically target the cancer screening market, as well as other oncology applications, including a general interest in companies developing blood-based early cancer screening tests. (RX3947 (Clinical OMICs) at 3; PX7096 (Song (Omniome) Dep. at 59–63, 66; [redacted] In addition, the proposed finding is contradicted by the testimony of Complaint Counsel's own witnesses. For example, [redacted]

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1383. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 117) (*in camera*)).

Response to Finding No. 1383:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 929, 1346, 1368 and 1381, which Respondents incorporate herein.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. At 275–76.)

1384. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 117) (*in camera*)).

Response to Finding No. 1384:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 929, 1346 and 1368, which Respondents incorporate herein. The proposed finding is inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore and PacBio sequencing technologies have the same capabilities.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. At 275–76.)

1385. [redacted]

(PX7051 (Lengauer (Third Rock Ventures) IHT at 116-17) (*in camera*)).

Response to Finding No. 1385:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 929, 1346 and 1348, which Respondents incorporate herein. [redacted] The proposed finding is inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore and PacBio sequencing technologies have the same capabilities.

[redacted]—while no Thrive witness provided any information about the sequencing required to perform CancerSEEK, and Exact/Thrive did not produce any information regarding the same during discovery—using Oxford Nanopore's PromethION with a throughput of 10 Tb in up to 72 hours (PFF ¶ 599 (RX3536 (ONT); RX3869 (Cote Expert Report) ¶ 293)), [redacted] Respondents also incorporate their responses to CCFF ¶ 1118 herein. Oxford Nanopore's PromethION sequencer has sequencing costs of as low as $2.55 per gigabase, which is lower than the per gigabase sequencing costs using Illumina's NovaSeq 6000. (*See* PFF ¶¶ 603–603.3.)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1386. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 107-09 (*in camera*)).

Response to Finding No. 1386:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 929, 1346, 1348, 1355 and 1368, which Respondents incorporate herein. The proposed finding is inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore and PacBio sequencing technologies have the same capabilities.

Contrary to Dr. Lengauer's unsupported testimony, the only technical expert on NGS technology who testified at trial on behalf of either side opined that Oxford Nanopore sequencing platforms are alternatives for CancerSEEK. His testimony is also supported by the testimony of Dr. Aravanis, who is the primary witness at trial who has experience in the technical division of a sequencing platform as well as a successful MCED test developer.

Dr. Aravanis further testified that it is possible to do short-read sequencing on Oxford Nanopore's platforms at very low cost; the Oxford Nanopore platform is a very high-output sequencing platform; the amount of data and cost per data is comparable to the high-end Illumina systems; Oxford Nanopore's NGS sequencing product can be used and have been for liquid biopsy oncology testing; Oxford Nanopore markets its NGS offering as an alternative to Illumina and Illumina views Oxford Nanopore as a competitor in NGS sequencing. (PFF ¶ 1308 (Aravanis (Illumina) Tr. 1856–59).) (*See also* PFF ¶¶ 1304–1310.)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. At 275–76.)

1387. [redacted] (PX7055 (Otte (Freenome) IHT at 64-66) (*in camera*)).

Response to Finding No. 1387:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 945, 1346 and 1348, which Respondents incorporate herein. The proposed finding is inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore and PacBio sequencing technologies have the same capabilities.

Recent improvements have made Oxford Nanopore long-read sequencing more suitable for multi-cancer screening.Researchers have demonstrated that Oxford Nanopore sequencers are capable of short-read sequencing. (PFF ¶¶ 601–601.4 (RX3446 (Martignano et al., 2021); RX3737 (Wei & Williams 2016); RX3744 (Wilson et al., 2019); RX3441 (Marcozzi A et al., 2020)).) Technology has been developed to conjoin (concatenate) short fragments of DNA into very, very long strands of DNA, allowing for efficient, high throughput sequencing of cell-free DNA using Oxford Nanopore's sequencers. (Cote Tr. 3754–56.) Oxford Nanopore "believe[s] that nanopore-based sequencing can provide rich biological insights that include the ability to directly characterise variants that are relevant in cancer, including methylation, structural variants, repeats and phasing. . . . Shorter fragments can be sequenced, in the case of circulating tumour DNA, or ultra-long fragments for other cancer related analyses." (RX3939 (Oxford Nanopore Registration Document), at 41, 56, 65–66.) Accordingly, Oxford Nanopore sequencers may be "a reliable alternative to Illumina sequencing, with the advantages of minute instrumentation costs and extremely short analysis time". (RX3446 (Martignano et al., 2021) at

1.) Mr. Otte did not consider the new technology of using concatenation to read cfDNA fragments using nanopore sequencing.

Contrary to Complaint Counsel's unproven contention regarding accuracy, Oxford Nanopore's sequencing technology is suitable for multi-cancer screening and has been used by test developers for that purpose. (*See* PFF ¶¶ 598–604.1.) Methods have been developed to obtain consensus sequences from homogenous DNA samples by genome assembly, resulting in accuracies of more than 99.999% (Q50). (RX3541 (ONT) at 1; RX3535 (ONT); RX3536 (ONT).) Oxford Nanopore has also announced that its single-molecule modal accuracy is now >99.3% (Q20) using its "Q20+" chemistry, and also developed a new approach termed "Duplex" sequencing, which enables the sequencing of both template and complementary strands and accuracy "trending towards 99.9% (Q30)". (RX3541 (ONT) at 1; RX3535 (ONT) at 1; *see also* PFF ¶¶ 604–604.1.) Oxford Nanopore claims its instruments have similar accuracy to Illumina. (*Compare* RX3541 (ONT) at 1; RX3535 (ONT) at 1 *with* RX3368 (Illumina).) Respondents incorporate their responses to CCFF ¶ 904 herein.

Furthermore, Respondents also note that PacBio, along with its recently-acquired Omniome, has publicly stated that they would specifically target the cancer screening market, as well as other oncology applications, including a general interest in companies developing bllod-based early cancer screening tests. (RX3947 (Clinical OMICs) at 3; PX7096 (Song (Omniome) Dep. at 59–63, 66; [redacted] In addition, the proposed finding is contradicted by the testimony of Complaint Counsel's own witnesses. For example, [redacted]

The proposed finding is incomplete and misleading including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 945 and 2355, which Respondents incorporate herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1388. [redacted] (PX7055 (Otte (Freenome) IHT at 72) (*in camera*)).

Response to Finding No. 1388:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 945 and 1387, which Respondents incorporate herein. The proposed finding is inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore and PacBio sequencing technologies have the same capabilities.

Contrary to Complaint Counsel's unproven contention regarding accuracy, Oxford Nanopore's sequencing technology is suitable for multi-cancer screening and has been used by test developers for that purpose. (*See* PFF ¶¶ 598–604.1.) Methods have been developed to obtain consensus sequences from homogenous DNA samples by genome assembly, resulting in

accuracies of more than 99.999% (Q50). (RX3541 (ONT) at 1; RX3535 (ONT); RX3536 (ONT).) Oxford Nanopore has also announced that its single-molecule modal accuracy is now >99.3% (Q20) using its "Q20+" chemistry, and also developed a new approach termed "Duplex" sequencing, which enables the sequencing of both template and complementary strands and accuracy "trending towards 99.9% (Q30)". (RX3541 (ONT) at 1; RX3535 (ONT) at 1; *see also* PFF ¶¶ 604–604.1.) Oxford Nanopore claims its instruments have similar accuracy to Illumina. (*Compare* RX3541 (ONT) at 1; RX3535 (ONT) at 1 *with* RX3368 (Illumina).) Respondents incorporate their responses to CCFF ¶ 904 herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1389. [redacted]

(PX7055 (Otte (Freenome) IHT at 72-73) (*in camera*)).

Response to Finding No. 1389:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 945 and 1387, which Respondents incorporate herein.

The cited testimony shows that Mr. Otte [redacted] (PFF ¶ 599.) [redacted] using Oxford Nanopore's PromethION with a throughput of 10 Tb in up to 72 hours (PFF ¶ 599 (RX3536 (ONT); RX3869 (Cote Expert Report) ¶ 293)), [redacted] Respondents also incorporate their responses to CCFF ¶ 1118 herein. Oxford Nanopore's PromethION sequencer has sequencing costs of as low as $2.55 per gigabase, which is lower than the per gigabase sequencing costs using Illumina's NovaSeq 6000. (*See* PFF ¶¶ 603–603.3.)

Contrary to Complaint Counsel's unproven contention regarding accuracy, Oxford Nanopore's sequencing technology is suitable for multi-cancer screening and has been used by

test developers for that purpose. (*See* PFF ¶¶ 598–604.1.) Methods have been developed to obtain consensus sequences from homogenous DNA samples by genome assembly, resulting in accuracies of more than 99.999% (Q50). (RX3541 (ONT) at 1; RX3535 (ONT); RX3536 (ONT).) Oxford Nanopore has also announced that its single-molecule modal accuracy is now >99.3% (Q20) using its "Q20+" chemistry, and also developed a new approach termed "Duplex" sequencing, which enables the sequencing of both template and complementary strands and accuracy "trending towards 99.9% (Q30)". (RX3541 (ONT) at 1; RX3535 (ONT) at 1; *see also* PFF ¶¶ 604–604.1.) Oxford Nanopore claims its instruments have similar accuracy to Illumina. (*Compare* RX3541 (ONT) at 1; RX3535 (ONT) at 1 *with* RX3368 (Illumina).) Respondents incorporate their responses to CCFF ¶ 904 herein.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. At 275–76.)

1390. [redacted] (PX7055 (Otte (Freenome) IHT at 18) (*in camera*)).

Response to Finding No. 1390:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 945, 1387 and 1389, which Respondents incorporate herein.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1391. Singlera Co-founder and former CEO Dr. Gary Gao testified at trial that long read sequencing technology is not a viable option for the PanSeer test. (Gao (Singlera) Tr. 2900-01).

Response to Finding No. 1391:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904, 982, 1011, 1346 and 1348 which Respondents incorporate herein. The proposed finding is inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore and PacBio sequencing technologies have the same capabilities.

Recent improvements have made Oxford Nanopore long-read sequencing more suitable for multi-cancer screening. (PFF ¶¶ 600–600.5.) Researchers have demonstrated that Oxford Nanopore sequencers are capable of short-read sequencing. (PFF ¶¶ 601–601.4 (RX3446 (Martignano et al., 2021); RX3737 (Wei & Williams 2016); RX3744 (Wilson et al., 2019); RX3441 (Marcozzi A et al., 2020)).) Technology has been developed to conjoin (concatenate) short fragments of DNA into very, very long strands of DNA, allowing for efficient, high throughput sequencing of cell-free DNA using Oxford Nanopore's sequencers. (Cote Tr. 3754–56.) Oxford Nanopore "believe[s] that nanopore-based sequencing can provide rich biological insights that include the ability to directly characterise variants that are relevant in cancer, including methylation, structural variants, repeats and phasing. . . . Shorter fragments can be sequenced, in the case of circulating tumour DNA, or ultra-long fragments for other cancer related analyses." (RX3939 (Oxford Nanopore Registration Document), at 41, 56, 65–66.) Accordingly, Oxford Nanopore sequencers may be "a reliable alternative to Illumina sequencing, with the advantages of minute instrumentation costs and extremely short analysis time".

(RX3446 (Martignano et al., 2021) at 1.) Dr. Gao did not consider the new technology of using concatenation to read cfDNA fragments using nanopore sequencing.

Furthermore, Respondents also note that PacBio, along with its recently-acquired Omniome, has publicly stated that they would specifically target the cancer screening market, as well as other oncology applications, including a general interest in companies developing bllod-based early cancer screening tests. (RX3947 (Clinical OMICs) at 3; PX7096 (Song (Omniome) Dep. at 59–63, 66; [redacted] In addition, the proposed finding is contradicted by the testimony of Complaint Counsel's own witnesses. For example, [redacted]

The proposed finding is also incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 982 and 2406, which Respondents incorporate herein.

1392. At trial, Dr. Gao explained that long read sequencers are prohibitively expensive compared to Illumina's sequencers for the PanSeer test. (Gao (Singlera) Tr. 2900-01).

Response to Finding No. 1392:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893 and 904, which Respondents incorporate herein. The proposed finding is inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore and PacBio sequencing technologies have the same capabilities.

Contrary to Complaint Counsel's unproven contention, Oxford Nanopore's PromethION sequencer has sequencing costs of as low as $2.55 per gigabase, which is lower than the per gigabase sequencing costs using Illumina's NovaSeq 6000. (*See* PFF ¶¶ 603–603.3.)

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 982, 1011 and 1391, which Respondents incorporate herein.

1393. Dr. Gao further explained at trial, "Illumina, like I said, even the small NextSeq Dx can carry 200 to 400 million read per run, and the long reader can only carry the millions of reads. . . . The cost will be much higher when we use it for cancer detection." (Gao (Singlera) Tr. 2901).

Response to Finding No. 1393:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893 and 904, which Respondents incorporate herein. The proposed finding is inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore and PacBio sequencing technologies have the same capabilities.

Oxford Nanopore's PromethION sequencer has sequencing costs of as low as $2.55 per gigabase, which is lower than the per gigabase sequencing costs using Illumina's NovaSeq 6000. (*See* PFF ¶¶ 603–603.3.)

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 982, 1011 and 1391–92, which Respondents incorporate herein.

1394. [redacted]

[redacted] (PX7111 (Fesko (Natera) Dep. at 55-56) (*in camera*)).

Response to Finding No. 1394:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893 and 904, which Respondents incorporate herein. The proposed finding is inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore and PacBio sequencing technologies have the same capabilities. Oxford Nanopore claims its instruments have similar accuracy to Illumina. (*Compare* RX3541 (ONT) at 1; RX3535 (ONT) at 1 *with* RX3368 (Illumina).)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1264, 1346, 1348 and 1355, which Respondents incorporate herein.

1395. [redacted] (PX7074 (Perettie (FMI-Roche) Dep. at 157) (*in camera*)).

Response to Finding No. 1395:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 904, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶¶ 893, 1190, 1346 and 1348 herein.

Recent improvements have made Oxford Nanopore long-read sequencing more suitable for multi-cancer screening. (PFF ¶¶ 600–600.5.) Researchers have demonstrated that Oxford Nanopore sequencers are capable of short-read sequencing. (PFF ¶¶ 601–601.4 (RX3446 (Martignano et al., 2021); RX3737 (Wei & Williams 2016); RX3744 (Wilson et al., 2019); RX3441 (Marcozzi A et al., 2020)).) Technology has been developed to conjoin (concatenate) short fragments of DNA into very, very long strands of DNA, allowing for efficient, high throughput sequencing of cell-free DNA using Oxford Nanopore's sequencers. (Cote Tr. 3754–56.) Oxford Nanopore "believe[s] that nanopore-based sequencing can provide rich biological insights that include the ability to directly characterise variants that are relevant in cancer, including methylation, structural variants, repeats and phasing. . . . Shorter fragments can be sequenced, in the case of circulating tumour DNA, or ultra-long fragments for other cancer related analyses." (RX3939 (Oxford Nanopore Registration Document), at 41, 56, 65–66.) Accordingly, Oxford Nanopore sequencers may be "a reliable alternative to Illumina sequencing, with the advantages of minute instrumentation costs and extremely short analysis time". (RX3446 (Martignano et al., 2021) at 1.) Ms. Perettie did not consider the new technology of using concatenation to read cfDNA fragments using nanopore sequencing.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1396. Helio Health CEO Dr. Kenneth Chahine testified that long-read NGS platforms "provid[e] information that today we don't believe is important. And so if you are going to … pay additional money for it … it doesn't make sense for us to do that to date." (PX7077 (Chahine (Helio Health) Dep. at 28)).

Response to Finding No. 1396:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893 and 904, which Respondents incorporate herein. The proposed finding is inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore and PacBio sequencing technologies have the same capabilities. Oxford Nanopore's PromethION sequencer has sequencing costs of as low as $2.55 per gigabase, which is lower than the per gigabase sequencing costs using Illumina's NovaSeq 6000. (*See* PFF ¶¶ 603–603.3.)

Respondents additionally note that [redacted] Respondents also incorporate their responses to CCFF ¶¶ 1346 and 1348 herein.

1397. Invitae's President of Oncology Joshua Stahl explained that long read sequencers have a low throughput so "you can't do applications like ctDNA" which require many reads of each sequence. (PX7044 (Stahl (Invitae) IHT at 97-100)).

Response to Finding No. 1397:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893 and 904, which Respondents incorporate herein. . The proposed finding is inaccurate and misleading because it oversimplifies the capabilities of various types of NGS platforms, and because it suggests that Oxford Nanopore and PacBio sequencing technologies have the same capabilities.

Mr. Stahl of Invitae also recognized that Thermo Fisher (along with Oxford Nanopore, BGI, and PacBio) is a participant in the NGS field and that there would be "no way to predict"

which NGS company would be successful over the next five or ten years. (PX7075 (Stahl (Invitae) Dep. at 43).)

Respondents additionally note that [redacted] (Stahl (Invitae) Dep. at 22, 44.)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1398. Invitae's Mr. Stahl testified that that long-read sequencing provider Oxford Nanopore's "error rates are high, higher than [Thermo Fisher's] Ion Torrent and their throughput . . . is very low and so it's not a practical sequencing instrument within the precision oncology space." (PX7075 (Stahl (Invitae) Dep. at 74)).

Response to Finding No. 1398:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 893, 904 and 1397, which Respondents incorporate herein.

Contrary to Complaint Counsel's unproven contention, Oxford Nanopore's sequencing technology is suitable for multi-cancer screening and has been used by test developers for that purpose. (*See* PFF ¶¶ 598–604.1.) Methods have been developed to obtain consensus sequences from homogenous DNA samples by genome assembly, resulting in accuracies of more than 99.999% (Q50). (RX3541 (ONT) at 1; RX3535 (ONT); RX3536 (ONT).) Oxford Nanopore has also announced that its single-molecule modal accuracy is now >99.3% (Q20) using its "Q20+" chemistry, and also developed a new approach termed "Duplex" sequencing, which enables the sequencing of both template and complementary strands and accuracy "trending towards 99.9% (Q30)". (RX3541 (ONT) at 1; RX3535 (ONT) at 1; *see also* PFF ¶¶ 604–604.1.) Oxford Nanopore claims its instruments have similar accuracy to Illumina. (*Compare* RX3541 (ONT) at

1; RX3535 (ONT) at 1 *with* RX3368 (Illumina).) Respondents incorporate their responses to CCFF ¶ 904 herein.

F. OTHER TESTING TECHNOLOGIES ARE NOT VIABLE SUBSTITUTES FOR NGS FOR MCED TESTS

1399. In a 2019 presentation discussing a combined Illumina-Grail entity, Illumina stated that "[n]o technology has demonstrated the ability to achieve the required analytical sensitivity of 0.01% of ctDNA from a couple of blood tubes worth of input. [Illumina's] hypothesis is that deeper sequencing (breadth and depth) will drive higher sensitivity and specificity than lower resolution methods like digital PCR and lower coverage WGS, which will be critical to performance in screening. Specifically, deeper sequencing allows more coverage of cancer relevant genes and deeper sampling of the cfDNA to find rare molecules." (PX2712 (Illumina) at 027 (Email from P. Scagnetti, Illumina, to M. Nguyen, Illumina, attaching Python: A Revolution in Early Cancer Detection Presentation, Dec. 3, 2019)).

Response to Finding No. 1399:

The proposed finding is incomplete and misleading. It is undisputed that there are at least two MCED tests on the market that are not based on NGS technology. (PFF ¶ 692.)

StageZero's Aristotle test is a microarray-based liquid biopsy test that interrogates mRNA to detect 10 cancer types. (PFF ¶¶ 543–52, 692.1.) Genesys Biolabs' OneTest is a proteomics-based test that measures seven cancer protein biomarkers to screen for lung, liver, pancreatic, ovarian, prostate and colon cancers. (PFF ¶¶ 553–56, 692.2.)

Moreover, a number of companies are developing cancer screening tests that are not based on NGS technology, including tests in development from InterVenn Biosciences (PFF ¶¶ 557–63.1), Seer's ProteographTM and PrognomiQ platforms (PFF ¶¶ 564–69) and Somalogic (PFF ¶¶ 570–73). (PFF ¶ 693.) There is no evidence, or reason to believe, that an MCED test must use NGS technology to launch an MCED test under Complaint Counsel's articulation. (PFF ¶ 694.) Nor is there any evidence, or reason to believe, that patients or doctors have any preference for an MCED test based on the platform used to run it. (PFF ¶ 695.) What patients

and doctors care about is whether a test works and for which indications, not how exactly it works. (PFF ¶ 696.)

The proposed finding also appears to suggest that MCED testing today requires "very deep sequencing", which is wrong. For example, GRAIL's Galleri test does not use "very deep sequencing", but relies on targeted methylation for cancer signal detection and localization. *(See, e.g.*, PFF ¶¶ 56, 345, 384, 1289.)

1400. Illumina materials state that no other DNA analysis technology can analyze as many DNA fragments as NGS or characterize almost all biomarkers contained within each fragment like NGS. (*See* PX0120 at 001 (Illumina, Advantages of next-generation sequencing vs. qPCR) (". . . qPCR can only detect known sequences. In contrast, NGS is a hypothesis-free approach that does not require prior knowledge of sequence information."); *see also* PX7097 (Felton (Thermo Fisher) Dep. at 39) (testifying that PCR is generally not used to detect unknown variants)).

Response to Finding No. 1400:

The proposed finding is not supported by the cited evidence. The two pieces of cited evidence both state that PCR can only detect known sequences; they do not provide support for the much broader first sentence of the proposed finding. PX0120 also states that "both [qPCR and NGS] offer highly sensitive and reliable variant detection". (*See* PX0120 (Illumina) at 1.) Respondents also incorporate their responses to CCFF ¶ 1399 herein.

1401. Illumina Senior VP of Corporate Development and Strategic Planning, Joydeep Goswami, explained, "NGS is a great solution" for applications like cancer screening because "cancer is by definition a disease that manifests due to changes in DNA" and "NGS helps customers assess the . . . changes in DNA . . . very, very quickly and comprehensively." (PX7087 (Goswami (Illumina) Dep. at 100-01)).

Response to Finding No. 1401:

Respondents have no specific response except to note that Dr. Goswami also testified that

[redacted]

[redacted] (PX7087 (Goswami (Illumina) Dep. at 99.) Respondents also incorporate their responses to CCFF ¶ 1399 herein.

1402. Dr. Felton testified that multi-cancer early detection is an application suited for high-throughput NGS sequencers because "[t]he collection of samples from a wide area of the population is inherently easier if it's funneled into a central facility … and then running those samples on a high throughput platform would reduce the amount of labor time involved in the processing of said samples." (Felton (Thermo Fisher) Tr. at 2002).

Response to Finding No. 1402:

The proposed finding is misleading and incomplete. It is evidence that "higher output platforms would be suited to a centralized environment", (Felton (Thermo Fisher) Tr. 2002) showing that, to the extent that test developers use a high-throughput approach for MCED testing, they are unlikely to pursue kitted IVD tests. [redacted] (Felton (Thermo Fisher) Tr. 2006.) Singlera's PanSeer test is compatible with both Illumina and Thermo Fisher systems. (PFF ¶¶ 533, 667–68.)

Respondents also incorporate their responses to CCFF ¶ 952 herein.

1403. [redacted] (PX7055 (Otte (Freenome) IHT at 63) (*in camera*)).

Response to Finding No. 1403:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945 and 1399, which Respondents incorporate herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1404. [redacted] (PX7100 (Chudova (Guardant) IHT at 20) (*in camera*)).

Response to Finding No. 1404:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927 and 1399, which Respondents incorporate herein.

For the purposes of this response, Respondents assume that "IHT" is a typographical error and the intended reference is Chudova (Guardant) Dep. at 20.

1405. [redacted] (Lengauer (Third Rock Ventures) Tr. 183 (*in camera*)).

Response to Finding No. 1405:

The proposed finding is not supported by the cited evidence. In particular, Respondents state that Thrive's CancerSEEK test uses a combination of NGS and proteomics technology.

(PFF ¶ 423 (Lengauer (Exact/Thrive) Tr. 210–11; RX3419 (Lennon 2020) at 3).) The CancerSEEK assay as it exists today is not a liquid biopsy-only test, and does not solely rely on NGS; in particular, it relies on a full-body PET-CT imaging step. (PFF ¶ 425.1.) Respondents also incorporate their responses to CCFF ¶¶ 929 and 1399 herein.

1406. [redacted] (Lengauer (Third Rock Ventures) Tr. 268-70 (*in camera*)).

Response to Finding No. 1406:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929, 1399 and 1405, which Respondents incorporate herein. The proposed finding is also incomplete and misleading insofar as it suggests that Exact is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future for the reasons explained in Respondents' responses to CCFF ¶¶ 414, 418, 905 and 1912, which Respondents incorporate herein.

[redacted] Exact/Thrive also admitted that, based on the DETECT-A trial, "[a]t present, we cannot be certain that the DETECT-A blood test"—the CancerSEEK test—"helped any participant." (RX3419 at 11.)

1. Microarray Platforms

1407. Microarrays test DNA fragments for the presence of predefined target sequences. (PX7072 (deSouza (Illumina) IHT at 55; PX7070 (Felton (Thermo Fisher) IHT at 20-21)).

Response to Finding No. 1407:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1399 and 1412; *see* also PFF ¶¶ 163–164.5.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1408. Microarrays determine whether specific sequences are present within a sample. (PX7070 (Felton (Thermo Fisher) IHT at 20-21) ("Q At a high level, what is the difference between Thermo's NGS business and its microarray business? A The microarray technology provides for so-called hypothesis-based experiments primarily for gene expression, genotyping, and copy. By that we mean, you have to know something about the sequences that you're trying to interrogate to place them onto the array to be detected; whereas, next-generation sequencing is a so-called hypothesis-free technology in which you do not have to understand the sequences that you are trying to interrogate. You just sequence them directly.")).

Response to Finding No. 1408:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1399 and 1412; *see* also PFF ¶¶ 163–164.5.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1409. A microarray is a device "that [labs] can hybridize DNA onto, and the device fluoresces, indicating what DNA is present…" (PX7113 (Rabinowitz (Natera) Dep. at 114)).

Response to Finding No. 1409:

Respondents have no specific response.

1410. Microarrays do not provide precise readouts of the sequence of nucleotides contained within fragments of DNA. (Chudova (Guardant) Tr. 1177).

Response to Finding No. 1410:

The proposed finding is incomplete and misleading. Dr. Chudova did not testify that microarrays "do not provide precise readouts"; she testified that "micro-arrays . . . would not provide the kind of precision that's needed for screening applications in terms of the readout of the fragments of DNA." (Chudova (Guardant) Tr. 1177.) In addition, StageZero's Aristotle test achieves a high degree of precision using microarray technology, specifically, Aristotle achieved sensitivity from 55.6% to 100% for various cancer types at 99.0% specificity, with mean false positive rates ranging from 0.3% to 6.8%. (PFF ¶ 550.) Respondents also incorporate their responses to CCFF ¶ 1399 herein.

1411. Microarray technology has a lower throughput than NGS. (Felton (Thermo Fisher) Tr. 1992-1993).

Response to Finding No. 1411:

The proposed finding is incomplete and misleading. When asked whether he knew how the throughput of Thermo's microarray technology compares to that of its NGS technology, Dr. Felton replied: "[n]ot well, no". He testified that "[g]enerally, it would – I would say [microarray] would be lower throughput than NGS". (Felton (Thermo Fisher) Tr. 1992–93.) This testimony is Dr. Felton's personal view about the general relationship between the two technologies, rather than the definitive view presented in the proposed finding.

Microarrays provide a high-throughput platform for simultaneously screening tens of thousands of biomolecular interactions. (PFF ¶ 164.) For example, microarray technology such as Thermo Fisher's Genome-Wide Human SNP Array 6.0 chip features 1.8 million genetic markers for single nucleotide polymorphisms (SNPs) and copy number variations (CNVs). (PFF ¶ 164.2.) Certain NGS systems such as the MiSeq may be used to interrogate a comparable number of genetic markers. (*See* e.g., PFF ¶ 575.)

1412. NGS is better suited than microarray for "more things like oncology testing, inherited disease testing where … you're looking to detect a relatively reasonable number of mutations, but across a large genomic footprint. That would tend to be the space that [NGS platform instruments] would have an advantage over a microarray platform." (Felton (Thermo Fisher) Tr. 1993).

Response to Finding No. 1412:

The proposed finding is misleading and incomplete. StageZero's Aristotle test is a microarray-based blood biopsy test that interrogates mRNA from whole blood (blood transcriptome) to detect gene expression profiles. (PFF ¶ 547.) Aristotle, which was launched as an LDT in 2021, detects 9 cancer types relevant for women and 6 cancer types relevant for men, for a total of 10 cancer types. (PFF ¶ 548.) In contrast to the DNA methylation or genomic mutation based approaches used by GRAIL, Thrive, and other companies, StageZero uses an approach called immunoediting. (PFF ¶ 549.) As a result of this immunoediting, gene expressions in the transforming cancer cells, *i.e.*, the mRNA in the transcriptome, display signature profiles, and cause a corresponding change in the mRNA profiles in the peripheral blood plasma. (PFF ¶ 549.1.) StageZero's Aristotle test detects this change in the mRNA profiles using microarray technology, which tests more than 36,000 gene transcripts and variants. (PFF ¶ 549.2.)

[redacted]

1413. Microarrays do not provide the level of accurate quantification that is possible with NGS technology. (Chudova (Guardant) Tr. 1143).

Response to Finding No. 1413:

The proposed conclusion is incomplete and misleading. In 2,845 unique blood samples validation study with 1,013 samples from patients diagnosed with 10 cancers and 1,832 control samples including 1,042 samples from healthy subjects and the remaining from patients diagnosed with non-cancer diseases, StageZero's microarray-based test, Aristotle, achieved sensitivity from 55.6% to 100% for various cancers at 99.0% specificity, with PPVs from 5.6–77.7% and mean false positive rate ranging from 0.3% to 6.8%. (PFF ¶ 550.) Respondents also incorporate their responses to CCFF ¶ 1412 herein.

1414. [redacted] (PX7114 (Stamatiou (StageZero) Dep. at 42) (*in camera*)).

Response to Finding No. 1414:

The proposed finding is incomplete and misleading. Thermo Fisher's Genome-Wide Human SNP Array 6.0 chip features 1.8 million genetic markers for single nucleotide polymorphisms (SNPs) and copy number variations (CNVs). (PFF ¶ 164.2.) Similarly, Agilent Technologies' Human Genome CGH Microarrays offers up to 1 million probes for genome-wide CNV identification and characterization. (PFF ¶ 164.4.)

1415. Microarray systems are limited in the number of genetic markers they can interrogate. (Chahine (Helio) Tr. 1020).

Response to Finding No. 1415:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1411 and 1412, which Respondents incorporate herein.

1416. Thermo Fisher's Felton acknowledged that while microarray technology "can generate a large number of data points, their throughput is relatively low compared to the highest throughput gene sequencing platforms." (PX7097 (Felton (Thermo Fisher) Dep. at 41)).

Response to Finding No. 1416:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1411 and 1412, which Respondents incorporate herein.

1417. [redacted]

(PX7111 (Fesko (Natera) Dep. at 64–65) (*in camera*)).

Response to Finding No. 1417:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 1264, 1411 and 1412, which Respondents incorporate herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Mr. Fesko has never worked at Ariosa and is not an expert with respect to its technology. Further, Ariosa (part of Roche at the time) switched its Harmony NIPT from an NGS-based approach to a microarray-based approach, and stated that

it achieved more accurate analysis with lower cost and decreased turnaround time by doing so. (PX7096 (Song (Omniome) Dep. at 124–28); RX3400 (Juneau et al., 2014).) This change did not interrupt Harmony's commercial availability. (PX7076 (Song (Omniome) Dep. at 125–26.)

The proposed finding is also incomplete and misleading insofar as it suggests that Natera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future.

[redacted] (PFF ¶¶ 508–09.) [redacted] (PFF ¶¶ 509–10.)

[redacted] (PFF ¶ 511

(RX3869 (Cote Expert Report) ¶ 227; [redacted]).) Respondents also incorporate their responses to CCFF ¶¶ 341, 774–775 and 794 herein.

1418. [redacted] (PX7111 (Fesko (Natera) Dep. at 62) (*in camera*)).

Response to Finding No. 1418:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1264, 1411–12 and 1417, which Respondents incorporate herein.

1419. Former Ariosa co-founder and CEO Dr. Ken Song testified that Ariosa abandoned its plans for developing oncology tests because ctDNA was not detectable on a microarray. (PX7071 (Song (Omniome) IHT at 98–99)).

Response to Finding No. 1419:

The proposed finding is incomplete and misleading. Dr. Song also testified that Ariosa (at the time part of Roche) switched its Harmony non-invasive prenatal test (which detects circulating cell-free DNA (cfDNA), of which ctDNA is one type (Cance (ACS) Tr. 609; RX3869 (Cote Expert Report) ¶ 43), from an NGS-based approach to a microarray-based approach, and claimed to have achieved lower cost and decreased turnaround time for the test. (PFF ¶ 653; PX7096 (Song (Omniome/Fmr. Ariosa) Dep. at 124– 28); RX3400 (Juneau et al., 2014).) Ariosa completed this platform switching without interrupting the commercial availability of the Harmony test. (PFF ¶ 653; PX7096 (Song (Omniome/Fmr. Ariosa) Dep. at 125–26).) Respondents also incorporate their responses to CCFF ¶¶ 1411, 1412.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1420. Dr. Song testified that detecting ctDNA was "beyond the technical possibilities of an array system" because microarrays do not have the level of sensitivity necessary to detect rare events such as ctDNA. (PX7071 (Song (Omniome) IHT at 99)).

Response to Finding No. 1420:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1411, 1412 and 1419, which Respondents incorporate herein.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1421. Guardant cannot use microarrays for its screening test in development. (Chudova (Guardant) Tr. 1177).

Response to Finding No. 1421:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1411 and 1412, which Respondents incorporate herein.

1422. Dr. Chudova analogized at trial that microarray technology is an "analog TV" while NGS is a "digital TV." (Chudova (Guardant) Tr. 1143).

Response to Finding No. 1422:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1411 and 1412, which Respondents incorporate herein.

1423. Guardant cannot use microarrays in place of NGS for its MCED test because microarrays would not provide the kind of precision that is needed for cancer screening applications. (Chudova (Guardant) Tr. 1177).

Response to Finding No. 1423:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1411 and 1412, which Respondents incorporate herein.

1424. Guardant Senior VP of Product, Nitin Sood, explained that microarrays are "very difficult" and "will not work because [MCED testing requires] very deep sequencing. . . . And microarrays just wouldn't have the sensitivity to analyze the small number of tumor DNA molecules present[.]" (PX7090 (Sood (Guardant) Dep. at 93)).

Response to Finding No. 1424:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1411 and 1412, which Respondents incorporate herein. The proposed finding also appears to suggest that MCED testing today requires "very deep sequencing", which is wrong. For example, GRAIL's Galleri test does not use "very deep sequencing", but relies on targeted methylation for cancer signal detection and localization. *(See, e.g.*, PFF ¶¶ 56, 345, 384, 1289.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1425. Mr. Sood testified that microarrays cannot look for the thousands of markers required by Guardant's MCED test "at the sensitivity required for detection." (PX7090 (Sood (Guardant) Dep. at 94)).

Response to Finding No. 1425:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1411 and 1412, which Respondents incorporate herein. The proposed finding also appears to suggest that MCED testing today requires "very deep sequencing", which is wrong. For example, GRAIL's Galleri test does not use "very deep sequencing", but relies on targeted methylation for cancer signal detection and localization. *(See, e.g.*, PFF ¶¶ 56, 345, 384, 1289.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1426. In comparison to microarray platforms, Dr. Chahine testified that "DNA sequencing" is able to "interrogate the entire genome," which is "in the billions of base[] [pairs]." (Chahine (Helio) Tr. 1020).

Response to Finding No. 1426:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1411 and 1412, which Respondents incorporate herein. The proposed finding also appears to suggest that MCED testing today requires a test developer to "interrogate the entire genome". Complaint Counsel presented no evidence of any putative MCED test that "interrogates the entire genome". For example, GRAIL's Galleri test relies on targeted methylation for cancer signal detection and localization. *(See, e.g.*, PFF ¶¶ 56, 345, 384, 1289.) [redacted] (*See, e.g.,* PFF ¶¶ 435– 36.) Guardant's LUNAR-2 CRC test uses genomic and methylation signatures. (*See, e.g.,* PFF ¶ 486.) Helio combines methylation data, protein biomarkers and demographic information for its early-stage liver cancer test. (*See, e.g.,* PFF ¶ 505.)

In addition, Helio currently uses Illumina's MiSeq sequencer for its Helio Liver test. (Chahine (Helio) Tr. 1010-12). Dr. Chahine testified Helio uses the MiSeq because "a smaller machine is more efficient" as a "company in its early stage" prior to "ramp[ing] up." (Chahine (Helio) Tr. 1012). Microarrays similarly provide a high-throughput platform for simultaneously screening tens of thousands of biomolecular interactions. (PFF ¶ 164.) For example, microarray technology such as Thermo Fisher's Genome-Wide Human SNP Array 6.0 chip features 1.8

million genetic markers for single nucleotide polymorphisms (SNPs) and copy number variations (CNVs). (PFF ¶ 164.2.) Certain NGS systems such as the MiSeq may be used to interrogate a comparable number of genetic markers. (*See e.g.*, PFF ¶ 575.)

1427. Dr. Chahine testified at trial that he "could say almost with certainty there's zero chance" of "catch[ing] any markers that" can distinguish cancer in the "early R&D phase" if you "limit[ed] yourself to, for example, 600,000 markers" with a microarray system. (Chahine (Helio) Tr. 1021).

Response to Finding No. 1427:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1411–12 and 1426, which Respondents incorporate herein.

In particular, Respondents note that Microarrays can interrogate many more genetic markers than what the cited testimony suggests. Thermo Fisher's Genome-Wide Human SNP Array 6.0 chip features 1.8 million genetic markers for single nucleotide polymorphisms (SNPs) and copy number variations (CNVs). (PFF ¶ 164.2.) Similarly, Agilent Technologies' Human Genome CGH Microarrays offers up to 1 million probes for genome-wide CNV identification and characterization. (PFF ¶ 164.4.)

1428. Freenome's Mr. Otte testified [redacted]

(PX7055 (Otte (Freenome) IHT at 59) (*in camera*)).

Response to Finding No. 1428:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945, 1411 and 1412, which Respondents incorporate herein.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1429. Freenome's Mr. Otte testified that [redacted]

(PX7055 (Otte (Freenome) IHT at 58-61) (*in camera*)).

Response to Finding No. 1429:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945, 1411 and 1412, which Respondents incorporate herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1430. FMI's Perettie testified that microarray technology [redacted] (PX7074 (Perettie (FMI-Roche) Dep. at 159) (*in camera*)).

Response to Finding No. 1430:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1190, 1411 and 1412, which Respondents incorporate herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1431. [redacted] (PX7114 (Stamatiou (StageZero) Dep. at 34–35, 38) (*in camera*)).

Response to Finding No. 1431:

Respondents have no specific response except to note that StageZero considered both the Illumina and Thermo Fisher platforms, and that StageZero has decided to switch *to* Illumina's NGS platform well after Illumina announced its decision to acquire GRAIL, showing that StageZero had no concerns about using Illumina as a platform even after the Transaction. (PX8540 (Stage Zero) at 2; PX7114 (Stamatiou (Stage Zero) Dep. at 33–34, 38–39.) Respondents also incorporate their responses to CCFF ¶¶ 1411–14 herein. Further, Stage Zero planned to launch its Aristotle test using microarray technology in Q2 or Q3 of 2021, and *then* transition to NGS technology; Stage Zero's transition document listed "ease of transition" as one of the factors encouraging this change. (PX8540 (Stage Zero) at 2; PX7114 (Stamatiou (Stage Zero) Dep. at 62–63.)

1432. [redacted] (PX7114 (Stamatiou (StageZero) Dep. at 33-34) (*in camera*)).

Response to Finding No. 1432:

Respondents have no specific response except to note that [redacted] (PX8540 (Stage Zero) at 2; PX7114 (Stamatiou (Stage Zero) Dep. at 33–34.) Respondents also note that StageZero also decided to switch because [redacted] Respondents also incorporate their responses to CCFF ¶¶ 1411–14 herein. With respect to costs, Respondents also incorporate their responses to CCFF ¶¶ 1436–37 herein.

1433. [redacted] (PX7114 (Stamatiou (StageZero) Dep. at 34-35) (*in camera*)).

Response to Finding No. 1433:

The proposed finding is incomplete and misleading. While a screening test that will identify 50 types of cancer (or 10 types of cancer, like the StageZero Aristotle test) from a single blood sample that can also identify the cancer signal of origin is likely to use NGS technology, a screening test for fewer types of cancer, particularly two or three types of cancer, can use other diagnostic platforms, such as proteomics, PCR or microarray technology. (PFF ¶ 1971.)

Because of its high sensitivity, PCR is currently used in a variety of early screening tests for several cancers. (PFF ¶ 161; Cote Tr. 3736–3737; RX3869 (Cote Expert Report) ¶ 80.) For example, both the National Cancer Institute and the American Cancer Society recommend a stool-based PCR test for early stage screening of colorectal cancer and human papillomavirus ("HPV") PCR test for early stage screening of cervical cancer. (PFF ¶ 161; RX3502 (National Cancer Institute) at 2; RX3029 (ACS) at 1–2; RX3869 (Cote Expert Report) ¶ 80.)

Many of the putative MCED test developers are using PCR for their cancer screening tests. For example, [redacted] Singlera is considering a qPCR version (not NGS) of the ColonES test. (PFF ¶ 542.) Helio has undertaken some clinical trials using ddPCR (rather than NGS) for its early-stage liver cancer test (PFF ¶¶ 505.1–506.) [redacted] (PFF ¶ 655.)

1434. [redacted] (PX7114 (Stamatiou (StageZero) Dep. at 35) (*in camera*)).

Response to Finding No. 1434:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1411 and 1412 herein.

1435. [redacted] (PX7114 (Stamatiou (StageZero) Dep. at 50–51) (*in camera*)).

Response to Finding No. 1435:

Respondents have no specific response except to note that [redacted] (PX8540 (Stage Zero) at 2; PX7114 (Stamatiou (Stage Zero) Dep. at 33–34, 38–39.) Respondents also incorporate their responses to CCFF ¶¶ 1411–1414 herein. Further, Stage Zero planned to launch its Aristotle test using microarray technology in Q2 or Q3 of 2021, and *then* transition to NGS technology; Stage Zero's transition document listed "ease of transition" as one of the factors encouraging this change. (PX8540 (Stage Zero) at 2; PX7114 (Stamatiou (Stage Zero) Dep. at 62–63.)

1436. [redacted] (PX7114 (Stamatiou (StageZero) Dep. at 33–34) (*in camera*)).

Response to Finding No. 1436:

Respondents have no specific response except to note that this further underscores Illumina's efforts to reduce costs for its customers. Illumina has developed its reputation by investing substantial amounts into innovation and dramatically lowering sequencing costs over time. (PFF ¶ 854; Aravanis (Illumina) Tr. 1922; (RX1100 (George (Invitae) Decl. ¶ 8).) The phenomenon of dramatically declining sequencing costs is known in the industry as "Flatley's law", referring to Jay Flatley, Illumina's former CEO and Chairman. (PFF ¶ 855.2; *See* Berry (Illumina) Tr. 811–12 ("'Flatley's law' was a term coined by . . . a writer in Forbes magazine when he wrote an article comparing the reduction in the price of sequencing to Moore's law, which describes the reduction in the price of like silicon wafers or something in the computer

industry, and [under Jay Flatley's] leadership where we really drove significant, significant reductions in the price of sequencing . . . down towards the level that they are today.").) Respondents also incorporate their responses to CCFF ¶¶ 1411–14 herein.

1437. [redacted] (PX7114 (Stamatiou (StageZero) Dep. at 47–50) (*in camera*)).

Response to Finding No. 1437:

Respondents have no specific response except to note that this further underscores Illumina's efforts to reduce costs for its customers. Reductions in sequencing costs have encouraged the development of entire industries that would not otherwise exist and for which Illumina is the primary supplier of sequencing inputs. (PFF ¶ 855.3; RX3864 (Carlton Expert Report) ¶ 77.) Respondents also incorporate their responses to CCFF ¶¶ 1411–14 herein.

1438. [redacted] (PX8540 (StageZero) at 002 [redacted] (*in camera*)).

Response to Finding No. 1438:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1411–14, 1436–37 herein.

1439. [redacted] (PX7114 (Stamatiou (StageZero) Dep. at 33–34) (*in camera*); (Rabinowitz (Natera) Tr. 346 (*in camera*)).

Response to Finding No. 1439:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1411 and 1412 herein.

1440. Thermo Fisher's Felton explained that [redacted]

[redacted] (PX7070 (Felton (Thermo Fisher) IHT at 68) (*in camera*)).

Response to Finding No. 1440:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 952, 1411 and 1412, which Respondents incorporate herein.

[redacted]

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2. PCR-Based Technology

1441. Dr. Felton of Thermo Fisher explained, "A PCR is a polymerase chain reaction. It's the process of making copies of a template DNA using the enzyme Taq polymerase. You take one copy of DNA, double strand DNA. You separate the two strands. You anneal a small sequence of the Taq polymerase and then rebuild the second strand. So you can generate multiple copies and consider it photocopying DNA and generate as many copies in principle as you wish from that original template." (PX7070 (Felton (Thermo Fisher) IHT at 66-67)).

Response to Finding No. 1441:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1442. [redacted] (PX7097 (Felton (Thermo Fisher) Dep. at 37-40); PX7058 (Conroy (Exact) IHT at 122) (*in camera*); PX0120 at 001 (Illumina, Advantages of next-generation sequencing vs. qPCR) (Although qPCR may be more cost effective than NGS for assays testing for less than 20 targets, qPCR "can only interrogate a limited set of variants" and has "low scalability")).

Response to Finding No. 1442:

The proposed finding is incomplete and misleading. While a screening test that will identify 50 types of cancer from a single blood sample that can also identify the cancer signal of origin is likely to use NGS technology, a screening test for fewer types of cancer, particularly two or three types of cancer, can use other diagnostic platforms, such as proteomics, PCR or microarray technology. (PFF ¶ 1971.)

Because of its high sensitivity, PCR is currently used in a variety of early screening tests for several cancers. (PFF ¶ 161; Cote Tr. 3736–3737; RX3869 (Cote Expert Report) ¶ 80.) For example, both the National Cancer Institute and the American Cancer Society recommend a stool-based PCR test for early stage screening of colorectal cancer and human papillomavirus ("HPV") PCR test for early stage screening of cervical cancer. (PFF ¶ 161; RX3502 (National Cancer Institute) at 2; RX3029 (ACS) at 1–2; RX3869 (Cote Expert Report) ¶ 80.)

Many of the putative MCED test developers are using PCR for their cancer screening tests. For example, [redacted] Singlera is considering a qPCR version

(not NGS) of the ColonES test. (PFF ¶ 542.) Helio has used ddPCR to study methylation for cancer screening. Helio is pursuing a path of using very limited numbers of biomarkers, (9, 8, 5 and even one), and has done some of their clinical studies not with NGS but with ddPCR. (PFF ¶ 505.1; *see* RX3747 (Xu et al 2017); RX3436 (Luo et al 2020).) In particular, Helio (and LAM) have conducted a few different trials relating to its liver cancer test, including certain trials relying on Bio-Rad's droplet digital platform (ddPCR) rather than NGS. (RX3265 (GenomeWeb) at 1.) [redacted] (PFF ¶ 655.) Respondents incorporate their responses to CCFF ¶¶ 929 and 952 herein.

With respect to the portion of this proposed finding which relies on testimony from Dr. Felton, [redacted]

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1443. PCR technology has several challenges. PCR "can only interrogate a limited set of variants," has "virtually no discovery power," and has "low scalability." (PX0120 at 001 (Illumina, Advantages of next-generation sequencing vs. qPCR); *see* PX7040 (Getty (Guardant) IHT at 39-40) (testifying that PCR, in comparison to NGS, does not provide the scale, depth, sensitivity, or turnaround times for blood-based tests)).

Response to Finding No. 1443:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927 and 1442, which Respondents incorporate herein.

The proposed finding is based in part on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1444. PCR is limited to interrogating specific regions or points in the genome to identify the presence or absence of pre-determined target sequences, and PCR is unable to detect novel genetic variants or mutations. (PX7072 (deSouza (Illumina) IHT at 240) ("A PCR test is a type of genomic test where you're looking at very specific regions of the genome."); PX7097 (Felton (Thermo Fisher) Dep. at 39)).

Response to Finding No. 1444:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1442, which Respondents incorporate herein.

With respect to the portion of this proposed finding which relies on testimony from Dr. Felton, [redacted]

[redacted]

[redacted]

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1445. The key different between NGS and qPCR is "discovery power." qPCR "can only detect known sequences. In contrast, NGS is a hypothesis-free approach that does not require prior knowledge of sequencing information. NGS provides higher discovery power to detect novel genes and higher sensitivity to quantify rare variants and transcripts." (PX0120 at 001 (Illumina, Advantages of next-generation sequencing vs. qPCR) ("discovery power is the ability to identify novel variants.")).

Response to Finding No. 1445:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1442, which Respondents incorporate herein.

1446. Andrew Felton, Vice President of Product Development at Thermo Fisher, a leading PCR-based technology provider, acknowledged that PCR-based technology is "entirely unlikely to be scalable or have enough data points generated in a reasonable amount of time [for MCED testing], and therefore, the economics and the scalability of the answer is likely highly unsuited for that environment." (PX7070 (Felton (Thermo Fisher) IHT at 67)).

Response to Finding No. 1446:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 952 and 1442, which Respondents incorporate herein.

[redacted]

[redacted] Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1447. PCR is not a substitute for NGS because PCR technology "only allows you to interrogate a very small number of genomic regions at a time," unlike NGS. (Felton (Thermo Fisher) Tr. at 1994).

Response to Finding No. 1447:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 952 and 1442, which Respondents incorporate herein.

1448. [redacted] *See* (PX7042 (Gao (Singlera) IHT at 38-40); PX7058 (Conroy (Exact) IHT at 65-68) (*in camera*)).

Response to Finding No. 1448:

The proposed finding is incomplete and misleading to the extent it suggests that PCR cannot be used for cancer detection tests for the reasons explained in Respondents' responses to CCFF ¶¶ 982 and 1442, which Respondents incorporate herein.

Contrary to the statements by Dr. Gao and Mr. Conroy, both of their respective companies are pursuing cancer *screening* tests that use PCR. For example, [redacted] Singlera is considering a qPCR version (not NGS) of the ColonES test. (PFF ¶ 542.) Given that PCR technology can support a single-cancer screening test, there is no reason why PCR technology cannot support a two or three cancer screening test, and Complaint Counsel has not presented any evidence to the contrary. (PFF ¶ 1971.)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1449. Mr. Felton explained that PCR technologies are "[n]ot able to generate sufficiently large number of data points at scale to make the test economic." (PX7097 (Felton (Thermo Fisher) Dep. at 38)).

Response to Finding No. 1449:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 952 and 1442, which Respondents incorporate herein.

[redacted]

1450. The throughput of PCR is significantly less than NGS. (Felton (Thermo Fisher) Tr. at 1994-1995; PX7097 (Felton (Thermo Fisher) Dep. at 38-39)).

Response to Finding No. 1450:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1442, which Respondents incorporate herein.

1451. NGS is a better option than PCR for applications in "oncology, inherited disease testing, reproductive health testing. . . ." (Felton (Thermo Fisher) Tr. at 1995).

Response to Finding No. 1451:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1442, which Respondents incorporate herein.

[redacted]

1452. Andrew Felton, Vice President of Product Development at Thermo Fisher, a leading PCR-based technology provider, acknowledged that PCR-based technology is "entirely unlikely to be scalable or have enough data points generated in a reasonable amount of time [for MCED testing], and therefore, the economics and the scalability of the answer is likely highly unsuited for that environment." (PX7070 (Felton (Thermo Fisher) IHT at 67)).

Response to Finding No. 1452:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 952 and 1442, which Respondents incorporate herein.

[redacted]

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1453. Mr. Felton testified that PCR technologies are generally not used to detect unknown DNA variants because PCR "requires the design of a primer, and therefore, a known sequence a priori to understand which variants you're detecting." (PX7097 (Felton (Thermo Fisher) Dep. at 39)).

Response to Finding No. 1453:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1442, which Respondents incorporate herein.

[redacted]

1454. "Generally at this time, [digital PCR is] not considered to be very useful" for multi-cancer early detection testing. (PX7097 (Felton (Thermo Fisher) Dep. at 40)).

Response to Finding No. 1454:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 952 and 1442, which Respondents incorporate herein.

[redacted]

[redacted]

1455. Mr. Felton testified that it would "almost certainly" cost more to run MCED tests on PCR, and likely "orders of magnitude" more. (PX7070 (Felton (Thermo Fisher) IHT at 67)).

Response to Finding No. 1455:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 952 and 1442, which Respondents incorporate herein.

[redacted]

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1456. [redacted] (Felton (Thermo Fisher) Tr. at 2010-2011) (*in camera*)).

Response to Finding No. 1456:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 952 and 1442, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention, many PCR-based cancer screening tests

have low costs, though some are reimbursed at higher costs. (PFF ¶ 162; RX3869 (Cote Expert Report) ¶ 81.) For example, while the maximum cost of Cologuard could be $649, the CMS 2021 Fee Schedule for an HPV PCR test is only $35.09. (PFF ¶ 162; RX3306 (Healthline Media) at 2; RX3869 (Cote Expert Report) ¶ 81.)

[redacted]

1457. [redacted]

[redacted]

(PX7055 (Otte (Freenome) IHT at 58-61) (*in camera*)).

Response to Finding No. 1457:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945, 1411–12, 1428 and 1442, which Respondents incorporate herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony

and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1458. [redacted]

(PX7055 (Otte (Freenome) IHT at 57-58 (*in camera*))).

Response to Finding No. 1458:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945, 1442 and 1457, which Respondents incorporate herein.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1459. Dr. Gao testified at trial that PCR technology is not suitable for use in the PanSeer test. (Gao (Singlera) Tr. 2893-94).

Response to Finding No. 1459:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 982, 1011 and 1442, which Respondents incorporate herein.

Contrary to the statements by Dr. Gao, Singlera is pursuing cancer *screening* tests that use PCR. For example, Singlera is considering a qPCR version (not NGS) of the ColonES test. (PFF ¶ 542.) Given that PCR technology can support a single-cancer screening test, there is no reason why PCR technology cannot support a two or three cancer screening test—or even a five cancer test like PanSeer—and Complaint Counsel has not presented any evidence to the contrary. (PFF ¶ 1971.)

1460. At trial, Dr. Gao explained that "[o]bviously you cannot use PCR to do, you know, 500 readings . . . in a cost-effective way." (Gao (Singlera) Tr. 2893).

Response to Finding No. 1460:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 982, 1011, 1442 and 1459, which Respondents incorporate herein.

1461. Singlera's Dr. Gao testified that Singlera's cancer screening test requires a sequencing instrument capable of analyzing "millions of base pairs" of DNA. (PX7042 (Gao (Singlera) IHT at 38-40)).

Response to Finding No. 1461:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 982, 1011, 1442 and 1459, which Respondents incorporate herein.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1462. Dr. Gao explained that, "[i]t's impossible" for Singlera to run its cancer screening test on sequencing instruments that use PCR technology because "PCR technology will only be able to analyze . . . tens of base pair[s]." (PX7042 (Gao (Singlera) IHT at 38-40)).

Response to Finding No. 1462:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 982, 1011, 1442 and 1459, which Respondents incorporate herein.

Respondents also note that in recent years, many improved PCR techniques have been developed and used in clinical cancer testing. (PFF ¶ 159; RX3869 (Cote Expert Report) ¶ 78.) Multiplex PCR allows simultaneous detection of multiple targets in a single test, with a different pair of primers for each target. (PFF ¶ 159; RX3686 (Thermo Fisher) at 1–2; RX3869 (Cote Expert Report) ¶ 78.) Multiplex PCR can generate higher throughput than traditional (singleplex) PCR and obtains more information with less sample. (PFF ¶ 159.1; RX3686 (Thermo Fisher) at 1–2; RX3869 (Cote Expert Report) ¶ 78.) Another category of new PCR technology is digital PCR (dPCR). (PFF ¶ 160; [redacted]; RX3869 (Cote Expert Report) ¶ 79.) Combinati is developing an Absolute Q Microfluidic Array Partitioning (MAP) dPCR system with 20,000 microchambers, pushing the microfluidic digital PCR technology forward even further. (PFF ¶ 160.2; RX3147 (Combinati) at 3; RX3869 (Cote Expert Report) ¶ 79.)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1463. Dr. Gao explained why the fact that PCR can only analyze a small number of base pairs is insufficient for cancer screening:

> The analogy I usually use is for police looking at a suspect. If you said the suspect has black hair, then it's not easy to identify. Then [if] you have a sketch of the suspect with many description[s] … the nose, the ear, the eye, the mouth, and [] the height, weight … shoe size, so the more kind[s] of biomarker[s], the better description, better sensitivity and the specificity you can detect cancer, especially in many different kind[s] of cancer. … That's why we had to go to thousands of region and millions of base pairs to analyze them."

(PX7042 (Gao (Singlera) IHT at 39-40)).

Response to Finding No. 1463:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 982, 1011, 1442 and 1459, which Respondents incorporate herein.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. At 275–76.)

1464. Dr. Gao testified that there is "no way" that a PCR version of PanSeer could compete with GRAIL's Galleri test. (PX7042 (Gao (Singlera) IHT at 92)).

Response to Finding No. 1464:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1442 and 1459, which Respondents incorporate herein.

Contrary to the statements by Dr. Gao, Singlera is pursuing cancer *screening* tests that use PCR. For example, Singlera is considering a qPCR version (not NGS) of the ColonES test. (PFF ¶ 542.) Given that PCR technology can support a single-cancer screening test, there is no reason why PCR technology cannot support a two or three cancer screening test—or even a five cancer test like PanSeer. (PFF ¶ 1971.) Additionally, Singlera's PanSeer test only requires

approximately 2 million sequencing reads per sample. (PFF ¶ 533 (RX3115 (Chen et al., 2020) at 7; RX3637 (Singlera) at 1–6; Gao (Singlera) Tr. 2875, 2894, 2928–29; PX7102 (Gao (Singlera) Dep. at 78); RX3869 (Cote Expert Report) ¶ 239).)

The proposed finding is also incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶ 2406, which Respondents incorporate herein. Therefore, it is irrelevant that Dr. Gao believes that a PCR version of PanSeer would be unable to compete with Galleri as well.

Although Singlera's "goal" may be to detect all kinds of cancer, Dr. Gao has also testified that Singlera is "far away" from starting clinical trials for PanSeer in the United States, and that it is "still not in the really starting clinical trial state." (Gao (Singlera) Tr. 2926; PX7102 (Gao (Singlera) Dep. at 113–14, 81–82; PFF ¶ 536.1.) By Dr. Gao's own calculation, PanSeer is at least eight to ten years away from potential launch in the United States, and Singlera does not currently have any clinical trials relating to screening for multiple cancers listed on clinicaltrials.gov. (PFF ¶¶ 536.1-36.2.) Accordingly, [redacted] Respondents also incorporate their responses to CCFF ¶¶ 447, 451, 982 and 1011 herein.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1465. In contrast to PanSeer, Dr. Gao explained that Singlera's single-cancer colorectal cancer test, ColonES, is able to use PCR technology—albeit with worse performance: "Because it's only one cancer type, we can only do a few marker. Basically, we can use qPCR. And it will not have the same high sensitivity, specificity . . ." (PX7042 (Gao (Singlera) IHT at 90-91)).

Response to Finding No. 1465:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 982, 1011, 1442 and 1459, which Respondents incorporate herein.

The proposed finding is also misleading to the extent it seems to suggest that Singlera's PanSeer would have worse specificity if it used PCR technology. To the contrary, the characteristics of the PanSeer test in development (which uses NGS technology)—in particular its specificity—are far from being suitable for being used in a multi-cancer screening test. In a retrospective, observational study of 418 participants from part of the Taizhou Longitudinal Study with samples from 113 post-diagnosis cancer patients, 98 prediagnostic cancer patients, and 207 healthy individuals, PanSeer achieved a 96% specificity. (PFF ¶ 532; RX3637 (Singlera) at 1–6; Gao (Singlera) Tr. 2877–79.) [redacted]

Further, the cited testimony supports the proposition that PCR may be used to support cancer screening tests directed to one, two or three cancer types. As Dr. Gao concedes, Singlera is pursuing cancer *screening* tests that use PCR. For example, Singlera is considering a qPCR version (not NGS) of the ColonES test. (PFF ¶ 542.) Given that PCR technology can support a

single-cancer screening test, there is no reason why PCR technology cannot support a two or three cancer screening test—or even a five cancer test like PanSeer. (PFF ¶ 1971.)

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1466. [redacted]

(PX7051 (Lengauer (Third Rock Ventures) IHT at 120-122) (*in camera*)).

Response to Finding No. 1466:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929 and 1442, which Respondents incorporate herein.

The proposed finding is incomplete and misleading to the extent it seems to suggest that Exact/Thrive's MCED test in development has "excellent specificity" that is better than what it would have if it used PCR technology. To the contrary, Respondents note that Exact/Thrive's CancerSEEK test in development currently uses a combination of NGS technology and proteomics technology, and was shown to have an unacceptably low specificity of 95.3% using a single blood test in the DETECT-A study. (PFF ¶¶ 173 ("Specificity . . . measures the proportion of actual negative samples that are correctly identified as such", so that a 95.3% specificity corresponds to a true negative rate of 95.3% and a false positive rate of 100% minus 95.3%), 428, 431 ("In the DETECT-A study, CancerSEEK obtained [a] specificit[y] of 95.3% in its baseline blood test (that is, with a single blood test).").) [redacted]

[redacted]

Further, the cited testimony supports the proposition that PCR may be used to support cancer screening tests directed to one, two or three cancer types. As Dr. Lengauer concedes, Exact markets a cancer *screening* test that uses PCR. Specifically, Exact's Cologuard test for colorectal cancer uses PCR. Given that PCR technology can support a single-cancer screening test, there is no reason why PCR technology cannot support a two or three cancer screening test, and Complaint Counsel has presented no evidence to the contrary. (PFF ¶ 1971.)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1467. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 122) (*in camera*)).

Response to Finding No. 1467:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929, 1442 and 1467, which Respondents incorporate herein.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1468. [redacted]

[redacted]

(PX7051 (Lengauer (Third Rock Ventures) IHT at 119-20) (*in camera*)).

Response to Finding No. 1468:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929, 1442 and 1467, which Respondents incorporate herein.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1469. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 121-22) (*in camera*)).

Response to Finding No. 1469:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929, 1442 and 1467, which Respondents incorporate herein.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1470. [redacted] PX7058 (Conroy (Exact) IHT at 65-68) (*in camera*)).

Response to Finding No. 1470:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929 and 1442, which Respondents incorporate herein.

The cited testimony supports the proposition that PCR may be used to support cancer screening tests directed to one, two or three cancer types. As Mr. Conroy concedes, Exact markets a cancer *screening* test that uses PCR. Specifically, Exact's Cologuard test for colorectal cancer uses PCR. Given that PCR technology can support a single-cancer screening test, there is no reason why PCR technology cannot support a two or three cancer screening test, and Complaint Counsel has presented no evidence to the contrary. (PFF ¶ 1971.)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1471. Exact's Conroy testified that [redacted] PX7058 (Conroy (Exact) IHT at 122) (*in camera*)).

Response to Finding No. 1471:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929, 1442 and 1470, which Respondents incorporate herein.

The proposed finding is incomplete and misleading to the extent it seems to suggest that Exact/Thrive's MCED test in development has sensitivity and specificity metrics that are better than what it would have if it used PCR technology.

Specificity. To the contrary, Respondents note that Exact/Thrive's CancerSEEK test in development currently uses a combination of NGS technology and proteomics technology, and

was shown to have an unacceptably low specificity of 95.3% using a single blood test in the DETECT-A study. (PFF ¶¶ 173 ("Specificity . . . measures the proportion of actual negative samples that are correctly identified as such", so that a 95.3% specificity corresponds to a true negative rate of 95.3% and a false positive rate of 100% minus 95.3%), 428, 431 ("In the DETECT-A study, CancerSEEK obtained [a] specificit[y] of 95.3% in its baseline blood test (that is, with a single blood test).").)

[redacted]

Sensitivity. Exact's Cologuard colorectal cancer screening test, which uses PCR technology, has a sensitivity of 92.3%, which is comparable to colonoscopy's sensitivity of 92.5%, but higher than Galleri's sensitivity of 82.0% for colorectal cancer. (PPF ¶ 180.2 (RX3222 (FDA) at 19); RX3409 (Klein et al., 2021) at 7, Fig. 3B.) This is also significantly higher than CancerSEEK's sensitivity for colorectal cancer, which is just over 60%. (RX3772 (Cohen 2018 Supplementary Material) at 15.) Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1472. Mr. Conroy testified that by using NGS sequencing technology: [redacted] (PX7058 (Conroy (Exact) IHT at 122) (*in camera*)).

Response to Finding No. 1472:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929 and 1470–71, which Respondents incorporate herein.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1473. [redacted] (PX7111 (Fesko (Natera) Dep. at 60) (*in camera*)).

Response to Finding No. 1473:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 1264, 1293 and 1442, which Respondents incorporate herein.

1474. [redacted] (PX7077 (Chahine (Helio) Dep. at 22) (*in camera*)).

Response to Finding No. 1474:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1177 and 1442, which Respondents incorporate herein.

[redacted] Helio is pursuing a path of using very limited numbers of biomarkers, (9, 8, 5 and even one), and has done some of their clinical studies not with NGS but with ddPCR. (PFF ¶ 505.1; *see* RX3747 (Xu et al 2017); RX3436 (Luo et al 2020).)

1475. [redacted] (Chahine (Helio) Tr. 1068 (*in camera*)).

Response to Finding No. 1475:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1177, 1442 and 1474.

The cited testimony supports the proposition that PCR may be used to support cancer screening tests directed to one, two or three cancer types. As Dr. Chahine concedes, Helio was pursuing ddPCR as a platform for its cancer screening test. (PFF ¶ 505.1; *see* RX3747 (Xu et al 2017); RX3436 (Luo et al 2020).) In particular, Helio (and LAM) have conducted a few different trials relating to its liver cancer test, including certain trials relying on Bio-Rad's droplet digital platform (ddPCR) rather than NGS. (RX3265 (GenomeWeb) at 1.)

Given that PCR technology can support a single-cancer screening test, there is no reason why PCR technology cannot support a two or three cancer screening test, and Complaint Counsel has presented no evidence to the contrary. (PFF ¶ 1971.)

1476. [redacted] (Chahine (Helio) Tr. 1068-69 (*in camera*)).

Response to Finding No. 1476:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1177, 1442 and 1474–75, which Respondents incorporate herein.

1477. [redacted] (Chahine (Helio) Tr. 1068 (*in camera*); *see* PX7077 (Chahine (Helio) Dep. at 24) (*in camera*)).

Response to Finding No. 1477:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1177, 1442 and 1474–75, which Respondents incorporate herein.

Contrary to the cited testimony, Helio itself, which has a test comprising as many as 9 biomarkers, has done some of its clinical studies not with NGS but with ddPCR. (PFF ¶ 505.1; *see* RX3747 (Xu et al 2017); RX3436 (Luo et al 2020).)

1478. [redacted] (PX7077 (Chahine (Helio) Dep. at 24) (*in camera*)).

Response to Finding No. 1478:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1177, 1442 and 1474–75, which Respondents incorporate herein.

Contrary to the cited testimony, Helio itself, which has a test comprising as many as 9 biomarkers, has done some of its clinical studies not with NGS but with ddPCR. (PFF ¶ 505.1; *see* RX3747 (Xu et al 2017); RX3436 (Luo et al 2020).)

1479. [redacted] (PX7077 (Chahine (Helio) Dep. at 25) (*in camera*)).

Response to Finding No. 1479:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1177, 1442 and 1474–75, which Respondents incorporate herein.

1480. [redacted] (Chahine (Helio) Tr. 1068-69 (*in camera*)).

Response to Finding No. 1480:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1177, 1442 and 1474–75, which Respondents incorporate herein.

Contrary to the cited testimony, Helio itself, which has a test comprising as many as 9 biomarkers, has done some of its clinical studies not with NGS but with ddPCR. (PFF ¶ 505.1; *see* RX3747 (Xu et al 2017); RX3436 (Luo et al 2020).)

1481. [redacted] (PX7077 (Chahine (Helio) Dep. at 36-37) (*in camera*)).

Response to Finding No. 1481:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1177, 1442 and 1474–75, which Respondents incorporate herein.

Contrary to the cited testimony, Helio itself, which has a test comprising as many as 9 biomarkers, has done some of its clinical studies not with NGS but with ddPCR. (PFF ¶ 505.1; *see* RX3747 (Xu et al 2017); RX3436 (Luo et al 2020).)

1482. Guardant's Mr. Getty explained that PCR technology would not be adequate for cancer screening tests because "you wouldn't be able to get the scale nor would you be able to mine the depths to find that, you know, proverbial needle in a haystack." (PX7040 (Getty (Guardant) IHT at 39)).

Response to Finding No. 1482:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1442, which Respondents incorporate herein.

The proposed finding is based in part on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1483. Mr. Getty testified that PCR technology "couldn't achieve the sensitivity" required for cancer screening tests. (PX7040 (Getty (Guardant) IHT at 39-40)).

Response to Finding No. 1483:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1442 and 1482, which Respondents incorporate herein. Exact's Cologuard, a PCR-based test, has a sensitivity of 92.3%. (RX3222 (FDA) at 19.) In contrast, Guardant's NGS-based LUNAR-2 colorectal cancer screening test only achieved a sensitivity of 90.3%. (RX3740 (Westesson et al., 2020) at 2; (RX3869 (Cote Expert Report) ¶ 209.))

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1484. Mr. Getty testified that PCR technology does not have "the ability to read the genome across . . . multiple sequences and really mine the depths of the DNA." (PX7040 (Getty (Guardant) IHT at 39)).

Response to Finding No. 1484:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1442 and 1482, which Respondents incorporate herein.

The proposed finding also appears to suggest that MCED testing today requires "very deep sequencing", which is wrong. For example, GRAIL's Galleri test does not use "very deep sequencing", but relies on targeted methylation for cancer signal detection and localization. *(See, e.g.*, PFF ¶¶ 56, 345, 384, 1289.)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1485. Guardant's Mr. Getty testified that PCR technology is unlikely to produce the large number of data points required for MCED and similar tests within a reasonable turnaround time:

> The ability to leverage PCR in just -- just by virtue of time that you would need to have in order to do the volume that we're doing in terms of testing, assuming you could actually achieve the sensitivity, which is really the bigger challenge there, you would be looking at probably doubling or tripling of turnaround times associated with the test going back to the clinician.

(PX7040 (Getty (Guardant) IHT at 39-40)).

Response to Finding No. 1485:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1442 and 1482, which Respondents incorporate herein.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1486. Guardant's Nitin Sood testified that attempting to run its cancer screening test using PCR technology "just wouldn't work[,]" explaining that, "[b]ecause the number of changes we want to look for [in DNA] and the granularity with which those changes we want to look at, I mean, the fine grain granularity, the single base by resolution that you want to look at, it would not be possible to do that by PCR." (PX7090 (Sood (Guardant) Dep. at 89-90)).

Response to Finding No. 1486:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927 and 1442, which Respondents incorporate herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1487. Guardant's Sood explained that Guardant cannot run its cancer screening test on PCR technology because, "when you're looking for multiple regions of a genome with high throughput, with sample multiplexing to bring costs down, I think next-generation sequencing is the platform of choice." (PX7090 (Sood (Guardant), Dep. at 89-90)).

Response to Finding No. 1487:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927 and 1442, which Respondents incorporate herein.

1488. Guardant cannot use qPCR for its MCED test because it could not design an MCED assay capable of finding rare tumor fragments by only profiling the presence or absence of a small number of particular mutations. (Chudova (Guardant) Tr. 1176-77) (explaining that Guardant's "technology step relies heavily on profiling a significant portion of the human genome with a sequencing-based readout. So [Guardant] will not be compatible with any QPCR solution.")).

Response to Finding No. 1488:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1442, which Respondents incorporate herein.

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 927 and 2273, which Respondents incorporate herein.

1489. Quantitative PCR ("qPCR") technology is suitable for assessing the presence or absence of a small number of mutations whose locations are known up front. (Chudova (Guardant) Tr. 1176; PX0096 at 001 (Illumina, Liquid Biopsy and NGS: Driving translational clinical research to the next level) ("qPCR is efficient when analyzing a small number of variants. However, qPCR assays are limited to the relatively few targets that are specified and assess only specified variant types, thus offering little discovery value.")).

Response to Finding No. 1489:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1442, which Respondents incorporate herein.

1490. FMI's Ms. Perettie testified that PCR technology would not be an option for FMI's early cancer detection test because [redacted] (PX7074 (Perettie (FMI-Roche) Dep. at 159) (*in camera*)).

Response to Finding No. 1490:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1190 and 1442, which Respondents incorporate herein.

Further, PCR can be used to detect methylation biomarkers known to be associated with cancer. (RX3869 (Cote Expert Report) ¶ 77.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1491. [redacted] (PX7068 (Perettie (FMI-Roche), IHT at 65) (*in camera*)).

Response to Finding No. 1491:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1190, 1442, 1483 and 1490, which Respondents incorporate herein. For example, Cologuard, Exact's colorectal cancer screening test, which is PCR-based, has a sensitivity of 92.3%. (RX3222 (FDA) at 19.) The is superior to Guardant's NGS-based LUNAR-2 colorectal cancer screening test, which achieved a sensitivity of only 90.3%. (RX3740 (Westesson et al., 2020) at 2; (RX3869 (Cote Expert Report) ¶ 209.))

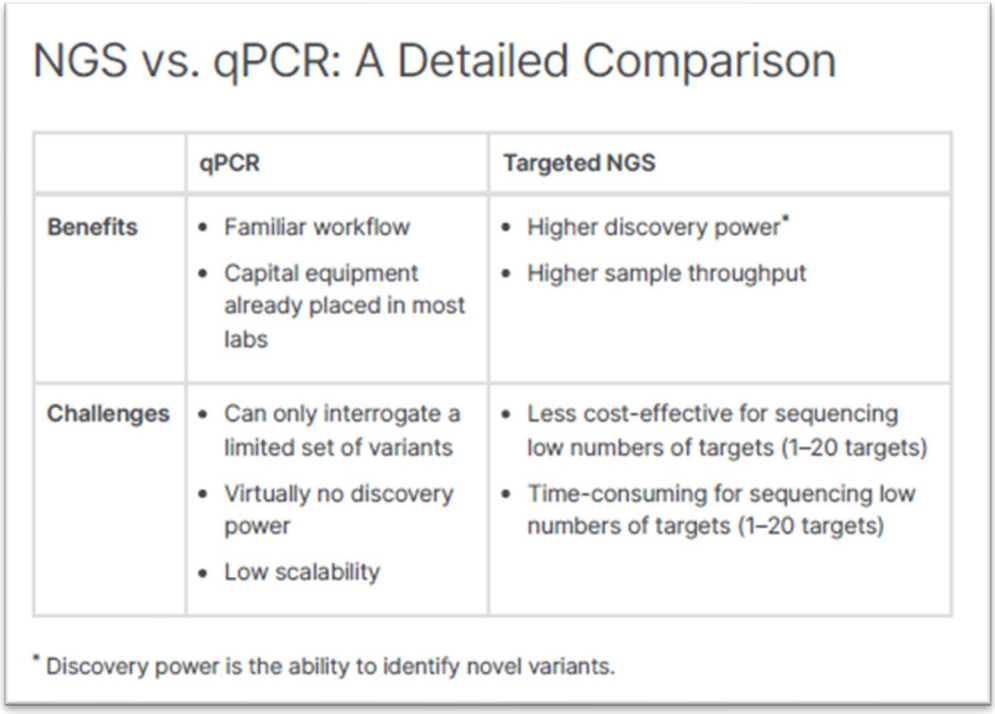
Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1492. Illumina's marketing materials also highlight the drawbacks of PCR-based detection technology relative to NGS, noting that "[w]hile qPCR is effective for low target numbers, the workflow can be cumbersome for multiple targets. NGS is preferable for studies with many targets or samples. A single NGS experiment can identify variants across thousands of target regions with single-base resolution." (PX0120 at 001 (Illumina, Advantages of next-generation sequencing vs. qPCR)).

Response to Finding No. 1492:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1442 herein.

1493. As seen in the screenshot below, Illumina's published marketing materials reflect PCR-based technology's limited "scalability" and ability to analyze more than "a limited set of variants":



NGS vs. qPCR: A Detailed Comparison

	qPCR	Targeted NGS
Benefits	• Familiar workflow • Capital equipment already placed in most labs	• Higher discovery power* • Higher sample throughput
Challenges	• Can only interrogate a limited set of variants • Virtually no discovery power • Low scalability	• Less cost-effective for sequencing low numbers of targets (1–20 targets) • Time-consuming for sequencing low numbers of targets (1–20 targets)

* Discovery power is the ability to identify novel variants.

(PX0120 at 001 (Illumina, Advantages of next-generation sequencing vs. qPCR)).

Response to Finding No. 1493:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1442 herein.

3. Other (Sanger & Proteomics)

1494. [redacted]

[redacted]

Response to Finding No. 1494:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1495. Andrew Felton of Thermo Fisher, a leading provider of Sanger sequencers, explained that Sanger sequencing is unsuitable for MCED tests as it "would take too much time, cost too much, and would not be scalable enough to deal with the very large number of samples that you would be trying to interrogate." (PX7070 (Felton (Thermo Fisher) IHT at 66)).

Response to Finding No. 1495:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1496. Proteomics analyzes protein levels as a biomarker for cancer. (PX7100 (Chudova (Guardant) Dep. at 106)).

Response to Finding No. 1496:

Respondents have no specific response.

1497. No existing technology can look at the number of proteins in the body that would be necessary to screen for multiple cancers. (*See* PX7090 (Sood (Guardant) Dep. at 92-93)).

Response to Finding No. 1497:

The proposed finding is inaccurate, incomplete and misleading. It is undisputed that Genesys Biolabs' OneTest is a proteomics-based test that measures seven cancer protein biomarkers to screen for lung, liver, pancreatic, ovarian, prostate and colon cancers. (PFF ¶¶ 692.2.) [redacted] (PFF ¶ 2094.) Seer also uses proteomics (not NGS) for its ProteographTM and PrognomiQ platforms which may be used to develop MCED tests. (PFF ¶ 564.) Somalogic also has a proteomics platform

which may be used to develop MCED tests. (PFF ¶ 570.) [redacted]

[redacted] (PFF ¶ 2095.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1498. Using proteomics in place of NGS would require developing a new platform capable of doing so. (*See* PX7090 (Sood (Guardant) Dep. at 92-93)).

Response to Finding No. 1498:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1497, which Respondents incorporate herein.

1499. [redacted] (PX7100 (Chudova (Guardant) Dep. at 106-107) (*in camera*)).

Response to Finding No. 1499:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927 and 1497, which Respondents incorporate herein.

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1500. [redacted] (*See, e.g.*, Cance (American Cancer Society) Tr. 613; Nolan (Freenome) Tr. 2759 (*in camera*)).

Response to Finding No. 1500:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1497, which Respondents incorporate herein.

G. SUFFICIENT AND TIMELY ENTRY OF A NEW SHORT-READ NGS PLATFORM SUITABLE FOR MCED TEST DEVELOPERS IS UNLIKELY

1. Significant Scientific, Legal, and Commercial Barriers to Entry Exist

a) Multiple Companies Have Attempted to Develop an NGS Platform Comparable to Illumina's and Have Failed

1501. Roche has spent nearly a decade and millions of dollars attempting to develop an NGS platform and still has not succeeded. (*See infra* Complaint Counsel's Proposed Findings of Facts ¶¶ 1622-1654).

Response to Finding No. 1501:

The proposed finding is misleading, inaccurate and ambiguous as to the term "succeeded". [redacted] (RX2697 (Roche) at 5; PX7074 (Perettie (FMI) Dep. at 110–11); PX7043 (Gunn (Roche) IHT at 164); *see also* PFF ¶¶ 785–85.3).)

1502. Qiagen developed and launched an NGS platform but Illumina sued Qiagen for patent infringement and won an injunction that prevented Qiagen from selling its NGS product in the United States, resulting in Qiagen's exit from the NGS market. (*See* PX9067 at 017 (Complaint for Violation of Federal Antitrust and California Unfair Competition Laws, *Complete Genomics, Inc., et al. v. Illumina, Inc.*, No. 3:21-cv-00217 (N.D. Cal.) (Jan. 11, 2021)) ("After introducing a sequencing system in 2016, [Qiagen] was forced to abandon the U.S. and worldwide sequencing market because of a series of challenges that Illumina initiated.") (citing *Illumina, Inc. v. Qiagen, N.V.*, 207 F. Supp. 3d 1081, 1083 (N.D. Cal. 2016) (granting preliminary injunction))).

Response to Finding No. 1502:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1205 herein.

Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 69), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1503. [redacted] (*See* PX7061 (Davy (Illumina) IHT at 127) (*in camera*)).

Response to Finding No. 1503:

The proposed finding is not supported by the cited evidence. Ms. Davy only testified that [redacted] (PX7061 (Davy (Illumina) IHT at 127) (in camera)). Respondents also incorporate their responses to CCFF ¶ 1205 herein.

1504. [redacted] (Rabinowitz (Natera) Tr. 336-37 (*in camera*)).

Response to Finding No. 1504:

The proposed finding is incomplete and misleading. [redacted] Respondents also incorporate their responses to CCFF ¶¶ 1205 and 1293 herein.

1505. [redacted] (Rabinowitz (Natera) Tr. 336-37 (*in camera*)).

Response to Finding No. 1505:

The proposed finding is incomplete and misleading. [redacted] Respondents also incorporate their responses to CCFF ¶¶ 1205 and 1293 herein.

1506. [redacted] (Rabinowitz (Natera) Tr. 336-37 (*in camera*)).

Response to Finding No. 1506:

The proposed finding is incomplete and misleading. Mr. Rabinowitz did not clarify the [redacted] Respondents also incorporate their responses to CCFF ¶¶ 1205 and 1293 herein.

1507. [redacted] (Rabinowitz (Natera) Tr. 349 (*in camera*)).

Response to Finding No. 1507:

The proposed finding is misleading and ambiguous to the extent it implies [redacted] Respondents also incorporate their responses to CCFF ¶¶ 1205 and 1293 herein.

1508. Thermo Fisher has spent years and millions of dollars trying to develop an NGS sequencer that performs as well as Illumina's NGS sequencers and has not yet succeeded (*See* supra Section V.E.1. (Thermo Fisher Is Not an Option for MCED Test Developers); *see also infra* Complaint Counsel's Proposed Findings of Facts ¶¶ 1577-1585).

Response to Finding No. 1508:

To the extent Complaint Counsel relies on its Proposed Findings in Section V.E.1 (CCFF ¶¶ 1212–68) and ¶¶ 1577–1585, Respondents incorporate their responses to those Proposed Findings herein.

1509. Omniome has spent years and millions of dollars trying to develop an NGS sequencer and has yet to complete development let alone commercially launch a sequencer. (*See infra* Complaint Counsel's Proposed Findings of Facts ¶¶ 1586-1621).

Response to Finding No. 1509:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1586–1621, which Respondents incorporate herein.

In particular, Omniome's technology has attracted a significant investment from PacBio, an established sequencing company. Specifically, Omniome was acquired by PacBio for $800 million in July 2021. (RX3533 (Omniome).) Omniome has stated that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72)**;** [redacted] (PX7096 (Song (Omniome) Dep. at 28–29, 56).)

1510. [redacted] (Rabinowitz (Natera) Tr. 348 (*in camera*)).

Response to Finding No. 1510:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1293 and 1501 herein, and to note that Dr. Rabinowitz was not privy to documents and testimony produced by Roche in this matter when he provided the testimony quoted by Complaint Counsel.

1511. [redacted] (PX7070 (Felton (Thermo Fisher) IHT at 38) (*in camera*)).

Response to Finding No. 1511:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1512. Thermo Fisher's Dr. Felton estimates that for company with no prior genome sequencing experience, entry into the NGS market would take "three to five years" and "hundreds of millions of dollars" depending on the complexity of the technology stating that a new

company would have to "provide enough differentiation [to] … gain significant market share" and "building a new technology from scratch is more difficult and expensive than iterating an existing technology." (PX7070 (Felton (Thermo Fisher) IHT at 39)).

Response to Finding No. 1512:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1513. [redacted] (Velarde (Singular Genomics) Tr. 4553 (*in camera*)).

Response to Finding No. 1513:

Respondents have no specific response.

1514. [redacted] (Velarde (Singular Genomics) Tr. 4554 (*in camera*)).

Response to Finding No. 1514:

Respondents have no specific response.

1515. "[I]n the past decade, there was really no NGS compan[y] that could compete with Illumina in a meaningful, material way." (PX7124 (He (Element) Dep. at 123)).

Response to Finding No. 1515:

The proposed finding also relies in part on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) As she was not offered as an expert witness, it was improper for Dr. He to offer a general opinion on the ability of NGS companies to compete with Illumina.

1516. An investor question posed to Illumina's board of directors was to "describe [Illumina's] competitive position." Illumina's response to this question was "[w]e have maintained our market share leadership position despite competitive announcements as evidenced by a stable win-rate. Customer feedback has been that the Sequel instrument by Pacific Biosciences is complimentary and that the recent [Thermo Fisher] Ion Torrent (Ion S5 and Ion S5 XL) are more revisions of the current platforms than a meaningful

advancement." (PX2551 (Illumina) at 12 (Illumina, Board of Directors Meeting Key Investor Q&A, Jan. 25, 2016)).

Response to Finding No. 1516:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 23), and while Complaint Counsel introduced this document at Mr. deSouza's deposition, they did not question Mr. de Souza on the particular language quoted. Thus, this portion of the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

b) Illumina Has an Extensive Patent Portfolio That Prevents Entry

1517. Dr. Aravanis prepared a response to anticipated investor questions for a large group investor meeting on Monday, February 22, 2021 representing that "Illumina owns a spectrum of IP covering various improvements that enable Illumina's superior sequencing accuracy, speed, and efficiency. These patents and pending applications have expiration dates ranging from 2023 to beyond 2030. Our patented innovations touch every aspect of the sequencing workflow, including nucleotides, enzymes, reagent mixes, instruments, optics, analysis software, and bioinformatics, which result from Illumina's significant investments in research and development." (deSouza (Illumina) Tr. 2229-32; PX2822 (Illumina) at 006-007 (Illumina, Baird Non-Deal Roadshow with Alex Aravanis, Feb. 22, 2021)).

Response to Finding No. 1517:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss the particular language quoted at trial, (deSouza (Illumina) Tr. 2229–32), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents have no specific response except to note that [redacted] (*See* PFF ¶¶ 924.1–924.3.) BGI also recently won a jury verdict that held three of Illumina's patents to be invalid meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States.

Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022). BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777–777.3.)

In addition to the deficiencies in this proposed finding shown by the evidence in the record, Respondents note that RX3929 that was not admitted into evidence shows that the NGS market is ripe for the imminent entry of several alternative platforms including Singular and Element and further undermines this finding.

1518. Illumina represented to investors in early January 2021, that it has "an extensive intellectual property portfolio" including "exclusive licenses to 901 issued U.S. patents and 650 pending U.S. patent applications …. [Illumina's] issued and pending patents cover various aspects of our arrays, assays, oligo synthesis, sequencing technology, instruments, digital microfluidics, software, bioinformatics, and chemical-detection technologies, and have terms that expire between 2021 and 2041. [Illumina] continue[s] to file new patent applications to protect the full range of our technologies." (PX0061 at 009 (Illumina 10K, Jan. 3, 2021)).

Response to Finding No. 1518:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1517, which Respondents incorporate herein.

1519. Singular Genomics describes the NGS sequencer market as characterized by "extensive intellectual property disputes and litigation." (PX0068 at 013 (Singular Genomics S-1, May 2021)).

Response to Finding No. 1519:

Respondents have no specific response except to note that the proposed finding is misleading to the extent it implies that Singular's S-1 reflects anything but Singular's opinion. Further, Mr. Velarde testified that [redacted] (Velarde (Singular Genomics) Tr. 4569–70.)

1520. Singular Genomics describes the NGS sequencing market as an "area in which there are numerous issued patents and patent applications and in which there has been substantial litigation regarding patent and other intellectual property rights." (PX0068 at 046 (Singular Genomics S-1, May 2021)).

Response to Finding No. 1520:

Respondents have no specific response except to note that the proposed finding is misleading to the extent it implies that Singular's S-1 reflects anything but Singular's opinion. Further, Mr. Velarde testified that [redacted] (Velarde (Singular Genomics) Tr. 4569–70.) He also testified that [redacted] (Velarde (Singular Genomics) Tr. 4569–70.)

1521. [redacted] (Velarde (Singular Genomics) Tr. 4548 (*in camera*)).

Response to Finding No. 1521:

Respondents have no specific response except to note that the proposed finding is misleading to the extent it implies that Mr. Velarde's testimony reflects anything but his own personal opinion and/or Singular's opinion. Further, Mr. Velarde testified that [redacted] (Velarde (Singular Genomics) Tr. 4569–70.) He also testified that [redacted] (Velarde (Singular Genomics) Tr. 4569–70.)

1522. [redacted] (*See* PX7050 (Nolan (Freenome) IHT at 101-03 (*in camera*))).

Response to Finding No. 1522:

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) There is nothing in the record supporting Mr. Nolan's ability to credibly speak about the relative strengths of the patents in the NGS IP landscape. Mr. Nolan has only held commercial and management roles at Freenome, having been Chief Commercial Officer, Chief Business Officer, and CEO. (Nolan (Freenome) Tr. 2695.) He has no background in patents, the law, or patent litigation. (Nolan (Freenome) Tr. 2695.) The testimony cited is also impermissible lay witness testimony to the extent it purports to provide an opinion regarding entry into the NGS.

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Further, Respondents incorporate their responses to CCFF ¶ 945 herein.

1523. [redacted] (PX7071 (Song (Omniome) IHT at 40) (*in camera*)).

Response to Finding No. 1523:

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding relies in part on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) The testimony cited is also impermissible lay

witness testimony to the extent it purports to provide an opinion regarding entry into the NGS market.

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1524. Mr. Song of Omniome testified that Illumina has "amassed a fairly large IP estate" surrounding NGS platforms and that Illumina "will use it almost as a weapon … to try and ensure that they maintain their dominance in the sequencing space." (PX7071 (Song (Omniome) IHT at 40)).

Response to Finding No. 1524:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1524, which Respondents incorporate herein.

1525. Natera represented to investors in its Form 10-K that "in the event that it is in our commercial or financial interest or we are forced to transition sequencing platforms … we may be unable to do so in a commercially sustainable way and that could survive claims of infringement of intellectual property rights of Illumina and other competitors in a timely manner or at all." (PX0155 at 32 (Natera, 2020 Form 10-K, Dec. 31, 2020)).

Response to Finding No. 1525:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 2), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1526. [redacted] (Rabinowitz (Natera) Tr. 337 (*in camera*)).

Response to Finding No. 1526:

The proposed finding is not supported by the cited evidence. Mr. Rabinowitz testified as follows: [redacted]

[redacted] (Rabinowitz (Natera) Tr. 337 (in camera) (emphasis added)). [redacted] Respondents also incorporate their responses to CCFF ¶ 1293 herein.

2. Even if a Company Develops a New NGS Platform, Significant Barriers to Commercialization Exist and It Will Take Years for a New Entrant to Gain the Reputation and Enough Widespread Commercial Use to Be an Option for MCEDs

a) Illumina Has Widespread Adoption and Good Reputation for Reliability

1527. Dr. Chahine testified at trial that Illumina is the preferred NGS platform because "from a business standpoint [ ] it is just considered the top technology with respect to its ability to sequence [ ] accurately . . . at larger scales" that create "some [very useful] economies of scale." (Chahine (Helio) Tr. 1044).

Response to Finding No. 1527:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not.

Contrary to the proposed finding, [redacted]

[redacted].) BGI also recently won a jury verdict that held three of Illumina's patents to be invalid meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022). BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents also incorporate their responses to CCFF ¶¶ 1177–79 and 1293 herein.

1528. Dr. Chahine testified at trial that the Illumina platform is "by far [ ] the preferred one that's used even at third-party shops" and the "leading one for many different [ ] reasons." (Chahine (Helio) Tr. 1044).

Response to Finding No. 1528:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. Respondents incorporate their responses to CCFF ¶ 1527 herein.

The proposed finding is also based entirely on inadmissible hearsay testimony because Dr. Chahine refers to "the preferred one that's used even at third-party shops", which is not based on Dr. Chahine's own experience, therefore, it should be accorded little weight.

1529. Dr. Chahine testified Helio is "very familiar with Illumina. That's what most people trust. That's what most people have equipment, even third parties." (PX7077 (Chahine (Helio) Dep. at 26)).

Response to Finding No. 1529:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. Respondents incorporate their responses to CCFF ¶ 1527 herein.

The proposed finding is also based entirely on inadmissible hearsay testimony because Dr. Chahine refers to "That's what most people trust. That's what most people have equipment, even third parties", which is not based on Dr. Chahine's own experience, therefore, it should be accorded little weight. The proposed finding is also irrelevant because it doesn't appear to relate to MCED tests.

1530. Mr. Gao testified that "unless you show superiority over Illumina, why [would] we want to throw away what we have done to go with you, so we never go with any other company." (PX7042 (Gao (Singlera) IHT at 60)).

Response to Finding No. 1530:

The proposed finding is inaccurate, incomplete and misleading. Dr. Gao of Singlera testified that the PanSeer test only needs over 5 million reads (Gao (Singlera) Tr. at 2893) and can be run using alternative NGS instruments such as Illumina's MiSeq and Thermo Fisher equipment. (*See* Gao (Singlera) Tr. at 2928–31; PFF ¶¶ 780–780.6.) [redacted] (PFF ¶¶ 778–778.2; 2085.) Thermo Fisher's Ion Torrent sequencers are suitable for certain MCED tests. (RX3869 (Cote Expert Report) ¶ 285.) [redacted]

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Respondents also incorporate their responses to CCFF ¶¶ 982 and 1171 herein.

1531. When Singlera chose to use Illumina, it chose the winner: "We had to be solid." (PX7042 (Gao (Singlera) IHT at 63)).

Response to Finding No. 1531:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. Respondents incorporate their responses to CCFF ¶ 1530 herein.

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1532. Dr. Vogelstein testified that Illumina's NGS sequencers are "incredibly reliable" and elaborated that they "work time and time again, over and over, both in our lab and numerous other labs." (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 59)).

Response to Finding No. 1532:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. Respondents incorporate their responses to CCFF ¶ 929 herein.

Further, Dr. Vogelstein, the founder of Thrive stated, [redacted]

BGI already has a commercially available NGS platform. (PFF ¶¶ 777–777.5.) [redacted] BGI recently won a jury

verdict that held three of Illumina's patents to be invalid meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022). BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777–777.3.)

1533. With respect to Illumina's NGS sequencers, Dr. Vogelstein testified that Illumina's "service is superb" and elaborated that his lab does "studies in which [they] have to return results to patients every week and [they're] on constant alert and anxiety to make sure the instruments don't break down because patients' lives depend on them" so they "need absolutely reliable instruments." (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 59-60)).

Response to Finding No. 1533:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. Respondents incorporate their responses to CCFF ¶¶ 929 and 1532 herein.

1534. Dr. Vogelstein testified that the "know-how that has been obtained on" Illumina's NGS sequencers "since their beginning is unbelievably strong" and he would characterize as "priceless." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 59)).

Response to Finding No. 1534:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. Respondents incorporate their responses to CCFF ¶¶ 929 and 1532 herein.

1535. [redacted] (PX7105 (Getty (Guardant) Dep. at 239-40) (*in camera*)).

Response to Finding No. 1535:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. Respondents incorporate their responses to CCFF ¶ 927 herein.

Mr. Getty admitted that Thermo Fisher Scientific Inc., and other companies developing next-generation sequencing platforms also provide NGS platforms that could be used for liquid biopsy testing. (Getty (Guardant) Tr. 2642.) [redacted] Dr. Chudova also stated that Guardant could use alternative sequencing platforms for its LUNAR-2 screening test in development that meet the throughput, error, time, and sequencing cost requirements. (PX7045 (Chudova (Guardant) IHT at 44–47.)

BGI also markets its NGS technology in many other countries and is expected to enter the U.S. market in the near future. [redacted]) BGI recently won a jury verdict that held three of Illumina's patents to be invalid meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022). BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777–777.3.)

Oxford Nanopore's PromethION sequencer has sequencing costs of as low as $2.55 per gigabase, which is lower than the per gigabase sequencing costs using Illumina's NovaSeq 6000. (*See* PFF ¶¶ 603–603.3.) Using Oxford Nanopore's PromethION with a throughput of 10 Tb in up to 72 hours (PFF ¶ 599 (RX3536 (ONT); RX3869 (Cote Expert Report) ¶ 293)), [redacted] —*a few more* samples in the same time frame. Respondents also incorporate their responses to CCFF ¶¶ 1115 and 1118 herein.

The proposed finding is based in part on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents also incorporate their responses to CCFF ¶ 927 herein.

1536. Dr. Lengauer explained:

[redacted]

(PX7051 (Lengauer (Third Rock Ventures) IHT at 109-10) (*in camera*)).

Response to Finding No. 1536:

The proposed finding is incomplete and misleading with respect to Exact/Thrive's purported reliance on Illumina's NGS systems. Respondents incorporate their responses to CCFF ¶ 929 herein. Respondents also note that Dr. Lengauer testified at trial that [redacted]

[redacted] (Lengauer (Exact/Thrive) Tr. 238–40.) Respondents also incorporate their responses to CCFF ¶ 1532 herein.

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2. Even if a Company Develops a New NGS Platform, Significant Barriers to Commercialization Exist and It Will Take Years for a New Entrant to Gain the Reputation and Enough Widespread Commercial Use to Be an Option for MCEDs

b) MCED Customers Would Not Switch to a New Platform Until It Has Widespread Adoption and Demonstrated Reliability

1537. [redacted] (PX7107 (deSouza (Illumina) Dep. at 259 (*in camera*) (referring to PX2544 (Illumina)-025)).

Response to Finding No. 1537:

Respondents have no specific response.

1538. In a conference call with investors, Illumina CEO Mr. deSouza noted the U.S. NGS market poses "significant hurdles" for entry and that Illumina "continue[s] to push this at a higher and higher bar in the market":

> [T]he U.S. is a very sophisticated genomics market both in terms of the research market and the clinical market. And so customers here have high expectations around the quality of the products, the accuracy of the product, the reliability of the product, the ease of the workflow, the validation of the products by the rest of the market. And so these present significant hurdles for anyone else coming in that we do believe that we continue to push this at a higher and higher bar in the market.

(PX2544 (Illumina) at 025 (Email from T. Peterson, JP Morgan, to F. deSouza, Sept. 5, 2019, attaching JP Morgan Life Sciences CEO Conference Call Transcript, Sept. 3, 2019)).

Response to Finding No. 1538:

The proposed finding is incomplete and misleading. When asked about the [redacted] (PX7107 (de Souza (Illumina) Dep. at 258–59.)) Mr. deSouza was merely pointing out that any NGS company that provided customers with inaccurate results, accuracy of results being a basic requirement, would struggle to succeed in the NGS market.

The proposed finding is also misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for achieving the accuracy required for an early detection test. As Dr. Vogelstein has stated, there are other viable NGS platforms on the market that compare to Illumina's level of accuracy. BGI's DNBSEQ sequencer's reported accuracy is comparable to that of Illumina's sequencers, at over 99.9% accuracy (>80% of bases >Q30). (PFF ¶ 591 (RX3465 (MGI Tech); RX3067 (BGI)).) Specifically, Dr. Vogelstein stated, [redacted]

Oxford Nanopore claims its instruments have similar accuracy to Illumina. (*Compare* RX3541 (ONT) at 1; RX3535 (ONT) at 1 *with* RX3368 (Illumina).)

Singular Genomics' G4 System's reported performance characteristics are comparable to those of Illumina's NextSeq and NovaSeq systems, with high accuracy of 99.7% on 150 base reads. (PX8561 (Singular) at 4-5; [redacted]

1539. A February 2020 UBS/DeciBio presentation on NGS use generally stated that "[d]espite increasing competition, Illumina is poised to maintain its leadership position over the next 5+ years" and notes that "NGS users have created an 'Illumina ecosystem' (e.g., bioinformatics pipeline) making it hard for competing technologies." (PX2030 (Illumina) at 006 (UBS/DeciBio, NGS and Spatial Omics Landscape and Trends, Feb. 24, 2020)).

Response to Finding No. 1539:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 5), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1540. The same UBS/DeciBio presentation states that ""Many players are expected to enter the market in the coming years but are unlikely to materially affect the market in the near term due to R&D timelines and Illumina ecosystem incompatibility." (PX2030 (Illumina) at 010 (UBS/DeciBio, NGS and Spatial Omics Landscape and Trends, Feb. 24, 2020)).

Response to Finding No. 1540:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 5), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1541. The same UBS/DeciBio presentation projects that "Illumina will continue to dominate the space," with other sequencing firms "carving out niches." (PX2030 (Illumina) at 009 (UBS/DeciBio, NGS and Spatial Omics Landscape and Trends, Feb. 24, 2020) (referring specifically to Thermo Fisher's "ex-U.S. commercial reach" and BGI's "(ex-U.S.) leadership position").

Response to Finding No. 1541:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 5), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1542. Illumina CEO Mr. deSouza distinguished U.S. clinical customers as being particular focused on "high accuracy results": "[O]n the clinical side, it's especially important that products deliver high accuracy results." (PX2544 (Illumina) at 025 (Email from T. Peterson, JP Morgan, to F. deSouza, Sept. 5, 2019, attaching JP Morgan Life Sciences CEO Conference Call Transcript, Sept. 3, 2019)).

Response to Finding No. 1542:

The proposed finding is incomplete. When questioned about the "high accuracy" language, Mr. deSouza testified that by "high accuracy" [redacted] (PX7107 (deSouza (Illumina) Dep. at 260.)) Respondents also incorporate their responses to CCFF ¶ 1538 herein.

1543. When Illumina launches a new platform, clinical customers do not immediately switch, but rather wait a year or two to observe the platform's performance. (deSouza (Illumina) Tr. 2409-10).

Response to Finding No. 1543:

Respondents have no specific response except to note that third-party testimony also shows that switching between Illumina platforms, which customers have to do every few years, poses a similar burden to switching from an Illumina platform to a non-Illumina platform. (*See* PFF ¶ 678.2.) For example, [redacted] Further, neither Complaint Counsel nor Dr. Scott Morton offered any empirical assessment of the *incremental* cost of switching from an Illumina platform to a third-party platform as compared to the switching cost that would be incurred by a test developer that seeks to upgrade to Illumina's next generation system. (PFF ¶ 948.2; RX3871 (Willig Expert Report) ¶¶ 46, 48.) Respondents also incorporate their responses to CCFF ¶ 1088 herein.

1544. Once customers have observed how a new sequencer "performs in the real market," customers will bring in a single sequencer to validate their workflows and train people on the new sequencer. (deSouza (Illumina) Tr. 2410).

Response to Finding No. 1544:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1543 herein.

1545. The validation process for evaluating a new sequencer takes months or quarters. (deSouza (Illumina) Tr. 2410).

Response to Finding No. 1545:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1543 herein.

1546. Only after observing the sequencer's performance in the market and validating the customer's workflow on the new sequencer will a customer begin selling its tests on a new sequencer. (deSouza (Illumina) Tr. 2409-10).

Response to Finding No. 1546:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1543 herein.

1547. It is "not uncommon" for clinical customers to wait years to adopt a new sequencer—"it could be three-plus years after a new sequencer comes out." (deSouza (Illumina) Tr. 2410).

Response to Finding No. 1547:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1543 herein.

1548. Clinical customers take years to adopt a new sequencer, because they wait to see how it will perform in the real world, then perform validation. (deSouza (Illumina) Tr. 2450).

Response to Finding No. 1548:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1543 herein.

1549. Clinical customers will ramp up on a new sequencer 2.5 to 3 years after the sequencer's launch. (deSouza (Illumina) Tr. 2450).

Response to Finding No. 1549:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1543 herein.

1550. Mr. deSouza pointed to customer adoption of the NovaSeq to exemplify how clinical customers' adoption cycles can take years: "For example, NovaSeq was launched on -- in 2017, first half of 2017, and we still have a substantial portion of our NovaSeq customers

that are new to high throughput or new to Illumina, and they are only now bringing the NovaSeq into their environment." (deSouza (Illumina) Tr. 2410-11).

Response to Finding No. 1550:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1543 herein.

1551. In evaluating a new NGS Platform, Dr. Lengauer testified that [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 105) (*in camera*)).

Response to Finding No. 1551:

The proposed finding is incomplete and misleading to the extent it suggests that only Illumina's platform can support Exact/Thrive's CancerSEEK test. Respondents also note that Dr. Lengauer testified at trial that [redacted] (Lengauer (Exact/Thrive) Tr. 238–40.)

Further, Dr. Vogelstein, the founder of Thrive stated, [redacted]

Respondents also incorporate their responses to CCFF ¶¶ 929 and 1532 herein.

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1552. [redacted]

[redacted]
(PX7051 (Lengauer (Third Rock Ventures) IHT at 105) (*in camera*)).

Response to Finding No. 1552:

The proposed finding is incomplete and misleading to the extent it suggests that only Illumina's platform can support Exact/Thrive's CancerSEEK test. Respondents also incorporate their responses to CCFF ¶¶ 929, 1532 and 1551 herein.

Respondents also note that [redacted] The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928 and 2833, which Respondents incorporate herein.

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1553. [redacted]
(PX7045 (Chudova (Guardant) IHT at 115-16) (*in camera*)).

Response to Finding No. 1553:

The proposed finding is inaccurate, incomplete and misleading to the extent it suggests that only Illumina's NovaSeq instrument is suitable for supporting Guardant's putative MCED test. [redacted]

[redacted] Dr. Chudova also stated that Guardant could use alternative sequencing platforms for its LUNAR-2 screening test in development that meet the throughput, error, time, and sequencing cost requirements. (PX7045 (Chudova (Guardant) IHT at 44–47.) Further, BGI is not a new platform: it launched its first NGS sequencer in 2015. (PFF ¶ 587 (RX3063 (BGI)).)

BGI also markets its NGS technology in many other countries and is expected to enter the U.S. market in the near future. [redacted] RX3869 (Cote Expert Report) ¶ 287; [redacted].) BGI also recently won a jury verdict that held three of Illumina's patents to be invalid meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022). BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777–777.3.)

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1554. [redacted] (Chudova (Guardant) Tr. 1228-29) (*in camera*).

Response to Finding No. 1554:

Respondents have no specific response except to incorporate PFF ¶¶ 645–656.1 and Respondents' responses to CCFF ¶¶ 927 and 1553 herein.

In particular, switching between Illumina's platform and alternative platforms is feasible. (PFF ¶ 645; RX3869 (Cote Expert Report) ¶ 336.) In fact, cancer screening developers will inevitably need to switch between different Illumina instruments in the course of developing their respective screening tests. (PFF ¶ 646; RX3869 (Cote Expert Report) ¶ 336.) Illumina's own model contemplates that a portion of test developers will switch to an alternative sequencing platform developer in the process of upgrading Illumina instruments. (PFF ¶ 646.1; PX7087 (Goswami (Illumina) Dep. at 16).)

Further, other NGS platforms have specifically been designed for ease of switching from one platform to another. [redacted]

1555. [redacted] (PX7055 (Otte (Freenome) IHT at 74) (*in camera*)).

Response to Finding No. 1555:

The proposed finding is incomplete and misleading to the extent it suggests that only Illumina's platform can support Freenome's putative MCED test. In particular, [redacted]

[redacted].) BGI also recently won a jury verdict that held three of Illumina's patents to be invalid meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022). BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777–777.3.)

Respondents also note that Singular's G4 NGS System's performance characteristics are stated to be comparable or better to Illumina's NextSeq and NovaSeq systems and that Singular states that the G4 System will compete with Illumina for sales to MCED test developers. (*See* PFF ¶¶ 609–10.) Singular has received positive feedback from cancer-screening test developers. (*See* PFF ¶ 612.)

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

c) Gaining Widespread Adoption Among Customers is Time Consuming and Difficult Because of Contracting Practices and Reputational Barriers

1556. Singular represented to investors that "customers' willingness and ability to adopt new products and workflows, including in light of commercial pressures applied by our competitors and pre-existing long-term contracts with our competitors" is a commercial risk that could prevent customer adoption of a new NGS Sequencing platform. (PX0068 at 031-32 (Singular Genomics S-1, May 2021)).

Response to Finding No. 1556:

Respondents have no specific response except to note that the cited source also observes that: (1) Singular's G4 System has performance characteristics Singular states are comparable or better than Illumina's NextSeq and NovaSeq (PX8561 (Singular) at 4–5); (2) Singular launched the G4 System at the end of 2021 and will begin shipping the G4 System in the first half of 2022 (PX8561 (Singular) at 1–2).

1557. [redacted] (Velarde (Singular Genomics) Tr. 4550 (*in camera*)).

Response to Finding No. 1557:

Respondents have no specific response except to note that Mr. Velarde also testified that [redacted] (Velarde (Singular) Tr. 4522, 4537; PX7117 (Velarde (Singular) Dep. at 97–98, 111–12).)

Respondents also note that under the Open Offer, any customer that has a long-term supply agreement with Illumina has the unilateral right to terminate its supply relationship with Illumina at any time and for any reason without termination liability upon ninety (90) days' prior written notice to Illumina. (PFF ¶ 1001.1; PX0064 (Illumina) at 10.)

1558. Dr. He testified that Element Biosciences is "worried … that Illumina can use its market power … and perhaps lock down their customers with multi-year agreements … to prevent any new NGS provider[] from entering the space or just make that very, very difficult." (PX7124 (He (Element) Dep. at 122)).

Response to Finding No. 1558:

The proposed finding is based on testimony for which the witness lacks personal knowledge and foundation. When asked by Complaint Counsel what Dr. He based the expressed belief quoted by Complaint Counsel, Dr. He testified that she "[did] not have specifics". Therefore, Dr. He's testimony is based on pure speculation and should be given no weight.

Respondents also note that under the Open Offer, any customer that has a long-term supply agreement with Illumina has the unilateral right to terminate its supply relationship with Illumina at any time and for any reason without termination liability upon ninety (90) days' prior written notice to Illumina. (PFF ¶ 1001.1; PX0064 (Illumina) at 10.)

1559. [redacted] (PX7071 (Song (Omniome) IHT at 58-59) (*in camera*)).

Response to Finding No. 1559:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Respondents also note that under the Open Offer, any customer that has a long-term supply agreement with Illumina has the unilateral right to terminate its supply relationship with Illumina at any time and for any reason without termination liability upon ninety (90) days' prior written notice to Illumina. (PFF ¶ 1001.1; PX0064 (Illumina) at 10.)

1560. Singular represented to investors that "[i]f our products fail to achieve early customer and scientific acceptance, we may not be able to achieve broader market acceptance for our products and our revenue and prospects may be harmed." (PX0068 at 025 (Singular Genomics S-1, May 2021)).

Response to Finding No. 1560:

Respondents have no specific response except to incorporate their responses to Proposed CCFF ¶¶ 1556–57 herein. [redacted] (Velarde (Singular) Tr. 4522, 4537; PX7117 (Velarde (Singular) Dep. at 97–98, 111–12).)

1561. Singular represented to investors that "the life sciences community is comprised of a small number of early adopters and key opinion leaders (KOLs) who significantly influence the rest of the community and the market-place in general." (PX0068 at 026 (Singular Genomics S-1, May 2021)).

Response to Finding No. 1561:

Respondents have no specific response except to incorporate their responses to Proposed CCFF ¶¶ 1556–57 herein. [redacted] (Velarde (Singular) Tr. 4522, 4537; PX7117 (Velarde (Singular) Dep. at 97–98, 111–12).)

1562. Singular represented to investors that "[e]nsuring that early adopters and KOLs publish research involving the use of our products is critical to ensuring our products gain widespread acceptance and market growth." (PX0068 at 026 (Singular Genomics S-1, May 2021)).

Response to Finding No. 1562:

Respondents have no specific response except to incorporate their responses to Proposed CCFF ¶¶ 1556–57 herein. [redacted] (Velarde (Singular) Tr. 4522, 4537; PX7117 (Velarde (Singular) Dep. at 97–98, 111–12).)

1563. Singular represented to investors that "[i]f early adopters and KOLs do not favorably describe the use of our products, do not compare our products favorably to existing product and technologies, or negatively describe the use and operation of our products in publications, it may drive potential customers away from our products and prevent broader market acceptance of our products, which could harm our business, financial condition and results of operations. (PX0068 at 026 (Singular Genomics S-1, May 2021)).

Response to Finding No. 1563:

Respondents have no specific response except to incorporate their responses to Proposed CCFF ¶¶ 1556–57 herein. [redacted] (Velarde (Singular) Tr. 4522, 4537; PX7117 (Velarde (Singular) Dep. at 97–98, 111–12).)

1564. [redacted]

[redacted] (PX7070 (Felton (Thermo Fisher) IHT at 28) (*in camera*)).

Response to Finding No. 1564:

The proposed finding is incomplete and misleading. Contrary to the proposed finding, evidence and testimony shows that entry into the NGS market is feasible and ongoing and switching from Illumina to a non-Illumina platform is feasible, unlikely to affect the timeline for MCED test development, and poses a similar burden to switching between Illumina platforms. (*See* PFF ¶¶ 605–74.) The proposed finding is also vague as to what Dr. Felton means by "dominant player"; even if Illumina has greater than 50 percent market share, there are many other sequencing alternatives for putative MCED test developers.

Furthermore, [redacted] Dr. Felton also testified that Thermo Fisher would be competing with BGI if they entered the U.S. market (Felton (Thermo Fisher) Tr. 1999) and that BGI (along with Illumina) was economical to deploy in an MCED testing environment. (RX3823 (Felton (Thermo Fisher) Dep. at 173).)

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1565. Mr. Conroy explained his expectation that once a company signs a supply agreement with Illumina, [redacted] (PX7058 (Conroy (Exact) IHT at 150-151) (*in camera*)).

Response to Finding No. 1565:

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding is also inaccurate and misleading. Under the Open Offer, any customer that has a long-term supply agreement with Illumina has the unilateral right to terminate its supply relationship with Illumina at any time and for any reason without termination liability upon ninety (90) days' prior written notice to Illumina. (PFF ¶ 1001.1; PX0064 (Illumina) at 10.)

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1566. Natera represented to investors in its Form 10-K that although it is "not bound to use exclusively Illumina's sequencing instruments and reagents for conducting our sequencing, … if we use other sequencing and reagents for more than specified percentages of our total NIPT clinical volume, we may no longer be entitled to discounts from Illumina." (PX0155 at 15 (Natera 2020 Form 10-K, Dec. 31, 2020).

Response to Finding No. 1566:

The proposed finding is irrelevant, including because it relates to NIPT and not oncology screening. Regardless of whatever Natera has stated about its supply agreement, the pricing in the Open Offer is not contingent on the customer purchasing any other products: any customer buying sequencing reagents for use with a cancer screening test will pay the Open Offer price, regardless of whether customer is purchasing a certain percentage of its oncology clinical volume from Illumina. (PX0064 (Illumina) at 6–7, 12–27; Berry (Illumina) Tr. 864–65.)

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 2), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

d) [redacted]

1567. [redacted]

Response to Finding No. 1567:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

In any event, [redacted] Dr. Chudova also stated that Guardant could use alternative sequencing platforms for its LUNAR-2 screening test in development that meet the throughput, error, time, and sequencing cost requirements. (PX7045 (Chudova (Guardant) IHT at 44–47.) BGI also markets its NGS technology in many other countries and is expected to enter the U.S. market in the near future. [redacted]; RX3869 (Cote Expert Report) ¶ 287; [redacted].) BGI also recently won a jury verdict that held three of Illumina's patents to be invalid meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022). BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777–777.3.)

Guardant itself also admits the viability of using Thermo Fisher equipment for "liquid biopsy" tests. (Getty (Guardant) Tr. 2642 (discussing statements made in Guardant's 10-K).) [redacted]

[redacted]

Respondents also incorporate their responses to CCFF ¶¶ 927, 1115 and 1118 herein.

Further, BGI and Thermo Fisher are not a new platforms: BGI launched its first NGS sequencer in 2015 (PFF ¶ 587; RX3063 (BGI)); and Thermo Fisher released its Ion Torrent NGS sequencers in 2010. (PFF ¶ 578; PX2482 (Thermo Fisher) at 50).)

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 927 and 2273, which Respondents incorporate herein. Given the stage of [redacted] (Cote Tr. 3776, 3833–34.)

1568. [redacted]

Response to Finding No. 1568:

Respondents have no specific response.

1569. [redacted]

Response to Finding No. 1569:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1567, which Respondents incorporate herein. Dr. Chudova also testified that [redacted] (Chudova (Guardant) Tr. 1300–01.) Respondents also incorporate their responses to CCFF ¶¶ 927–28, 1115 and 1118 herein.

1570. [redacted]

Response to Finding No. 1570:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1567, which Respondents incorporate herein. The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1571. [redacted]

Response to Finding No. 1571:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1567, which Respondents incorporate herein. The proposed finding relies on IH testimony which is hearsay and which Respondents had no

opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1572. [redacted]

Response to Finding No. 1572:

Respondents have no specific response.

e) MCED Customers Would Be Reluctant to Use NGS Platform with Unclear Freedom to Operate from Illumina's Patents

1573. Dr. Gao testified that Singlera has "invested tens of millions, hundreds of millions [of] dollars into product development" and it will "only work with [a] company with clear IP rights." (Gao (Singlera) Tr. 2895).

Response to Finding No. 1573:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 896 and 1011, which Respondents incorporate herein.

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1269, 1276, 1290 and 1318, which Respondents incorporate herein.

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding is also incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 982 and 2406, which Respondents incorporate herein. Given the stage of Singlera's putative MCED test development, Singlera could switch platforms without affecting its development timeline. (Cote Tr. 3776, [redacted].)

1574. [redacted]

Response to Finding No. 1574:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1269, 1276 and 1287, which Respondents incorporate herein.

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1575. Multiple MCED customers are reluctant to work with BGI because of the uncertainty of BGI's freedom to operate in the U.S. without infringing Illumina's patents. (*See supra* Section V.E.2.c).

Response to Finding No. 1575:

BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777–777.3.) *Illumina, Inc. v. BGI Genomics, Co.*, 20-cv-01465-WHO (N.D. Cal. Mar. 27, 2022), ECF No. 665 at 48 ("If [BGI] make[s] offers to sell Accused Products in the U.S. before the expiration of the patents-in-suit—as they are permitted—they must include the following conspicuous written

disclaimer: 'No sales will occur, and no purchase orders will be accepted, until after August 23, 2022.'") It acquired California-based sequencing company Complete Genomics in 2013 and launched its BGISEQ-500 NGS sequencer in 2015. (PFF ¶ 587; RX3063 (BGI).)

BGI recently won a jury verdict that held three of Illumina's patents to be invalid meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022).

3. No NGS Platform Likely to Enter the NGS Market That Would Be a Viable Option for MCED Test Developers in a Timely Manner

1576. [redacted] (PX7050 (Nolan (Freenome) IHT at 101-104) (*in camera*)).

Response to Finding No. 1576:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The testimony also constitutes impermissible and purely speculative lay witness testimony to the extent it purports to offer a general opinion on the feasibility of

entry into the NGS market. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

[redacted] Cote Tr. 3776, [redacted].)

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

a) Thermo Fisher

1577. [redacted] (Felton (Thermo Fisher) Tr. 2011) (*in camera*)).

Response to Finding No. 1577:

Respondents have no specific response.

1578. [redacted] (Felton (Thermo Fisher) Tr. at 2012) (*in camera*)).

Response to Finding No. 1578:

Respondents have no specific response.

1579. [redacted] (Felton (Thermo Fisher) Tr. 2012-2013) (*in camera*)).

Response to Finding No. 1579:

The proposed finding is misleading to the extent that it implies that [redacted] (*See* PFF ¶¶ 1924–25.)

For example, putative MCED test developers *do* use Illumina's lower throughput NextSeq and MiSeq instruments for their early detection tests. For example, Singlera's PanSeer test only requires approximately 2 million sequencing reads per sample, and is compatible with both Illumina's MiSeq or NextSeq systems and Thermo Fisher's Ion Torrent S5 systems, though it appears to primarily use the NextSeq 550Dx system from Illumina. (PFF ¶ 533 (RX3115 (Chen et al., 2020) at 7; RX3637 (Singlera) at 1–6; Gao (Singlera) Tr. 2875, 2894, 2928–29; PX7102 (Gao (Singlera) Dep. at 78); RX3869 (Cote Expert Report) ¶ 239).) Helio currently uses Illumina's MiSeq sequencer for its Helio Liver test. (Chahine (Helio) Tr. 1010-12). Dr. Chahine testified Helio uses the MiSeq because "a smaller machine is more efficient" as a "company in its early stage" prior to "ramp[ing] up." (Chahine (Helio) Tr. 1012). [redacted] (Rabinowitz (Natera) Tr. 361) (*in camera*)). Respondents also incorporate their responses to CCFF ¶¶ 928, 980 and 1115 herein.

1580. [redacted]

[redacted] (PX7070 (Felton (Thermo Fisher) IHT at 55) (*in camera*)).

Response to Finding No. 1580:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1579, which Respondents incorporate herein.

Respondents also note that [redacted] (RX3869 (Cote Expert Report) ¶ 285; *see* PFF ¶¶ 1924–25.)

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1581. Respondents' own expert, Dr. Richard Cote, acknowledged that Thermo Fisher's sequencing platform is "somewhere between the mid and low throughput" Illumina sequencing platforms. (Cote Tr. 3760).

Response to Finding No. 1581:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1579–80 herein.

1582. [redacted] (Felton (Thermo Fisher) Tr. 2013) (*in camera*)).

Response to Finding No. 1582:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1579–80 herein. The proposed finding is also irrelevant because many test developers are pursuing test development using platforms without lower throughput than the NovaSeq.

1583. [redacted]

[redacted] (PX7070 (Felton (Thermo Fisher) IHT at 56) (*in camera*)).

Response to Finding No. 1583:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1579–80 herein. The proposed finding is also irrelevant because many test developers are pursuing test development using platforms without lower throughput than the NovaSeq.

1584. Thermo Fisher's Dr. Felton acknowledged that despite its research and development work, [redacted] (PX7070 (Felton (Thermo Fisher) IHT at 59-60) (*in camera*); *see also* PX7070 (Felton (Thermo Fisher) IHT at 60-61) (testifying that NGS platforms offered by Thermo Fisher, Pacific Biosciences and Oxford Nanopore "are really not suited to [MCED] testing.")).

Response to Finding No. 1584:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1579–80 herein.

Contrary to the cited testimony, [redacted]

Further, at least one putative MCED test developer already uses Thermo Fisher's platform. For example, Singlera's PanSeer test only requires approximately 2 million sequencing reads per sample, and is compatible with both Illumina's MiSeq or NextSeq systems and Thermo Fisher's Ion Torrent S5 systems. (PFF ¶ 533 (RX3115 (Chen et al., 2020) at 7; RX3637 (Singlera) at 1–6; Gao (Singlera) Tr. 2875, 2894, 2928–29; PX7102 (Gao (Singlera) Dep. at 78); RX3869 (Cote Expert Report) ¶ 239).)

Dr. Aravanis also testified that Thermo Fisher's Ion Torrent can be used as an alternative for many Illumina applications; that the Ion Torrent platform is adequate in terms of the type of sequencing data it produces, the accuracy and the cost and that Thermo Fisher markets the Ion Torrent as an alternative to Illumina. (PFF ¶ 1305 (Aravanis (Illumina) Tr. 1848–52).)

With respect to Oxford Nanopore, Oxford Nanopore's PromethION has total throughput per run of up to 10 Tb, much higher than the up to 50 Gb per run generated by Thermo Fisher's Ion GeneStudio S5. (*See* PFF ¶¶ 579, 598–604.1.) Dr. Felton did not consider the new technology of using concatenation to read cfDNA fragments using nanopore sequencing. Respondents also incorporate their responses to CCFF ¶ 904 herein.

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1585. [redacted] (Felton (Thermo Fisher) Tr. 2015) (*in camera*)).

Response to Finding No. 1585:

The proposed finding is incomplete to the extent it suggests that Thermo Fisher does not already have an FDA-approved NGS sequencer. Dr. Felton explained how the PGM Dx

platform, a fully FDA-approved system, is used in oncology applications. (Felton (Thermo Fisher) Tr. 1983–87.) [redacted]

The proposed finding is also misleading to the extent it implies that a distributed IVD model will be part of the plan for any putative MCED test. Several features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (PFF ¶ 675; RX3869 (Cote Expert Report) ¶ 359.) The test developer's decision whether to proceed with an IVD kit as opposed to a centralized model is an economic decision driven by test-specific factors. (Goswami (Illumina) Tr. 3197.) IVD kits are most suitable for tests that have precious samples, that present shipping challenges and require fast turnaround times. (Goswami (Illumina) Tr. 3196–3200; *see also* RX3869 (Cote Expert Report) § XI, ¶¶ 360–63.)

b) Omniome

1586. Omniome was founded in 2013. (PX7071 (Song (Omniome) IHT at 13)).

Response to Finding No. 1586:

Respondents have no specific response.

1587. Omniome currently does not have a commercial NGS platform on the market. (deSouza (Illumina) Tr. 2473-74).

Response to Finding No. 1587:

Respondents have no specific response.

1588. [redacted] (PX7071 (Song (Omniome), IHT at 38-39) (*in camera*)).

Response to Finding No. 1588:

Respondents have no specific response.

(1) [redacted]

1589. [redacted] (PX7096 (Song (Omniome) Dep. at 13–16) (*in camera*)).

Response to Finding No. 1589:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1591 herein.

1590. [redacted] (PX7096 (Song (Omniome) Dep. at 17–18) (*in camera*)).

Response to Finding No. 1590:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1591 herein.

1591. [redacted] (PX7096 (Song (Omniome) Dep. at 18–19) (*in camera*)).

Response to Finding No. 1591:

Respondents have no specific response except to note that [redacted] (PX7096 (Song (Omniome) Dep. at 53–54, 56.))

Since Dr. Song testified, Omniome was acquired by PacBio for $800 million in July 2021. (RX3533 (Omniome).) Omniome states that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72)**;** [redacted] Omniome's sequencer will reportedly have comparable throughput and run times to Illumina's NextSeq sequencers, but with better accuracy—98%> Q50 to 99% Q70—10 to 100x better than the accuracy of Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 82, 100–01); [redacted] (PX7096 (Song (Omniome) Dep. at 28–29, 56).)

1592. [redacted] (PX7096 (Song (Omniome) Dep. at 20-27) (*in camera*)).

Response to Finding No. 1592:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1591 herein.

1593. [redacted] (PX7071 (Song (Omniome) IHT at 27–28) (*in camera*)).

Response to Finding No. 1593:

Since Dr. Song testified, Omniome was acquired by PacBio for $800 million in July 2021. (RX3533 (Omniome).) Omniome states that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72)**;** [redacted]

[redacted] (PX7096 (Song (Omniome) Dep. at 28–29, 56).)

1594. [redacted] (PX7096 (Song (Omniome) Dep at 28) (*in camera*)).

Response to Finding No. 1594:

The proposed finding is incomplete. [redacted] (PX7096 (Song (Omniome) Dep. at 28–29, 56).)

1595. [redacted] (PX7096 (Song (Omniome) Dep at 28–29) (*in camera*)).

Response to Finding No. 1595:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1591 herein.

1596. [redacted] (PX7096 (Song (Omniome) Dep. at 13–29)) (*in camera*)).

Response to Finding No. 1596:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1591 herein.

1597. [redacted] (PX7071 (Song (Omniome) IHT at 22-25) (*in camera*)).

Response to Finding No. 1597:

Since Dr. Song testified, Omniome was acquired by PacBio for $800 million in July 2021. (RX3533 (Omniome).) Omniome states that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72)**;** [redacted]

[redacted] (PX7096 (Song (Omniome) Dep. at 28–29, 56).)

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(2) [redacted]

1598. [redacted] (PX7096 (Song (Omniome) Dep. at 144-45) (*in camera*)).

Response to Finding No. 1598:

The proposed finding is speculative. Dr. Song testified that there had been discussions about whether or not to change Omniome's instrument before commercial release, whether there would be time, and the impact this would have. (PX7096 (Song (Omniome) Dep. at 144–45).)

1599. Omniome has had to make changes to the design of its sequencer "quite a bit" since it began development. (PX7096 (Song (Omniome) Dep. at 143) (*in camera*)).

Response to Finding No. 1599:

Respondents have no specific response except to note that Omniome states that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72)**;** [redacted] Respondents also incorporate their responses to CCFF ¶ 1591 herein.

1600. [redacted] (PX7096 (Song (Omniome) Dep. at 143) (*in camera*)).

Response to Finding No. 1600:

Respondents have no specific response except to note that Omniome states that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent

costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72)**;** [redacted] Respondents also incorporate their responses to CCFF ¶ 1591 herein.

1601. [redacted] (PX7096 (Song (Omniome) Dep. at 144) (*in camera*)).

Response to Finding No. 1601:

Respondents have no specific response except to note that Omniome states that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72)**;** [redacted] Respondents also incorporate their responses to CCFF ¶ 1591 herein.

1602. [redacted] (PX7096 (Song (Omniome) Dep. at 144–45) (*in camera*)).

Response to Finding No. 1602:

Respondents have no specific response except to note that Omniome states that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72)**;** [redacted] Respondents also incorporate their responses to CCFF ¶ 1591 herein.

1603. [redacted] (PX7096 (Song (Omniome) Dep. at 144–45) (*in camera*)).

Response to Finding No. 1603:

Respondents have no specific response except to note that Omniome states that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72)**;** [redacted] Respondents also incorporate their responses to CCFF ¶ 1591 herein.

1604. [redacted] (PX7096 (Song (Omniome) Dep. at 145) (*in camera*)).

Response to Finding No. 1604:

Respondents have no specific response except to note that Omniome states that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72); [redacted] Respondents also incorporate their responses to CCFF ¶ 1591 herein.

1605. [redacted] (PX7096 (Song (Omniome) Dep. at 145) (*in camera*)).

Response to Finding No. 1605:

Respondents have no specific response to note that Omniome states that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72); [redacted] Respondents also incorporate their responses to CCFF ¶ 1591 herein.

1606. The role of early access customers is to provide manufacturers with feedback on a multitude of different factors. (PX7096 (Song (Omniome) Dep. at 145–46)).

Response to Finding No. 1606:

Respondents have no specific response to note that Omniome states that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72); [redacted] Respondents also incorporate their responses to CCFF ¶ 1591 herein.

1607. Dr. Song testified that depending on the feedback that early access customers provide, companies think about whether they want to delay the commercial launch to incorporate the feedback into the instrument. (PX7096 (Song (Omniome) Dep. at 146)).

Response to Finding No. 1607:

Respondents have no specific response to note that Omniome states that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than

Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72)**;** [redacted] Respondents also incorporate their responses to CCFF ¶ 1591 herein.

1608. Mr. Song warned that, [redacted] (PX7071 (Song (Omniome) IHT at 28) (*in camera*)).

Response to Finding No. 1608:

Since Dr. Song testified, Omniome was acquired by PacBio for $800 million in July 2021. (RX3533 (Omniome).) Omniome states that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72)**;** [redacted] (PX7096 (Song (Omniome) Dep. at 28–29, 56).)

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1609. [redacted] (PX7071 (Song (Omniome) IHT at 27-28) (*in camera*)).

Response to Finding No. 1609:

Since Dr. Song testified, Omniome was acquired by PacBio for $800 million in July 2021. (RX3533 (Omniome).) Omniome states that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72)**;** [redacted] Omniome's sequencer will reportedly have comparable throughput and run times to Illumina's NextSeq sequencers, but with better accuracy—98%> Q50 to 99% Q70—10 to 100x better than the

accuracy of Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 82, 100–01); [redacted] (PX7096 (Song (Omniome) Dep. at 28–29, 56).)

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1610. [redacted] (PX7071 (Song (Omniome) IHT at 24-25) (*in camera*)).

Response to Finding No. 1610:

The proposed finding is misleading and inaccurate. [redacted] (PX7096 (Song (Omniome) Dep. at 53–54, 56.))

1611. Omniome anticipates spending another $60 to $80 million before having an NGS platform ready for early access. (PX7071 (Song (Omniome) IHT at 26)).

Response to Finding No. 1611:

Since Dr. Song testified, Omniome was acquired by PacBio for $800 million in July 2021. (RX3533 (Omniome).)

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1612. Depending on the feedback from early access release, [redacted] (PX7071 (Song (Omniome) IHT at 26-27) (*in camera*)).

Response to Finding No. 1612:

Since Dr. Song testified, Omniome was acquired by PacBio for $800 million in July 2021. (RX3533 (Omniome).)

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(3) [redacted]

1613. [redacted] (PX7071 (Song (Omniome) IHT at 15) (*in camera*)).

Response to Finding No. 1613:

Respondents have no specific response.

1614. [redacted] (PX7071 (Song (Omniome) IHT at 22) (*in camera*)).

Response to Finding No. 1614:

The proposed finding is misleading and incomplete. Omniome's sequencer will reportedly have comparable throughput and run times to Illumina's NextSeq sequencers, but with better accuracy—98%> Q50 to 99% Q70—10 to 100x better than the accuracy of Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 82, 100–01); [redacted] Omniome has stated that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72); [redacted] In a recent earnings call,

PacBio CEO Christian Henry claimed that PacBio/Omniome's "error rates are so low, we're more than 15-fold better than what other SBS players can do today". (RX4050 (PacBio) at 7.)

Additionally, to the extent the proposed finding suggests that only high throughput sequencers that are comparable to the NovaSeq may be used for MCED, putative MCED test developers *do* use Illumina's lower throughput NextSeq and MiSeq instruments. For example, Singlera's PanSeer test only requires approximately 2 million sequencing reads per sample, and is compatible with both Illumina's MiSeq or NextSeq systems and Thermo Fisher's Ion Torrent S5 systems, though it appears to primarily use the NextSeq 550Dx system from Illumina. (PFF ¶ 533 (RX3115 (Chen et al., 2020) at 7; RX3637 (Singlera) at 1–6; Gao (Singlera) Tr. 2875, 2894, 2928–29; PX7102 (Gao (Singlera) Dep. at 78); RX3869 (Cote Expert Report) ¶ 239).) Helio currently uses Illumina's MiSeq sequencer for its Helio Liver test. (Chahine (Helio) Tr. 1010-12). Dr. Chahine testified Helio uses the MiSeq because "a smaller machine is more efficient" as a "company in its early stage" prior to "ramp[ing] up." (Chahine (Helio) Tr. 1012).

[redacted] (Rabinowitz (Natera) Tr. 361) (*in camera*)). Respondents also incorporate their responses to CCFF ¶¶ 928 and 1115 herein.

1615. [redacted] (PX7055 (Otte (Freenome) IHT at 121-22) (*in camera*)).

Response to Finding No. 1615:

The proposed finding is inadmissible hearsay and should be accorded little weight.

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1616. [redacted] (PX7121 (Otte (Freenome) Dep. at 63) (*in camera*)).

Response to Finding No. 1616:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1591 herein.

1617. [redacted] (PX7121 (Otte (Freenome) Dep. at 63-64) (*in camera*)).

Response to Finding No. 1617:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1614, which Respondents incorporate herein. Omniome states that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72); [redacted]

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1618. [redacted] (PX7121 (Otte (Freenome) Dep. at 64) (*in camera*)).

Response to Finding No. 1618:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1617, which Respondents incorporate herein.

1619. [redacted] (PX7055 (Otte (Freenome) IHT at 121-22) (*in camera*)).

Response to Finding No. 1619:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1614, which Respondents incorporate herein. The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1620. Freenome's current CEO testified that Freenome determined that "[Omniome (and others) isn't] far enough along and that [it's] ability to meet [Freenome's] requirements, even just the high-level must-have requirements wasn't sufficient[.]" (Nolan (Freenome) Tr. 2741).

Response to Finding No. 1620:

The proposed finding is misleading and inaccurate. Mr. Nolan did not mention any specific company in the answer Complaint Counsel quotes above. The mention of Omniome has been implied into the answer by Complaint Counsel, as evidenced by the brackets. Moreover, Mr. Nolan admitted that, consistent with his IH testimony, *he was not aware that Freenome had evaluated any non-Illumina platform*. (Nolan (Freenome) Tr. 2736–37.) Further, Respondents incorporate their responses to CCFF ¶ 945 herein.

1621. [redacted] (PX7071 (Song (Omniome) IHT at 41-42) (*in camera*)).

Response to Finding No. 1621:

The proposed finding is based on pure speculation and relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. At 275–76). To date, Illumina has not filed any litigation against Omniome.

c) [redacted]

1622. [redacted]

Response to Finding No. 1622:

Respondents have no specific response.

1623. [redacted]

Response to Finding No. 1623:

Respondents have no specific response.

1624. [redacted]

Response to Finding No. 1624:

The proposed finding is vague and misleading. [redacted] (RX2697 (Roche) at 5; PX7074 (Perettie (FMI) Dep. at 110–11); PX7043 (Gunn (Roche) IHT at 164).) [redacted] (PX7043 (Gunn (Roche) IHT at 94).

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1625. [redacted]

Response to Finding No. 1625:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1624, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1626. [redacted]

Response to Finding No. 1626:

Respondents have no specific response.

1627. [redacted]

Response to Finding No. 1627:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1628. [redacted]

Response to Finding No. 1628:

Respondents have no specific response except to note that Roche intends to launch a research use only version of its platform around 2024. (*See* PX7043 (Gunn (Roche) IHT at 93-94) (*in camera*)).

1629. [redacted]

Response to Finding No. 1629:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1624 herein.

1630. [redacted]

Response to Finding No. 1630:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1631. [redacted]

Response to Finding No. 1631:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1632. [redacted]

Response to Finding No. 1632:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1633. [redacted]

Response to Finding No. 1633:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1634. [redacted]

Response to Finding No. 1634:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1624 herein. [redacted] (RX2697 (Roche) at 5; PX7074 (Perettie (FMI) Dep. at 110–11); PX7043 (Gunn (Roche) IHT at 164).) [redacted] (PX7043 (Gunn (Roche) IHT at 94).

1635. [redacted]

Response to Finding No. 1635:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1624 herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1636. [redacted]

Response to Finding No. 1636:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1624 herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1637. [redacted]

Response to Finding No. 1637:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1624 herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1638. [redacted]

Response to Finding No. 1638:

The proposed finding is incomplete and misleading to the extent it suggests that Roche's final per gigabase cost will be the same as what it observes with the prototype instrument, nearly two years before launch. [redacted] (RX2697 (Roche) at 16; PX7043 (Gunn (Roche) IHT at 110).)

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1639. [redacted]

Response to Finding No. 1639:

The proposed finding is incomplete and misleading. [redacted] (RX2697 (Roche/FMI) at 26; PX7074 (Perettie (FMI) Dep. at 115).) Respondents also incorporate their responses to CCFF ¶ 1624 herein. (*See also* PFF ¶¶ 627–628.1, 631.)

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1640. [redacted]

Response to Finding No. 1640:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1639, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1641. [redacted]

Response to Finding No. 1641:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1639, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1642. [redacted]

Response to Finding No. 1642:

Respondents have no specific response except to note that the cited testimony supports the proposition that Roche's NGS platform is likely to compete with Illumina's offerings and establish a nearly 10% market share by 2030. (PFF ¶¶ 627–28.1, 631.)

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1643. [redacted]

Response to Finding No. 1643:

The proposed finding is vague and misleading. [redacted]

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1644. [redacted]

Response to Finding No. 1644:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is irrelevant because it does not relate to MCED tests. [redacted]

[redacted]

Dr. Fiedler also testified that: [redacted] (Fiedler (FMI) Tr. 4471–72.) Further, Respondents incorporate their responses to CCFF ¶ 904 and 1190–91 herein, and refer to Section IV of PFF (PFF ¶¶ 574–678.5), which sets out the extensive upstream competition facing Illumina.

1645. [redacted]

Response to Finding No. 1645:

The proposed finding is incomplete and misleading to the extent it suggests that Roche's final platform accuracy will be the same as what it observes with the prototype instrument, nearly two years before launch. [redacted] (RX2697 (Roche) at 14; PX8447 (Roche) at 19; PX7074 (Perettie (FMI) Dep. at 121–22).) Respondents also note that although [redacted] (RX2697 (Roche) at 15; PX7074 (Perettie (FMI) Dep. at 122, 213).) [redacted] (RX2697 (Roche) at 16; PX7043 (Gunn (Roche) IHT at 110).)

1646. [redacted]

Response to Finding No. 1646:

The proposed finding is incomplete and misleading. In particular, Freenome's current CEO, Mr. Nolan admitted that, consistent with his IH testimony, *he was not aware that Freenome had evaluated any non-Illumina platform*. (Nolan (Freenome) Tr. 2736–37.) Further,

Respondents incorporate their responses to CCFF ¶¶ 945 and 1620 herein. Given the stage of Freenome's putative MCED test development, Freenome could switch platforms without affecting its development timeline. (Cote Tr. 3776, [redacted].)

1647. [redacted] (Chudova (Guardant) Tr. 1225) (*in camera*).

Response to Finding No. 1647:

The proposed finding is misleading. Virtually immediately prior to giving the testimony cited, [redacted] (Chudova (Guardant) Tr. 1225) (in camera). Respondents also incorporate their responses to CCFF ¶ 904 and 927 herein.

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 927 and 2273, which Respondents incorporate herein. Given the stage of [redacted] (Cote Tr. 3776, 3833–34.)

1648. [redacted] (PX7045 (Chudova (Guardant) IHT at 114) (*in camera*)).

Response to Finding No. 1648:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1649. [redacted] (PX2776 (Illumina) at 001 (Email from J. Seaton, Illumina, to F. deSouza, Illumina, Feb. 13, 2018) (*in camera*)).

Response to Finding No. 1649:

The proposed finding is outdated, incomplete and misleading. Although the cited source is from February 2018, the proposed finding appears to suggest that, [redacted]. (RX2697 (Roche) at 9–10.) [redacted]

Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 31), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1650. [redacted] (PX2776 (Illumina) at 001 (Email from J. Seaton, Illumina, to F. deSouza, Illumina, Feb. 13, 2018) (*in camera*)).

Response to Finding No. 1650:

The proposed finding is outdated, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1649, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention, [redacted] (Project "HTP XT"). (RX2697 (Roche) at 9–10.)

1651. [redacted] (PX2776 (Illumina) at 001 (Email from J. Seaton, Illumina, to F. deSouza, Illumina, Feb. 13, 2018) (*in camera*)).

Response to Finding No. 1651:

The proposed finding is outdated, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1649, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention, [redacted] (Project "HTP XT"). (RX2697 (Roche) at 9–10.)

1652. [redacted] (PX2776 (Illumina) at 001 (Email from J. Seaton, Illumina, to F. deSouza, Illumina, Feb. 13, 2018) (*in camera*)).

Response to Finding No. 1652:

The proposed finding is outdated, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1649, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention, [redacted]

[redacted] (Project "HTP XT"). (RX2697 (Roche) at 9–10.)

1653. [redacted] (PX2776 (Illumina) at 001 (Email from J. Seaton, Illumina, to F. deSouza, Illumina, Feb. 13, 2018) (*in camera*)).

Response to Finding No. 1653:

The proposed finding is outdated, incomplete and misleading. Although the cited source is from February 2018, the proposed finding appears to suggest that, even today, more than four years later, the internal emails reflect Illumina's current thinking. [redacted] (Leite (Illumina/InterVenn) Tr. 2127–28; RX3973 (Roche) at 4.)

1654. [redacted] (PX2776 (Illumina) at 001 (Email from J. Seaton, Illumina, to F. deSouza, Illumina, Feb. 13, 2018) (*in camera*)).

Response to Finding No. 1654:

The proposed finding is incomplete and misleading. [redacted] (RX2697 (Roche/FMI) at 26; PX7074 (Perettie (FMI) Dep. at 115).) Respondents also incorporate their responses to CCFF ¶ 1624 herein. (*See also* PFF ¶¶ 627–628.1, 631.)

d) Singular Genomics

1655. Singular is developing an NGS sequencer called the G4 sequencer. (Velarde (Singular Genomics) Tr. 4513).

Response to Finding No. 1655:

Respondents have no specific response.

1656. Singular's target throughput for its sequencer is [redacted] (PX7117 (Velarde (Singular Genomics) Dep. at 48-49) (*in camera*)).

Response to Finding No. 1656:

Respondents have no specific response.

1657. [redacted] (*See* PX7117 (Velarde (Singular Genomics) Dep. at 48-49 (*in camera*)); *see also* PX0085 at 001 (Illumina NovaSeq 6000 System Specifications); *see also* (PX2169 (Illumina) at 025 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*)).

Response to Finding No. 1657:

The proposed finding is misleading. [redacted] The G4 Systems's performance characteristics claim to be comparable to that of Illumina's NextSeq and NovaSeq systems, with read lengths of 50 to 150 bases, targeted 400 Gbs per sequencing run, high speed sequencing at 4–minute cycle times and high accuracy of 99.7% on 150 base reads. (PFF ¶ 783.1; PX8561 (Singular) at 4–5; [redacted]

Additionally, to the extent the proposed finding suggests that only high throughput sequencers that are comparable to the NovaSeq may be used for MCED, putative MCED test developers *do* use Illumina's lower throughput NextSeq and MiSeq instruments. For example,

Singlera's PanSeer test only requires approximately 2 million sequencing reads per sample, and is compatible with both Illumina's MiSeq or NextSeq systems and Thermo Fisher's Ion Torrent S5 systems, though it appears to primarily use the NextSeq 550Dx system from Illumina. (PFF ¶ 533 (RX3115 (Chen et al., 2020) at 7; RX3637 (Singlera) at 1–6; Gao (Singlera) Tr. 2875, 2894, 2928–29; PX7102 (Gao (Singlera) Dep. at 78); RX3869 (Cote Expert Report) ¶ 239).) Helio currently uses Illumina's MiSeq sequencer for its Helio Liver test. (Chahine (Helio) Tr. 1010-12). Dr. Chahine testified Helio uses the MiSeq because "a smaller machine is more efficient" as a "company in its early stage" prior to "ramp[ing] up." (Chahine (Helio) Tr. 1012).

[redacted] (Rabinowitz (Natera) Tr. 361) (*in camera*)). Respondents also incorporate their responses to CCFF ¶¶ 928 and 1115 herein.

1658. [redacted] (Velarde (Singular Genomics) Tr. 4549-50 (*in camera*)).

Response to Finding No. 1658:

The proposed finding is misleading and incomplete. While Mr. Velarde admitted the statements in Singular's S-1 that Complaint Counsel identified (of which the proposed finding is one), Mr. Velarde also confirmed that [redacted]

[redacted] (Velarde (Singular) Tr. 4514, 4569–70.)

1659. [redacted] (Velarde (Singular Genomics) Tr. 4545 (*in camera*)).

Response to Finding No. 1659:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1658, which Respondents incorporate herein.

1660. [redacted] (Velarde (Singular Genomics) Tr. 4545 (*in camera*)).

Response to Finding No. 1660:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1658, which Respondents incorporate herein.

1661. Singular identified as a risk to its investors that "we may not be able to generate sufficient revenue to achieve and maintain profitability." (PX0068 at 023 (Singular Genomics S-1, May 2021)).

Response to Finding No. 1661:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1658, which Respondents incorporate herein.

1662. [redacted] (Velarde (Singular Genomics) Tr. 4552 (*in camera*)).

Response to Finding No. 1662:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1658, which Respondents incorporate herein. [redacted] (Velarde (Singular) Tr. 4514, 4569–70.)

1663. [redacted] (Velarde (Singular Genomics) Tr. 4552 (*in camera*)).

Response to Finding No. 1663:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1658, which Respondents incorporate herein. [redacted] (Velarde (Singular) Tr. 4514, 4569–70.)

1664. [redacted] (Velarde (Singular Genomics) Tr. 4555 (*in camera*)).

Response to Finding No. 1664:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1658, which Respondents incorporate herein. [redacted] (Velarde (Singular) Tr. 4514, 4569–70.)

1665. Singular identified as a risk to its investors that "our limited operating history makes it difficult to evaluate our future prospects." (PX0068 at 023 (Singular Genomics S-1, May 2021)).

Response to Finding No. 1665:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1658, which Respondents incorporate herein.

1666. Singular identified as a risk to its investors that "we may require substantial additional funding." (PX0068 at 035 (Singular Genomics S-1, May 2021)).

Response to Finding No. 1666:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1658, which Respondents incorporate herein. [redacted]

1667. Singular identified as a risk to its investors that if it is unable to obtain additional funding, it may be required "to delay, scale back, or cease our product development or commercialization activities." (PX0068 at 035 (Singular Genomics S-1, May 2021)).

Response to Finding No. 1667:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1658, which Respondents incorporate herein. [redacted]

1668. Singular represented to investors that "[i]f we are sued for infringing, misappropriating or otherwise violating intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates." (PX0068 at 045 (Singular Genomics S-1, May 2021)).

Response to Finding No. 1668:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1658, which Respondents incorporate herein.

1669. Singular represented to investors that it "expect[s] to be exposed to, or threatened with, future litigation by third parties, including our primary competitors, who have patent and other intellectual property rights and may allege that our research and development activities, products, manufacturing methods, software and/or technologies infringe, misappropriate or otherwise violate their intellectual property rights." (PX0068 at 046 (Singular Genomics S-1, May 2021)).

Response to Finding No. 1669:

The proposed finding is incomplete, and misleading for the reasons explained in

Respondents' responses to CCFF ¶ 1658, which Respondents incorporate herein.

1670. Singular represented to investors that it "expect[s] that [it's] competitors will, in connection with our launch of our G4 Integrated Solution and our planned PX Integrated Solution and later stage product offerings assert that we are infringing, or have in the past infringed, as part of our research and development activities, their patent and other intellectual property rights and that we are employing their proprietary technology without authorization." (PX0068 at 046 (Singular Genomics S-1, May 2021)).

Response to Finding No. 1670:

The proposed finding is incomplete, and misleading for the reasons explained in

Respondents' responses to CCFF ¶ 1658, which Respondents incorporate herein.

1671. Singular represented to investors that as a result of another company initiating a patent lawsuit against Singular upon launch of its NGS sequencer, "[w]e could also be required to obtain a license to such patents in order to continue the development and commercialization of the infringing product or technology" which "may require substantial payments or cross-licenses" and "have a material adverse effect on our business, financial condition, results of operation or prospects." (PX0068 at 046 (Singular Genomics S-1, May 2021)).

Response to Finding No. 1671:

The proposed finding is incomplete, and misleading for the reasons explained in

Respondents' responses to CCFF ¶ 1658, which Respondents incorporate herein.

1672. [redacted]
(Velarde (Singular Genomics) Tr. 4548 (*in camera*)).

Response to Finding No. 1672:

The proposed finding is incomplete, and misleading for the reasons explained in

Respondents' responses to CCFF ¶ 1658, which Respondents incorporate herein.

1673. [redacted]
(Velarde (Singular Genomics) Tr. 4549 (*in camera*)).

Response to Finding No. 1673:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1658, which Respondents incorporate herein.

1674. [redacted] (Velarde (Singular Genomics) Tr. 4548 (*in camera*)).

Response to Finding No. 1674:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1658, which Respondents incorporate herein.

1675. [redacted] (Velarde (Singular Genomics) Tr. 4548-49 (*in camera*)).

Response to Finding No. 1675:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1658, which Respondents incorporate herein. Respondents also note that Singular commercially launched its G4 instrument in 2021. (PFF ¶ 607; Velarde (Singular) Tr. 4515–16, 4522; *see also* PX8561 (Singular) at 1–2; PX7117 (Velarde (Singular) Dep. at [redacted]–31).)

1676. [redacted] (Velarde (Singular Genomics) Tr. 4549 (*in camera*)).

Response to Finding No. 1676:

Respondents have no specific response.

1677. [redacted] (PX7058 (Conroy (Exact) IHT at 127) (*in camera*)).

Response to Finding No. 1677:

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1678. [redacted] (Conroy (Exact) Tr. 1754 (*in camera*)).

Response to Finding No. 1678:

Respondents have no specific response.

1679. [redacted] (PX7058 (Conroy (Exact) IHT at 127 (*in camera*)).

Response to Finding No. 1679:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929 and 1657–58, which Respondents incorporate herein. Respondents also note that Mr. Conroy also testified that [redacted] (Conroy (Exact/Thrive) Tr. 1756–57). Respondents also note that the CEO of Singular Genomics, Dave Daly, is the former CEO of Thrive. (RX3835 (Daly (Singular/Thrive) Dep. at 13–14).) (showing that Daly was CEO of Thrive)

1680. [redacted] (PX7058 (Conroy (Exact) IHT at 127-28 (*in camera*)).

Response to Finding No. 1680:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929, 1657–58 and 1679 herein.

The G4 Systems's performance characteristics claim to be comparable to that of Illumina's NextSeq and NovaSeq systems, with read lengths of 50 to 150 bases, targeted 400 Gbs per sequencing run, high speed sequencing at 4–minute cycle times and high accuracy of 99.7% on 150 base reads. (PFF ¶ 783.1; PX8561 (Singular) at 4–5; [redacted]

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1681. [redacted] (PX7058 (Conroy (Exact) IHT at 129) (*in camera*)).

Response to Finding No. 1681:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929, 1657–58, 1679 herein.

Mr. Conroy also did not describe any so-called technological hurdles that are faced by Singular. To the contrary, Singular Genomics's G4 sequencer is reportedly [redacted] (PFF ¶ 609-609.6.)

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1682. [redacted] (Conroy (Exact) Tr. 1760 (*in camera*)).

Response to Finding No. 1682:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929, 1657–58, 1679 and 1682 herein.

[redacted] The G4 Systems's performance characteristics claim to be comparable to that of Illumina's NextSeq and NovaSeq systems, with read lengths of 50 to 150 bases, targeted 400 Gbs per sequencing run, high speed sequencing at 4–minute cycle times and high accuracy of 99.7% on 150 base reads. (PFF ¶ 783.1; PX8561 (Singular) at 4–5; [redacted]

[redacted]

Third, switching is unlikely to impact Exact/Thrive's development timeline. [redacted] RX3419 (Lennon et al., 2020) at 18; RX3772 (Cohen 2018 Supplementary Material) at 2–3.) [redacted] (PFF ¶ 441; Conroy (Exact/Thrive) Tr. 1709,

1717; [redacted]

1683. Mr. Michael Nolan of Freenome testified that [redacted] (PX7094 (Nolan (Freenome) Dep. at 168-69) (*in camera*)).

Response to Finding No. 1683:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945, 1658, 1679 and 1682 herein. At trial, Mr. Nolan admitted that, consistent with his IH testimony, *he was not aware that Freenome had evaluated any non-Illumina platform*. (Nolan (Freenome) Tr. 2736–37.)

From a technical perspective, there is no reason why Freenome could not switch to Singular. (*See* RRFF ¶ 1682). Similarly, Singular has developed a framework to allow test developers to switch. (*See* RRFF ¶ 1682). Further, [redacted] (*See* RRFF ¶¶ 945 and 2355.)

e) [redacted]

1684. [redacted]

Response to Finding No. 1684:

The proposed finding is misleading and incomplete. [redacted]

Respondents also incorporate their responses to CCFF ¶ 1115 herein.

1685. As of June 2021, Ultima hopes to [redacted]

Response to Finding No. 1685:

Respondents have no specific response.

1686. [redacted]

Response to Finding No. 1686:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

1687. [redacted]

Response to Finding No. 1687:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1686, which Respondents incorporate herein.

1688. [redacted]

Response to Finding No. 1688:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1686, which Respondents incorporate herein.

1689. [redacted]

Response to Finding No. 1689:

The proposed finding is irrelevant [redacted] (*See* RRFF ¶ 1684.)

1690. [redacted]

Response to Finding No. 1690:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1686, which Respondents incorporate herein.

1691. [redacted]

Response to Finding No. 1691:

The proposed finding is incomplete and misleading. [redacted] (PX7119 (Lauer (Ultima) Dep. at 46, 94–95).) Furthermore, [redacted] (*See*, e.g., RX2703 (Roche) at 1, 4, 6); PX7074 (Perettie (FMI) Dep. at 106–09).) [redacted] (RX2705 (Roche/FMI) at 2.) [redacted]

[redacted] (PX7074 (Perettie (FMI) Dep. at 93–94).) [redacted]

[redacted] (RX2707 (Roche/FMI) at 8.)

Respondents also incorporate their responses to CCFF ¶ 1686 herein.

1692. [redacted]

Response to Finding No. 1692:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1686 and 1691, which Respondents incorporate herein.

1693. [redacted]

Response to Finding No. 1693:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1686 and 1691, which Respondents incorporate herein.

1694. [redacted]

Response to Finding No. 1694:

Respondents have no specific response.

1695. [redacted] (PX6082 (Grail Responses & Objections to FTC Requests for Admissions) at 7 (RFA No. 3) (*in camera*)).

Response to Finding No. 1695:

The proposed finding is irrelevant because Ultima is in "stealth mode". (*See* RRFF ¶ 1684.)

1696. [redacted]

Response to Finding No. 1696:

The proposed finding is misleading and incomplete. [redacted] (PX7074 (Perettie (FMI) Dep. at 93–94).) [redacted] (RX2707 (Roche/FMI) at 8.) [redacted]; PX7068 (Perettie (FMI) IHT at 60–64).) [redacted]

1697. [redacted]

Response to Finding No. 1697:

Respondents have no specific response.

1698. [redacted] (Chudova (Guardant) Tr. 1225 (*in camera*))).

Response to Finding No. 1698:

The proposed finding is misleading and inaccurate. [redacted]

[redacted] (PX7119 (Lauer (Ultima) Dep. at 28–29, 43–45).) Respondents also incorporate their responses to CCFF ¶¶ 1686 and 1691 herein.

1699. [redacted] (Chudova (Guardant) Tr. 1226-27 (*in camera*)).

Response to Finding No. 1699:

Respondents have no specific response.

f) [redacted]

1700. [redacted]

Response to Finding No. 1700:

Respondents have no specific response.

1701. [redacted]

Response to Finding No. 1701:

Respondents have no specific response.

1702. [redacted]

Response to Finding No. 1702:

Respondents have no specific response.

1703. [redacted]

Response to Finding No. 1703:

Respondents have no specific response except to note that Dr. He also testified that [redacted] (PX7124 (He (Element) Dep. at 26.)

1704. [redacted]

Response to Finding No. 1704:

The proposed finding is incomplete and misleading. Dr. He also testified that [redacted] (PX7124 (He (Element) Dep. at 126); RX0003 (Element); RX0008 (Element); RX0009 (Element); RX0007 (Element) at 19.) Respondents also incorporate their responses to CCFF ¶ 1703.

1705. [redacted]

Response to Finding No. 1705:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1703–1704, which Respondents incorporate herein.

1706. [redacted]

Response to Finding No. 1706:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1703–1704, which Respondents incorporate herein.

1707. [redacted]

Response to Finding No. 1707:

The proposed finding is incomplete and misleading. [redacted] (PX7124 (He (Element) Dep. at 64–65).)

Respondents also incorporate their responses to CCFF ¶¶ 1703–1704 herein.

1708. [redacted]

Response to Finding No. 1708:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1703–1704 and 1707, which Respondents incorporate herein.

1709. [redacted]

Response to Finding No. 1709:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1703–1704 and 1707, which Respondents incorporate herein.

1710. [redacted]

[redacted]

Response to Finding No. 1710:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1703–1704 and 1707, which Respondents incorporate herein.

1711. [redacted]

Response to Finding No. 1711:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1703–1704 and 1707, which Respondents incorporate herein.

1712. [redacted]

Response to Finding No. 1712:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1703–1704 and 1707, which Respondents incorporate herein.

1713. [redacted]

Response to Finding No. 1713:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1703–1704 and 1707, which Respondents incorporate herein.

1714. [redacted]

Response to Finding No. 1714:

The proposed finding is incomplete and misleading. Dr. He also testified that [redacted] Respondents also incorporate their responses to CCFF ¶¶ 1703–1704 and 1707 herein.

1715. [redacted]

Response to Finding No. 1715:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1703–1704 and 1707, which Respondents incorporate herein.

1716. [redacted]

Response to Finding No. 1716:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1703–1704 and 1707, which Respondents incorporate herein.

1717. [redacted]

Response to Finding No. 1717:

The proposed finding is incomplete and misleading. [redacted] Respondents also incorporate their responses to CCFF ¶¶ 1703–1704 and 1707 herein.

1718. [redacted] (Chudova (Guardant) Tr. 1225 (*in camera*)).

Response to Finding No. 1718:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1703–1704 and 1707 herein.

1719. [redacted] (Chudova (Guardant) Tr. 1226-27) (*in camera*).

Response to Finding No. 1719:

Respondents have no specific response.

1720. [redacted] (PX7055 (Otte (Freenome) IHT at 121-22) (*in camera*)).

Response to Finding No. 1720:

Respondents have no specific response.

1721. [redacted] (PX7055 (Otte (Freenome) IHT at 121-22) (*in camera*)).

Response to Finding No. 1721:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1703–1704 and 1707 herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1722. [redacted] (PX7121 (Otte (Freenome) Dep. at 65) (*in camera*)).

Response to Finding No. 1722:

The proposed finding is incomplete and misleading and relies on inadmissible hearsay. [redacted] (PX7124 (He (Element) Dep. at 61–62, 64.)) Respondents also incorporate their responses to CCFF ¶¶ 1703–1704 and 1707 herein.

1723. [redacted]

Response to Finding No. 1723:

The proposed finding is misleading and inaccurate. Mr. Nolan did not mention any specific company in the answer Complaint Counsel quotes above. The mention of Element has been implied into the answer by Complaint Counsel, as evidenced by the brackets. Moreover, Mr. Nolan admitted that, consistent with his IH testimony, *he was not aware that Freenome had evaluated any non-Illumina platform*. (Nolan (Freenome) Tr. 2736–37.) Further, Respondents incorporate their responses to CCFF ¶ 945 herein.

g) No Other NGS Platforms in Development Is Likely to Replace Illumina

1724. Dr. Vogelstein testified that although "[t]here may be other companies that are developing sequencing platforms . . . [,] the only effective platform today is Illumina's platform." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 67-68)).

Response to Finding No. 1724:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 904, 928, 1293, 1614, 1624, 1649, 1658, 1679, 1686, 1691, 1703–1704 and 1709 herein. Dr. Vogelstein, the founder of Thrive stated, [redacted] (Lengauer (Exact/Thrive) Tr. 238–40.)

Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1725. [redacted] (Conroy (Exact) Tr. 1582 (*in camera*)).

Response to Finding No. 1725:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not.

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1682 and 1724, which Respondents incorporate herein.

[redacted] (Lengauer (Exact/Thrive) Tr. 190–91; PX8572 (Exact/Thrive) at 135–39; PX7110 (Conroy (Exact/Thrive) Dep. at 33).) [redacted] (Lengauer (Exact/Thrive) Tr. 215; PX8572 (Exact/Thrive) at 48; RX3869 (Cote Expert Report) ¶ 183.)

Moreover, [redacted] (PX7085 (Harada (Exact/Thrive) Dep. at 239); PX7091 (Lengauer (Exact/Thrive) Dep. at 38, 106).) [redacted] (PX7091 (Lengauer (Exact/Thrive) Dep. at 41–42).) However, [redacted] (RX3869 (Cote Expert Report) ¶ 340.)

In addition to Singular (*see* RRFF ¶ 1682), other sequencing alternatives that are available to Exact/Thrive include BGI, Thermo Fisher and Oxford Nanopore. As noted in RRFF ¶ 1724, CancerSEEK can be performed using BGI's sequencing platform. While Singular, Thermo Fisher and Oxford Nanopore are all currently available in the United States (PFF ¶¶ 607 ((Velarde (Singular) Tr. 4515–16, 4522; see also PX8561 (Singular) at 1–2; PX7117 (Velarde (Singular) Dep. at 30–31)), 579 (RX3688 (Thermo Fisher); RX3689 (Thermo Fisher); RX3687 (Thermo Fisher); RX3685 (Thermo Fisher)), 599 (RX3913 (ONT,) at 1–5; RX3543 (ONT) at 1;

RX3536 (ONT); RX3542 (ONT)), BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.)

Further, Respondents incorporate their responses to CCFF ¶ 929 and 1724 herein.

1726. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 117-18) (*in camera*)).

Response to Finding No. 1726:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929, 1682 and 1724–25, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1727. Mr. Nolan testified that "with the information I have today, I don't know of a suitable substitute [for Illumina's NGS platform] anywhere on the near or midterm horizon." (Nolan (Freenome) Tr. 2729).

Response to Finding No. 1727:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945 and 1724 herein. Mr. Nolan also admitted that,

consistent with his IH testimony, he was not aware that Freenome had evaluated any non-Illumina platform. (Nolan (Freenome) Tr. 2736–37).

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1728. Guardant's Mr. Getty testified at trial that Guardant cannot run its MCED test on non-Illumina NGS platforms like those from companies currently developing NGS sequencing platforms. (Getty (Guardant) Tr. 2688).

Response to Finding No. 1728:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927–28 and 1724 herein. Mr. Getty admitted that Thermo Fisher Scientific Inc., and other companies developing next-generation sequencing platforms also provide NGS platforms that could be used for liquid biopsy testing. (Getty (Guardant) Tr. 2642.)

[redacted]

[redacted] Dr. Chudova also stated that Guardant could use alternative sequencing platforms for its LUNAR-2 screening test in development that meet the throughput, error, time, and sequencing cost requirements. (PX7045 (Chudova (Guardant) IHT at 44–47.) BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony

and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1729. Mr. Nolan testified that switching to an alternative to Illumina's NGS platform, "within three years . . . would be highly unlikely, and I'm not sure if it's even, you know -- when it would be possible after that." (Nolan (Freenome) Tr. 2729-30).

Response to Finding No. 1729:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945, 1140 and 1724 herein. Mr. Nolan admitted that, consistent with his IH testimony, he was not aware that Freenome had evaluated any non-Illumina platform. (Nolan (Freenome) Tr. 2736–37).

In particular, [redacted]

BGI also markets its NGS technology in many other countries and is expected to enter the U.S. market in the near future. [redacted]; RX3869 (Cote Expert Report) ¶ 287; [redacted].) BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Furthermore, switching between Illumina's platform and alternative platforms is feasible and would not delay the MCED test' development timeline. (*See* PFF ¶¶ 645–674.)

1730. [redacted] (PX7055 (Otte (Freenome) IHT at 74) (*in camera*)).

Response to Finding No. 1730:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945, 1140 and 1724 herein.

[redacted]; RX3869 (Cote Expert Report) ¶ 287; [redacted].) BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1731. [redacted] (Rabinowitz (Natera) Tr. 341 (*in camera*)).

Response to Finding No. 1731:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 1293 and 1724 herein.

Natera and BGI Genomics formed a partnership to commercialize Natera's Signatera NGS-based cancer monitoring test on BGI's DNBSEQ platform in China, and has now launched a version of the Signatera test in China "that incorporates MGI sequencing platforms." [redacted] RX3062 (BGI) at 1.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

[redacted] (RX3869 (Cote Expert Report) ¶ 227; [redacted]

[redacted] the last time Natera mentioned anything related to early-detection appears to be 2017 ((RX3495 (Natera) at 7 (discussing exploring breast and ovarian cancer screening); RX3491 (Natera) at 18.) and Natera's CEO has publicly stated that "[Natera is] ***not focused on asymptomatic cancers strain or early detection.***" (RX3492 (Natera) at 6.) Respondents also incorporate their responses to CCFF ¶¶ 928, 965, 1099, 1269 and 1293 herein.

4. Even if Another NGS Platform Entered the U.S. Market Comparable to Illumina's Current Platform, Illumina Plans to Continue to Improve its Existing Platform

1732. [redacted] (Aravanis (Illumina) Tr. 1794 (*in camera*); deSouza (Illumina) Tr. 2270-2271 (*in camera*); PX2169 (Illumina) at 024 (Illumina Strategic Plan 2021-2025, Oct. 23, 2020) (*in camera*); PX5026 (Illumina) at 009 (FY20-25 Strategic Plan Initial Revenue Discussion, Jun. 4, 2020) (*in camera*)).

Response to Finding No. 1732:

Complaint Counsel did not present the exhibit PX5026 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 54), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also incorporate their responses to CCFF ¶ 1044 herein.

1733. [redacted] (*in camera*)).

Response to Finding No. 1733:

Respondents have no specific response except to note that BGI's highest throughput instrument, the DNBSEQ-T10, has a higher reported throughput (20 Tb per day) than the highest performance instrument and flow cell currently offered by Illumina, the NovaSeq 6000 with the S4 flow cell (up to 6 Tb/run), [redacted]

[redacted] (PFF ¶ 592; *compare* RX4004 (MGI Tech) at 1–2 *with* RX3357 (Illumina) at 7; [redacted]

Complaint Counsel did not present the exhibit RX1254 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (RC Exhibit Index at 64), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also incorporate their responses to CCFF ¶ 1045 herein.

1734. [redacted] (Aravanis (Illumina) Tr. 1797; PX6056 (Illumina) at 017 (Illumina, Narrative Response of Illumina, Inc. to the Second Request, Mar. 1, 2021) (*in camera*) [redacted]; RX1254 (Illumina) at 010 (*in camera*) [redacted]); PX2558 (Illumina) at 005 (Board of Directors Executive Session, Feb. 9, 2021) (*in camera*) [redacted]; PX2169 (Illumina) at 025 (Illumina Strategic Plan 2021 - 2025, Oct. 23, 2020) (*in camera*) [redacted]).

Response to Finding No. 1734:

Respondents have no specific response except to note that [redacted] (deSouza (Illumina) Tr. 2301 (in camera)). Furthermore, [redacted]

(RX1600 (Illumina) at 19, 25; Cote Tr. 3743–44; RX3869 (Cote Expert Report) ¶ 287.)

Respondents also note that BGI announced that its DNBSEQ-T10×4RS sequencers can generate $100 genomes, making it per Gb cost only $1.00. (PFF ¶ 594.2; RX4004 (MGI); *see*

also deSouza (Illumina) Tr. 2331 ("Last year, BGI announced its hundred-dollar genome and has talked about its T-10 being ready to be deployed around the world").

Complaint Counsel did not present the exhibit RX1254 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (RC Exhibit Index at 64), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also incorporate their responses to CCFF ¶¶ 1044–46 herein.

1735. [redacted] (Aravanis (Illumina) Tr. 1799 (*in camera*); PX2612 (Illumina) at 013 [redacted] (*in camera*)).

Response to Finding No. 1735:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1734 herein.

1736. [redacted] (deSouza (Illumina) Tr. 2301 (*in camera*)).

Response to Finding No. 1736:

Respondents have no specific response.

1737. [redacted] (PX2558 (Illumina) at 005-006 (Board of Directors Executive Session, Feb. 9, 2021) (*in camera*); PX2560 (Illumina) at 007 [redacted] **(*in camera*).** [redacted] (Aravanis (Illumina) Tr. 1800) (*in camera*)).

Response to Finding No. 1737:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1734 herein. Respondents also note that other NGS platform developers are also working to

reduce their sequencing prices. For example, BGI announced that its DNBSEQ-T10×4RS sequencers can generate $100 genomes, making it per Gb cost only $1.00. (PFF ¶ 594.2; RX4004 (MGI); *see also* deSouza (Illumina) Tr. 2331 ("Last year, BGI announced its hundred-dollar genome and has talked about its T-10 being ready to be deployed around the world"). Oxford Nanopore's PromethION sequencer is reported to have sequencing costs of as low as $2.55 per gigabase. (*See* PFF ¶¶ 603–603.3.) [redacted] (RX2697 (Roche) at 16; PX7043 (Gunn (Roche) IHT at 110).)

1738. [redacted] (Aravanis (Illumina) Tr. 1788, 1797-1798) (*in camera*)).

Response to Finding No. 1738:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1734, 1737 and 1739 herein.

1739. [redacted] (Aravanis (Illumina) Tr. 1788; PX2595 (Illumina) at 005 (Board of Directors Executive Session, Feb. 9, 2021) (*in camera*)).

Response to Finding No. 1739:

The proposed finding is incomplete, and misleading for the reasons explained in CCFF ¶¶ 928, 1115, 1118, 1734 and 1737 herein. BGI's second highest throughput instrument, the DNBSEQ-T7, is reported to simultaneously sequence 20 billion DNA fragments in less than 24 hours, which is less than the 45 hours required for the NovaSeq to sequence the same number of fragments. (PFF ¶ 590.) BGI's highest throughput instrument, the DNBSEQ-T10, is reported to simultaneously sequence 80 billion DNA fragments in less than 24 hours. (PFF ¶ 590.) Oxford Nanopore states that its highest throughput instrument, PromethION, has a higher throughput

than the highest performance instrument and flow cell currently offered by Illumina, the NovaSeq 6000 with the S4 flow cell. (RX3543 (ONT); RX1205 (Illumina); RX3869 (Cote Expert Report) ¶ 294.) (*See also* PFF ¶¶ 287, 294.)

1740. [redacted] (PX2595 (Illumina) at 005 (Board of Directors Executive Session, Feb. 9, 2021) (*in camera*)).

Response to Finding No. 1740:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1734, 1737 and 1739 herein. BGI's highest throughput instrument, the DNBSEQ-T10, is reported to simultaneously sequence 80 billion DNA fragments in less than 24 hours. (PFF ¶ 590.)

1741. [redacted] (Aravanis (Illumina) Tr. 1799 (*in camera*); PX2169 (Illumina) at 025, 028 (Illumina Strategic Plan 2021-2025, Oct. 23, 2020) (*in camera*) [redacted].

Response to Finding No. 1741:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1734, 1737 and 1739 herein. While [redacted] (PX2595 (Illumina) at 005 (Board of Directors Executive Session, Feb. 9, 2021) (*in camera*)), BGI's highest throughput instrument, the DNBSEQ-T10, is reported to simultaneously sequence 80 billion DNA fragments in less than 24 hours. (PFF ¶ 590.)

1742. [redacted] (RX1254 (Illumina) at 014 [redacted] (*in camera*)). [redacted]

[redacted] (RX1254 (Illumina) at 014 [redacted] (*in camera*)).

Response to Finding No. 1742:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1734, 1737 and 1739 herein.

1743. [redacted] (*in camera*)).

Response to Finding No. 1743:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1734, 1737 and 1739 herein.

1744. [redacted] (Aravanis (Illumina) Tr. 1799-1800) (*in camera*); PX6056 (Illumina) at 017 (Illumina, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*); RX1254 (Illumina) at 018 [redacted] (*in camera*); PX5026 (Illumina) at 009 (FY20-25 Strategic Plan Initial Revenue Discussion, Jun. 4, 2020 [redacted] (*in camera*)); PX2581 (Illumina) at 001, 003 [redacted] (*in camera*); PX7072 (deSouza (Illumina) IHT at 247) (*in camera*)).

Response to Finding No. 1744:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1734, 1737 and 1739 herein.

1745. [redacted] (PX2560 (Illumina) at 004-005 [redacted] (*in camera*); PX2558 (Illumina) at 006, 008 (Board of Directors Executive Session, Feb. 9, 2021) (*in camera*); *see* PX7107 (deSouza (Illumina) Dep. at 271) (*in camera*)).

Response to Finding No. 1745:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1734, 1737 and 1739 herein.

1746. [redacted] (RX1994 (Illumina) at 023, 025 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching "Illumina Strategic Plan 2021 - 2025," Nov. 5, 2020) (*in camera*)). [redacted] (RX1994 (Illumina) at 025 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching "Illumina Strategic Plan 2021 - 2025," Nov. 5, 2020) (*in camera*)).

Response to Finding No. 1746:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1734, 1737 and 1739 herein. Respondents also note that other NGS platform developers are also working to reduce their sequencing prices. For example, BGI announced that its DNBSEQ-T10×4RS sequencers can generate $100 genomes, making it per Gb cost only $1.00. (PFF ¶ 594.2; RX4004 (MGI); *see also* deSouza (Illumina) Tr. 2331 ("Last year, BGI announced its hundred-dollar genome and has talked about its T-10 being ready to be deployed around the world").

1747. [redacted] (Aravanis (Illumina) Tr. 1801).

Response to Finding No. 1747:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1734, 1737 and 1739 herein.

1748. [redacted] (PX7107 (deSouza (Illumina) Dep. at 277-78) (*in camera*)).

Response to Finding No. 1748:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1734, 1737 and 1739 herein.

1749. [redacted]

(RX1254 (Illumina) at 013 [redacted] (*in camera*)).

Response to Finding No. 1749:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (Respondents' Exhibit Index at 64), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1750. [redacted] (***in camera***)). (RX1254 (Illumina) at 013 [redacted]

Response to Finding No. 1750:

Respondents have no specific response except to note that [redacted] Conroy (Exact/Thrive) Tr. 1583; Chudova (Guardant) Tr. 1196; Nolan (Freenome) Tr. 2715; PX7112 (Bailey (PGDx) Dep. at 107).)

1751. [redacted] (RX1254 (Illumina) at 029 [redacted] (*in camera*)).

Response to Finding No. 1751:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1750 herein. Respondents also note that the proposed finding is in contravention of the parties' agreement because it mentions Caris. (*See* Feb. 16, 2022 Order Granting Feb. 9, 2022 Joint Stipulation to Exclude Caris-Related Materials from the Record.)

1752. [redacted] (*in camera*)).

Response to Finding No. 1752:

The proposed finding is incomplete. Mr. deSouza clarified that [redacted] (deSouza (Illumina) Tr. 2276–77.)

Respondents also note that other NGS platform developers are also working to reduce their sequencing prices. For example, BGI announced that its DNBSEQ-T10×4RS sequencers can generate $100 genomes, making it per Gb cost only $1.00. (PFF ¶ 594.2; RX4004 (MGI); *see also* deSouza (Illumina) Tr. 2331 ("Last year, BGI announced its hundred-dollar genome and has talked about its T-10 being ready to be deployed around the world"). Respondents also incorporate their responses to CCFF ¶¶ 1734, 1737 and 1739 herein.

1753. [redacted] (*in camera*)).

Response to Finding No. 1753:

The proposed finding is incomplete and misleading. RX1254 was prepared before the Open Offer issued in March 2021. The Open Offer requires Illumina to provide customers with the same access to purchase sequencing instruments and core consumables that GRAIL or any other For-Profit Entity has within 5 days of when GRAIL or such For-Profit Entity receives access. (PFF ¶ 1007; Berry (Illumina) Tr. 878–79; deSouza (Illumina) Tr. 2434–35, 2437–38; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) The Open Offer also requires Illumina to give customers access to purchase any Pre-Release Sequencing Products to which GRAIL or any For-Profit Entity is offered access within 5 days of when GRAIL or such For-Profit Entity is offered access. (PFF ¶ 1008; [redacted] Berry (Illumina) Tr. 702; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) Respondents also incorporate their responses to CCFF ¶¶ 1734, 1737 and 1739 herein.

1754. [redacted] (PX7123 (Fellis (Illumina) Dep. at 29) (*in camera*)).

Response to Finding No. 1754:

Respondents have no specific response.

1755. [redacted] (deSouza (Illumina) Tr. 2273-2274 (*in camera*); PX2334 (Illumina) at 003 (Email from A. Aravanis, Illumina, to F. deSouza, Illumina, attaching "Factory Sequencing Roadmap," Nov. 4, 2020) (*in camera*)).

Response to Finding No. 1755:

Respondents have no specific response.

1756. [redacted] (deSouza (Illumina) Tr. 2273 (*in camera*); PX2334 (Illumina) at 003 (Email from A. Aravanis, Illumina, to F. deSouza, Illumina, attaching "Factory Sequencing Roadmap," Nov. 4, 2020) (*in camera*)).

Response to Finding No. 1756:

Respondents have no specific response except to note [redacted].

1757. [redacted] (deSouza (Illumina) Tr. 2273-74 (*in camera*)).

Response to Finding No. 1757:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 1734, 1737 and 1739 herein.

1758. [redacted] (deSouza (Illumina) Tr. 2277-2278 (*in camera*)).

Response to Finding No. 1758:

Respondents have no specific response.

1759. [redacted] (deSouza (Illumina) Tr. 2269-2270 (*in camera*)).

Response to Finding No. 1759:

Respondents have no specific response.

1760. [redacted] (deSouza (Illumina) Tr. 2277-2278 (*in camera*)).

Response to Finding No. 1760:

Respondents have no specific response except to note it is possible to run IVD assays on the RUO side, not Dx, of an Illumina NGS platform. (Leite (Illumina/InterVenn) Tr. 2160.)

1761. [redacted] (deSouza (Illumina) Tr. 2277-2279 (*in camera*); PX2853 (Illumina) at 001, 004 (Email from E. Milsovic, Illumina, to F. deSouza, Illumina, attaching "Executive Session," May 2, 2021) (*in camera*)).

Response to Finding No. 1761:

Respondents have no specific response.

1762. [redacted]
(deSouza (Illumina) Tr. 2277-2279; PX2853 (Illumina) at 001, 004 (Email from E. Milsovic, Illumina, to F. deSouza, Illumina, attaching "Executive Session," May 2, 2021) (*in camera*)).

Response to Finding No. 1762:

Respondents have no specific response.

1763. [redacted]
(deSouza (Illumina) Tr. 2277-2279 (*in camera*); PX2853 (Illumina) at 004 (Email from E. Milsovic, Illumina, to F. deSouza, Illumina, attaching "Executive Session," May 2, 2021) (*in camera*)).

Response to Finding No. 1763:

The proposed finding is incomplete and misleading. When questioned about the language quoted above, Mr. deSouza testified that [redacted] (deSouza (Illumina) Tr. 2280.)

1764. According to Illumina's Strategic Plan, [redacted] (RX1994 (Illumina) at 025 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching "Illumina Strategic Plan 2021 - 2025," Nov. 5, 2020) (*in camera*) (*see* inset image).

[redacted]

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (Respondents' Exhibit Index at 92), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1765. [redacted] (RX1994 (Illumina) at 029 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching "Illumina Strategic Plan 2021 - 2025," Nov. 5, 2020) (*in camera*)).

Response to Finding No. 1765:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (Respondents' Exhibit Index at 92), or in any deposition, and

therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1766. [redacted] (RX1994 (Illumina) at 029 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching "Illumina Strategic Plan 2021 - 2025," Nov. 5, 2020) (*in camera*)).

Response to Finding No. 1766:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (Respondents' Exhibit Index at 92), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1767. [redacted] (RX1994 (Illumina) at 037 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching "Illumina Strategic Plan 2021 - 2025," Nov. 5, 2020) (*in camera*)).

Response to Finding No. 1767:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (Respondents' Exhibit Index at 92), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

H. SWITCHING TO ANOTHER NGS PLATFORM WOULD CAUSE SIGNIFICANT DELAYS, REQUIRE SIGNIFICANT COSTS, AND POSE REGULATORY AND FINANCIAL RISKS FOR MCED TEST DEVELOPERS

1. MCED Tests are Developed to Run on a Specific NGS Platform

1768. [redacted] (Lengauer (Third Rock Ventures) Tr. 179 (*in camera*)).

Response to Finding No. 1768:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1682, which Respondents incorporate herein.

Dr. Lengauer testified that [redacted] RX3419 (Lennon et al., 2020) at 18; RX3772 (Cohen 2018 Supplementary Material) at 2–3.) [redacted] (PX7085 (Harada (Exact/Thrive) Dep. at 239); PX7091 (Lengauer (Exact/Thrive) Dep. at 38, 106).) [redacted] (PX7091 (Lengauer (Exact/Thrive) Dep. at 41–42).) However, [redacted] (RX3869 (Cote Expert Report) ¶ 340.)

Furthermore, [redacted] (Conroy (Exact/Thrive) Tr. 1754–55); [redacted]

[redacted] (Conroy (Exact/Thrive) Tr. 1756–57.)

Respondents also incorporate their responses to CCFF ¶ 929 herein.

1769. [redacted] (Lengauer (Third Rock Ventures) Tr. 179 (*in camera*)).

Response to Finding No. 1769:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929, 1682 and 1768, which Respondents incorporate herein.

Respondents also note that Dr. Vogelstein, a founder of Thrive, stated, [redacted]

Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1770. Thrive's Lengauer testified, [redacted]

[redacted]
(PX7051 (Lengauer (Third Rock Ventures) IHT at 71-72 (*in camera*); *see also* PX7051 (Lengauer (Third Rock Ventures) IHT at 70) (*in camera*)).

Response to Finding No. 1770:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929, 1682 and 1768, which Respondents incorporate herein.

1771. [redacted]

(PX7110 (Conroy (Exact) Dep. at 66-67) (*in camera*)).

Response to Finding No. 1771:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929, 1682 and 1768, which Respondents incorporate herein.

1772. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 124) (*in camera*)).

Response to Finding No. 1772:

The proposed finding is inaccurate, incomplete, and misleading.

Switching between Illumina's platform and alternative platforms is feasible. (RX3869 (Cote Expert Report) ¶ 338.) [redacted]

In fact, cancer screening developers will inevitably need to switch between different Illumina instruments in the course of developing their respective screening tests. (RX3869 (Cote

Expert Report) ¶ 338.) [redacted] (PFF ¶ 646.1 (PX7087 (Goswami (Illumina) Dep. at 16).) Test developers routinely re-validate their tests to account for new developments in their tests, new and improved technology relating to consumables or sequencers, or for any number of other reasons. (RX3869 (Cote Expert Report) ¶ 338.) These revalidations are part of a good test developer's business plan. (RX3869 (Cote Expert Report) ¶ 338.) It is routine to switch or to upgrade platforms (which from a re-validation point of view is equivalent). (Cote Tr. 3739; Aravanis (Illumina) Tr. 1865; (RX3869 (Cote Expert Report) ¶ 338.) This is built into all clinical labs' workflow and plan for long-term functioning for the lab. (Cote Tr. 3771.) (*See* generally PFF ¶¶ 645–74.)

Respondents also incorporate their responses to CCFF ¶ 904, 928, 929, 1074, 1088, 1115 and 1293 herein.

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1773. Exact's CEO, Kevin Conroy, testified, [redacted] (PX7058 (Conroy (Exact) IHT at 128-129) (*in camera*)).

Response to Finding No. 1773:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, misleading for the reasons explained in Respondent's responses to CCFF ¶¶ 929, 1084 and 1772 herein. [redacted]

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1774. (Chudova (Guardant) Tr. 1301-1302 (*in camera*)).

Response to Finding No. 1774:

The proposed finding is inaccurate, incomplete, misleading for the reasons explained in Respondent's responses to CCFF ¶¶ 927–28 and 1772 herein. Further, Dr. Chudova admitted

(Chudova (Guardant) Tr. 1303.) Dr Chudova also admitted

(Chudova (Guardant) Tr. 1301.)

(Cote Tr. 3776, 3833–34.) (*See* RRFF ¶¶ 927 and 2273).

1775. (PX7045 (Chudova (Guardant) IHT at 40-41) (*in camera*)).

Response to Finding No. 1775:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, misleading for the reasons explained in Respondent's responses to CCFF ¶¶ 927, 1772 and 1774 herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1776. According to Nitin Sood, Guardant's Senior VP of Product, "Illumina is central to what we do. . . . [W]e built part of our world around the Illumina ecosystem." (PX7090 (Sood (Guardant) Dep. at 112-13)).

Response to Finding No. 1776:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, misleading for the reasons explained in Respondent's responses to CCFF ¶¶ 927, 1772 and 1774 herein. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 928, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

1777. [redacted] (Rabinowitz (Natera) Tr. 415 (*in camera*)).

Response to Finding No. 1777:

The proposed finding is inaccurate, incomplete, and misleading. Dr. Rabinowitz admitted [redacted] (Rabinowitz (Natera) Tr. 415–17, 419.) Respondents also incorporate their responses to CCFF ¶¶ 928 and 1293, which discusses, *inter alia*, the availability of alternative sequencing platforms, herein.

[redacted] (RX3869 (Cote Expert Report) ¶ 227; [redacted] the last time Natera mentioned anything related to early-detection appears to be 2017 ((RX3495 (Natera) at 7 (discussing exploring breast and ovarian cancer screening); RX3491 (Natera) at 18.) and Natera's CEO has

publicly stated that "[Natera is] ***not focused on asymptomatic cancers strain or early detection.***" (RX3492 (Natera) at 6.)

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents also incorporate their responses to CCFF ¶¶ 928, 965, 1099, 1269 and 1293 herein.

1778. [redacted] (Chahine (Helio) Tr. 1071 (*in camera*)).

Response to Finding No. 1778:

The proposed finding is incomplete and misleading to the extent that it seems to suggest that Illumina's NGS sequencers are essential for an earlier detection test, which they are not. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1177, 1772 and 1774 herein. Further, Dr. Chahine admitted [redacted]

1779. [redacted] (PX6049 (Grail) at 023 (Grail, Narrative Response to FTC Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 1779:

The proposed finding is incomplete and misleading. [redacted] (PX6049 (Grail) at 023 (Grail, Narrative Response to FTC Second Request, Mar. 1, 2021) (in camera)).

Dr. Aravanis testified that GRAIL considered BGI, Thermo Fisher, Oxford Nanopore and Genapsys NGS sequencers for GRAIL's Galleri test, and determined that many of them would be a viable alternative. (PFF ¶ 1311 (Aravanis (Illumina) Tr. 1862–63).) Dr. Aravanis also testified that BGI's systems are used for liquid biopsy applications; BGI has an NGS sequencing product that could be used for multicancer screening; BGI competes with Illumina for liquid biopsy applications in the countries in which it operates; BGI markets its NGS offerings as an alternative to Illumina. (PFF ¶ 1306 (Aravanis (Illumina) Tr. 1852–54).)

Dr. Aravanis also testified that Thermo Fisher's Ion Torrent can be used as an alternative for many Illumina applications; that the Ion Torrent platform is adequate in terms of the type of

sequencing data it produces, the accuracy and the cost and that Thermo Fisher markets the Ion Torrent as an alternative to Illumina. (PFF ¶ 1305 (Aravanis (Illumina) Tr. 1848–52).)

Dr. Aravanis further testified that it is possible to do short-read sequencing on Oxford Nanopore's platforms at very low cost; the Oxford Nanopore platform is a very high-output sequencing platform; the amount of data and cost per data is comparable to the high-end Illumina systems; Oxford Nanopore's NGS sequencing product can be used and have been for liquid biopsy oncology testing; Oxford Nanopore markets its NGS offering as an alternative to Illumina and Illumina views Oxford Nanopore as a competitor in NGS sequencing. (PFF ¶ 1308 (Aravanis (Illumina) Tr. 1856–59).) (*See also* PFF ¶¶ 1304–1310.)

2. Every MCED Test Developer Testified that Switching NGS Platforms is Difficult, Time Consuming, Expensive, and Would Substantially Delay Development and Commercialization

a) Grail

1780. [redacted] (Freidin (Grail) Tr. 3066 (*in camera*)).

Response to Finding No. 1780:

The proposed finding is misleading to the extent that it suggests that [redacted] To the contrary, Mr. Bishop (GRAIL's CEO at the time of trial) testified that, while GRAIL uses the Illumina NovaSeq, the choice to use it relates mainly to the fact that it was used when Illumina founded GRAIL; GRAIL uses a variety of reagents and consumables and not all of these inputs are from Illumina; and Illumina has no role in running the Galleri test. (PFF ¶ 1560; Bishop (GRAIL) Tr. 1381–82.) Respondents also incorporate their responses to CCFF ¶¶ 341, 928, 969 and 1293 herein.

Similarly, Dr. Alex Aravanis testified that when he was at GRAIL, GRAIL considered using BGI, Thermo Fisher and Oxford Nanopore; GRAIL evaluated these platforms and

determined that many of them would be a viable alternative. (Aravanis (Illumina) Tr. 1863.) Dr. Aravanis noted that that customers switch from one Illumina NGS platform to another every few years; in order to switch from an Illumina NGS platform to another NGS platform, GRAIL would need to do an analytical bridging study to demonstrate that the test performs similarly on an alternative sequencing platform, there might be other steps where minor modifications to some of the library prep or analysis would also be required; an alternative NGS platform would not need FDA approval before it could be used for development or commercialization of an MCED test like Galleri; if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (Aravanis (Illumina) Tr. 1861–65.)

Respondents also note that GRAIL has used both Illumina's HiSeq platform and NovaSeq platform with S2 and S4 flow cells (Cote Tr. 3739–40; PX7104 (Aravanis (Illumina) Dep.) at 168–69; RX3773 (Supplement Information to Klein 2021) at 11, 13, 15–16), and [redacted] (PX7103 (Jamshidi (GRAIL) Dep. at 189–90.)

Further, Mr. Freidin is the Senior Vice President of Finance at GRAIL; in this finance role, his key responsibilities are to develop budgets and put together long-range plans. He is not an expert in NGS technology, and cannot compare Illumina's platform with others. (Freidin (GRAIL) Tr. 2967.)

Respondents also incorporate their responses to CCFF ¶¶ 928, 1074 and 1772 herein.

1781. [redacted] (PX7066 (Freidin (Grail) IHT at 212-13) (*in camera*)).

Response to Finding No. 1781:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which they incorporate herein.

Further, Mr. Freidin is the Senior Vice President of Finance at GRAIL; in this finance role, his key responsibilities are to develop budgets and put together long-range plans. He is not an expert in NGS technology, and cannot compare Illumina's platform with others. (Freidin (GRAIL) Tr. 2967.)

The proposed finding relies on IH testimony in which Respondents had no opportunity to conduct re-direct or meaningfully object and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1782. [redacted] (PX7066 (Freidin (Grail) IHT at 212-13) (*in camera*)).

Response to Finding No. 1782:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which they incorporate herein.

Further, Mr. Freidin is the Senior Vice President of Finance at GRAIL; in this finance role, his key responsibilities are to develop budgets and put together long-range plans. He is not an expert in NGS technology, and cannot compare Illumina's platform with others. (Freidin (GRAIL) Tr. 2967.)

The proposed finding relies on IH testimony in which Respondents had no opportunity to conduct re-direct or meaningfully object and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Respondents also incorporate their responses to CCFF ¶¶ 928, 1074 and 1772 herein.

b) [redacted]

1783. [redacted]

Response to Finding No. 1783:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. Dr. Cote estimates that re-validating a test on a new NGS platform would take approximately 6–12 months. (Cote Tr. 3774–75.) Respondents also incorporate their responses to CCFF ¶¶ 929, 1772, 1774 and 1780 herein.

1784. [redacted]

Response to Finding No. 1784:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929, 1682, 1772, 1774 and 1780, which Respondents incorporate herein.

Dr. Cote estimates that re-validating a test on a new NGS platform would take approximately 6–12 months. (Cote Tr. 3774–75.) Similarly, Dr. Aravanis noted that that customers switch from one Illumina NGS platform to another every few years; in order to switch from an Illumina NGS platform to another NGS platform, GRAIL would need to do an analytical

bridging study to demonstrate that the test performs similarly on an alternative sequencing platform, there might be other steps where minor modifications to some of the library prep or analysis would also be required; an alternative NGS platform would not need FDA approval before it could be used for development or commercialization of an MCED test like Galleri; if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (Aravanis (Illumina) Tr. 1861–65.) According to Dr. Febbo, Illumina's Chief Medical Officer, switching an LDT's NGS platform takes approximately six to twelve months. (Febbo (Illumina) Tr. 4325).

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Exact Sciences does not have any tests that use NGS technology and Exact Sciences was not an Illumina customer until its acquisition of Thrive. (*See* Conroy (Exact Sciences) Tr. 1542–43, [redacted].)

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1785. [redacted]

Response to Finding No. 1785:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed

finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 929, 1682, 1772, 1774, 1780 and 1784, which Respondents incorporate herein.

[redacted]

Similarly, Natera switched from Illumina to the BGI platform. [redacted] (PX7111 (Fesko (Natera) Dep. at 251–52); RX3062 (BGI) at 1.) Natera's Signatera test was initially validated on Illumina's HiSeq 2500 NGS platform. (RX3499 (Natera) at 6.)

Second, switching is unlikely to impact Exact/Thrive's development timeline. [redacted]

[redacted] This is likely to be true if Thrive switches from Illumina to BGI or to Singular. [redacted] (Lengauer (Exact/Thrive) Tr. 190–91; PX8572 (Exact/Thrive) at 135–39; PX7110 (Conroy (Exact/Thrive) Dep. at 33).) [redacted] (Lengauer (Exact/Thrive) Tr. 215; PX8572 (Exact/Thrive) at 48; RX3869 (Cote Expert Report) ¶ 183.)

In addition to Singular (*see* RRFF ¶ 1682), other sequencing alternatives that are available to Exact/Thrive before it commences the SOAR trial, including BGI, Thermo Fisher and Oxford Nanopore. As noted in RRFF ¶ 1724, CancerSEEK can be performed using BGI's sequencing platform. While Singular, Thermo Fisher and Oxford Nanopore are all currently

available in the United States (PFF ¶¶ 607 ((Velarde (Singular) Tr. 4515–16, 4522; see also PX8561 (Singular) at 1–2; [redacted]), 579 (RX3688 (Thermo Fisher); RX3689 (Thermo Fisher); RX3687 (Thermo Fisher); RX3685 (Thermo Fisher)), 599 (RX3913 (ONT,) at 1–5; RX3543 (ONT) at 1; RX3536 (ONT); RX3542 (ONT)), BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Respondents incorporate their responses to CCFF ¶ 1784 herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1786. [redacted]

Response to Finding No. 1786:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1784–85, which Respondents incorporate herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper

Lay Witness Opinion Testimony (Aug. 5, 2021).) Respondents also incorporate their responses to CCFF ¶¶ 929, 1682, 1772, 1774 and 1780 herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1787. [redacted]

Response to Finding No. 1787:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1784–85, which Respondents incorporate herein.

Respondents also note Dr. Lengauer confirmed that: [redacted]" (Lengauer (Exact/Thrive) Tr. 238–39.)

The proposed finding is also misleading to the extent it suggests that other NGS platforms would not support the CancerSEEK test. For example, Dr. Vogelstein, the founder of Thrive stated, [redacted] [redacted]

[redacted]

The proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶¶ 929, 1682, 1772, 1774 and 1780 herein.

1788. [redacted]

Response to Finding No. 1788:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1784–85, which Respondents incorporate herein.

[redacted]

[redacted] This is likely to be true if Thrive switches from Illumina to BGI or to Singular. [redacted]

The proposed finding is also misleading to the extent it suggests that other NGS platforms would not support the CancerSEEK test. For example, Dr. Vogelstein, the founder of Thrive stated, [redacted]

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶¶ 929, 1682, 1772, 1774 and 1780 herein.

1789. [redacted]

Response to Finding No. 1789:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed

finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1784–85, which Respondents incorporate herein. Specifically, Dr. Cote estimated that re-validating a test on a new NGS platform would take approximately 6–12 months. (Cote Tr. 3774–75.) Similarly, Dr. Aravanis testified that if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (Aravanis (Illumina) Tr. 1861–65.)

[redacted] This is likely to be true if Thrive switches from Illumina to BGI or to Singular. [redacted]

The proposed finding is also misleading to the extent it suggests that other NGS platforms would not support the CancerSEEK test. For example, Dr. Vogelstein, the founder of Thrive stated, [redacted].

[redacted]

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶¶ 929, 1682, 1772, 1774 and 1780 herein.

1790. [redacted]

Response to Finding No. 1790:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1784–85, which Respondents incorporate herein.

[redacted] This is likely to be true if Thrive switches from Illumina to BGI or to Singular. [redacted]

The proposed finding is also misleading to the extent it suggests that other NGS platforms would not support the CancerSEEK test. For example, Dr. Vogelstein, the founder of Thrive stated, [redacted]

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶¶ 929, 1682, 1772, 1774 and 1780 herein.

1791. [redacted]

Response to Finding No. 1791:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1252, 1784–85, which Respondents incorporate herein. [redacted]

[redacted]

Respondents also note Dr. Lengauer confirmed that: [redacted]

[redacted]

" (Lengauer (Exact/Thrive) Tr. 238–39.)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶¶ 929, 952, 1682, 1772, 1774 and 1780 herein.

1792. [redacted]

Response to Finding No. 1792:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1784–85, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Respondents also incorporate their responses to CCFF ¶¶ 929, 952, 1682, 1772, 1774 and 1780 herein.

1793. [redacted]

Response to Finding No. 1793:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1784–85, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶¶ 929, 952, 1682, 1772, 1774 and 1780 herein.

1794. [redacted]

Response to Finding No. 1794:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1784–85, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Respondents also incorporate their responses to CCFF ¶¶ 929, 1682, 1772, 1774 and 1780 herein.

c) [redacted]

1795. [redacted]

Response to Finding No. 1795:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 965, 1105, 1293, 1331–42, 1772 and 1780, which Respondents incorporate herein.

Contrary to the statement that Natera has not "validated any alternative sequencing platform", [redacted] (PX7111 (Fesko (Natera) Dep. at 251–52); RX3062 (BGI) at 1.) Natera's Signatera test was initially validated on Illumina's HiSeq 2500 NGS platform. (RX3499 (Natera) at 6.)

Complaint Counsel did not present the exhibit PX0155 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 2), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1796. [redacted]

Response to Finding No. 1796:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 929, 1293, 1331–41, 1772, 1780 and 1795 herein.

1797. [redacted]

Response to Finding No. 1797:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. Specifically, Dr. Cote estimated that re-validating a test on a new NGS platform would take approximately 6–12 months. (Cote Tr. 3774–75.) Similarly, Dr. Aravanis testified that if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (Aravanis (Illumina) Tr. 1861–65.)

The proposed finding is also misleading to the extent that it suggests that switching from Illumina to BGI was a hypothetical endeavor. To the contrary, in June of 2021, BGI and Natera announced that, after two years of development alongside BGI, Natera was officially launching its Signatera MRD test in China, using BGI sequencers. (RX3473 (Natera) at 1.) [redacted] Respondents also incorporate their responses to CCFF ¶¶ 929, 1293, 1331–41, 1772, 1780 and 1795 herein.

1798. [redacted]

Response to Finding No. 1798:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. Respondents also incorporate their responses to CCFF ¶¶ 929, 1293, 1331–41, 1772, 1780 and 1795 herein. Specifically, Dr. Cote estimated that re-validating a test on a new NGS platform would take approximately 6–12 months. (Cote Tr. 3774–75.) Similarly, Dr. Aravanis testified that if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (Aravanis (Illumina) Tr. 1861–65.)

d) Guardant

1799. [redacted] (PX7045 (Chudova (Guardant) IHT at 109-10) (*in camera*)).

Response to Finding No. 1799:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1772 and 1780, which Respondents incorporate herein. Dr. Chudova admitted [redacted]

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1785, which Respondents incorporate herein.

From a technical perspective, there is no reason why Guardant could not switch to BGI, Singular, ONT, Thermo Fisher virtually immediately, or Omniome, Element, Roche Nanopore or Ultima in the foreseeable future. (*See* RRFF ¶¶ 901 (ONT), 928 (all sequencers), 1293 (BGI), 1567 (Thermo Fisher), 1579 (Thermo Fisher), 1584 (Thermo Fisher), 1682 (Singular)). Similarly, each of these sequencing platforms has developed a framework to allow test developers to switch or test developers have successfully switched historically. (*See* RRFF ¶¶ 928 (BGI), 1293 (BGI), 1682 (Singular), 1785 (Thermo Fisher)). [redacted] (*See* RRFF ¶¶ 927 and 2273.) While Singular, Thermo Fisher and Oxford Nanopore are all currently available in the United States (PFF ¶¶ 607 ((Velarde (Singular) Tr. 4515–16, 4522; see also PX8561 (Singular) at 1–2; PX7117 (Velarde (Singular) Dep. at 30–31)), 579 (RX3688 (Thermo Fisher); RX3689 (Thermo Fisher); RX3687 (Thermo Fisher); RX3685 (Thermo Fisher)), 599 (RX3913 (ONT,) at 1–5; RX3543 (ONT) at 1; RX3536 (ONT); RX3542 (ONT)), BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3; RRFF ¶ 928.) Omniome, Element, Roche Nanopore and Ultima all state that they will enter in the foreseeable future. (RRFF ¶ 928; PFF ¶¶ 614–644.)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1800. [redacted]

[redacted] (*in camera*)).

Response to Finding No. 1800:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses CCFF ¶¶ 927, 1772, 1780 and 1799, which Respondents incorporate herein.

Respondents note that Dr. Chudova's testimony is contradicted by that of other witnesses testifying for Complaint Counsel. For example, [redacted]

1801. [redacted] (Chudova (Guardant) Tr. 1234-35) (*in camera*)).

Response to Finding No. 1801:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1772, 1780, 1799 and 1800, which Respondents incorporate herein.

Dr. Aravanis noted that that customers switch from one Illumina NGS platform to another every few years; in order to switch from an Illumina NGS platform to another NGS platform, a putative MCED test developer would need to do an analytical bridging study to demonstrate that the test performs similarly on an alternative sequencing platform, there might be other steps where minor modifications to some of the library prep or analysis would also be required; an alternative NGS platform would not need FDA approval before it could be used for development or commercialization of an MCED test like Galleri; if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (Aravanis (Illumina) Tr. 1861–65.)

Dr. Cote testified that for a single-site IVD test approved by the FDA, if the clinical testing portion of the IVD test has changed since the clinical trial demonstrating its efficacy, the FDA requires the IVD sponsor to provide data from a bridging or comparison study to demonstrate that the new clinical test using the third party NGS platform "has performance characteristics that are very similar to those of the test that was used in the trial," *i.e.*, using the Illumina platform. (Cote Tr. 3776; RX3218 (FDA) at 30).) The performance similarity is often demonstrated in a bridging or comparison study by performing the new test using original clinical trial samples and a pre-specified statistical analysis plan, thereby showing both concordance and discordance between the two tests using the same specimens. (RX3218 (FDA) at 30.)

Such a requirement also means that a costly new clinical trial need not be conducted: the IVD sponsor just need to run the new test on the already collected sample to show consistent results. (RX3869 (Cote Expert Report) ¶ 350.) If the results of the bridging or comparison study

demonstrate that the two platforms lead to equivalent performance, no additional clinical trials may be required. (RX3869 (Cote Expert Report) ¶ 350.) Dr. Cote estimates that conducting the bridging or comparison study—including a repeatability study—would take approximately one month to complete. (Cote Tr. 3773.) It would cost approximately $1 million to $2 million if samples need to be purchased. (Cote Tr. 3775.) [redacted] The time and cost of these bridging or comparison studies are both relatively low compared to overall development time and cost for clinical tests. (PX7065 (Aravanis (Illumina) IHT at 164–66); RX3869 (Cote Expert Report) ¶ 351.)

1802. [redacted] (Chudova (Guardant) Tr. 1234-35) (*in camera*)).

Response to Finding No. 1802:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1772, 1780, 1799 and 1800, which Respondents incorporate herein.

Dr. Aravanis noted that that customers switch from one Illumina NGS platform to another every few years; in order to switch from an Illumina NGS platform to another NGS platform, a putative MCED test developer would need to do an analytical bridging study to demonstrate that the test performs similarly on an alternative sequencing platform, there might be other steps where minor modifications to some of the library prep or analysis would also be required; an alternative NGS platform would not need FDA approval before it could be used for development or commercialization of an MCED test like Galleri; if the platform produces very

similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (Aravanis (Illumina) Tr. 1861–65.)

1803. [redacted] (Chudova (Guardant) Tr. 1307-08 (*in camera*)).

Response to Finding No. 1803:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1772, 1780, 1799 and 1800, which Respondents incorporate herein.

Dr. Aravanis noted that that customers switch from one Illumina NGS platform to another every few years; in order to switch from an Illumina NGS platform to another NGS platform, a putative MCED test developer would need to do an analytical bridging study to demonstrate that the test performs similarly on an alternative sequencing platform, there might be other steps where minor modifications to some of the library prep or analysis would also be required; an alternative NGS platform would not need FDA approval before it could be used for development or commercialization of an MCED test like Galleri; if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (Aravanis (Illumina) Tr. 1861–65.)

1804. [redacted] (Chudova (Guardant) Tr. 1308-09) (*in camera*)).

Response to Finding No. 1804:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1772, 1780, 1799 and 1800, which Respondents incorporate herein.

Dr. Aravanis noted that that customers switch from one Illumina NGS platform to another every few years; in order to switch from an Illumina NGS platform to another NGS platform, a putative MCED test developer would need to do an analytical bridging study to demonstrate that the test performs similarly on an alternative sequencing platform, there might be other steps where minor modifications to some of the library prep or analysis would also be required; an alternative NGS platform would not need FDA approval before it could be used for development or commercialization of an MCED test like Galleri; if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (Aravanis (Illumina) Tr. 1861–65.)

1805. [redacted]

(PX7045 (Chudova (Guardant) IHT at 49-51) (*in camera*)).

Response to Finding No. 1805:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1772, 1780, 1799 and 1800, which Respondents incorporate herein.

Dr. Aravanis noted that that customers switch from one Illumina NGS platform to another every few years; in order to switch from an Illumina NGS platform to another NGS platform, a putative MCED test developer would need to do an analytical bridging study to demonstrate that the test performs similarly on an alternative sequencing platform, there might be other steps where minor modifications to some of the library prep or analysis would also be required; an alternative NGS platform would not need FDA approval before it could be used for development or commercialization of an MCED test like Galleri; if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (Aravanis (Illumina) Tr. 1861–65.)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1806. [redacted] (Chudova (Guardant) Tr. 1234-35 (*in camera*)).

Response to Finding No. 1806:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed

finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1772, 1780, 1799 and 1800, which Respondents incorporate herein.

Dr. Aravanis noted that that customers switch from one Illumina NGS platform to another every few years; in order to switch from an Illumina NGS platform to another NGS platform, a putative MCED test developer would need to do an analytical bridging study to demonstrate that the test performs similarly on an alternative sequencing platform, there might be other steps where minor modifications to some of the library prep or analysis would also be required; an alternative NGS platform would not need FDA approval before it could be used for development or commercialization of an MCED test like Galleri; if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (Aravanis (Illumina) Tr. 1861–65.)

1807. [redacted] (Chudova (Guardant) Tr. 1234-35 (*in camera*)).

Response to Finding No. 1807:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1772, 1780, 1799 and 1800, which Respondents incorporate herein.

Dr. Aravanis noted that that customers switch from one Illumina NGS platform to another every few years; in order to switch from an Illumina NGS platform to another NGS platform, a putative MCED test developer would need to do an analytical bridging study to demonstrate that the test performs similarly on an alternative sequencing platform, there might

be other steps where minor modifications to some of the library prep or analysis would also be required; an alternative NGS platform would not need FDA approval before it could be used for development or commercialization of an MCED test like Galleri; if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (Aravanis (Illumina) Tr. 1861–65.)

1808. [redacted] (Chudova (Guardant) Tr. 1235-36) (*in camera*)).

Response to Finding No. 1808:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1772, 1780, 1799 and 1800, which Respondents incorporate herein.

Dr. Aravanis noted that that customers switch from one Illumina NGS platform to another every few years; in order to switch from an Illumina NGS platform to another NGS platform, a putative MCED test developer would need to do an analytical bridging study to demonstrate that the test performs similarly on an alternative sequencing platform, there might be other steps where minor modifications to some of the library prep or analysis would also be required; an alternative NGS platform would not need FDA approval before it could be used for development or commercialization of an MCED test like Galleri; if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (Aravanis (Illumina) Tr. 1861–65.)

1809. [redacted] (Chudova (Guardant) Tr. 1236) (*in camera*)).

Response to Finding No. 1809:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1772, 1780, 1799 and 1800, which Respondents incorporate herein.

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1785, which Respondents incorporate herein.

From a technical perspective, there is no reason why Guardant could not switch to BGI, Singular, ONT, Thermo Fisher virtually immediately, or Omniome, Element, Roche Nanopore or Ultima in the foreseeable future. (*See* RRFF ¶¶ 901 (ONT), 928 (all sequencers), 1293 (BGI), 1567 (Thermo Fisher), 1579 (Thermo Fisher), 1582–83 (Thermo Fisher), 1682 (Singular)). Similarly, each of these sequencing platforms has developed a framework to allow test developers to switch or test developers have successfully switched historically. (*See* RRFF ¶¶ 928 (BGI), 1293 (BGI), 1682 (Singular), 1785 (Thermo Fisher)). [redacted] (*See* RRFF ¶¶ 927 and 2273.) While Singular, Thermo Fisher and Oxford Nanopore are all currently available in the United States (PFF ¶¶ 607 ((Velarde (Singular) Tr. 4515–16, 4522; see also PX8561 (Singular) at 1–2; PX7117 (Velarde (Singular) Dep. at 30–31)), 579 (RX3688 (Thermo Fisher); RX3689 (Thermo Fisher); RX3687 (Thermo Fisher); RX3685 (Thermo Fisher)), 599 (RX3913 (ONT,) at 1–5; RX3543 (ONT) at 1; RX3536 (ONT); RX3542 (ONT)), BGI may enter the United States market

as soon as August 2022. (PFF ¶¶ 777-777.3; RRFF ¶ 928.) Omniome, Element, Roche Nanopore and Ultima all state that they will enter in the foreseeable future. (RRFF ¶ 928.)

1810. After redesigning its MCED test, a test developer would need to revalidate its test on the new platform and, at a minimum, perform "a smaller scale clinical sample analysis." (PX7100 (Chudova (Guardant) Dep. at 82)).

Response to Finding No. 1810:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1772, 1780, 1799 and 1800, which Respondents incorporate herein.

Dr. Aravanis noted that that customers switch from one Illumina NGS platform to another every few years; in order to switch from an Illumina NGS platform to another NGS platform, a putative MCED test developer would need to do an analytical bridging study to demonstrate that the test performs similarly on an alternative sequencing platform, there might be other steps where minor modifications to some of the library prep or analysis would also be required; an alternative NGS platform would not need FDA approval before it could be used for development or commercialization of an MCED test like Galleri; if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (Aravanis (Illumina) Tr. 1861–65.)

1811. To switch to a new platform, an MCED test developer must redesign its test to be compatible with the new NGS instrument, which although "theoretically possible" involves a "significant amount of development work." (PX7045 (Chudova (Guardant) IHT at 53-56)).

Response to Finding No. 1811:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1772, 1780, 1799 and 1800, which Respondents incorporate herein.

Dr. Aravanis noted that that customers switch from one Illumina NGS platform to another every few years; in order to switch from an Illumina NGS platform to another NGS platform, a putative MCED test developer would need to do an analytical bridging study to demonstrate that the test performs similarly on an alternative sequencing platform, there might be other steps where minor modifications to some of the library prep or analysis would also be required; an alternative NGS platform would not need FDA approval before it could be used for development or commercialization of an MCED test like Galleri; if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (Aravanis (Illumina) Tr. 1861–65.)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1812. [redacted] (PX7045 (Chudova (Guardant) IHT at 88) (*in camera*)).

Response to Finding No. 1812:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed

finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1772, 1780, 1799 and 1800, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1813. [redacted] (PX7045 (Chudova (Guardant) IHT at 109-10) (*in camera*)).

Response to Finding No. 1813:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1772, 1780, 1799 and 1800, which Respondents incorporate herein.

Contrary to Complaint Counsel's unproven contention, Mr. Getty admitted that Thermo Fisher Scientific Inc., and other companies developing next-generation sequencing platforms also provide NGS platforms that could be used for liquid biopsy testing. (Getty (Guardant) Tr. 2642.) [redacted] Dr. Chudova also stated that Guardant could use alternative sequencing platforms for its LUNAR-2 screening test in development that meet the throughput, error, time, and sequencing cost requirements. (PX7045 (Chudova (Guardant) IHT at 44–47.) BGI also markets its NGS technology in many other countries and is expected to enter the U.S. market in the near future. [redacted]**.)**

BGI also recently won a jury verdict that held three of Illumina's patents to be invalid meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022). BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.) Respondents also incorporate their responses to CCFF ¶¶ 1115 and 1118 herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1814. [redacted]

(PX7045 (Chudova (Guardant) IHT at 109-10) (*in camera*)).

Response to Finding No. 1814:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1772, 1780, 1799 and 1800, which Respondents incorporate herein.

Dr. Aravanis noted that that customers switch from one Illumina NGS platform to another every few years; in order to switch from an Illumina NGS platform to another NGS platform, a putative MCED test developer would need to do an analytical bridging study to demonstrate that the test performs similarly on an alternative sequencing platform, there might be other steps where minor modifications to some of the library prep or analysis would also be

required; an alternative NGS platform would not need FDA approval before it could be used for development or commercialization of an MCED test like Galleri; if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (Aravanis (Illumina) Tr. 1861–65.)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1815. Dr. Chudova testified that after Guardant receives FDA approval for its screening test "[t]he cost of switching [to a new platform] would increase" because "if we have approval on existing sequencing configuration today and then we go back into development to adapt our library preparation workflows to be compatible with different sequencing system and then adapt the software to the new system, we have to go through the same validation cycle again given the amount of modifications in the workflow, so we'll have to conduct full analytical validation of the system given that scope of change." (PX7045 (Chudova (Guardant) IHT at 111-12)).

Response to Finding No. 1815:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1772, 1780, 1799, 1800 and 1873, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1816. Guardant's Dr. Chudova testified that the costs of switching could be so significant that it may no longer make business sense to pursue the test because switching would "delay and potentially annihilate existence of such test on the market because the cost of development and implementation would start being prohibitive from a business standpoint to continue on that path, so again I think it would lead from the path to 2023 launch to infinite path to launch." (PX7045 (Chudova (Guardant) IHT at 118-19)).

Response to Finding No. 1816:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1772, 1780, 1799 and 1800, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1817. Dr. Chudova testified that the only circumstance in which Guardant would consider switching from Illumina to Roche is "in a very hypothetical space, if Illumina cuts all of the supply to their reagents and instruments and there's nobody else on the market that becomes—and they have something that works, which they don't today, we could discuss that option. I don't think it's a serious discussion for us today given the three above are not met." (PX7045 (Chudova (Guardant) IHT 114)).

Response to Finding No. 1817:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1772, 1780, 1799 and 1800, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1818. Guardant represented to investors in its 2019 Form 10-K filed with the Securities and Exchange Commission that:

> The use of equipment or materials furnished by [any] replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time-consuming and expensive, may result in interruptions in our laboratory operations, could affect the performance specification of our laboratory operations or could require that we revalidate our tests. There can be no assurance that we will be able to secure alternative equipment, reagents and other materials, bring such equipment, reagents and materials on line, and revalidate our tests without experiencing disruptions in workflow. In the case

> of alternative supplier for Illumina, for example, there can be no assurance that replacement sequencers and various associated reagents will be available or will meet our quality control and performance requirements for our laboratory operations.

(PX0059 at 045 (Guardant 2019 Form 10-K)).

Response to Finding No. 1818:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1772, 1780, 1799 and 1800, which Respondents incorporate herein.

e) [redacted]

1819. [redacted]

Response to Finding No. 1819:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945, 1772, 1780 and 1785, which Respondents incorporate herein.

From a technical perspective, there is no reason why Freenome could not switch to BGI, Singular, ONT, Thermo Fisher virtually immediately, Omniome, Element, Roche Nanopore or Ultima in the foreseeable future. (*See* RRFF ¶¶ 901 (ONT), 928 (all sequencers), 1293 (BGI), 1567 (Thermo Fisher), 1579 (Thermo Fisher), 1584 (Thermo Fisher), 1682 (Singular)). Similarly, each of these sequencing platforms has developed a framework to allow test developers to switch or test developers have successfully switched historically. (*See* RRFF ¶¶ 928 (BGI), 1293 (BGI), 1682 (Singular), 1785 (Thermo Fisher)). Further, [redacted]

[redacted] (*See* RRFF ¶¶ 945 and 2355.) While Singular, Thermo Fisher and Oxford Nanopore are all currently available in the United States (PFF ¶¶ 607 ((Velarde (Singular) Tr. 4515–16, 4522; see also PX8561 (Singular) at 1–2; PX7117 (Velarde (Singular) Dep. at 30–31)), 579 (RX3688 (Thermo Fisher); RX3689 (Thermo Fisher); RX3687 (Thermo Fisher); RX3685 (Thermo Fisher)), 599 (RX3913 (ONT,) at 1–5; RX3543 (ONT) at 1; RX3536 (ONT); RX3542 (ONT)), BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3; RRFF ¶ 928.) Omniome, Element, Roche Nanopore and Ultima all state that they will enter in the foreseeable future. (RRFF ¶ 928; PFF ¶¶ 614–644.)

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Freenome's current CEO, Mr. Nolan admitted that, consistent with his IH testimony, *he was not aware that Freenome had evaluated any non-Illumina platform*. (Nolan (Freenome) Tr. 2736–37.) Further, Respondents incorporate their responses to CCFF ¶¶ 945 and 1620 herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1820. [redacted]

Response to Finding No. 1820:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945, 1772, 1780 and 1819, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1821. [redacted]

Response to Finding No. 1821:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945, 1772, 1780 and 1819, which Respondents incorporate herein.

Further, Mr. Nolan admitted that, consistent with his IH testimony, he was not aware that Freenome had evaluated switching to any non-Illumina platform. (Nolan (Freenome) Tr. 2736–37)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1822. [redacted]

Response to Finding No. 1822:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945, 1772, 1780, 1819 and 1821, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1823. [redacted]

Response to Finding No. 1823:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945, 1772, 1780, 1819 and 1821, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1824. [redacted]

Response to Finding No. 1824:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed

finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 945, 1772, 1780, 1819 and 1821, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

f) Singlera

1825. Even if a hypothetical NGS platform had similar characteristics to Illumina, MCED test developers would not necessarily use the new platform due to high switching costs. (*See* PX7042 (Gao (Singlera) IHT at 55-56)).

Response to Finding No. 1825:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1011, 1772, 1780 and 1785, which Respondents incorporate herein.

From a technical perspective, there is no reason why Singlera could not switch to BGI, Singular, ONT, Thermo Fisher virtually immediately, or Omniome, Element, Roche Nanopore or Ultima in the foreseeable future. (*See* RRFF ¶¶ 901 (ONT), 928 (all sequencers), 1293 (BGI), 1567 (Thermo Fisher), 1579 (Thermo Fisher), 1584 (Thermo Fisher), 1682 (Singular)). Similarly, each of these sequencing platforms has developed a framework to allow test developers to switch or test developers have successfully switched historically. (*See* RRFF ¶¶ 928 (BGI), 1293 (BGI), 1682 (Singular), 1785 (Thermo Fisher)). Further, [redacted] (*See* RRFF ¶¶ 982 and 2406.) While Singular, Thermo Fisher and Oxford Nanopore are all currently available in the United States (PFF ¶¶ 607 ((Velarde (Singular) Tr. 4515–16, 4522; see also PX8561 (Singular) at 1–2;

PX7117 (Velarde (Singular) Dep. at 30–31)), 579 (RX3688 (Thermo Fisher); RX3689 (Thermo Fisher); RX3687 (Thermo Fisher); RX3685 (Thermo Fisher)), 599 (RX3913 (ONT,) at 1–5; RX3543 (ONT) at 1; RX3536 (ONT); RX3542 (ONT)), BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3; RRFF ¶ 928.) Omniome, Element, Roche Nanopore and Ultima all state that they will enter in the foreseeable future. (RRFF ¶ 928; PFF ¶¶ 614–644.)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1826. Singlera's Dr. Gao testified that switching would mean "redevelopment . . . . You [have] to redo it every – replicate it every study you done on Illumina . . . to convince yourself this is comparable." (PX7042 (Gao (Singlera) IHT at 55-56)).

Response to Finding No. 1826:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 982, 1011, 1772, 1780 and 1825, which Respondents incorporate herein.

Further, Dr. Gao admitted that Singlera's PanSeer test was not designed to solely on Illumina equipment and it is compatible with Thermo Fisher's NGS systems, including the Ion Torrent S5. (Gao (Singlera) Tr. 2928.) Dr. Gao estimates that it would take about six months to a year to switch from Illumina to Thermo Fisher NGS equipment for the PanSeer test; if Singlera were to switch to Thermo Fisher equipment today, it would not have to rerun any clinical trial that it had previously run for PanSeer, would not even need any bridging study to revalidate any PanSeer trial results, and would not disrupt any ongoing clinical trial work for PanSeer. (Gao (Singlera) Tr. 2942–43.)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1827. Dr. Gao testified that Singlera would have to conduct a new viability trial if Singlera switched to a non-Illumina NGS platform. (PX7042 (Gao (Singlera) IHT at 56-57)).

Response to Finding No. 1827:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 982, 1011, 1772, 1780 and 1825–26, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. At 275–76.)

1828. Singlera would not be able to use data from its trials using Illumina's instrument in a new viability trial if Singlera switched to a non-Illumina sequencer. (PX7042 (Gao (Singlera) IHT at 57)).

Response to Finding No. 1828:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 982, 1011, 1772, 1780 and 1825–26, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1829. Switching to a new NGS platform would mean that "many years [have] gone down the drain and there's hundreds of million[s of] dollar[s] down the drain" which would be bad for business and for investors. (PX7042 (Gao (Singlera) IHT at 58)).

Response to Finding No. 1829:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 982, 1011, 1772, 1780 and 1825–26, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. At 275–76.)

1830. Dr. Gao testified that if Singlera switched from Illumina's NGS platform to Thermo Fisher's NGS platform, for example, "you just need to spend more money, more time to develop, and why we want bother [sic] with that." (PX7042 (Gao (Singlera) IHT at 48-49)).

Response to Finding No. 1830:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 982, 1011, 1772, 1780 and 1825–26, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1831. Singlera's Gao testified that switching to a non-Illumina NGS platform would delay the commercial launch of Singlera's cancer screening test "at least a year or two . . . or it could be five, seven years longer, because we had to make sure every study we did with Illumina, which works or won't work. Then we had to publish again on a journal to show [that the non-Illumina platform] work[s]. That will be a long process." (PX7042 (Gao (Singlera) IHT at 56)).

Response to Finding No. 1831:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 982, 1011, 1772, 1780 and 1825–26, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

g) [redacted]

1832. [redacted]

Response to Finding No. 1832:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1177, 1772, 1780 and 1785, which Respondents incorporate herein. Further, [redacted] (Chahine (Helio) Tr. 1109–11.)

From a technical perspective, there is no reason why Helio could not switch to BGI, Singular, ONT, Thermo Fisher virtually immediately, or Omniome, Element, Roche Nanopore or Ultima in the foreseeable future. (*See* RRFF ¶¶ 901 (ONT), 928 (all sequencers), 1293

(BGI), 1567 (Thermo Fisher), 1579 (Thermo Fisher), 1584 (Thermo Fisher), 1682 (Singular)). Similarly, each of these sequencing platforms has developed a framework to allow test developers to switch or test developers have successfully switched historically. (*See* RRFF ¶¶ 928 (BGI), 1293 (BGI), 1682 (Singular), 1785 (Thermo Fisher)). Further, [redacted] (*See* RRFF ¶ 1177.) While Singular, Thermo Fisher and Oxford Nanopore are all currently available in the United States (PFF ¶¶ 607 ((Velarde (Singular) Tr. 4515–16, 4522; see also PX8561 (Singular) at 1–2; PX7117 (Velarde (Singular) Dep. at 30–31)), 579 (RX3688 (Thermo Fisher); RX3689 (Thermo Fisher); RX3687 (Thermo Fisher); RX3685 (Thermo Fisher)), 599 (RX3913 (ONT,) at 1–5; RX3543 (ONT) at 1; RX3536 (ONT); RX3542 (ONT)), BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3; RRFF ¶ 928.) Omniome, Element, Roche Nanopore and Ultima all state that they will enter in the foreseeable future. (RRFF ¶ 928; PFF ¶¶ 614–644.)

1833. [redacted]

Response to Finding No. 1833:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1177, 1772, 1780 and 1832, which Respondents incorporate herein.

1834. [redacted]

Response to Finding No. 1834:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1177, 1772, 1780, 1832 and 1873, which Respondents incorporate herein.

h) [redacted]

1835. [redacted]

Response to Finding No. 1835:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1190, 1772, 1780 and 1785, which Respondents incorporate herein. Further, [redacted] is using Illumina's HiSeq 2500 and 4000 as its NGS platforms for the FoundationOne CDx test for tissue biopsy sample based therapy selection, but switched to Illumina's NovaSeq 6000 for its FoundationOne® Liquid CDx test for liquid biopsy sample based therapy selection. (RX3231 (FMI) at 4; RX3234 (FMI) at 7.) [redacted]. (RX3869 (Cote Expert Report) ¶ 341.)

From a technical perspective, there is no reason why [redacted] could not switch to BGI, Singular, ONT, Thermo Fisher virtually immediately, or Omniome, Element, Roche

Nanopore or Ultima in the foreseeable future. (*See* RRFF ¶¶ 901 (ONT), 928 (all sequencers), 1293 (BGI), 1567 (Thermo Fisher), 1579 (Thermo Fisher), 1584 (Thermo Fisher), 1682 (Singular)). Similarly, each of these sequencing platforms has developed a framework to allow test developers to switch or test developers have successfully switched historically. (*See* RRFF ¶¶ 928 (BGI), 1293 (BGI), 1682 (Singular), 1785 (Thermo Fisher)). [redacted] *See* RRFF ¶ 1190.) While Singular, Thermo Fisher and Oxford Nanopore are all currently available in the United States (PFF ¶¶ 607 ((Velarde (Singular) Tr. 4515–16, 4522; see also PX8561 (Singular) at 1–2; PX7117 (Velarde (Singular) Dep. at 30–31)), 579 (RX3688 (Thermo Fisher); RX3689 (Thermo Fisher); RX3687 (Thermo Fisher); RX3685 (Thermo Fisher)), 599 (RX3913 (ONT,) at 1–5; RX3543 (ONT) at 1; RX3536 (ONT); RX3542 (ONT)), BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3; RRFF ¶ 928.) Omniome, Element, Roche Nanopore and Ultima all state that they will enter in the foreseeable future. (RRFF ¶ 928; PFF ¶¶ 614–644.)

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1836. [redacted]

Response to Finding No. 1836:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1190, 1772, 1780 and 1835, which Respondents incorporate herein.

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1837. [redacted]

Response to Finding No. 1837:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1190, 1772, 1780 and 1835 which Respondents incorporate herein.

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

[redacted]

1838. [redacted]

Response to Finding No. 1838:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1190, 1772, 1780 and 1835, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1839. [redacted]

[redacted]

Response to Finding No. 1839:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe and for a reasonable cost. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1190, 1772, 1780 and 1835, which Respondents incorporate herein.

3. Illumina, Grail, and Other NGS Market Participants Recognize High Switching Costs

a) Despite the Risks From Having a Sole Supplier, Grail Is Not Likely to Switch NGS Platforms

1840. If Grail were to switch to a non-Illumina sequencer, Grail CEO Hans Bishop testified that it's "a reasonable assumption" that Grail would need to revalidate its test on the non-Illumina sequencer. (Bishop (Grail) Tr. 1339).

Response to Finding No. 1840:

The proposed finding is misleading to the extent that it suggests that [redacted] Respondents have no specific response other than to incorporate their responses to CCFF ¶¶ 1772 and 1780 herein.

1841. Grail identified the risks associated with switching its MCED test to a new NGS system. (Bishop (Grail) Tr. 1339-41).

Response to Finding No. 1841:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is misleading and incomplete for the

reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein.

1842. [redacted] (Freidin (Grail) Tr. 3133 (*in camera*)).

Response to Finding No. 1842:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein.

Dr. Aravanis testified that GRAIL considered BGI, Thermo Fisher, Oxford Nanopore and Genapsys NGS sequencers for GRAIL's Galleri test, and determined that many of them would be a viable alternative. (PFF ¶ 1311 (Aravanis (Illumina/Fmr. GRAIL) Tr. 1862–63).) Dr. Aravanis also testified that BGI's systems are used for liquid biopsy applications; BGI has an NGS sequencing product that could be used for multicancer screening; BGI competes with Illumina for liquid biopsy applications in the countries in which it operates; BGI markets its NGS offerings as an alternative to Illumina. (PFF ¶ 1306 (Aravanis (Illumina) Tr. 1852–54).) Dr. Aravanis also testified that Thermo Fisher's Ion Torrent can be us as an alternative for many Illumina applications; that the Ion Torrent platform is adequate in terms of the type of sequencing data it produces, the accuracy and the cost and that Thermo Fisher markets the Ion Torrent as an alternative to Illumina. (PFF ¶ 1305 (Aravanis (Illumina) Tr. 1848–52).) Dr. Aravanis further testified that it is possible to do short-read sequencing on Oxford Nanopore's platforms at very low cost; the Oxford Nanopore platform is a very high-output sequencing platform; the amount of data and cost per data is comparable to the high-end Illumina systems; Oxford Nanopore's NGS sequencing product can be used and have been for liquid biopsy

oncology testing; Oxford Nanopore markets its NGS offering as an alternative to Illumina and Illumina views Oxford Nanopore as a competitor in NGS sequencing. (PFF ¶ 1308 (Aravanis (Illumina) Tr. 1856–59).) (*See also* PFF ¶¶ 1304–1310.)

1843. [redacted] (Freidin (Grail) Tr. 3066 (*in camera*)).

Response to Finding No. 1843:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein.

1844. Grail's Freidin testified that [redacted] (PX7066 (Freidin (Grail) IHT at 183) (*in camera*)).

Response to Finding No. 1844:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1845. [redacted] (PX7066 (Freidin (Grail) IHT at 212-13) (*in camera*)).

Response to Finding No. 1845:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1846. [redacted] (PX7066 (Freidin (Grail) IHT at 212-13) (*in camera*)).

Response to Finding No. 1846:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1847. [redacted] (PX7066 (Freidin (Grail) IHT at 212-13) (*in camera*)).

Response to Finding No. 1847:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1848. [redacted] (PX7103 (Jamshidi (Grail) Dep. at 169) (*in camera*)).

Response to Finding No. 1848:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein.

1849. Grail has never physically performed technical evaluations of non-Illumina sequencers. (PX7103 (Jamshidi (Grail) Dep. at 33)).

Response to Finding No. 1849:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein.

Dr. Aravanis testified that GRAIL considered BGI, Thermo Fisher, Oxford Nanopore and Genapsys NGS sequencers for GRAIL's Galleri test, and determined that many of them would be a viable alternative. (PFF ¶ 1311 (Aravanis (Illumina/fmr. GRAIL) Tr. 1862–63).) Dr. Aravanis also testified that BGI's systems are used for liquid biopsy applications; BGI has an NGS sequencing product that could be used for multicancer screening; BGI competes with Illumina for liquid biopsy applications in the countries in which it operates; BGI markets its NGS offerings as an alternative to Illumina. (PFF ¶ 1306 (Aravanis (Illumina) Tr. 1852–54).) Dr. Aravanis also testified that Thermo Fisher's Ion Torrent can be us as an alternative for many

Illumina applications; that the Ion Torrent platform is adequate in terms of the type of sequencing data it produces, the accuracy and the cost and that Thermo Fisher markets the Ion Torrent as an alternative to Illumina. (PFF ¶ 1305 (Aravanis (Illumina) Tr. 1848–52).) Dr. Aravanis further testified that it is possible to do short-read sequencing on Oxford Nanopore's platforms at very low cost; the Oxford Nanopore platform is a very high-output sequencing platform; the amount of data and cost per data is comparable to the high-end Illumina systems; Oxford Nanopore's NGS sequencing product can be used and have been for liquid biopsy oncology testing; Oxford Nanopore markets its NGS offering as an alternative to Illumina and Illumina views Oxford Nanopore as a competitor in NGS sequencing. (PFF ¶ 1308 (Aravanis (Illumina) Tr. 1856–59).) (*See also* PFF ¶¶ 1304–1310.)

1850. Dr. Jamshidi testified that, to his knowledge, Grail has never conducted any feasibility analyses of running Galleri on alternative platforms. (PX7103 (Jamshidi (Grail) Dep. at 171)).

Response to Finding No. 1850:

The proposed finding is misleading to the extent that it suggests that [redacted] [redacted] The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein.

1851. Dr. Jamshidi explained that if Grail replaced Illumina's NGS platform with a NGS platform from another provider, Grail "would have to probably do some additional work just to make sure, for example, that the key metrics are in line with the new instruments that you are bringing in." (PX7103 (Jamshidi (Grail) Dep. at 181-82)).

Response to Finding No. 1851:

The proposed finding is misleading to the extent that it suggests that [redacted] [redacted] The proposed finding is misleading and incomplete for the

reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein.

1852. Grail's Jamshidi testified, "even if you, you know, just bring in a new instrument of a similar brand and characteristics, you would actually do some qualification on that instrument where you would test it and just make sure it works properly and has the right characterizations." (PX7103 (Jamshidi (Grail) Dep. at 182)).

Response to Finding No. 1852:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein.

1853. Grail's Form S-1 identified several risks to Grail from switching suppliers, including its NGS supply from Illumina, as follows:

> Transitioning to a new supplier for this equipment or these materials would be time-consuming and expensive, could result in interruptions in or otherwise affect the performance specifications of our laboratory operations and sample processing or could require that we revalidate our products and, if we receive FDA clearance or approval for our products, could require a new submission to FDA and other regulatory bodies to approve or clear such changes.

(PX4082 (Grail) at 034 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 1853:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein.

1854. At trial, Mr. Bishop confirmed the risk of switching suppliers as stated in the Form S-1, stating: "our understanding of the risks are as written in the sentence you've highlighted for us. Transitioning to a new supplier for the equipment or materials listed above could take time, could be expensive, could result in interruptions and, as it goes on to say, could require that we revalidate our products if we receive FDA clearance or approval for those products, so it's speculating on a number of scenarios." (Bishop (Grail) Tr. 1341).

Response to Finding No. 1854:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein.

1855. Grail's Form S-1 identified a "consistent source of supply" as a risk to Grail that could force Grail to alter its laboratory operations and test procedures: "[W]e purchase certain products on a purchase order basis and cannot guarantee a consistent source of supply. The use of equipment or materials provided by a replacement supplier could require us to alter our laboratory operations and sample collection and processing and related procedures." (PX4082 (Grail) at 034 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 1855:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein.

1856. Grail's Form S-1 specifies that a qualitative substitute for Illumina "may not be available at all": "In the case of attempting to obtain an alternative supplier for Illumina, Streck, or Twist, replacement instruments and associated reagents, tubes, and panels that meet our quality control and performance requirements may not be available at all, or may not be available on reasonable terms or in a timely manner." (PX4082 (Grail) at 034 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 1856:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein.

1857. Grail's Form S-1 explains how delays or difficulty in securing supply or revalidating equipment and reagents could cause "significant delays in commercializing" Grail's products and alter Grail's financial condition:

> If we encounter delays or difficulties in securing, reconfiguring or revalidating the equipment, reagents and other materials that we require for our laboratory operations and sample collection and processing, we would likely face significant delays in commercializing our products and our business, financial condition, results of operations, and growth prospects would be adversely affected.

(PX4082 (Grail) at 034 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 1857:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein.

1858. [redacted]
(PX4140 (Grail) at 004 (R&D Portfolio Planning - Part B, Sequencing Technology) (*in camera*)).

Response to Finding No. 1858:

The proposed finding is misleading to the extent that it suggests that [redacted] The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein.

Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 38), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

b) Illumina Recognizes High Switching Costs

1859. [redacted] (*in camera*)).

Response to Finding No. 1859:

The proposed finding is incomplete and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772, 1780, 1785 and 1873, which Respondents incorporate herein.

Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 8), and did not ask any deposition witness about the specific language quoted, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1860. According to Dr. Febbo, Illumina's Chief Medical Officer, switching an LDT's NGS platform takes approximately six to twelve months. (Febbo (Illumina) Tr. 4325).

Response to Finding No. 1860:

Respondents have no specific response.

1861. Illumina represented to investors in its 2020 Form 10-K that "customers invest time in selecting and learning to use a new product and may be reluctant to switch once that selection is made." (PX0061 at 013 (Illumina 2020 Form 10-K)).

Response to Finding No. 1861:

The proposed finding is incomplete and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe and for a reasonable

cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein.

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this particular language quoted at trial, or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1862. Illumina represented to investors in its 2020 Form 10-K that "customers in our markets display a significant amount of loyalty to their initial supplier of a particular product ….") (PX0061 at 015 (Illumina 2020 Form 10-K)).

Response to Finding No. 1862:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein.

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this particular language quoted at trial, or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

c) Other Industry Participants Acknowledge High Switching Costs

1863. Dr. Felton explained, "it's very difficult once you generated your data sets to show that you can detect that. Typically those data sets require many tens to hundreds of thousands of patient samples to show that you can detect it sensitively and specifically. And you would have to do some level of equivalence testing to show the new technology could recapitulate the data you generated on that original data set, which is not an insubstantial amount of work in and of itself." (PX7070 (Felton (Thermo Fisher) IHT at 61)).

Response to Finding No. 1863:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe and for a reasonable

cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 952, 1772 and 1780, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine—it should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Dr. Felton [redacted]

1864. [redacted] (Felton (Thermo Fisher) Tr. 2009-2010 (*in camera*)).

Response to Finding No. 1864:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 952, 1772, 1780 and 1863, which Respondents incorporate herein. Dr. Felton [redacted]

[redacted]

1865. Dr. Felton explained, "[f]or comparability of data sets. You want to ensure that your data from one technology platform is as comparable as possible. Introducing new technologies can lead to difficulty in interpreting between the two data sets." (PX7070 (Felton (Thermo Fisher) IHT at 29)).

Response to Finding No. 1865:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 952, 1772, 1780 and 1864, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine—it should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1866. Dr. Felton testified that customers are reluctant to switch NGS platforms because once "you have generated research data sets on a single platform, it's generally preferable that you continue to use the same platform for comparability over time, and … changing technologies becomes more difficult[] unless there are very compelling reasons to do so." (PX7070 (Felton (Thermo Fisher) IHT at 29)).

Response to Finding No. 1866:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in

Respondents' responses to CCFF ¶¶ 952, 1772, 1780 and 1864, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine—it should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1867. [redacted]

[redacted]

Response to Finding No. 1867:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772 and 1780, which Respondents incorporate herein. Ariosa (at the time part of Roche) switched its Harmony non-invasive prenatal test from an NGS-based approach to a microarray-based approach, and claimed to have achieved lower cost and decreased turnaround time for the test. (PX7096 (Song (Omniome/Fmr. Ariosa) Dep. at 124– 28); RX3400 (Juneau et al., 2014).) Ariosa completed this platform switching without interrupting the commercial availability of the Harmony test. (PX7096 (Song (Omniome/Fmr. Ariosa) Dep. at 125–26).)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1868. [redacted]

Response to Finding No. 1868:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772, 1780 and 1867, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine—it should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1869. [redacted]

Response to Finding No. 1869:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in

Respondents' responses to CCFF ¶¶ 1772, 1780 and 1867, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1870. [redacted]**).**

Response to Finding No. 1870:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772, 1780 and 1867, which Respondents incorporate herein. Roche [redacted]

[redacted]

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1871. [redacted]

Response to Finding No. 1871:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1772, 1780, 1867 and 1870, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine—it should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony

and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

4. Switching NGS Platforms Is Even More Difficult if the MCED Test Has Begun the FDA Approval Process

1872. [redacted] (PX7058 (Conroy (Exact) IHT at 151-54) (*in camera*)).

Response to Finding No. 1872:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine—it should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1873, which Respondents incorporate herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents also incorporate their responses to CCFF ¶¶ 346, 929, 1682, 1348 and 1785 herein.

1873. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 78-80) (*in camera*)).

Response to Finding No. 1873:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is inaccurate, incomplete, and misleading. For a single-site IVD test approved by the FDA, if the clinical testing portion of the IVD test has changed since the clinical trial demonstrating its efficacy, the FDA requires the IVD sponsor to provide data from a bridging or comparison study to demonstrate that the new clinical test using the third party NGS platform "has performance characteristics that are very similar to those of the test that was used in the trial," *i.e.*, using the Illumina platform. (Cote Tr. 3776; RX3218 (FDA) at 30).) The performance similarity is often demonstrated in a bridging or comparison study by performing the new test using original clinical trial samples and a pre-specified statistical analysis plan, thereby showing both concordance and discordance between the two tests using the same specimens. (RX3218 (FDA) at 30.)

Such a requirement also means that a costly new clinical trial need not be conducted: the IVD sponsor just need to run the new test on the already collected sample to show consistent results. (RX3869 (Cote Expert Report) ¶ 350.) If the results of the bridging or comparison study demonstrate that the two platforms lead to equivalent performance, no additional clinical trials may be required. (RX3869 (Cote Expert Report) ¶ 350.) Dr. Cote estimates that conducting the bridging or comparison study—including a repeatability study—would take approximately one month to complete. (Cote Tr. 3773.) It would cost approximately $1 million to $2 million if samples need to be purchased. (Cote Tr. 3775.) [redacted] The time and cost of these bridging or comparison studies are both

relatively low compared to overall development time and cost for clinical tests. (PX7065 (Aravanis (Illumina) IHT at 164–66); RX3869 (Cote Expert Report) ¶ 351.)

The chance for a bridging or comparison study failing to show the Illumina platform and the third-party platform to be equivalent is very low, because given the comparable accuracy of the third-party platforms, they should be able to accurately reproduce the sequence obtained using the Illumina platform. (Cote Tr. 3775–76; RX3869 (Cote Expert Report) ¶ 352.)

Respondents incorporate their responses to CCFF ¶ 929 herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine—it should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1874. [redacted] (PX7058 (Conroy (Exact) IHT at 151-52) (*in camera*)).

Response to Finding No. 1874:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 929, 1682, 1785 and 1873, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine—it should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1875. [redacted] (PX7058 (Conroy (Exact) IHT at 151-54) (*in camera*)).

Response to Finding No. 1875:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 929, 1682, 1785 and 1873, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine—it should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1876. [redacted] (PX7058 (Conroy (Exact) IHT at 153-54) (*in camera*)).

Response to Finding No. 1876:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 929, 1682, 1785 and 1873, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine—it should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1877. [redacted] (PX7058 (Conroy (Exact) IHT at 153) (*in camera*)).

Response to Finding No. 1877:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 929, 1682, 1785 and 1873, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine—it should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony

and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Exact Sciences does not have any tests that use NGS technology and Exact Sciences was not an Illumina customer until its acquisition of Thrive. (*See* Conroy (Exact Sciences) Tr. 1542–43, [redacted].)

1878. [redacted] (Conroy (Exact) Tr. 1582).

Response to Finding No. 1878:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. Respondents have no specific response other than to incorporate their responses to CCFF ¶¶ 929, 1682, 1785 and 1873 herein.

1879. [redacted] (Conroy (Exact) Tr. 1583).

Response to Finding No. 1879:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. Respondents have no specific response other than to incorporate their responses to CCFF ¶¶ 929, 1682, 1785 and 1873 herein.

1880. [redacted] (Conroy (Exact) Tr. 1582).

Response to Finding No. 1880:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a

reasonable timeframe and for a reasonable cost. The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1725, which Respondents incorporate herein.

1881. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 87-88) (*in camera*)).

Response to Finding No. 1881:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 929, 1682, 1785 and 1873, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine—it should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1882. [redacted] (Chudova (Guardant) Tr. 1286-87 (*in camera*)).

Response to Finding No. 1882:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1785 and 1873, which Respondents incorporate herein.

Respondents also note that switching between two Illumina NGS platforms will also require additional clinical validation. For example, [redacted]

From a technical perspective, there is no reason why Guardant could not switch to BGI, Singular, ONT, Thermo Fisher virtually immediately, or Omniome, Element, Roche Nanopore or Ultima in the foreseeable future. (*See* RRFF ¶¶ 901 (ONT), 928 (all sequencers), 1293 (BGI), 1567 (Thermo Fisher), 1579 (Thermo Fisher), 1584 (Thermo Fisher), 1682 (Singular)). Similarly, each of these sequencing platforms has developed a framework to allow test developers to switch or test developers have successfully switched historically. (*See* RRFF ¶¶ 928 (BGI), 1293 (BGI), 1682 (Singular), 1785 (Thermo Fisher)). Further, [redacted] (*See* RRFF ¶¶ 927 and 2273.) While

Singular, Thermo Fisher and Oxford Nanopore are all currently available in the United States (PFF ¶¶ 607 ((Velarde (Singular) Tr. 4515–16, 4522; see also PX8561 (Singular) at 1–2; PX7117 (Velarde (Singular) Dep. at 30–31)), 579 (RX3688 (Thermo Fisher); RX3689 (Thermo Fisher); RX3687 (Thermo Fisher); RX3685 (Thermo Fisher)), 599 (RX3913 (ONT,) at 1–5; RX3543 (ONT) at 1; RX3536 (ONT); RX3542 (ONT)), BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3; RRFF ¶ 928.) Omniome, Element, Roche Nanopore and Ultima all state that they will enter in the foreseeable future. (RRFF ¶ 928; PFF ¶¶ 614–644.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies in part on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1883. Guardant's Chudova explained that clinical trials and regulatory approvals are tied to the particular NGS instrument and its associated reagents used to develop an MCED test:

> [O]nce you've submitted the data to -- and once you've locked the system, characterized it through analytical validation and submitted your data from that analytical validation for consideration for an IDE ["Investigational Device Exemption"], you're locked. You cannot modify reagents. You cannot modify any component of the system without additional validation and approval from the agency to continue conducting the clinical trial with a modified device.

(PX7045 (Chudova (Guardant) IHT at 73-74)).

Response to Finding No. 1883:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and

incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 927, 1873 and 1882, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine—it should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies in part on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1884. [redacted]

Response to Finding No. 1884:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1190, 1772, 1780, 1785 and 1873, which Respondents incorporate herein.

From a technical perspective, there is no reason why Roche/FMI could not switch to BGI, Singular, ONT, Thermo Fisher virtually immediately, or Omniome, Element, Roche Nanopore or Ultima in the foreseeable future. (*See* RRFF ¶¶ 901 (ONT), 928 (all sequencers), 1293 (BGI), 1567 (Thermo Fisher), 1579 (Thermo Fisher), 1584 (Thermo Fisher), 1682 (Singular)). Similarly, each of these sequencing platforms has developed a framework to allow test developers to switch or test developers have successfully switched historically. (*See* RRFF

¶¶ 928 (BGI), 1293 (BGI), 1682 (Singular), 1785 (Thermo Fisher)). Further, [redacted]. (*See* RRFF ¶ 1190.) While Singular, Thermo Fisher and Oxford Nanopore are all currently available in the United States (PFF ¶¶ 607 ((Velarde (Singular) Tr. 4515–16, 4522; see also PX8561 (Singular) at 1–2; PX7117 (Velarde (Singular) Dep. at 30–31)), 579 (RX3688 (Thermo Fisher); RX3689 (Thermo Fisher); RX3687 (Thermo Fisher); RX3685 (Thermo Fisher)), 599 (RX3913 (ONT,) at 1–5; RX3543 (ONT) at 1; RX3536 (ONT); RX3542 (ONT)), BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3; RRFF ¶ 928.) Omniome, Element, Roche Nanopore and Ultima all state that they will enter in the foreseeable future. (RRFF ¶ 928; PFF ¶¶ 614–644.)

1885. [redacted]

Response to Finding No. 1885:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1190, 1772, 1780, 1873 and 1884, which Respondents incorporate herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies in part on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1886. [redacted]

Response to Finding No. 1886:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1190, 1772, 1780, 1873 and 1884, which Respondents incorporate herein.

Further, [redacted] (*See* RRFF ¶ 1190.) [redacted] While Singular, Thermo Fisher and Oxford Nanopore are all currently available in the United States (PFF ¶¶ 607 ((Velarde (Singular) Tr. 4515–16, 4522; see also PX8561 (Singular) at 1–2; PX7117 (Velarde (Singular) Dep. at 30–31)), 579 (RX3688 (Thermo Fisher); RX3689 (Thermo Fisher); RX3687 (Thermo Fisher); RX3685 (Thermo Fisher)), 599 (RX3913 (ONT,) at 1–5; RX3543 (ONT) at 1; RX3536 (ONT); RX3542 (ONT)), BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3; RRFF ¶ 928.) Omniome, Element, Roche Nanopore and Ultima all state that they will enter in the foreseeable future. (RRFF ¶ 928; PFF ¶¶ 614–644.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony

and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1887. [redacted]

Response to Finding No. 1887:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1190, 1772, 1780, 1873 and 1884, which Respondents incorporate herein.

Further, [redacted] (*See* RRFF ¶ 1190.) [redacted] While Singular, Thermo Fisher and Oxford Nanopore are all currently available in the United States (PFF ¶¶ 607 ((Velarde (Singular) Tr. 4515–16, 4522; see also PX8561 (Singular) at 1–2; PX7117 (Velarde (Singular) Dep. at 30–31)), 579 (RX3688 (Thermo Fisher); RX3689 (Thermo Fisher); RX3687 (Thermo Fisher); RX3685 (Thermo Fisher)), 599 (RX3913 (ONT,) at 1–5; RX3543 (ONT) at 1; RX3536 (ONT); RX3542 (ONT)), BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3;

RRFF ¶ 928.) Omniome, Element, Roche Nanopore and Ultima all state that they will enter in the foreseeable future. (RRFF ¶ 928; PFF ¶¶ 614–644.)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1888. Switching may also require redoing entire clinical trials or obtaining new regulatory approvals, which could take "a couple years to finish, then a couple years to basically submit and get published." (PX7042 (Gao (Singlera) IHT at 57)).

Response to Finding No. 1888:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 982, 1011, 1772, 1780, 1785 and 1873, which Respondents incorporate herein. Dr. Gao of Singlera testified that the PanSeer test only needs over 5 million reads (Gao (Singlera) Tr. at 2893) and can be run using alternative NGS instruments such as Illumina's MiSeq and Thermo Fisher equipment. (*See* Gao (Singlera) Tr. at 2928–31; PFF ¶¶ 780–780.6.)

From a technical perspective, there is no reason why Singlera could not switch to BGI, Singular, ONT, Thermo Fisher virtually immediately, or Omniome, Element, Roche Nanopore or Ultima in the foreseeable future. (*See* RRFF ¶¶ 901 (ONT), 928 (all sequencers), 1293 (BGI), 1567 (Thermo Fisher), 1579 (Thermo Fisher), 1584 (Thermo Fisher), 1682 (Singular)). Similarly, each of these sequencing platforms has developed a framework to allow test developers to switch or test developers have successfully switched historically. (*See* RRFF ¶¶ 928 (BGI), 1293 (BGI), 1682 (Singular), 1785 (Thermo Fisher)). [redacted]

[redacted]

[redacted] (*See* RRFF ¶¶ 982 and 2406.) While Singular, Thermo Fisher and Oxford Nanopore are all currently available in the United States (PFF ¶¶ 607 ((Velarde (Singular) Tr. 4515–16, 4522; see also PX8561 (Singular) at 1–2; PX7117 (Velarde (Singular) Dep. at 30–31)), 579 (RX3688 (Thermo Fisher); RX3689 (Thermo Fisher); RX3687 (Thermo Fisher); RX3685 (Thermo Fisher)), 599 (RX3913 (ONT,) at 1–5; RX3543 (ONT) at 1; RX3536 (ONT); RX3542 (ONT)), BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3; RRFF ¶ 928.) Omniome, Element, Roche Nanopore and Ultima all state that they will enter in the foreseeable future. (RRFF ¶ 928; PFF ¶¶ 614–644.)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1889. Singlera could not use the data it has already accumulated using Illumina's system—"there's no practical use." (PX7042 (Gao (Singlera) IHT at 57)).

Response to Finding No. 1889:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 982, 1011, 1772, 1780, 1873 and 1888, which Respondents incorporate herein. Dr. Gao of Singlera testified that the PanSeer test only needs over 5 million reads (Gao (Singlera) Tr. at 2893) and can be run using alternative NGS instruments such as Illumina's MiSeq and Thermo Fisher equipment. (*See* Gao (Singlera) Tr. at 2928–31; PFF ¶¶ 780–780.6.)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1890. Freenome's Nolan testified that [redacted]

[redacted]

(PX7050 (Nolan (Freenome) IHT at 111) (*in camera*)).

Response to Finding No. 1890:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 945, 1772, 1780, 1785 and 1873, which Respondents incorporate herein.

From a technical perspective, there is no reason why Freenome could not switch to BGI, Singular, ONT, Thermo Fisher virtually immediately, Omniome, Element, Roche Nanopore or Ultima in the foreseeable future. (*See* RRFF ¶¶ 901 (ONT), 928 (all sequencers), 1293 (BGI), 1567 (Thermo Fisher), 1579 (Thermo Fisher), 1584 (Thermo Fisher), 1682 (Singular)). Similarly, each of these sequencing platforms has developed a framework to allow test developers to switch or test developers have successfully switched historically. (*See* RRFF ¶¶ 928 (BGI), 1293 (BGI), 1682 (Singular), 1785 (Thermo Fisher)). [redacted]

[redacted] (*See* RRFF ¶¶ 945 and 2355.) While Singular, Thermo Fisher and Oxford Nanopore are all currently available in the United States (PFF ¶¶ 607 ((Velarde (Singular) Tr. 4515–16, 4522; see also PX8561 (Singular) at 1–2;

PX7117 (Velarde (Singular) Dep. at 30–31)), 579 (RX3688 (Thermo Fisher); RX3689 (Thermo Fisher); RX3687 (Thermo Fisher); RX3685 (Thermo Fisher)), 599 (RX3913 (ONT,) at 1–5; RX3543 (ONT) at 1; RX3536 (ONT); RX3542 (ONT)), BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3; RRFF ¶ 928.) Omniome, Element, Roche Nanopore and Ultima all state that they will enter in the foreseeable future. (RRFF ¶ 928; PFF ¶¶ 614–644.)

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

In particular, Freenome's current CEO, Mr. Nolan admitted that, consistent with his IH testimony, *he was not aware that Freenome had evaluated any non-Illumina platform*. (Nolan (Freenome) Tr. 2736–37.) Further, Respondents incorporate their responses to CCFF ¶¶ 945 and 1620 herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1891. [redacted]

(PX7050 (Nolan (Freenome) IHT at 112) (*in camera*)).

Response to Finding No. 1891:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 945, 1772, 1780, 1785, 1873 and 1890, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1892. [redacted] **(Chahine (Helio) Tr. 1070-71 (*in camera*)).**

Response to Finding No. 1892:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 1177, 1772, 1780 and 1873, which Respondents incorporate herein.

From a technical perspective, there is no reason why Helio could not switch to BGI, Singular, ONT, Thermo Fisher virtually immediately, or Omniome, Element, Roche Nanopore or Ultima in the foreseeable future. (*See* RRFF ¶¶ 901 (ONT), 928 (all sequencers), 1293 (BGI), 1567 (Thermo Fisher), 1579 (Thermo Fisher), 1584 (Thermo Fisher), 1682 (Singular)). Similarly, each of these sequencing platforms has developed a framework to allow test developers to switch or test developers have successfully switched historically. (*See* RRFF

¶¶ 928 (BGI), 1293 (BGI), 1682 (Singular), 1785 (Thermo Fisher)). [redacted] (*See* RRFF ¶ 1177.) While Singular, Thermo Fisher and Oxford Nanopore are all currently available in the United States (PFF ¶¶ 607 ((Velarde (Singular) Tr. 4515–16, 4522; see also PX8561 (Singular) at 1–2; PX7117 (Velarde (Singular) Dep. at 30–31)), 579 (RX3688 (Thermo Fisher); RX3689 (Thermo Fisher); RX3687 (Thermo Fisher); RX3685 (Thermo Fisher)), 599 (RX3913 (ONT,) at 1–5; RX3543 (ONT) at 1; RX3536 (ONT); RX3542 (ONT)), BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3; RRFF ¶ 928.) Omniome, Element, Roche Nanopore and Ultima all state that they will enter in the foreseeable future. (RRFF ¶ 928; PFF ¶¶ 614–644.)

1893. [redacted]

Response to Finding No. 1893:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 1264, 1293, 1772, 1780, 1785 and 1873, which Respondents incorporate herein.

From a technical perspective, there is no reason why Natera could not switch to BGI, Singular, ONT, Thermo Fisher virtually immediately, or Omniome, Element, Roche Nanopore or Ultima in the foreseeable future. (*See* RRFF ¶¶ 901 (ONT), 928 (all sequencers), 1293

(BGI), 1567 (Thermo Fisher), 1579 (Thermo Fisher), 1584 (Thermo Fisher), 1682 (Singular)). Similarly, each of these sequencing platforms has developed a framework to allow test developers to switch or test developers have successfully switched historically. (*See* RRFF ¶¶ 928 (BGI), 1293 (BGI), 1682 (Singular), 1785 (Thermo Fisher)). [redacted] (*See* RRFF ¶ 928.) While Singular, Thermo Fisher and Oxford Nanopore are all currently available in the United States (PFF ¶¶ 607 ((Velarde (Singular) Tr. 4515–16, 4522; see also PX8561 (Singular) at 1–2; PX7117 (Velarde (Singular) Dep. at 30–31)), 579 (RX3688 (Thermo Fisher); RX3689 (Thermo Fisher); RX3687 (Thermo Fisher); RX3685 (Thermo Fisher)), 599 (RX3913 (ONT,) at 1–5; RX3543 (ONT) at 1; RX3536 (ONT); RX3542 (ONT)), BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3; RRFF ¶ 928.) Omniome, Element, Roche Nanopore and Ultima all state that they will enter in the foreseeable future. (RRFF ¶ 928; PFF ¶¶ 614–644.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies in part on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. At 275–76.)

1894. [redacted]

Response to Finding No. 1894:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a

reasonable timeframe and for a reasonable cost. Respondents incorporate their responses to CCFF ¶¶ 928, 1293, 1772, 1780, 1785, 1873 and 1893. The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine—it should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies in part on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1895. [redacted]

Response to Finding No. 1895:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. Respondents incorporate their responses to CCFF ¶¶ 928, 1293, 1772, 1780, 1785, 1873 and 1893.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1896. [redacted]

Response to Finding No. 1896:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 1293, 1772, 1780, 1785, 1873 and 1893, which Respondents incorporate herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1897. [redacted]

Response to Finding No. 1897:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 1293, 1772, 1780, 1785, 1873 and 1893, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1898. [redacted]

Response to Finding No. 1898:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. Respondents incorporate their responses to CCFF ¶¶ 928, 1293, 1772, 1780, 1785, 1873 and 1893 herein. The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine—it should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies in part on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1899. [redacted]

Response to Finding No. 1899:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 928, 1293, 1772, 1780, 1785, 1873 and 1893, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine—it should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies in part on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1900. Thermo Fisher's Felton testified that in order for an MCED test developer to switch NGS instruments after it received FDA approval on a particular instrument, "you have to generate equivalence data to show that the answers that you generate of the second technology are exactly the same as the first technology. And the FDA may require -- may require a lot of data to generate that evidence." (PX7070 (Felton (Thermo Fisher) IHT at 64)).

Response to Finding No. 1900:

The proposed finding is inaccurate and misleading to the extent it suggests that it is not possible to switch between sequencing platforms, including for an FDA approved product, in a reasonable timeframe and for a reasonable cost. The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 952, 1772, 1780 and 1873, which Respondents incorporate herein.

[redacted]

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine—it should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies in part on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

1901. According to Phillip Febbo, Illumina's Chief Medical Officer, switching a test's NGS platform when that test has already received a PMA could take nine to 18 months. (Febbo (Illumina) Tr. 4325-26).

Response to Finding No. 1901:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1873 herein.

VI. COMPETITORS ARE RACING TO DEVELOP MCED TESTS

1902. [redacted] (PX6049 (Grail) at 034 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 1902:

The proposed finding is incomplete and misleading. Respondents incorporate their responses to CCFF ¶¶ 378, 382, 398 and 709 herein.

1903. [redacted] (PX6049 (Grail) at 034 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 1903:

The proposed finding is incomplete and misleading. Respondents incorporate their responses to CCFF ¶¶ 378, 382, 398 and 709 herein.

A. EXACT SCIENCES IS DEVELOPING AN MCED TEST CALLED CANCERSEEK

1. Exact Is a Commercial Oncology Company That Launched Cologuard, an FDA-Approved and CMS-Reimbursed Stool-Based Colorectal Cancer Screening Test

1904. Exact is headquartered in Madison, Wisconsin with locations across the United States and in Europe. (PX7058 (Conroy (Exact) IHT at 33-34)).

Response to Finding No. 1904:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1905. Exact has experience bringing cancer screening tests to market from initial biomarker identification all the way to the patient. (PX7058 (Conroy (Exact) IHT at 24)).

Response to Finding No. 1905:

The proposed finding is inaccurate and misleading because it refers to "cancer screening tests". Exact's experience was limited to Cologuard, which is a single cancer screening test for colon cancer; Exact does not have experience bringing an MCED test from biomarker identification to the patient. (Conroy (Exact) Tr. 1533.) The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Contrary to Complaint Counsel's unproven contention, Exact has not completed initial biomarker identification for any test. (*See* PPF ¶ 442 (Lengauer (Exact/Thrive) Tr. 212–13.) Exact acquired Thrive, which had started biomarker identification for its CancerSEEK test as part of PapGene. Respondents note that CancerSEEK is still under development (PFF ¶ 417 (Lengauer (Exact/Thrive) Tr. 158)), that [redacted] (Conroy (Exact) Tr. 1717) Respondents also note that Exact has not commercialized any MCED test. (Conroy (Exact) Tr. 1621.) Respondents further incorporate PFF ¶¶ 414–43, 709.3, 717.1.1, 721.1–21.2, 726–26.8, 735, 738–40.1 and their responses to CCFF ¶¶ 413–14, 697, 703, 736, 773–76, and 929 herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1906. Exact has five core values, one of which is innovation. (Conroy (Exact) Tr. 1541).

Response to Finding No. 1906:

The proposed finding is irrelevant.

1907. At trial, Mr. Conroy explained what innovation means to Exact:

> Innovation means looking at a complex problem and thinking about it in different ways, ways that maybe others have never thought about solving those problems, and then investing in a collaborative effort to solve them, bringing together people of all different perspectives and backgrounds and experiences and skill sets to do so. Cologuard is an example of that. Oncotype DX is an example of that. These were far-out-there ideas when first thought of, and so it is a core value to constantly innovate and work with others internally and externally so that you can make a difference in people's lives.

(Conroy (Exact) Tr. 1541-42).

Response to Finding No. 1907:

The proposed finding is irrelevant.

1908. In April 2009, Exact's start-up business was developing a colon cancer screening test and a pan-cancer screening test from a blood draw. (Conroy (Exact) Tr. 1532).

Response to Finding No. 1908:

The proposed finding is inaccurate, incomplete and misleading, and not supported by the cited evidence. Mr. Conroy expressly states in the cited testimony that in April 2009, it was merely "an idea" for Exact to develop "a pan-cancer screening test or a universal cancer screening test from a simple blood draw" in the "long term". (Conroy (Exact) Tr. 1532). In addition, there is no such thing as a "pan-cancer test" because there is no such thing as a universal cancer biomarker. (PFF ¶ 308; Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106.)

1909. Today, Exact develops and sells tests that look at hereditary or germline cancers, that screen for cancer, that indicate the best cancer treatment for a patient's cancer, and a test that detects the recurrence of cancer. (Conroy (Exact) Tr. 1531).

Response to Finding No. 1909:

The proposed finding is irrelevant to the extent it discusses hereditary or germline cancers, therapy selection tests (*i.e.*, tests that indicate the best cancer treatment for a patient's cancer) and MRD tests (a test that detects the recurrence of cancer). The proposed finding is also inaccurate and misleading because it refers to "tests that screen for cancer". Exact's experience is limited to Cologuard, which is a single cancer screening test for colon cancer.

1910. [redacted] (PX7058 (Conroy (Exact) IHT at 19-20; 54-55) (*in camera*)).

Response to Finding No. 1910:

Respondents have no specific response except to note that [redacted] (Conroy (Exact) Tr. 1597).

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1911. [redacted] (Lengauer (Third Rock Ventures) Tr. 157; PX7091 (Lengauer (Third Rock Ventures) Dep. at 13-14) (*in camera*); PX7051 (Lengauer (Third Rock Ventures) IHT at 28-29, 29-32) (*in camera*)).

Response to Finding No. 1911:

The proposed finding is incomplete and misleading including insofar as it suggests that Exact/Thrive is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. Respondents note that [redacted] (Conroy (Exact) Tr. 1621.) Respondents incorporate PFF ¶¶ 414–43, 709.3, 717.1.1, 721.1–

21.2, 726–26.8, 735, 738–40.1 and their responses to CCFF ¶¶ 413–14, 697, 703, 736, 773–76, and 929 herein. Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1912. [redacted] (Lengauer (Third Rock Ventures) Tr. 158; PX7051 (Lengauer (Third Rock Ventures) IHT at 28-29) (*in camera*)).

Response to Finding No. 1912:

The proposed finding is inaccurate, incomplete and misleading. CancerSEEK requires a whole-body PET-CT scan, which [redacted] (*See*, *e.g.*, Lengauer (Exact/Thrive) Tr. 248; RX3419 (Lennon et al., 2020) at 3; [redacted]; PFF ¶¶ 419, [redacted], 425, [redacted], [redacted] 739, 760, [redacted] 841.3, [redacted], 1723–24.) Consequently, CancerSEEK is not [redacted]

Respondents also note that whole body PET-CT scans are not recommended for routine early cancer screening, because of cost and radiation concerns, as well as the inability of PET-CT scanning to detect very small tumors. (RX3624 (Schöder & Gonen 2007) at 9–10; Cote Tr. 3812–13; RX3869 (Cote Expert Report) ¶ 72.) Diagnostic PET-CT will necessitate further evaluation of true-positive or false-positive finding and therefore impose downstream costs on the health care system as a whole. (RX3624 (Schöder & Gonen 2007) at 9–10.) Whole-body PET-CT scan [redacted]

The proposed finding is incomplete and misleading including insofar as it suggests that Exact/Thrive is an actual competitor to GRAIL today or will be a competitor to GRAIL in the

foreseeable future. Respondents note that CancerSEEK is still under development (PFF ¶ 417 (Lengauer (Exact/Thrive) Tr. 158)), that [redacted] (Conroy (Exact) Tr. 1717), and that CancerSEEK is combined with a whole-body PET-CT, which [redacted] (*See*, *e.g.*, Lengauer (Exact/Thrive) Tr. 248; RX3419 (Lennon et al., 2020) at 3; [redacted]; PFF ¶¶ 419, [redacted] 425, [redacted], 739, 760, [redacted] 841.3, [redacted], 1723–24.) Respondents also note that Exact has not commercialized any MCED test. (Conroy (Exact) Tr. 1621.) Respondents incorporate PFF ¶¶ 414–43, 709.3, 717.1.1, 721.1–21.2, 726–26.8, 735, 738–40.1 and their responses to CCFF ¶¶ 389, 413–14, 418–19, 696–97, 703, 715, 736, 738-39, 773–76, 785, and 929 herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1913. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 28) (*in camera*)).

Response to Finding No. 1913:

The proposed finding is irrelevant because it does not relate to MCED tests.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1914. [redacted] (PX7058 (Conroy (Exact) IHT at 19-20; 83-84) (*in camera*)).

Response to Finding No. 1914:

The proposed finding is also misleading to the extent [redacted] (PX7058 (Conroy (Exact) IHT at 19-20; 83-84.) The proposed finding is irrelevant because it does not relate to MCED tests. Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1915. [redacted] (PX7058 (Conroy (Exact) IHT at 83-84) (*in camera*)).

Response to Finding No. 1915:

The proposed finding is irrelevant because it does not relate to MCED tests. Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2. In January 2021, Exact Acquired Thrive, the Developer of an MCED Test Called CancerSEEK

1916. [redacted] (PX7110 (Conroy (Exact) Dep. at 12) (*in camera*); PX7058 (Conroy (Exact) IHT at 201-02) (*in camera*); Conroy (Exact) Tr. 1550-51)).

Response to Finding No. 1916:

Respondents have no specific response except to note that Exact announced its agreement to acquire Thrive one month after Illumina announced its agreement to acquire GRAIL. (PFF ¶ 929.1; RX3196 (Exact) at 1; *see also* PFF ¶ 929.2.)

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1917. Exact completed its acquisition of Thrive in early January 2021. (PX4331 (Grail) (Email Attaching Exact Sciences Completes Acquisition of Thrive Earlier Detection, Creating a Leader in Blood-Based, Multi-Cancer Screening, Jan. 5, 2021); PX7051 (Lengauer (Third Rock Ventures) IHT at 24)).

Response to Finding No. 1917:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶ 1917 herein.

1918. [redacted] (PX7110 (Conroy (Exact) Dep. at 12-13) (*in camera*)). [redacted] (PX7110 (Conroy (Exact) Dep. at 12-13) (*in camera*); PX7058 (Conroy (Exact) IHT at 200) (*in camera*)).

Response to Finding No. 1918:

The proposed finding is incomplete and misleading. Respondents note that Mr. Conroy states in the cited testimony that [redacted]. (PX7110 (Conroy (Exact) Dep. at 13; PX7058 (Conroy (Exact) IHT) at 200.) Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See*

Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶ 1917 herein.

1919. Thrive was founded in 2019 by Third Rock Ventures. (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 27); Lengauer (Third Rock Ventures) Tr. 155-156).

Response to Finding No. 1919:

The proposed finding is misleading. Thrive was originally founded based on the research from the company PapGene, which was founded in 2014, as well as research from Johns Hopkins University. (*See* PFF ¶¶ 296, 416, **1721**.) Respondents also incorporate their responses to CCFF ¶¶ 357–365 herein.

1920. CancerSEEK was co-developed by Dr. Bert Vogelstein at Johns Hopkins University. (Conroy (Exact) Tr. 1542-43; PX7101 (Vogelstein (Johns Hopkins University), Dep. at 27); *see* Conroy (Exact) Tr. 1542-43 (testifying that Dr. Vogelstein developed CancerSEEK within his own lab)).

Response to Finding No. 1920:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 361–62, 365 and 1919, which Respondents incorporate herein.

1921. Thrive's predecessor in the development of the CancerSEEK test, PapGene, first described the screening test in Science magazine in approximately 2016 or 2017. (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 40, 46)).

Response to Finding No. 1921:

The proposed finding is inaccurate, incomplete and misleading. Respondents note that Dr. Vogelstein states in the cited testimony that the technology underlying CancerSEEK's blood-based screening test was first described in Science and was the basis of Dr. Vogelstein's interaction with PapGene, which was founded in 2014. (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 40; PFF ¶¶ 296, 416.) The technology underlying CancerSEEK's blood-based screening test was first described in Science Translational Medicine by Bettegowda et al. in 2014. (*See* RX3059 (Bettegowda et al., 2014).)

1922. Dr. Vogelstein "ran clinical studies to demonstrate the ability from a single blood draw to detect cancer earlier across many different types of cancer." (Conroy (Exact) Tr. 1542-43).

Response to Finding No. 1922:

The proposed finding is inaccurate, incomplete and misleading. Respondents note that Dr. Vogelstein and his group only conducted one clinical study—the Cohen study—which is a case-control study involving 1817 participants (1005 cancer patients and 812 healthy individuals) and only focused on eight cancer types. (*See* PFF ¶¶ 427, 1699.) Respondents also incorporate their responses to CCFF ¶¶ 361–62 herein.

1923. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 38) (*in camera*)).

Response to Finding No. 1923:

The proposed finding is inaccurate, incomplete and misleading. Respondents note that the cited testimony only states that the knowledge of [redacted] (PX7051 (Lengauer (Exact/Thrive) IHT at 38.) Respondents also note that CancerSEEK is still under development (PFF ¶ 417 (Lengauer (Exact/Thrive) Tr. 158)), [redacted] (Conroy (Exact) Tr. 1717).

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1924. [redacted]

[redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 38) (*in camera*)).

Response to Finding No. 1924:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1923, which Respondents incorporate herein. The proposed finding is also irrelevant.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1925. Dr. Vogelstein is the Clayton Professor of Oncology and Co-Director of the Ludwig Center for Cancer, Genetics and Therapeutics at the Sidney Kimmel Comprehensive Cancer Center of Johns Hopkins University School of Medicine. (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 63-64)).

Response to Finding No. 1925:

Respondents have no specific response.

1926. Dr. Vogelstein has devoted his career to researching and understanding the role of genetic alterations in human cancer and he, along with his team, has been credited with a number of scientific breakthroughs in this area. (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 64); PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶ 2)).

Response to Finding No. 1926:

Respondents have no specific response.

1927. Dr. Vogelstein holds a joint appointment in molecular biology and genetics at the Johns Hopkins University and as an investigator at the Howard Hughes Medical Institute. (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 64)).

Response to Finding No. 1927:

Respondents have no specific response.

1928. Alongside teams of researchers, Dr. Vogelstein helped discover that "a relatively small number of genes [play] a major role in most human cancer types." (PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶ 2)).

Response to Finding No. 1928:

Respondents have no specific response except to note that Dr. Vogelstein's discovery focused on "a relatively small number of genes". (PX8400 (Vogelstein (Johns Hopkins University) Decl.) ¶ 2.) These genes and corresponding protein biomarkers only focus on epithelial cancers and not non-epithelial cancers. (Cote Tr. 3810–11.) Therefore, the biomarkers interrogated by the CancerSEEK test, now owned by Exact, are not capable of detecting "all" types of cancer, but only a subset of cancer types. (Cote Tr. 3810–11.) Respondents also incorporate their responses to CCFF ¶¶ 361–62 herein.

1929. Dr. Vogelstein and the group of researchers with whom he works were awarded the international prize from the American Association of Cancer Research for "pioneering the development of liquid biopsies." (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 78-79)).

Response to Finding No. 1929:

The proposed finding is irrelevant because Dr. Vogelstein testified in the cited testimony that "our lab's current work, which considerably is quite different from what Thrive is doing". (PX7101 (Vogelstein (Johns Hopkins University), Dep.) at 54–55.) The proposed finding is incomplete and misleading to the extent it uses the term "liquid biopsies", which does not refer only to early cancer screening. (*See, e.g.*, PFF ¶¶ 123–139.) Respondents also incorporate their responses to CCFF ¶¶ 361–362 herein.

1930. Dr. Vogelstein's lab is currently working on using "the genetic alterations responsible for cancer to develop new diagnostic tests to identify cancers earlier and new therapies to treat patients with advanced disease." (PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶ 4)).

Response to Finding No. 1930:

The proposed finding is irrelevant for the reasons explained in Respondents' responses to CCFF ¶ 1929, which Respondents incorporate herein.

1931. Dr. Vogelstein's lab is currently developing tests that rely on NGS to "find cancer DNA in a small amount of blood or bodily fluids and can be used to detect cancer in asymptomatic individuals, personalize therapies to combat the unique genetic alterations within a tumor, and to monitor cancer's response to treatment." (PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶¶ 4, 6)).

Response to Finding No. 1931:

The proposed finding is irrelevant for the reasons explained in Respondents' responses to CCFF ¶ 1929, which Respondents incorporate herein.

1932. Dr. Vogelstein testified that his lab "published the first description of cancer genomes, what we called cancer genome landscapes, using an Illumina instrument" in approximately 2009 or 2010. (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 61)).

Response to Finding No. 1932:

The proposed finding is irrelevant for the reasons explained in Respondents' responses to CCFF ¶ 1929, which Respondents incorporate herein. Respondents also note that Dr. Vogelstein started PapGene in 2014, now Thrive, an Exact company, and it has still not launched a commercial version of its cancer screening test, CancerSEEK, eight years later. (*See* PFF ¶¶ 296–296.3 (PX7101 (Vogelstein (Johns Hopkins University) Dep.) at 27–28; [redacted].)

1933. Dr. Vogelstein previously served as a consultant to Thrive—a role that involved advising Thrive on the science and scientific issues associated with improving its test in development. (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 30)).

Response to Finding No. 1933:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1929 herein.

1934. Dr. Vogelstein testified that his work at Johns Hopkins University and Howard Hughes Medical Institute includes an unpaid collaboration agreement with Thrive intended to facilitate "work[ing] together to develop the best test possible for [Thrive's] earlier diagnosis of cancer." (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 36-37)).

Response to Finding No. 1934:

The proposed finding is inaccurate, incomplete and misleading. Dr. Vogelstein testified in the cited testimony that he retains "an equity interest" in Thrive. (PX7101 (Vogelstein (Johns Hopkins University), Dep.) at 26.)

3. CancerSEEK is an MCED Test Designed to Detect All Cancer Types Using Multiple Analytes and Next Generation Sequencing

1935. Exact, through Thrive, is developing an MCED test called CancerSEEK. (Lengauer (Third Rock Ventures) Tr. 157; PX7091 (Lengauer (Third Rock Ventures) Dep. at 13-14) (*in camera*); PX7051 (Lengauer (Third Rock Ventures) IHT at 28-29, 29-32) (*in camera*)).

Response to Finding No. 1935:

The proposed finding is incomplete and misleading including insofar as it suggests that Exact/Thrive is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. Respondents incorporate PFF ¶¶ 414–43, 709.3, 717.1.1, 721.1–21.2, 726–26.8, 735, 738–40.1 and their responses to CCFF ¶¶ 413–14, 697, 703, 736, 773–76, 929, and 1912 herein. Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1936. [redacted] (Lengauer (Third Rock Ventures) Tr. 158; PX7051 (Lengauer (Third Rock Ventures) IHT at 28) (*in camera*)).

Response to Finding No. 1936:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1912, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1937. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 28-29) (*in camera*)).

Response to Finding No. 1937:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1912, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1938. CancerSEEK "is a test…intended to detect all types of cancers." (Lengauer (Third Rock Ventures) Tr. 159-60).

Response to Finding No. 1938:

The proposed finding is inaccurate, incomplete and misleading. In the DETECT-A trial, which is the most recent clinical trial conducted for the Exact/Thrive CancerSEEK test (*see* (Lengauer (Exact/Thrive) Tr. 169–70, 212), [redacted] (*See* (Lengauer (Exact/Thrive) Tr. 243; Conroy (Exact/Thrive) Tr. 1706–07; PFF ¶¶ [redacted], 721.1 1699.) [redacted] Further, CancerSEEK's design does not support the proposition that it was "intended to detect all types of cancers"; to the contrary,

its biomarkers shows that it focuses on epithelial cancers. (PFF ¶ 428-29.1 (RX3419 (Lennon et al., 2020) at 9, Fig. 3; RX3869 (Cote Expert Report) ¶ 177; PFF ¶ 169.1 (Cote Tr. 3810-11)).

Respondents also incorporate PFF ¶¶ 414–43, 709.3, 717.1.1, 721.1–21.2, 726–26.8, 735, 738–40.1 and their responses to CCFF ¶¶ 389, 413–14, 418–19, 696–97, 703, 715, 736, 738-39, 773–76, 785, and 929 herein.

1939. [redacted] (Conroy (Exact) Tr. 1650 (*in camera*)).

Response to Finding No. 1939:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1938, which Respondents incorporate herein.

1940. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 53-55, 57-59) (*in camera*)).

Response to Finding No. 1940:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938 and 1939, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1941. CancerSEEK uses NGS and protein detection to accurately find cancers with a high level of specificity. (Conroy (Exact) Tr. 1544).

Response to Finding No. 1941:

The proposed finding is inaccurate, incomplete and misleading to the extent it suggests that the CancerSEEK test has a "high level of specificity". Exact/Thrive's CancerSEEK test in development was shown to have a specificity of 95.3% using a single blood test in the DETECT-

A study. (PFF ¶¶ 173 ("Specificity . . . measures the proportion of actual negative samples that are correctly identified as such", so that a 95.3% specificity corresponds to a true negative rate of 95.3% and a false positive rate of 100% minus 95.3%), 428, 431 ("In the DETECT-A study, CancerSEEK obtained [a] specificit[y] of 95.3% in its baseline blood test (that is, with a single blood test).").) [redacted] (*See also* RX3419 (Lennon et al., 2020) at 8 & Table 2; PFF ¶¶ 431–432.)

The proposed finding is also inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938 and 1939, which Respondents incorporate herein.

1942. [redacted] (PX7051 (Conroy (Exact) IHT at 29-32) (*in camera*)).

Response to Finding No. 1942:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938 and 1939, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1943. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 33-34) (*in camera*)).

Response to Finding No. 1943:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938 and 1939, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1944. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 39) (*in camera*)).

Response to Finding No. 1944:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938 and 1939, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1945. [redacted] (Lengauer (Third Rock Ventures) Tr. 175 (*in camera*); Conroy (Exact) Tr. 1544; PX7091 (Lengauer (Third Rock Ventures) Dep. at 13-14) (*in camera*); *see* PX7051 (Lengauer (Third Rock Ventures) IHT at 28-37) (*in camera*) (testifying that [redacted]).

Response to Finding No. 1945:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938 and 1939, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is inaccurate, incomplete and misleading. Although [redacted]. (*See* [redacted]) Respondents note that the cited testimony indicates that [redacted]

1946. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 34) (*in camera*)).

Response to Finding No. 1946:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938 and 1939, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1947. [redacted]

[redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 35-36) (*in camera*)).

Response to Finding No. 1947:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938 and 1939, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1948. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 35-36) (*in camera*)).

Response to Finding No. 1948:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938 and 1939, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Respondents note that the cited testimony indicates that [redacted]. (PX7051 (Lengauer (Exact/Thrive) IHT) at 35–36.)

1949. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 36) (*in camera*)).

Response to Finding No. 1949:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938 and 1939, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Respondents note that while [redacted]

1950. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 36) (*in camera*)).

Response to Finding No. 1950:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1949, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1951. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 36) (*in camera*)).

Response to Finding No. 1951:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1949, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1952. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 36-37) (*in camera*)).

Response to Finding No. 1952:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1949, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1953. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 144) (*in camera*)).

Response to Finding No. 1953:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938 and 1945, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1954. [redacted] (Conroy (Exact) Tr. 1571 (*in camera*)).

Response to Finding No. 1954:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938–39 and 1945, which Respondents incorporate herein.

Further, there is no evidence that [redacted] (*See* Conroy (Exact/Thrive) Tr. 1706–07; PFF ¶¶ [redacted], 1699). The genes and corresponding protein biomarkers "curated" by Dr. Vogelstein in his laboratory only focus on epithelial cancers and not non-epithelial cancers. (Cote Tr. 3810–11.) Therefore, the biomarkers interrogated by the CancerSEEK test, now owned by Exact, are not capable of detecting "all" types of cancer, but only a subset of cancer types. (Cote Tr. 3810–11.) Respondents also incorporate their responses to CCFF ¶¶ 361–62 herein.

1955. [redacted] (PX8572 (Exact) at 046 (Exact Sciences, Innovation & Technology Committee Spring Meeting Presentation, Apr. 16, 2021 (*in camera*)) [redacted]; PX7091 (Lengauer (Third Rock Ventures) Dep. at 17-19) (*in camera*)).

Response to Finding No. 1955:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938–39 and 1945, which Respondents incorporate herein.

Respondents also note that the cited testimony indicates that [redacted] (Conroy (Exact) Tr. 1717.)

1956. Exact's CEO Mr. Conroy confirmed at trial that, for CancerSEEK, Exact is continuing to explore multiple different biomarker combinations. (Conroy (Exact) Tr. 1717).

Response to Finding No. 1956:

Respondents have no specific response except to note that the cited testimony indicates that [redacted]. (Conroy (Exact) Tr. 1717.)

1957. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 39-40, 142) (*in camera*)).

Response to Finding No. 1957:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938–39 and 1945, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1958. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 33-37) (*in camera*)).

Response to Finding No. 1958:

Respondents have no specific response except to notet that this is a different approach from GRAIL's. [redacted] Further, the proposed finding relies on IH testimony which

Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1959. [redacted] (Conroy (Exact) Tr. 1622 (*in camera*)).

Response to Finding No. 1959:

The proposed finding is inaccurate, incomplete and misleading to the extent it suggests that CancerSEEK [redacted]. The cited testimony by Mr. Conroy indicates that [redacted] (**Conroy (Exact) Tr. 1717**.)

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938–39 and 1945, which Respondents incorporate herein.

1960. [redacted] (Lengauer (Third Rock Ventures) Tr. 171; PX6049 (Grail) at 036 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*) [redacted]).

Response to Finding No. 1960:

The proposed finding is inaccurate, incomplete, misleading, and not supported by the cited evidence. The cited testimony by Dr. Lengauer indicates that [redacted]

1961. [redacted] (Conroy (Exact) Tr. 1628-29 (*in camera*)).

Response to Finding No. 1961:

[redacted]

[redacted]

1962. [redacted] (Conroy (Exact) Tr. 1583 (*in camera*); *see* PX7051 (Lengauer (Third Rock Ventures) IHT at 69-70) (*in camera*) [redacted]).

Response to Finding No. 1962:

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding is inaccurate, incomplete and misleading with respect to Exact/Thrive's purported reliance on Illumina's NGS systems. [redacted] BGI's systems may be available in the United States as early as August 2022. [redacted]

[redacted]

Further, Dr. Vogelstein, the founder of Thrive stated, [redacted]

Respondents also incorporate their responses to CCFF ¶¶ 341, 344, 928–29, 940, 971, 980, 1115, 1118 and 2833 herein.

Respondents also note that the proposed finding relies in part on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

a) [redacted]

1963. [redacted] (Lengauer (Third Rock Ventures) Tr. 270-71 (*in camera*); *see* Conroy (Exact) Tr. 1655-56 (*in camera*)

[redacted]

Response to Finding No. 1963:

The proposed response is inaccurate, incomplete and misleading. Respondents note that full-body PET-CT is a fairly poor tool for cancer signal of origin determination. This is reflected in Exact/Thrive's own study. Of the 53 patients identified by PET-CT as having imaging concerning for cancer in the DETECT-A study, only 15 were determined to have cancer, with only a 28.3% detection rate, compared with the 88.7% accuracy of cancer signal of origin prediction achieved by GRAIL's Galleri v1 in the CCGA3 study. (*See* PFF ¶¶ 426.3–426.4.) [redacted] (*See* PFF ¶ 439.) [redacted] and the Cohen study found the PET-CT approach is not well suited to be a primary screening modality for the general population also because it is financially and operationally impractical (Conroy (Exact/Thrive) Tr. 1707–08). (*See* PFF ¶ 1700.)

Dr. Lengauer admitted that a diagnostic full-body PET-CT confers a higher radiation exposure than a standard CT; the radiation exposure from diagnostic PET-CT and follow-up imaging tests in the participants without cancer is a recognized source of potential harm associated with the DETECT-A CancerSEEK protocol; investigators of the DETECT-A trial recognized that the diagnostic PET-CT scans are not well suited to be the primary screening modality for the general population, in part because of a low disease prevalence and a relatively high rate of incidental findings; and even after the full-body PET-CT scan, there may be a need

to do additional biopsies to further characterize the cancer. (*See* Lengauer (Exact/Thrive) Tr. 248–50; PFF ¶ 1724.)

Respondents also note that [redacted] RX3419 (Lennon et al., 2020); Cote Tr. 3811–14.)

Respondents incorporate their responses to CCFF ¶¶ 1938–39 herein.

1964. [redacted] (Lengauer (Third Rock Ventures) Tr. 270-72 (*in camera*)).

Response to Finding No. 1964:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938–39 and 1963, which Respondents incorporate herein. The proposed finding is also inaccurate and misleading to the extent it suggests that Galleri's determination of the cancer signal of origin is inaccurate because it is an "approximation." To the contrary, Galleri v1 demonstrated a cancer signal of origin prediction accuracy of 93%. (PFF ¶ 389 (RX3430 (Liu et al., 2020) at 1, 9; RX0744 (GRAIL) at 68; RX3869 (Cote Expert Report) ¶ 143).) CCGA3, the third CCGA sub-study, reported that Galleri v2 demonstrated a cancer signal of origin prediction accuracy of 88.7%. (PFF ¶ 393 (RX3408 (Klein et al., 2021) at 10; RX3869 (Cote Expert Report) ¶ 144).)

By contrast, the CancerSEEK assay does not identify the cancer signal of origin, which is why it is combined with a whole-body PET-CT. (PFF ¶ 419 (RX3869 (Cote Expert Report) ¶ 174).) Full-body PET-CT is a fairly poor tool for cancer signal of origin determination,

compared with the 93% accuracy of cancer signal of origin prediction achieved by GRAIL's Galleri v1 in the CCGA2 study. (PFF ¶ 426.4 (RX3869 (Cote Expert Report) at n.173 (Liu 2020 at 745, 754; RX0744 (GRAIL) at 68; RX3409 (Klein et al., 2021) at 1).)

Further, [redacted]

1965. [redacted] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 67-68) (*in camera*)).

Response to Finding No. 1965:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938–39 and 1963, which Respondents incorporate herein.

1966. [redacted] (Lengauer (Third Rock Ventures) Tr. 270-72 (*in camera*)).

Response to Finding No. 1966:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1963, which Respondents incorporate herein.

1967. [redacted] (Lengauer (Third Rock Ventures) Tr. 270-72 (*in camera*)).

Response to Finding No. 1967:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1963, which Respondents incorporate herein.

In particular, Dr. Lengauer admitted that a diagnostic full-body PET-CT confers a higher radiation exposure than a standard CT and the radiation exposure from diagnostic PET-CT and follow-up imaging tests in the participants without cancer is a recognized source of potential harm associated with the DETECT-A CancerSEEK protocol. (*See* Lengauer (Exact/Thrive) Tr. 248–50; PFF ¶ 1724.)

1968. [redacted] (PX7110 (Conroy (Exact) Dep. at 244) (*in camera*)).

Response to Finding No. 1968:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938–39 and 1963, which Respondents incorporate herein.

b) Exact Plans to Continue Improving CancerSEEK Using NGS to Compete with Other MCED Test Developers

1969. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 139-40) (*in camera*)).

Response to Finding No. 1969:

The proposed finding is incomplete and misleading to the extent that it suggests that CancerSEEK's sensitivity will improve. In fact, Respondents note that the cited testimony indicates that [redacted] (PX7051 (Lengauer

(Exact/Thrive) IHT) at 139–40.) Respondents also note that [redacted] There is also no reason to believe that CancerSEEK will improve when it has in fact gotten worse on some metrics. (*Compare*, *e.g.*, PFF ¶ 426.1 (RX3142 (Cohen 2018) at 3), *with* PFF ¶ 426.3 (Lengauer (Exact/Thrive) Tr. 248; RX3869 (Cote Expert Report at n.240).) Further, [redacted] (PFF ¶ 726.6; RX4007 (Exact/Thrive) at 7.)

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶¶ 1938–39 herein.

1970. Dr. Lengauer testified that even if performance of CancerSEEK is "outstanding," Thrive "want[s] to always improve [its] test, and with that spirit in mind, [Thrive has] engaged in further improvements of the test while [ ] preparing towards a registrational trial." (Lengauer (Third Rock Ventures) Tr. 168-69).

Response to Finding No. 1970:

The proposed finding is incomplete and misleading, including because it seems to suggest that the performance of CancerSEEK is "outstanding". To the contrary, as Thrive recognized, "[a]t present, we cannot be certain that the DETECT-A blood test used in our study helped any participant." (RX3419 (Lennon et al., 2020) at 11.) The CancerSEEK blood test obtained specificities of only 95.3% in its baseline blood test in the DETECT-A study, with a

sensitivity of only 30.2% and PPV (positive predictive value) of only 5.9%. (*See* RX3419 (Lennon et al., 2020) at 8 & Table 2; PFF ¶¶ 431–432.) [redacted] The CancerSEEK blood test identified only ten cancer types and failed to detect six cancers in the DETECT-A study. (*See* Conroy (Exact/Thrive) Tr. 1706–07; PFF ¶¶ 430.1, 1699.) [redacted] (Lengauer (Exact/Thrive) Tr. 168–69.) Respondents also incorporate their responses to CCFF ¶¶ 1938–39 and 1969 herein.

1971. Innovation has allowed Thrive and Exact to constantly improve CancerSEEK "with the use of next-generation sequencing technologies and other technologies." (Conroy (Exact) Tr. 1546).

Response to Finding No. 1971:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1970, which Respondents incorporate herein.

The proposed finding is inaccurate, incomplete and misleading, and not supported by the cited evidence. [redacted] (Conroy (Exact) Tr. 1623.) There is no evidence that there has been any improvement to the CancerSEEK test in development. [redacted]

[redacted] (Conroy (Exact) Tr. 1546.)

1972. Innovation has improved the CancerSEEK product. (Conroy (Exact) Tr. 1546).

Response to Finding No. 1972:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1971, which Respondents incorporate herein.

1973. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 140 (*in camera*))).

Response to Finding No. 1973:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1971, which Respondents incorporate herein. The proposed finding is speculative because there is no basis to show that the sensitivity and specificity of CancerSEEK will improve by the time of launch.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1974. [redacted] (*in camera*) (*see* inset image)).

[redacted]

[redacted] (RX0074 (Exact) at 008 [redacted] (*in camera*))).

Response to Finding No. 1974:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1971, which Respondents incorporate herein.

Respondents note that the cited source indicates that [redacted].

Respondents also note that Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 5), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

1975. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 141 (*in camera*))).

Response to Finding No. 1975:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1971, which Respondents incorporate herein.

Respondents also note that the cited testimony indicates that [redacted]

Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1976. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 141 (*in camera*))).

Response to Finding No. 1976:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1977. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 141 (*in camera*))).

Response to Finding No. 1977:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1971, which Respondents incorporate herein.

Respondents note that the cited testimony indicates that [redacted]

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1978. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 142 (*in camera*))).

Response to Finding No. 1978:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1971, which Respondents incorporate herein.

Respondents note that the cited testimony indicates that [redacted]

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1979. [redacted] (Lengauer (Third Rock Ventures) Tr. 187 (*in camera*)).

Response to Finding No. 1979:

The proposed finding is inaccurate, incomplete and misleading, and not supported by the cited evidence, including because it seems to suggest that Illumina's switch of NGS platforms caused Thrive to change the tubes used to collect blood. Dr. Lengauer only testified in the cited testimony that [redacted]

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1971, which Respondents incorporate herein.

1980. Mr. Conroy testified at trial that Exact plans on continuing to innovate to develop the CancerSEEK product "[e]very day." (Conroy (Exact) Tr. 1546).

Response to Finding No. 1980:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1971, which Respondents incorporate herein.

Respondents also note that the cited testimony indicates that [redacted]. (Conroy (Exact) Tr. 1545–46.)

1981. Mr. Conroy stated at trial that Exact "absolutely" plans to continue innovating to develop the CancerSEEK product for the benefit of patients. (Conroy (Exact) Tr. 1546).

Response to Finding No. 1981:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1971, which Respondents incorporate herein.

Respondents also note that the cited testimony indicates that [redacted] (Conroy (Exact) Tr. 1545–46.)

1982. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 140 (*in camera*))).

Response to Finding No. 1982:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1971, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1983. [redacted] (Conroy (Exact) Tr. 1615 (*in camera*)).

Response to Finding No. 1983:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1971, which Respondents incorporate herein.

In particular, unlike CancerSEEK, GRAIL's Galleri test is based on targeted methylation. By contrast, although [redacted] Further, while Mr. Conroy claims that [redacted] (PX7051 (Lengauer (Third

Rock Ventures) IHT at 144) (*in camera*). Therefore, Complaint Counsel's witness testimony contradicts the proposed finding.

The proposed finding also seems to suggest that [redacted]. (Conroy (Exact) Tr. 1623.)

1984. [redacted] (Conroy (Exact) Tr. 1615 (*in camera*)).

Response to Finding No. 1984:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1971, which Respondents incorporate herein.

The proposed finding is incomplete and misleading, including because it seems to suggest that [redacted]. (Conroy (Exact) Tr. 1623.) Respondents also note that [redacted]

1985. [redacted] (Conroy (Exact) Tr. 1615 (*in camera*)).

Response to Finding No. 1985:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1971, which Respondents incorporate herein.

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony

and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents also note that [redacted]

1986. [redacted] (Conroy (Exact) Tr. 1615-16 (*in camera*)).

Response to Finding No. 1986:

The proposed finding is inaccurate and misleading. As Thrive recognized about CancerSEEK in their published paper, "we cannot be certain that the DETECT-A blood test used in our study helped any participant." (RX3419 (Lennon et al., 2020) at 11.) Respondents also note that there is no CancerSEEK product in the market for people to benefit from. (Conroy (Exact) Tr. 1623.) Respondents also incorporate their responses to CCFF ¶ 1971 herein.

1987. [redacted] (Conroy (Exact) Tr. 1617 (*in camera*)).

Response to Finding No. 1987:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1971, which Respondents incorporate herein. Respondents also note that this cited testimony is inconsistent with Complaint Counsel's proposed finding that CancerSEEK purportedly detects "all types" of cancer. (*See* CCFF ¶¶ 1938–39.)

1988. [redacted]

[redacted] (Conroy (Exact) Tr. 1576-77 (*in camera*)).

Response to Finding No. 1988:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938–39, which Respondents incorporate herein.

1989. At trial, Respondents' expert, Dr. Richard Cote, agreed that [redacted] (Cote, Tr. 3823 (*in camera*)).

Response to Finding No. 1989:

The proposed finding is inaccurate, incomplete, and misleading. Dr. Cote testified in the cited testimony that [redacted]

c) [redacted]

1990. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 146-47; 157 (*in camera*)); PX7058 (Conroy (Exact) IHT at 142 (*in camera*)); PX8402 (Exact/Thrive) at 002 [redacted]

Response to Finding No. 1990:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Complaint Counsel did not present exhibit PX8402 cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 61), and therefore, the

document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

Respondents note that Mr. Conroy testified at trial that [redacted] Respondents also incorporate their responses to CCFF ¶ 1939 herein.

1991. [redacted] (Conroy (Exact) Tr. 1625 (*in camera*)).

Response to Finding No. 1991:

The proposed finding is inaccurate and misleading, especially as Exact has not yet launched its CancerSEEK test as an LDT (PFF ¶ 296.1) and Mr. Conroy testified at trial that [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶ 1939 herein.

1992. [redacted] (PX7058 (Conroy (Exact) IHT at 142 (*in camera*)); (Conroy (Exact) Tr. 1558 (*in camera*))).

Response to Finding No. 1992:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1991, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1993. [redacted] (Conroy (Exact) Tr. 1625 (*in camera*)). [redacted] (Conroy (Exact) Tr. 1625 (*in camera*)).

Response to Finding No. 1993:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1991, which Respondents incorporate herein.

1994. [redacted] (Conroy (Exact) Tr. 1558 (*in camera*)).

Response to Finding No. 1994:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1991, which Respondents incorporate herein.

1995. [redacted] (Conroy (Exact) Tr. 1627-28 (*in camera*)).

Response to Finding No. 1995:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1991, which Respondents incorporate herein. Contrary to Mr. Conroy's testimony, [redacted]

1996. [redacted] (Conroy (Exact) Tr. 1558-59 (*in camera*)).

Response to Finding No. 1996:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1991, which Respondents incorporate herein.

1997. [redacted] (Conroy (Exact) Tr. 1558 (*in camera*)).

Response to Finding No. 1997:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1991, which Respondents incorporate herein.

1998. [redacted] (Conroy (Exact) Tr. 1558-59 (*in camera*)); PX7058 (Conroy (Exact) IHT at 143 (*in camera*)) [redacted]).

Response to Finding No. 1998:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1991, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

1999. [redacted] (Conroy (Exact) Tr. 1556-57 (*in camera*)).

Response to Finding No. 1999:

Respondents have no specific response.

2000. [redacted] (Conroy (Exact) Tr. 1626 (*in camera*)). [redacted] (Conroy (Exact) Tr. 1626 (*in camera*)).

Response to Finding No. 2000:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1991, which Respondents incorporate herein.

The proposed finding is also speculative because CancerSEEK has not launched as an LDT, no patients have taken CancerSEEK and there is no way to know (or for Mr. Conroy to know) how many patients "could" take CancerSEEK if it launched as an LDT.

2001. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 160-62 (*in camera*))).

Response to Finding No. 2001:

The proposed finding is inaccurate, incomplete and misleading, and not supported by the cited evidence. Dr. Lengauer only testified in the cited testimony that [redacted]

The proposed finding also lacks foundation because it cites the deposition testimony of a third party without established expertise regarding FDA and CMS review processes. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2002. [redacted] (PX7109 (Daly (Singular Genomics) Dep. at 180 (*in camera*))).

Response to Finding No. 2002:

The proposed finding is inaccurate, incomplete and misleading, and not supported by the cited evidence. Mr. Daly only testified in the cited testimony that [redacted]

The proposed finding also lacks foundation because it cites the deposition testimony of a third party without established expertise regarding the USPSTF. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

2003. [redacted] (PX7058 (Conroy (Exact) IHT at 145 (*in camera*))).

Response to Finding No. 2003:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1991, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2004. [redacted] (PX7058 (Conroy (Exact) IHT at 145 (*in camera*))).

Response to Finding No. 2004:

The proposed finding is hearsay because it relies on [redacted] and the cited testimony should be accorded no weight.

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1991, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2005. [redacted] (PX7058 (Conroy (Exact) IHT at 145 (*in camera*))).

Response to Finding No. 2005:

The proposed finding is hearsay because it relies on statements from integrated health systems and the cited testimony should be accorded no weight.

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1991, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2006. [redacted] (PX7058 (Conroy (Exact) IHT at 145-46 (*in camera*))).

Response to Finding No. 2006:

The proposed finding is hearsay because it relies on statements from integrated health systems and the cited testimony should be accorded no weight.

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1991, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2007. [redacted] (PX7058 (Conroy (Exact) IHT at 146 (*in camera*))).

Response to Finding No. 2007:

The proposed finding is hearsay because it relies on [redacted] and the cited testimony should be accorded no weight.

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1991, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4. [redacted]

2008. [redacted] (PX7058 (Conroy (Exact) IHT at 141 (*in camera*))).

Response to Finding No. 2008:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1990, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2009. [redacted] (PX7110 (Conroy (Exact) Dep. at 33) (*in camera*)).

Response to Finding No. 2009:

Respondents have no specific response except to note that Mr. Conroy testified at trial that [redacted]

2010. A registrational trial is what "devices, tests, and so on [usually seek] or companies usually seek approval by the agency, in this case the FDA, that evaluates the benefit/risk ratio and… can give the approval stamp to a test." The FDA's approval stamp is "very, very important for acceptance of tests in the community" and "for potential reimbursement of the test." (Lengauer (Third Rock Ventures) Tr. 169).

Response to Finding No. 2010:

Respondents have no specific response.

2011. [redacted] (PX7051 ((Lengauer (Third Rock Ventures) Tr. 190 (*in camera*); Lengauer (Third Rock Ventures) IHT at 157 (*in camera*); PX8402 (Exact/Thrive) at 002 [redacted] (*in camera*)).

Response to Finding No. 2011:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 61), and therefore, the document

should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

Respondents incorporate their responses to CCFF ¶ 1990 herein.

2012. [redacted] (Conroy (Exact) Tr. 1628 (*in camera*)).

Response to Finding No. 2012:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1990, which Respondents incorporate herein. Respondents note that [redacted] (PFF ¶ 441; Conroy (Exact/Thrive) Tr. 1709, 1717; [redacted] Mr. Conroy testified that "there can be no guarantee that the FDA would clear or approve any future product or service that [Exact/Thrive] may develop," and that Exact Sciences' 10-K acknowledged that "[d]eveloping new or improved cancer tests is a speculative and risky endeavor". (Conroy (Exact/Thrive) Tr. 1713–18.)

2013. [redacted] (PX8402 (Exact/Thrive) at 002 [redacted] (*in camera*)).

Response to Finding No. 2013:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1990, which Respondents incorporate herein. Mr. Conroy testified that "there can be no guarantee that the FDA would clear or approve any future product

or service that [Exact/Thrive] may develop," and that Exact Sciences' 10-K acknowledged that "[d]eveloping new or improved cancer tests is a speculative and risky endeavor". (Conroy (Exact/Thrive) Tr. 1713–18.)

Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 61), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2014. [redacted] (Conroy (Exact) Tr. 1556-57 (*in camera*)).

Response to Finding No. 2014:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1990, which Respondents incorporate herein. Mr. Conroy testified that "there can be no guarantee that the FDA would clear or approve any future product or service that [Exact/Thrive] may develop," and that Exact Sciences' 10-K acknowledged that "[d]eveloping new or improved cancer tests is a speculative and risky endeavor". (Conroy (Exact/Thrive) Tr. 1713–18.)

5. CancerSEEK Has Already Undergone a Prospective, Interventional Clinical Trial, and Exact is Preparing for Its FDA Registrational Trial

2015. There are two published studies on CancerSEEK. (Conroy (Exact) Tr. 1697).

Response to Finding No. 2015:

The proposed finding is inaccurate, incomplete and misleading to the extent it suggests that the version of CancerSEEK that Exact/Thrive intends to launch has undergone any clinical studies; it has not. The version of CancerSEEK used in the DETECT-A trial (also known as

"Lennon") was known as Version zero. (CCFF ¶ 1976.) The version of CancerSEEK that Exact/Thrive intends to use at launch is known as version 1.1. (*See* CCFF ¶ 1975.)

a) The Cohen Study

2016. [redacted] (Conroy (Exact) Tr. 1545-46; Lengauer (Third Rock Ventures) Tr. 202 (*in camera*)).

Response to Finding No. 2016:

Respondents have no specific response except to note that the first clinical study of a different version of CancerSEEK—the Cohen study—was a case-control study that focused on only eight types of cancer. (*See* RX3142 (Cohen 2018) at 1; PFF ¶¶ 426.1, 427.) Respondents also incorporate their responses to CCFF ¶¶ 1938–39 herein.

2017. The first CancerSEEK study, referred to as the "Cohen study," was published in the Journal of Science in 2018. (RX3142 (Cohen et. al, Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test, Feb. 23, 2018)).

Response to Finding No. 2017:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2016 herein.

2018. The Cohen study examined CancerSEEK's ability to "detect eight common cancer types through [the] assessment of the levels of circulating proteins and mutations in cell-free DNA." (RX3142 at 001 (Cohen et. al, Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test, Feb. 23, 2018)).

Response to Finding No. 2018:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2016 herein.

2019. The Cohen study applied CancerSEEK to 1,005 patients with "nonmetastatic clinically detected cancers of the ovary, liver, stomach, pancreas, esophagus, colorectum, lung, or breast." (RX3142 (Cohen et al., Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test)).

Response to Finding No. 2019:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2016 herein.

2020. The Cohen study focused on eight cancer types: ovary, liver, stomach, pancreas, esophagus, colorectal, lung, and breast. (RX3142 (Cohen et al., Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test)).

Response to Finding No. 2020:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2016 herein.

2021. Mr. Conroy explained at trial that the Cohen study did not use the current version of CancerSEEK. (Conroy (Exact) Tr. 1742).

Response to Finding No. 2021:

The proposed finding is inaccurate, incomplete and misleading, including because it seems to suggest that [redacted] Respondents incorporate their responses to CCFF ¶¶ 1945 and 2016 herein.

2022. The CancerSEEK test used in the Cohen study tested "positive in a median of 70% of the eight cancer types. The sensitivities ranged from 69 to 98 percent for the detection of five cancer types (ovary, liver, stomach, pancreas, and esophagus) for which there are no screening tests available for average-risk individuals." (RX3142 at 001 (Cohen et. al, Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test, Feb. 23, 2018)).

Response to Finding No. 2022:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2016 herein.

2023. The Cohen study acknowledged that the patient cohort was comprised of individuals who had been diagnosed with stage I to III cancers of the ovary, liver, stomach, pancreas, esophagus, colorectum, lung, or breast. (RX3142 at 002 (Cohen et. al, Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test, Feb. 23,

2018 (49% of patients had stage II cancer; 20% of patients had stage I cancer; and 31 % of patients had stage III cancer.); Conroy (Exact) Tr. 1701).

Response to Finding No. 2023:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2016 herein.

2024. The Cohen study used a "healthy control cohort" of "812 individuals of median age 55 (range 17 to 88) with no known history of cancer, high-grade dysplasia, auto-immune disease, or chronic kidney disease." (RX3142 at 002 (Cohen et. al, Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test, Feb. 23, 2018)).

Response to Finding No. 2024:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2016 herein.

2025. The eight cancer types were chosen because they are common in western populations and because no blood-based tests for their earlier detection are in common clinical use. (RX3142 at 001 (Cohen et. al, Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test, Feb. 23, 2018)).

Response to Finding No. 2025:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2016 herein.

2026. The researchers in the Cohen study estimated that the sensitivity of CancerSEEK was 55 percent among all eight cancer types selected. (Conroy (Exact) Tr. 1702-03; RX3142 at 004 (Cohen et. al, Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test, Feb. 23, 2018)).

Response to Finding No. 2026:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2016 herein.

b) The DETECT-A Study

2027. The second CancerSEEK study was "DETECT-A." (Conroy (Exact) Tr. 1703-04).

Response to Finding No. 2027:

Respondents have no specific response except to note that in the DETECT-A clinical trial: only women were studied; two blood tests were performed in the CancerSEEK workflow and individuals remaining positive after the two blood tests were then scanned using full-body PET-CT imaging; the CancerSEEK baseline blood test obtained specificities of only 95.3%, with a sensitivity of only 30.2% and PPV (positive predictive value) of only 5.9%; the CancerSEEK blood test identified only ten cancer types and failed to detect six cancers. (*See* RX3419 (Lennon et al., 2020); PFF ¶¶ 422–432, 1699.) Also, the CancerSEEK blood test does not identify the cancer signal of origin, which is why it is combined with a whole-body PET-CT. (*See* PFF ¶¶ 419 (RX3869 (Cote Expert Report) ¶ 174), [redacted] 684.2 (Lengauer (Exact/Thrive) Tr. 248), 735, 839.7, 841.3, [redacted] Respondents also incorporate their responses to CCFF ¶¶ 1912 and 1938–39 herein.

2028. The results of DETECT-A were published in July 2020 in Science Magazine, a prominent peer-reviewed scientific journal, under the title, "Feasibility of blood testing combined with PET-CT to screen for cancer and guide intervention." (Conroy (Exact) Tr. 1703; Lengauer (Third Rock Ventures) Tr. 164-65; RX3419 (Lennon et al., Feasibility of Blood Testing Combined with PET-CT to Screen for Cancer and Guide Intervention, *Science* 369, 49 (2020))).

Response to Finding No. 2028:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2027 herein.

2029. [redacted] (PX7085 (Harada (Exact) Dep. at 20) (*in camera*)).

Response to Finding No. 2029:

The proposed finding is inaccurate, incomplete and misleading. The CancerSEEK workflow in the DETECT-A study required full-body PET-CT imaging, therefore, [redacted] (*See* PFF ¶¶ 425, **426**.)

Respondents incorporate their responses to CCFF ¶¶ 1912, 1938–39 and 2027 herein.

2030. Thrive completed a large interventional study of CancerSEEK involving the multi-cancer screening of 10,000 women called DETECT-A. (Lengauer (Third Rock Ventures) Tr. 163-65; Conroy (Exact) Tr. 1704).

Response to Finding No. 2030:

The proposed finding is incomplete and misleading including insofar as it suggests that Exact/Thrive is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. Respondents incorporate their responses to CCFF ¶¶ 1912, 1938–39 and 2027 herein.

2031. DETECT-A was an exploratory prospective interventional study. (Conroy (Exact) Tr. 1703).

Response to Finding No. 2031:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2027 herein.

2032. Dr. Lengauer testified that DETECT-A was the largest and only interventional study in the screening setting of a multicancer test. (Lengauer (Third Rock Ventures) Tr. 164).

Response to Finding No. 2032:

The proposed finding is inaccurate, incomplete and misleading, including because it seems to suggest that DETECT-A was the only interventional study of a putative multicancer

screening test. PATHFINDER is also a prospective, interventional multi-center study of GRAIL's multi-cancer screening test, Galleri, in 6,662 participants. (*See* PFF ¶¶ 394–402.)

Respondents also incorporate their responses to CCFF ¶ 2027 herein.

2033. An interventional study involves testing patients, getting results, and giving those results back to the physician and patient. (Lengauer (Third Rock Ventures) Tr. 164).

Response to Finding No. 2033:

Respondents have no specific response.

2034. Dr. Lengauer testified at trial that Thrive is the only MCED test developer to conduct an interventional study. (Lengauer (Third Rock Ventures) Tr. 164).

Response to Finding No. 2034:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2032, which Respondents incorporate herein.

2035. The purpose of Thrive's DETECT-A study was to understand the sensitivity, specificity, and safety of its CancerSEEK test, as well as how it fits within the existing physician workflow. (Lengauer (Third Rock Ventures) Tr. 165).

Response to Finding No. 2035:

The proposed finding is inaccurate, incomplete and misleading. The workflow used in DETECT-A is not the final workflow that will be used for CancerSEEK if it is commercialized. (*See* PFF ¶¶ 438–48.) The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents also incorporate their responses to CCFF ¶ 2027 herein.

2036. Dr. Lengauer testified that specificity "is a measure that relates to how frequently one generates false-positives, or in other words, a false alarm; for example, if you were to say you have cancer, but it ends up being that there is no cancer." (Lengauer (Third Rock Ventures) Tr. 166).

Response to Finding No. 2036:

Respondents have no specific response.

2037. The specificity of CancerSEEK was measured in the DETECT-A study at "a little bit over 99 percent, which is an important requirement for a screening test of asymptomatic individuals." (Lengauer (Third Rock Ventures) Tr. 166-67).

Response to Finding No. 2037:

The proposed finding is inaccurate, incomplete and misleading. In the DETECT-A clinical trial, the CancerSEEK workflow obtained specificities of only 95.3% with the baseline blood test and 98.9% with both baseline and confirmational blood tests. (*See* RX3419 (Lennon et al., 2020) at 8 & Table 2; PFF ¶ 431.) [redacted]

Respondents also incorporate their responses to CCFF ¶ 2027 herein.

2038. Dr. Lengauer explained that specificity is an important requirement because CancerSEEK "is designed for individuals that are asymptomatic, which means individuals that would go to their annual exam, not that they have cancer by any means, and in that context get this test. In such a group it is very, very important that we are not causing false alarm because there are consequences." These consequences include a follow up doctor visit and interventional methods such as biopsies and other forms of surgeries to try and find the cancer after a positive screening test result. Thus, "in an asymptomatic – or maybe we call it in lay terms healthy population – when you apply a test, it's extremely important that the false-positives that such a test cause are very, very rare." (Lengauer (Third Rock Ventures) Tr. 167).

Response to Finding No. 2038:

Respondents have no specific response.

2039. Dr. Lengauer testified that sensitivity means "what's the fraction of cancers that one can identify from all the cancers that are out there in principle." (Lengauer (Third Rock Ventures) Tr. 166768).

Response to Finding No. 2039:

Respondents have no specific response.

2040. The sensitivity of CancerSEEK was measured in the DETECT-A study across all cancer types. DETECT-A makes a determination of "sensitivity for an interventional cancer type that relates to a certain organ, like breast or colon." (Lengauer (Third Rock Ventures) Tr. 168).

Response to Finding No. 2040:

The proposed finding is incomplete and misleading to the extent that it suggests that CancerSEEK can detect all cancer types. Respondents incorporate their response to CCFF ¶ 2027 herein.

2041. "Today, only 25 percent of cancers can be detected by screening methods. 75 percent of cancers are detected by symptoms, signs and symptoms, which means cancers are usually detected late." (Lengauer (Third Rock Ventures) Tr. 168-69).

Response to Finding No. 2041:

The proposed finding is incomplete and misleading. Current single-cancer screening tests can detect only five cancer types in the United States, which represents only 10% of the cancers that Galleri can detect and an even smaller percentage of all cancers that exist. (Bishop (GRAIL) Tr. 1374; Ofman (GRAIL) Tr. 3308; Abrams Tr. 3729.)

2042. The outcome of the DETECT-A study "showed that now 52 percent, which means – of cancers can be detected by screening first, which means we can now double the number[ ] of cancers first detected by screening, which means cancer in most individuals can be detected now earlier." (Lengauer (Third Rock Ventures) Tr. 169).

Response to Finding No. 2042:

The proposed finding is inaccurate, incomplete and misleading. Dr. Lengauer made no explanation of his calculations. (*See* Lengauer (Third Rock Ventures) Tr. 169.) Given that there are over 200 cancer types and CancerSEEK could only detect 10 cancer types, including one of

unknown primary, the DETECT-A clinical trial results does not account for his claim. (PFF ¶ 429 (RX3419 (Lennon et al., 2020) at 4, 6–7, 9; Lengauer (Exact/Thrive) Tr. 243, 260–61).) In the DETECT-A study, the CancerSEEK workflow obtained a sensitivity of only 30.2% in its baseline blood test (that is, with a single blood test), 27.1% with both baseline and confirmational blood tests *without* PET-CT imaging, and 15.6% with both blood tests and PET-CT imaging. (*See* RX3419 (Lennon et al., 2020) at 8 & Table 2; PFF ¶ 431.)

CancerSEEK is also unable to detect several cancers that Galleri has detected. (PFF ¶ 430.1; *compare* RX3419 (Lennon et al., 2020) at 1, 6–7, 9 *with* (RX3409 (Klein et al., 2021) at 1, 5; Cote Tr. 3818–19.) Respondents also incorporate their responses to CCFF ¶ 2027 herein.

2043. Dr. Lengauer testified that the DETECT-A study provided Thrive with a "good understanding about the performance of the [CancerSEEK] test." The results can be "summarized by saying that [CancerSEEK] could [ ] more than double the cancers detected… compared to the classical standard of screening methods." (Lengauer (Third Rock Ventures) Tr. 165-66).

Response to Finding No. 2043:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2042 herein.

2044. The DETECT-A study also showed that CancerSEEK "is very safe" and how the integration of CancerSEEK into clinical care "had no impact on compliance to the standard of care, which is a very important from a safety perspective." (Lengauer (Third Rock Ventures) Tr. 166).

Response to Finding No. 2044:

The proposed finding is inaccurate, incomplete and misleading because the authors of the Lennon paper, which reported on the DETECT-A study, also recognized many shortcomings and safety concerns from the DETECT-A CancerSEEK protocol. As Thrive recognized in DETECT-A, "[a]t present, we cannot be certain that the DETECT-A blood test used in our study helped any participant." (RX3419 (Lennon et al., 2020) at 11.) Respondents also note that

whole body PET-CT scans are not recommended for routine early cancer screening, because of cost and radiation concerns, as well as the inability of PET-CT scanning to detect very small tumors. (RX3624 (Schöder & Gonen 2007) at 9–10; Cote Tr. 3812–13; RX3869 (Cote Expert Report) ¶ 72.) Diagnostic PET-CT will necessitate further evaluation of true-positive or false-positive finding and therefore impose downstream costs on the health care system as a whole. (RX3624 (Schöder & Gonen 2007) at 9–10.) Whole-body PET-CT scan [redacted]

Respondents also incorporate their responses to CCFF ¶ 2027 herein.

2045. Overall the DETECT-A study showed how well CancerSEEK "integrates [ ] into the work flow of physicians." (Lengauer (Third Rock Ventures) Tr. 166).

Response to Finding No. 2045:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2035, which Respondents incorporate herein.

2046. DETECT-A used a three-step testing process: a baseline blood test, a confirmation blood test, and then imaging using a PET-CT scan. (Conroy (Exact) Tr. 1704; RX3419 (Lennon et al., Feasibility of Blood Testing Combined with PET-CT to Screen for Cancer and Guide Intervention, *Science* 369, 49 (2020))).

Response to Finding No. 2046:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2027 herein and note that [redacted]. (*See*, *e.g.*, [redacted]

2047. DETECT-A's baseline blood test was an early version of CancerSEEK. (Conroy (Exact) Tr. 1704).

Response to Finding No. 2047:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2027 herein.

2048. DETECT-A's confirmation blood test was given to participants that scored positive on the baseline blood test. (Conroy (Exact) Tr. 1704).

Response to Finding No. 2048:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2027 herein. Respondents also note that the confirmation blood test was used to rule out an abnormal biomarker reading due to clonal hematopiesis (CHiP), which is a blood mutation that might cause false positives in DNA or protein markers. (PFF ¶ 424.1 (Lengauer (Exact/Thrive) Tr. 247; [redacted]); RX3419 (Lennon et al., 2020) at 3).)

2049. DETECT-A used a diagnostic PET-CT scan to confirm the results of CancerSEEK and localize the potential cancer. (Conroy (Exact) Tr. 1704).

Response to Finding No. 2049:

The proposed finding is inaccurate and misleading. DETECT-A used a whole body diagnostic PET-CT scan as the third step of the CancerSEEK protocol. Respondents also incorporate their responses to CCFF ¶¶ 1963–64, 2027 and 2046 herein.

2050. CancerSEEK identified ten types of cancer in DETECT-A: appendix, breast, carcinoma, unknown primary origin, colorectal, kidney, lung, lymphoma, ovary, thyroid, and uterine. (Conroy (Exact) Tr. 1706).

Response to Finding No. 2050:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2027 herein. Respondents also note that a cancer type of unknown primary origin does not count as a cancer type that CancerSEEK can detect, insofar as CancerSEEK seeks to compete with Galleri according to the number of cancer types detected, as Galleri detects over 50 types of

cancer, the primary origin of which are known, by the same measure. (PFF ¶ 61 (PX0043 (GRAIL) at 97, 5; *see also* Ofman (GRAIL) Tr. 3312.)

2051. The DETECT-A study showed that CancerSEEK could more than double the cancers detected by standard screening methods. (Lengauer (Third Rock Ventures) Tr. 165-66).

Response to Finding No. 2051:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2042, which Respondents incorporate herein.

2052. The DETECT-A study showed that CancerSEEK is safe and integrated into clinical care in a way that had no impact on compliance with standard of care screening. (Lengauer (Third Rock Ventures) Tr. 165-66).

Response to Finding No. 2052:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2044, which Respondents incorporate herein.

2053. The DETECT-A study established that CancerSEEK's specificity was over 99 percent. (Lengauer (Third Rock Ventures) Tr. 166-67).

Response to Finding No. 2053:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2037, which Respondents incorporate herein.

2054. The DETECT-A study established that CancerSEEK's sensitivity was 52 percent, detecting double the number of cancers first detected by standard screening methods. (Lengauer (Third Rock Ventures) Tr. 168-69).

Response to Finding No. 2054:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2042, which Respondents incorporate herein.

2055. [redacted] (Lengauer (Third Rock Ventures) Tr. 273-74 (*in camera*)).

Response to Finding No. 2055:

The proposed finding inaccurate, incomplete and misleading. In the Lennon paper, where the DETECT-A study was reported, the authors (and investigators) recognized that "At present, we cannot be certain that the DETECT-A blood test used in our study helped any participant." (RX3419 (Lennon et al., 2020) at 11.) Complaint Counsel also presented no evidence that [redacted] and incorporate their responses to CCFF ¶ 2027 herein.

2056. In an email dated April 30, 2020, Ammar Qadan, Illumina's Vice President and Global Head of Market Access, explained that "[t]he data published in Science about the Thrive test shows a very carefully designed study in many ways." (PX2731 (Illumina) at 001 (Email from A. Qadan, Illumina, to J. Goswami, Illumina, Apr. 30, 2020) (adding "These guys know exactly what they're doing.") .

Response to Finding No. 2056:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2027 herein. Respondents also note that Mr. Qadan's email cited to data that was newly released in April 2020, and GRAIL has continued to conduct clinical studies and published results from those studies since that time. (*See* PX2731 (Illumina) at 1; PFF ¶¶ 403–12.) Further, since the date of Mr. Qadan's email, it has become clear that Thrive's study was highly flawed, as shown by the fact that Exact has since gone back to the drawing board with CancerSEEK. (PFF ¶ 726.6 (RX4007 (Exact/Thrive) at 7).) [redacted]

[redacted]

2057. Mr. Qadan explained in an email that, "In my humble opinion, the above could accelerate the Thrive test approval process and uptake as it is very defined[.]" (PX2731 (Illumina) at 001 (Email from A. Qadan, Illumina, to J. Goswami, Illumina, Apr. 30, 2020)).

Response to Finding No. 2057:

Respondents have no specific response except to note that the CancerSEEK test is still under development and is still years away from FDA approval. (*See* Lengauer (Exact/Thrive) Tr. 158; [redacted] As Exact Sciences' 10-K form acknowledged to its investors, "[t]he FDA's clearance or approval pathways are likely to involve significant time, as well as additional research, development and clinical study expenditures," and "[t]here can be no guarantee that the FDA would clear or approve any future product or service we may develop." (RX3197 (Exact Sciences Corp., Form 10-K for the Period Ending 12/31/20).) Respondents also incorporate their responses to CCFF ¶ 2027 herein.

2058. Since the DETECT-A study, Thrive has continued to improve CancerSEEK. (Lengauer (Third Rock Ventures) Tr. 169-70).

Response to Finding No. 2058:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 1971, which Respondents incorporate herein.

2059. [redacted] (Lengauer (Third Rock Ventures) Tr. 187-88 (*in camera*)).

Response to Finding No. 2059:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1945 and 1971, which Respondents incorporate herein.

2060. After DETECT-A, Thrive plans to further improve its test and are preparing for a registrational trial. (Lengauer (Third Rock Ventures) Tr. 169-70).

Response to Finding No. 2060:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1945 and 1971, which Respondents incorporate herein.

c) [redacted]

2061. [redacted] (Conroy (Exact) Tr. 1632-33 (*in camera*)).

Response to Finding No. 2061:

The proposed finding is inaccurate, incomplete, and misleading because there is no evidence to date that [redacted] (Conroy (Exact) Tr. 1632–33 (*in camera*).)

2062. [redacted] (Conroy, (Exact) Tr. 1633 (*in camera*)).

Response to Finding No. 2062:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2061, which Respondents incorporate herein.

2063. [redacted] (Conroy (Exact) Tr. 1633 (*in camera*)).

Response to Finding No. 2063:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2061, which Respondents incorporate herein.

2064. [redacted] (Conroy (Exact) Tr. 1564 (*in camera*)).

Response to Finding No. 2064:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2061 herein.

2065. [redacted] (Conroy (Exact) Tr. 1564) (*in camera*)).

Response to Finding No. 2065:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2061, which Respondents incorporate herein.

2066. [redacted] (Conroy (Exact) Tr. 1564 (*in camera*)).

Response to Finding No. 2066:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2061, which Respondents incorporate herein.

2067. [redacted] (Conroy (Exact) Tr. 1564 (*in camera*)).

Response to Finding No. 2067:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2061, which Respondents incorporate herein.

2068. [redacted] (Conroy (Exact) Tr. 1633 (*in camera*)).

Response to Finding No. 2068:

The proposed finding is incomplete and misleading. Mr. Conroy testified in the cited testimony that [redacted] (Conroy (Exact) Tr. 1633.)

Respondents also incorporate their responses to CCFF ¶ 2061 herein.

d) [redacted]

2069. For FDA approval, test developers undergo a "registrational trial," which allows the FDA to evaluate the benefits-to-risk ratio of a test or device. (Lengauer (Third Rock Ventures) Tr. 170).

Response to Finding No. 2069:

The proposed finding is based on testimony for which the witnesses lack personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Respondents also incorporate their responses to CCFF ¶ 528 herein.

2070. [redacted] (Conroy (Exact) Tr. 1634 (*in camera*)).

Response to Finding No. 2070:

Respondents have no specific response except to note that [redacted]

[redacted] (Conroy (Exact) Tr. 1628, 1634–35.)

2071. [redacted] (Lengauer (Third Rock Ventures) Tr. 189-190 (*in camera*)).

Response to Finding No. 2071:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2070 herein.

2072. [redacted] (Lengauer (Third Rock Ventures) Tr. 1190-91 (*in camera*)).

Response to Finding No. 2072:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2070 herein.

2073. [redacted] (Lengauer (Third Rock Ventures) Tr. 189-90 (*in camera*)).

Response to Finding No. 2073:

The proposed finding is not supported by the source provided and is inaccurate and misleading to the extent it suggests that [redacted], which there is no evidence to support. Dr. Lengauer testified, [redacted] Additionally, [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 467, 640 and 2070 herein.

2074. [redacted] (Conroy (Exact) Tr. 1559-60 (*in camera*)).

Response to Finding No. 2074:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2073, which Respondents incorporate herein.

2075. [redacted] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 137) (*in camera*)).

Response to Finding No. 2075:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2073, which Respondents incorporate herein. [redacted], even though Exact and Thrive were served with respective subpoenas by both Complaint Counsel and Respondents. (*See* RX5009-RX5010, RX5044-RX5045 (Exact and Thrive)). Nor has Complaint Counsel identified such a document. Therefore, this cited testimony should be accorded little weight.

2076. [redacted] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 137-38) (*in camera*)).

Response to Finding No. 2076:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2073 and 2075, which Respondents incorporate herein.

2077. [redacted] (Conroy, (Exact) Tr. 1634 (*in camera*)).

Response to Finding No. 2077:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2070 herein.

2078. [redacted] 176-77) (*in camera*); PX7091 (Lengauer (Third Rock Ventures) Dep. at 82) (*in camera*); PX8317 (Exact) at 022 [redacted] (*in camera*))).

Response to Finding No. 2078:

Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 59), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents incorporate their responses to CCFF ¶ 2070 herein.

2079. [redacted] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 134) (*in camera*)).

Response to Finding No. 2079:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2070 herein.

2080. [redacted] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 134) (*in camera*)).

Response to Finding No. 2080:

The proposed finding is hearsay and should be accorded little weight. Respondents also incorporate their responses to CCFF ¶ 2070 herein.

2081. [redacted] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 134) (*in camera*)).

Response to Finding No. 2081:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2070 herein.

2082. [redacted] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 135) (*in camera*)).

Response to Finding No. 2082:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2070 herein.

2083. [redacted] (Conroy (Exact) Tr. 1634 (*in camera*)).

Response to Finding No. 2083:

The proposed finding is misleading because there is no evidence that the SOAR trial has started. Therefore, the number of patients for that proposed trial is merely theoretical. Respondents also incorporate their responses to CCFF ¶ 2070 herein.

2084. [redacted] (Lengauer (Third Rock Ventures) Tr. 193 (*in camera*)).

Response to Finding No. 2084:

Respondents have no specific response.

2085. [redacted] (Lengauer (Third Rock Ventures) Tr. 192-93 (*in camera*)).

Response to Finding No. 2085:

Respondents have no specific response.

2086. In a prospective study, the patient gets a blood tube drawn before being diagnosed with cancer. (Conroy (Exact) Tr. 1744-45).

Response to Finding No. 2086:

Respondents have no specific response.

2087. A prospective study will then use another means of determining whether the patient has cancer. (Conroy (Exact) Tr. 1744-45).

Response to Finding No. 2087:

Respondents have no specific response.

2088. [redacted] (Lengauer (Third Rock Ventures) Tr. 192-93 (*in camera*)).

Response to Finding No. 2088:

Respondents have no specific response.

2089. [redacted] (Lengauer (Third Rock Ventures) Tr. 192-93 (*in camera*)).

Response to Finding No. 2089:

The proposed finding is inaccurate, incomplete and misleading to the extent it suggests that [redacted] (RX3142 (Cohen 2018) at 2 ("We then used CancerSEEK to study 1005 patients *who had been diagnosed* with stage I to III cancers of the ovary, liver, stomach, pancreas, esophagus, colorectum, lung, or breast.") (emphasis added); PFF ¶¶ 426.1, 427.) By contrast, GRAIL's CCGA study is a *prospective*, multi-center, case-control, observational study with longitudinal follow-up of 15,254 participants. (PFF ¶ 370 (RX3409 (Klein 2021) at 2; (RX3430 (Liu 2020) at 1; Ofman (GRAIL) Tr. 3291–95; [redacted] RX0744 (GRAIL) at 47–48).) It is believed to be the largest case-control study that there has ever been for early detection. (Ofman (GRAIL) Tr. 3291.) The

study was unique because the samples were prospectively collected. As Dr. Cote explained: "[The] case-control trial was actually prospectively collected, and it was done under a strict protocol for the collection of all of these samples. That makes it unique in terms of the case-control study, and . . . it was designed that way to provide sample collection under circumstances that would be similar to an actual clinical collection of samples." (Cote Tr. 3794–95.)

Respondents note that GRAIL's PATHFINDER study is a prospective, interventional study of 6,662 participants over the age of 50 with a cohort with additional risk of a positive cancer result (3695; ~55% of total enrollment), and another cohort containing participants without any heightened risk (2934). (PFF ¶¶ 394 (RX3044 (GRAIL) at 1–2), 399 (Ofman (GRAIL) Tr. 3293; RX0744 (GRAIL) at 73), 1290 (Aravanis (Illumina) Tr. 1891–92).) In February 2021, GRAIL released interim prospective interventional study (PATHFINDER) results that were positive and largely confirmed the previous studies. (Ofman (GRAIL) Tr. 3293; [redacted] The interim results showed that Galleri detected three cancer types for which stage designation is not applicable (lymphoid leukemia, plasma cell neoplasm, and Waldenstrom macroglobulinemia), one recurrent cancer type at the "local" stage (prostate), and one cancer for which the stage was unknown (colon or rectum). (RX3041 at 005 (Thomasz Beer, Interim Results of Pathfinder, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, June 4, 2021). Galleri has been shown to detect the largest number of cancer types in a prospective clinical trial.

Respondents further note that GRAIL's STRIVE study is a prospective, observational, longitudinal study of approximately 100,000 women undergoing mammography (PFF ¶ 403

(Ofman (GRAIL) Tr. 3293–95; RX0744 (GRAIL) at 71), GRAIL's SUMMIT study is a prospective, observational study of approximately 13,000 participants between the ages of 50–77 with a substantial smoking history (PFF ¶¶ 407–409 (RX3291 (GRAIL) at 1; RX0744 (GRAIL) at 46–47, 72), and [redacted] and a prospective, real-world, pragmatic, randomized clinical study in the U.K. with the NHS in 140,000 screening-eligible individuals (PFF ¶¶ 1603 (Ofman (GRAIL) Tr. 3291–300), 1648 (Freidin (GRAIL) Tr. 3008)). Respondents also incorporate their responses to CCFF ¶¶ 1938–39 and 6270 herein.

2090. According to Mr. Conroy, Grail's previous studies have been case-controlled retrospective studies. (Conroy (Exact) Tr. 1743).

Response to Finding No. 2090:

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding is inaccurate, incomplete and misleading, based on testimony for which the witness lacks personal knowledge or foundation, and contradicted by the weight of the evidence. GRAIL's CCGA studies are *prospective* studies with longitudinal follow-ups. (PFF ¶ 370 (RX3430 (Liu et al., 2020) at 1; Ofman (GRAIL) Tr. 3291–95; [redacted] RX0744 (GRAIL) at 47–48.)).) Like DETECT-A, GRAIL's PATHFINDER study is a *prospective*, interventional study. (PFF ¶ 394 (RX3044 (GRAIL) at 1–2).) Respondents also incorporate their responses to CCFF ¶¶ 1938–39 and 2089 herein.

2091. A case-controlled study is "a study where samples are collected from patients after they've already been diagnosed with disease." (Conroy (Exact) Tr. 1744).

Response to Finding No. 2091:

Respondents have no specific response except incorporate their responses to CCFF ¶ 1089 herein.

2092. Mr. Conroy testified that, in case-controlled studies, sensitivity is "typically significantly better because the cases that you find are typically later stage[.]" (Conroy (Exact) Tr. 1744-45).

Response to Finding No. 2092:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2089–2090, which Respondents incorporate herein.

2093. Mr. Conroy testified at trial that it is unfair to compare the sensitivity results of a prospective study to a case-control study because case-control studies almost always have higher sensitivities and typically slightly better specificities than a prospective study. (Conroy (Exact) Tr. 1745).

Response to Finding No. 2093:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2089–2090, which Respondents incorporate herein.

2094. The SOAR study has a different trial design from the Cohen study and DETECT-A. (Conroy (Exact) Tr. 1742-43).

Response to Finding No. 2094:

Respondents have no specific response except to note that the proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

2095. The DETECT-A study and the SOAR study differ because the DETECT-A study only examined women in one health system. (Conroy (Exact) Tr. 1742-43).

Response to Finding No. 2095:

Respondents have no specific response.

2096. The DETECT-A study was a smaller study than SOAR. (Conroy (Exact) Tr. 1742-43).

Response to Finding No. 2096:

Respondents have no specific response.

2097. Grail is in the process of doing a prospective study in a high-risk population. (Conroy (Exact) Tr. 1743).

Response to Finding No. 2097:

The proposed finding is inaccurate, incomplete and misleading, based on testimony for which the witness lacks personal knowledge or foundation, and contradicted by the weight of the evidence. GRAIL's PATHFINDER prospective study includes a cohort containing 2,934 participants over the age of 50 without any heightened risk. (PFF ¶ 399 (Ofman (GRAIL) Tr. 3293; RX0744 (GRAIL) at 73).) Respondents note that Thrive's DETECT-A study was of 10,006 women at 65 to 75 years of age—a much higher age group that also carriers higher cancer risk than participants over the age of 50 without any heightened risk in GRAIL's PATHFINDER cohort. (RX3419 (Lennon et al., 2020) at 3.) Respondents also incorporate their responses to CCFF ¶¶ 2089–2090 herein.

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

2098. Mr. Conroy testified that Grail's prospective study will have a narrower population than that of the DETECT-A study. (Conroy (Exact) Tr. 1743).

Response to Finding No. 2098:

The proposed finding is inaccurate, incomplete and misleading, based on testimony for which the witness lacks personal knowledge or foundation, and contradicted by the weight of the evidence. GRAIL's PATHFINDER prospective study of 6,662 participants over the age of 50 includes a cohort containing 2,934 participants without any heightened risk as well as a cohort of 3,695 participants with additional risk of a positive cancer result. (PFF ¶ 399 (Ofman (GRAIL) Tr. 3293; RX0744 (GRAIL) at 73).) In contrast, Thrive's DETECT-A study was of 10,006 women at 65 to 75 years of age—a single sex population at a much higher, narrower age group than GRAIL's PATHFINDER study. (RX3419 (Lennon et al., 2020) at 3.) Respondents also incorporate their responses to CCFF ¶¶ 2089–2090 and 2097 herein.

2099. [redacted] (Conroy (Exact) Tr. 1560 (*in camera*)).

Response to Finding No. 2099:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2070 and 2083 herein. Exact Sciences' 10-K itself acknowledged the risk that the FDA would not approve CancerSEEK, stating that, "[d]eveloping new or improved cancer tests is a speculative and risky endeavor", "[t]he FDA's clearance or approval pathways are likely to involve significant time, as well as additional research, development and clinical study expenditures", and "[t]here can be no guarantee that the FDA would clear or approve any future product or service we may develop." (RX3197 (Exact Sciences Corp., Form 10-K for the Period Ending 12/31/20).)

2100. [redacted] (Conroy (Exact) Tr. 1559 (*in camera*)).

Response to Finding No. 2100:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2070 herein.

2101. [redacted] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 135) (*in camera*)).

Response to Finding No. 2101:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2073, which Respondents incorporate herein.

2102. [redacted] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 135-36) (*in camera*)).

Response to Finding No. 2102:

The proposed finding is hearsay and should be accorded little weight. Respondents also incorporate their responses to CCFF ¶¶ 2070 and 2073 herein.

2103. [redacted] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 139) (*in camera*)).

Response to Finding No. 2103:

The proposed finding is hearsay and should be accorded little weight. Respondents also incorporate their responses to CCFF ¶¶ 2070 and 2073 herein.

2104. [redacted]

[redacted] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 140-41) (*in camera*)).

Response to Finding No. 2104:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2070 and 2075, which Respondents incorporate herein.

6. [redacted]

2105. [redacted] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 87) (*in camera*)).

Response to Finding No. 2105:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1912 herein.

2106. [redacted] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 87) (*in camera*)).

Response to Finding No. 2106:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1912 herein.

2107. [redacted]).

Response to Finding No. 2107:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be

given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents incorporate their responses to CCFF ¶ 1912 herein.

2108. [redacted] (PX7110 (Conroy (Exact) Dep. at 48) (*in camera*); PX8572 (Exact) at 033 (Exact, Innovation & Technology Committee Spring Meeting Presentation, Apr. 16, 2020) (*in camera*)).

Response to Finding No. 2108:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 1912 herein.

2109. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 50-51) (*in camera*); PX7058 (Conroy (Exact) IHT at 80-82) (*in camera*)).

Response to Finding No. 2109:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents incorporate their responses to CCFF ¶¶ 929, 1912, 1938–39 and 2070 herein.

2110. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 50-51) (*in camera*)).

Response to Finding No. 2110:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents incorporate their responses to CCFF ¶¶ 929, 1912, 1938–39 and 2070 herein.

2111. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 88) (*in camera*)).

Response to Finding No. 2111:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents incorporate their responses to CCFF ¶¶ 929, 1912, 1938–39 and 2070 herein.

7. Prior to Acquiring Thrive and CancerSEEK, Exact Conducted MCED Research & Development, Dating Back to 2009

2112. Exact's principal collaboration for research and development efforts is with the Mayo Clinic. (Conroy (Exact) Tr. 1536-37).

Response to Finding No. 2112:

The proposed finding is vague and misleading to the extent it suggests that the CancerSEEK study was developed with the Mayo Clinic. Respondents note that since [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 144) (*in camera*); (Conroy (Exact) Tr. 1543).

2113. The Exact-Mayo Clinic partnership started in June 2009. (Conroy (Exact) Tr. 1536-37; PX7110 (Conroy (Exact) Dep. at 10) (*in camera*)).

Response to Finding No. 2113:

Respondents have no specific response except to note that Exact still has not commercialized any MCED test nearly 12 years later. (Conroy (Exact) Tr. 1621.) Exact's collaborative effort with Mayo Clinic has resulted in the development of Exact's Cologuard product for colorectal cancer screening, which uses PCR technology, not NGS. (Conroy (Exact) Tr. 1538–42, 1597.) Respondents note that since Thrive became part of Exact, Exact has stopped developing any separate test and is incorporating biomarkers from Exact's research into CancerSEEK. (PX7051 (Lengauer (Third Rock Ventures) IHT at 144) (*in camera*); (Conroy (Exact) Tr. 1543).

2114. [redacted] (PX7110 (Conroy (Exact) Dep. at 10) (*in camera*)).

Response to Finding No. 2114:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 357–58 and 2113 herein.

2115. [redacted] (PX7110 (Conroy (Exact) Dep. at 10) (*in camera*)).

Response to Finding No. 2115:

The proposed finding is inaccurate, incomplete and misleading, including because it seems to suggest that [redacted] (PX7110 (Conroy (Exact) Dep. at 10 (emphasis added).) There is no evidence that [redacted]. Respondents have also note that Exact still has not commercialized any MCED test even 10 years after identifying these putative biomarkers. (Conroy (Exact) Tr. 1621.) Respondents note that since [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 144) (*in camera*); (Conroy (Exact) Tr. 1543).

Respondents also incorporate their responses to CCFF ¶¶ 357–58 herein.

2116. The Exact-Mayo Clinic partnership has continued for 12 years. (Conroy (Exact) Tr. 1536-37).

Response to Finding No. 2116:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2112 herein.

2117. Dr. Dave Ahlquist was a gastroenterologist at Mayo Clinic. (Conroy (Exact) Tr. 1538-39).

Response to Finding No. 2117:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2112 herein.

2118. Dr. Ahlquist participated in the Exact-Mayo Clinic partnership. (Conroy (Exact) Tr. 1539-40).

Response to Finding No. 2118:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2112 herein.

2119. Mr. Conroy explained that Dr. Ahlquist's work was integral to Exact's product development. (Conroy (Exact) Tr. 1539-41).

Response to Finding No. 2119:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2112 herein.

2120. Dr. Ahlquist conducted research for years on colon cancer screening. (Conroy (Exact) Tr. 1538-39).

Response to Finding No. 2120:

Respondents have no specific response except to note that Dr. Ahlquist only had research data demonstrating the ability to detect colon cancer and precancerous polyps accurately from a stool sample. (Conroy (Exact) Tr. 1538–40.) Respondents also incorporate their responses to CCFF ¶¶ 357–58 and 2115–16 herein.

2121. Dr. Ahlquist looked for biomarkers that could identify colon cancer early. (Conroy (Exact) Tr. 1538-39).

Response to Finding No. 2121:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2112, 2115 and 2120 herein.

2122. Dr. Ahlquist looked for these colon cancer biomarkers in stool, blood, and other patient samples. (Conroy (Exact) Tr. 1538-39).

Response to Finding No. 2122:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2112, 2115 and 2120 herein.

2123. Dr. Ahlquist's research looked at data demonstrating the ability to detect colon cancer and even precancerous polyps accurately from a stool sample. (Conroy (Exact) Tr. 1539).

Response to Finding No. 2123:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2112, 2115 and 2120 herein.

2124. In March 2009, Dr. Ahlquist told Exact CEO, Mr. Conroy, of his vision for detecting many or most cancers from a simple blood draw. (Conroy (Exact) Tr. 1539).

Response to Finding No. 2124:

Respondents have no specific response except to note that both of Exact's "core tests", Cologuard and Oncotype DX, are built on what's called a PCR technology, and they don't require next-generation sequencing." (Conroy (Exact) Tr. 1597.) Respondents also note that Exact has not commercialized any MCED test. (Conroy (Exact) Tr. 1621.) (*See also* RRFF ¶¶ 929, 1912, 1938–39). Respondents also incorporate their responses to CCFF ¶¶ 2112, 2115 and 2120 herein.

2125. Dr. Ahlquist called this vision a "pan-cancer" test, which would look for tiny fragments of cancer DNA in a patient's blood. (Conroy (Exact) Tr. 1539-40).

Response to Finding No. 2125:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2112, 2115 and 2124 herein. In addition, there is no such thing as a "pan-cancer test" because there is no such thing as a universal cancer biomarker. (PFF ¶ 308; Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106.)

2126. Dr. Ahlquist's vision for a pan-cancer test became the genesis of Exact's mission to detect cancer earlier. (Conroy (Exact) Tr. 1540).

Response to Finding No. 2126:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2112, 2115 and 2124 herein. In addition, there is no such thing as a "pan-cancer test" because there is no such thing as a universal cancer biomarker. (PFF ¶ 308; Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106.)

2127. [redacted] (PX7058 (Conroy (Exact) IHT at 53-54) (*in camera*)).

Response to Finding No. 2127:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2112, 2115 and 2124, which Respondents incorporate herein. Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2128. [redacted] (PX7058 (Conroy (Exact) IHT at 53-54) (*in camera*)).

Response to Finding No. 2128:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2112, 2115 and 2124, which Respondents incorporate herein. Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Exact Sciences does not have any tests that use NGS technology and Exact Sciences was not an Illumina customer until its acquisition of Thrive. (*See* Conroy (Exact Sciences) Tr. 1542–43, 1597.) [redacted] (Conroy (Exact) Tr. 1597.)

2129. [redacted] (PX7058 (Conroy (Exact) IHT at 54) (*in camera*)).

Response to Finding No. 2129:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2112, 2115 and 2124, which Respondents incorporate herein. Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2130. Exact has a development partnership with City of Hope. (Conroy (Exact) Tr. 1536-37).

Response to Finding No. 2130:

Respondents have no specific response.

2131. Exact has a partnership with Johns Hopkins University. (Conroy (Exact) Tr. 1536-37).

Response to Finding No. 2131:

Respondents have no specific response.

2132. Thrive has a collaboration agreement with Johns Hopkins University and Howard Hughes Medical Institute that involves sharing research between the organizations. (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 37-38)).

Response to Finding No. 2132:

Respondents have no specific response.

2133. Exact is in the process of combining CancerSEEK with Exact and Dr. Ahlquist's biomarker research to bring the best of both of those technologies together to develop the best, most accurate MCED test for physicians and patients. (Conroy (Exact) Tr. 1543).

Response to Finding No. 2133:

Respondents have no specific response except to note that the cited testimony indicates that [redacted]. (Conroy (Exact) Tr. 1543, 1717.) Respondents incorporate their responses to CCFF ¶¶ 1912, 1953, 2112, 2115 and 2124 herein.

8. Background on Exact Sciences' Oncology Start-Up Pedigree: Product Development, Regulatory Success, and Salesforce Expansion

a) Exact's Cologuard Test

2134. The first test Exact developed was Cologuard. (PX7058 (Conroy (Exact) IHT at 20)).

Response to Finding No. 2134:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Respondents note that Exact's Cologuard product is a stool-based (not blood-based) single cancer test for colorectal cancer screening, which uses PCR technology, *not* NGS. (Conroy (Exact) Tr. 1546–47, [redacted].)

2135. Exact has screened over 6 million people with its colon cancer screening test, Cologuard. (Conroy (Exact) Tr. 1541).

Response to Finding No. 2135:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2134 herein.

2136. Of the 6 million Cologuard patients, approximately 200,000 people found precancerous polyps and had those polyps removed. (Conroy (Exact) Tr. 1541).

Response to Finding No. 2136:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2134 herein.

2137. Of the 6 million Cologuard patients, approximately 30,000 people have been diagnosed with early, treatable-stage colon cancer versus later stage. (Conroy (Exact) Tr. 1541).

Response to Finding No. 2137:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2134 herein.

2138. The goal of Cologuard is "to shift detection from late stage, which is largely where colon cancer is detected today, to early stage," where it frequently can be surgically cured without chemotherapy. (Conroy (Exact) Tr. 1540).

Response to Finding No. 2138:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2134 herein.

2139. Cologuard is an FDA-approved test. (Conroy (Exact) Tr. 1547; PX6049 (Grail) at 036 [redacted]

Response to Finding No. 2139:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2134 herein.

2140. Cologuard was the first product for which Exact obtained FDA approval. (Conroy (Exact) Tr. 1547).

Response to Finding No. 2140:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2134 herein.

2141. To receive FDA approval for Cologuard, Exact ran a 10,000-patient study where every patient underwent a colonoscopy, took a Cologuard test, and took a fecal immunochemical test. (Conroy (Exact) Tr. 1547-48).

Response to Finding No. 2141:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2134 herein.

2142. In the Cologuard 10,000 patient study, Exact was able to demonstrate the accuracy of Cologuard and the relative accuracy of its fecal immunochemical ("FIT") test. (Conroy (Exact) Tr. 1547-48).

Response to Finding No. 2142:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2134 herein.

2143. Exact submitted the data from the Cologuard study in its PMA application to the FDA. (Conroy (Exact) Tr. 1547-48).

Response to Finding No. 2143:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2134 herein.

2144. The Cologuard 10,000 patient study took over two years to complete. (Conroy (Exact) Tr. 1547-48).

Response to Finding No. 2144:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2134 herein.

2145. To receive FDA approval for Cologuard, Exact provided extensive information to the FDA. (Conroy (Exact) Tr. 1548).

Response to Finding No. 2145:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2134 herein.

2146. Exact was required to provide the FDA information about Cologuard's third-party suppliers. (Conroy (Exact) Tr. 1548-49).

Response to Finding No. 2146:

Respondents have no specific response except to note that [redacted] (Conroy (Exact) Tr. 1597.) Respondents incorporate their responses to CCFF ¶ 2134 herein.

2147. The FDA inspected Guardant's "key suppliers," who are "critical" to the FDA approval process. (Conroy (Exact) Tr. 1548-49).

Response to Finding No. 2147:

The proposed finding is inaccurate, incomplete and misleading, and not supported by the cited evidence. Mr. Conroy did not testify that the FDA "inspected Guardant's 'key suppliers.'" (Conroy (Exact) Tr. 1548–49.) Respondents incorporate their responses to CCFF ¶¶ 2134 and 2146 herein.

2148. Mr. Conroy testified at trial that "key suppliers are inspected by the FDA to help ensure that the quality measures are put into place and being followed prior to FDA approval and since FDA approval." (Conroy (Exact) Tr. 1548-49).

Response to Finding No. 2148:

The proposed finding is inaccurate, incomplete and misleading to the extent it is applied to the approval of an NGS-based MCED test, rather than about [redacted], which was the subject of Mr. Conroy's testimony. Respondents also incorporate their responses to CCFF ¶¶ 2134 and 2146 herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

2149. [redacted] (PX7110 (Conroy (Exact) Dep. at 29) (*in camera*)).

Response to Finding No. 2149:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2134 and 2146 herein.

2150. [redacted] (Conroy (Exact) Tr. 1629 (*in camera*)).

Response to Finding No. 2150:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2134 and 2146 herein.

2151. [redacted] (PX7058 (Conroy (Exact) IHT at 27-28) (*in camera*)).

Response to Finding No. 2151:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents incorporate their responses to CCFF ¶¶ 2134 and 2146 herein.

2152. "[T]he American Cancer Society and the U.S. Preventive Services Task Force did include Cologuard in those screening guidelines." (PX7058 (Conroy (Exact) IHT at 21)).

Response to Finding No. 2152:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents incorporate their responses to CCFF ¶¶ 2134 and 2146 herein.

2153. In June 2016, the USPSTF issued its final guidance document which approved Cologuard. (PX7058 (Conroy (Exact) IHT at 33)).

Response to Finding No. 2153:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents incorporate their responses to CCFF ¶¶ 2134 and 2146 herein.

2154. [redacted] (PX7058 (Conroy (Exact) IHT at 28-29) (*in camera*)).

Response to Finding No. 2154:

The proposed finding is inaccurate, incomplete and misleading to the extent it is applied to the approval of an NGS-based MCED test, rather than about [redacted], which was the subject of Mr. Conroy's testimony. The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents incorporate their responses to CCFF ¶¶ 2134 and 2146 herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

2155. [redacted] (PX7058 (Conroy (Exact) IHT at 29) (*in camera*) [redacted]

Response to Finding No. 2155:

The proposed finding is inaccurate, incomplete and misleading to the extent it is applied to the approval of an NGS-based MCED test, rather than about [redacted], which was the subject of Mr. Conroy's testimony. The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents incorporate their responses to CCFF ¶¶ 2134 and 2146 herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

2156. [redacted]

[redacted] (PX7110 (Conroy (Exact) Dep. at 60-62) (*in camera*)).

Response to Finding No. 2156:

The proposed finding is inaccurate, incomplete and misleading to the extent it is applied to the approval of an NGS-based MCED test, rather than about [redacted] which was the subject of Mr. Conroy's testimony. The proposed finding is incomplete and misleading to the extent it may seem to suggest that [redacted]. Respondents incorporate their responses to CCFF ¶¶ 2089–2090, 2134 and 2146 herein.

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

2157. When Exact went through the regulatory and reimbursement process for Cologuard, it was the first time Exact had ever gone through the regulatory process. (PX7058 (Conroy (Exact) IHT at 33)).

Response to Finding No. 2157:

The proposed finding is inaccurate, incomplete and misleading to the extent it is applied to the approval of an NGS-based MCED test, rather than about Exact's PCR-based Cologuard test, which was the subject of Mr. Conroy's testimony. The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents incorporate their responses to CCFF ¶¶ 2134 and 2146 herein.

2158. [redacted] (PX7110 (Conroy (Exact) Dep. at 62-63) (*in camera*)).

Response to Finding No. 2158:

The proposed finding is inaccurate, incomplete and misleading to the extent it is applied to the approval of an NGS-based MCED test, rather than about Exact's PCR-based Cologuard test, which was the subject of Mr. Conroy's testimony. Respondents also incorporate their responses to CCFF ¶¶ 2134 and 2146 herein.

2159. [redacted] (PX7058 (Conroy (Exact) IHT at 58) (*in camera*)).

Response to Finding No. 2159:

The proposed finding is inaccurate, incomplete and misleading to the extent it is applied to the approval of an NGS-based MCED test, rather than about Exact's PCR-based Cologuard test, which was the subject of Mr. Conroy's testimony. The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents incorporate their responses to CCFF ¶¶ 2134 and 2146 herein.

b) Exact Used Multiple Consultants to Aid Its Regulatory Approval

2160. To facilitate Cologuard's FDA approval, Exact worked with many regulatory consultants and biostatisticians who know the FDA process well. (Conroy (Exact) Tr. 1549-50; *see* PX7110 (Conroy (Exact) Dep. at 26-28) (*in camera*) [redacted]).

Response to Finding No. 2160:

The proposed finding is inaccurate, incomplete and misleading to the extent it suggests GRAIL could achieve the same acceleration benefits regarding Galleri's FDA approval through the use of consultants as it could by reuniting with Illumina. GRAIL could not achieve the same

acceleration benefits by hiring additional personnel or outside consultants because the pool of individuals with such experience is limited and it can take a long time for consultants to get up to speed on the specific needs in a new area such as NGS-based liquid biopsy tests for multiple cancer types. (*See* PFF ¶¶ 1175–[redacted] (Febbo (Illumina) Tr. 4365; Qadan (Illumina) Tr. 4167–68; [redacted]), 1175.4.3 (RX6000 (Carlton Trial Dep. at 61)), 1398 (Febbo (Illumina) Tr. 4365), 1482–84 (Qadan (Illumina) Tr. 4165–68), 1654 [redacted]**.)** The same cannot be said for the FDA approval process for Cologuard; colorectal cancer screening has an established standard-of-care and obtaining FDA approval only required demonstrating Cologuard's performance in comparison to colonoscopy. (PFF ¶ 145.3 (RX3723 (USPSTF, A and B Recommendations) at 3; Cance (ACS) Tr. 606; Cote Tr. 3729–30).)

2161. [redacted] (PX7110 (Conroy (Exact) Dep. at 27) (*in camera*)).

Response to Finding No. 2161:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2160, which Respondents incorporate herein.

2162. [redacted] (PX7110 (Conroy (Exact) Dep. at 27) (*in camera*)).

Response to Finding No. 2162:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2160, which Respondents incorporate herein.

2163. [redacted] (PX7110 (Conroy (Exact) Dep. at 28) (*in camera*)).

Response to Finding No. 2163:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2160, which Respondents incorporate herein.

2164. Exact's consultants helped Exact set up quality systems as part of the FDA process. (Conroy (Exact) Tr. 1549-50).

Response to Finding No. 2164:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2160, which Respondents incorporate herein.

2165. Exact decided to use consultants for the FDA process because these consultants are experts in working with the FDA, and it is "very hard to do that just internally." (Conroy (Exact) Tr. 1550).

Response to Finding No. 2165:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2160, which Respondents incorporate herein.

2166. At trial, Mr. Conroy pointed to Exact's use of a biostatistician consultant as "critical" to Cologuard's FDA review: "For example, our biostatistician was somebody who had been in front of 50 FDA panel meetings. And we have never been in front of a panel meeting, so getting that type of input and support and help is just critical to having a smooth working relationship with FDA." (Conroy (Exact) Tr. 1550).

Response to Finding No. 2166:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2160, which Respondents incorporate herein.

2167. These consultants helped "accelerate" and "enable" Cologuard's FDA approval process. (Conroy (Exact) Tr. 1550).

Response to Finding No. 2167:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2160, which Respondents incorporate herein.

2168. [redacted] (PX7110 (Conroy (Exact) Dep. at 28) (*in camera*)).

Response to Finding No. 2168:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2160, which Respondents incorporate herein.

c) Exact Built its Salesforce from Scratch, Expanding as Cologuard Received Regulatory Approvals and Reimbursement Status

2169. Today, Exact is a commercial company that has teams of people who educate healthcare providers about the tests Exact offers and provides clinical testing services. (Conroy (Exact) Tr. 1532-33).

Response to Finding No. 2169:

The proposed finding is irrelevant and misleading. Exact's commercial infrastructure has no relation to whether or not Illumina can accelerate GRAIL's ability to commercialize Galleri better than Galleri could on its own. Respondents also note that [redacted] Respondents also note that Illumina has a much larger sales force than GRAIL and Illumina would be able to leverage its international presence very directly even if the sales force were separate and that Illumina's infrastructure would dramatically accelerate GRAIL's ability to bring Galleri to other markets of the world and to do that quite quickly. (*See* PFF ¶¶ 1366 (Flatley (Illumina) Tr. 4083), 1368 (Flatley (Illumina) Tr. 4087–88).)

2170. Exact has a clinical sales force. (Conroy (Exact) Tr. 1534).

Response to Finding No. 2170:

The proposed finding is irrelevant and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2169, which Respondents incorporate herein.

2171. [redacted] (PX7110 (Conroy (Exact) Dep. at 41-42) (*in camera*)).

Response to Finding No. 2171:

The proposed finding is irrelevant and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2169, which Respondents incorporate herein.

2172. [redacted] (PX7110 (Conroy (Exact) Dep. at 42) (*in camera*)).

Response to Finding No. 2172:

The proposed finding is irrelevant and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2169, which Respondents incorporate herein.

2173. [redacted] (PX7058 (Conroy (Exact) IHT at 36-37) (*in camera*)).

Response to Finding No. 2173:

The proposed finding is irrelevant and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2169, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2174. [redacted] (PX7058 (Conroy (Exact) IHT at 36-37) (*in camera*)).

Response to Finding No. 2174:

The proposed finding is irrelevant and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2169, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2175. [redacted] (PX7058 (Conroy (Exact) IHT at 37) (*in camera*)).

Response to Finding No. 2175:

The proposed finding is irrelevant and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2169, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2176. [redacted] (PX7058 (Conroy (Exact) IHT at 37) (*in camera*)).

Response to Finding No. 2176:

The proposed finding is irrelevant and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2169, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2177. [redacted] (PX7058 (Conroy (Exact) IHT at 37) (*in camera*)).

Response to Finding No. 2177:

The proposed finding is irrelevant and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2169, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2178. [redacted]

Response to Finding No. 2178:

The proposed finding is irrelevant and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2169, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2179. [redacted]

Response to Finding No. 2179:

The proposed finding is irrelevant and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2169, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2180. [redacted]

Response to Finding No. 2180:

The proposed finding is irrelevant and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2169, which Respondents incorporate herein.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2181. [redacted]

Response to Finding No. 2181:

The proposed finding is irrelevant and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2169, which Respondents incorporate herein.

2182. [redacted]

Response to Finding No. 2182:

The proposed finding is irrelevant and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2169, which Respondents incorporate herein.

2183. [redacted]

Response to Finding No. 2183:

The proposed finding is irrelevant and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2169, which Respondents incorporate herein.

2184. [redacted]

Response to Finding No. 2184:

Respondents have no specific response except to note that as an executive at Exact, Mr. Conroy lacks personal knowledge to opine on what Illumina's capabilities are.

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents incorporate their responses to CCFF ¶ 2169 herein.

9. [redacted].

B. [redacted]

1. [redacted]

2185. [redacted]

Response to Finding No. 2185:

Respondents have no specific response.

2186. [redacted]

Response to Finding No. 2186:

Respondents have no specific response.

2187. [redacted]

Response to Finding No. 2187:

Respondents have no specific response.

2188. [redacted]

Response to Finding No. 2188:

[redacted]

2189. [redacted]

Response to Finding No. 2189:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2188, which Respondents incorporate herein.

2190. [redacted]

Response to Finding No. 2190:

Respondents have no specific response.

2191. [redacted]

Response to Finding No. 2191:

Respondents have no specific response.

2192. [redacted]

Response to Finding No. 2192:

Respondents have no specific response.

2193. [redacted]

Response to Finding No. 2193:

Respondents have no specific response.

2194. [redacted]

Response to Finding No. 2194:

Respondents have no specific response.

2195. [redacted]

Response to Finding No. 2195:

Respondents have no specific response except reiterate that the proposed finding is evidence that [redacted] Respondents also incorporate PFF ¶¶ 950–63.4 and their responses to CCFF ¶¶ 4124–64 herein.

2196. [redacted]

Response to Finding No. 2196:

Respondents have no specific response.

2197. [redacted]

Response to Finding No. 2197:

Respondents have no specific response.

2198. [redacted]

Response to Finding No. 2198:

Respondents have no specific response.

2199. [redacted]

Response to Finding No. 2199:

[redacted]

[redacted]

2200. [redacted]

Response to Finding No. 2200:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2199, which Respondents incorporate herein.

2201. [redacted]

Response to Finding No. 2201:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2199, which Respondents incorporate herein.

2202. [redacted]

Response to Finding No. 2202:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2199, which Respondents incorporate herein.

2203. [redacted]

Response to Finding No. 2203:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2199, which Respondents incorporate herein.

2204. [redacted]

Response to Finding No. 2204:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2199, which Respondents incorporate herein.

2205. [redacted]

Response to Finding No. 2205:

Respondents have no specific response except to note that in order to market a test under CLIA and CAP guidelines, [redacted] (PFF ¶ 1375.)

2206. [redacted]

Response to Finding No. 2206:

Respondents have no specific response except to note that [redacted]

2207. [redacted]

Response to Finding No. 2207:

The proposed finding is irrelevant because it is unrelated to MCED tests. Respondents have no specific response.

2. [redacted]

2208. [redacted]

Response to Finding No. 2208:

Respondents have no specific response.

2209. [redacted]

Response to Finding No. 2209:

Respondents have no specific response. To the extent Complaint Counsel relies on its proposed findings in CCFF ¶¶ 2226-27, Respondents incorporate their responses to those proposed findings herein.

2210. [redacted]

Response to Finding No. 2210:

The proposed finding is vague and ambiguous as to what is meant by a [redacted]

2211. [redacted]

Response to Finding No. 2211:

The proposed finding is incomplete and misleading including insofar as it suggests that Natera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future.

The proposed finding is also incomplete and misleading as well as contradicted by the weight of the evidence. For example, [redacted]

2212. [redacted]

Response to Finding No. 2212:

[redacted]

[redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶ 2211 herein.

2213. [redacted]

Response to Finding No. 2213:

[redacted]

2214. [redacted]

Response to Finding No. 2214:

Respondents have no specific response.

2215. [redacted]

Response to Finding No. 2215:

The proposed finding is misleading to the extent it suggests [redacted]

(PFF ¶ 1375.) Further, despite Respondents' document subpoena (RX5022), [redacted]

3. [redacted]

2216. [redacted]

Response to Finding No. 2216:

[redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 341, 420, 422, 613, 774–75, 792, 794, 928 and 965 herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

To the extent Complaint Counsel relies on its proposed findings in CCFF ¶¶ 2217–56, Respondents incorporate their responses to those proposed findings herein.

2217. [redacted]

Response to Finding No. 2217:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2216, which Respondents incorporate herein. Respondents also note that [redacted]

2218. [redacted]

Response to Finding No. 2218:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2216 herein.

2219. [redacted]

Response to Finding No. 2219:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2216–17, which Respondents incorporate herein. [redacted] which contradicts Complaint Counsel's assertion that putative "MCED test developers expect to market and sell their tests to primary

care physicians or other physicians conducting annual wellness screenings." (CCFF ¶¶ 709-11, 715-17.)

2220. [redacted]

Response to Finding No. 2220:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2216–17, which Respondents incorporate herein.

2221. [redacted]

Response to Finding No. 2221:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2216–17, which Respondents incorporate herein.

[redacted]

2222. [redacted]

Response to Finding No. 2222:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2216–17, which Respondents incorporate herein.

The proposed finding is also misleading to the extent it suggests that [redacted]

[redacted] (PFF ¶ 526.2.) [redacted]. ***We're not focused on asymptomatic cancer [screening] or early detection.***" (PFF ¶ 526.3.)

Further, [redacted]: [redacted] 2223. [redacted]

Response to Finding No. 2223:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2216–17 and 2222, which Respondents incorporate herein. Respondents also note that while [redacted] may have been focused on early detection in 2015, more than 7 years ago, it clearly shifted its focus to MRD [redacted] appears to have last mentioned its efforts in early detection in 2016 and 2017. (PFF ¶ 526.2.) By November 2015, Illumina had already formed GRAIL. (*See* PFF ¶ 44.)

Further, Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 7), and therefore should be entitled to little weight.

2224. [redacted] (PX7113 (Rabinowitz (Natera) Dep. at 266) (*in camera*)).

Response to Finding No. 2224:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2216–17 and 2222, which Respondents incorporate herein.

[redacted] which contradicts Complaint Counsel's assertion that "MCED test developers expect to market and sell their tests to primary care physicians or other physicians conducting annual wellness screenings." (CCFF ¶¶ 709–11, 715–17).

2225. [redacted]

Response to Finding No. 2225:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2216–17 and 2222, which Respondents incorporate herein.

2226. [redacted]

Response to Finding No. 2226:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1099, 2216–17, 2222, and 2277, which Respondents incorporate herein.

Further, [redacted] CEO has stated publicly to [redacted] investors that [redacted] technology is not something that can be used for early detection." (PFF ¶ 516.2; *see also* [redacted]) [redacted] As Complaint Counsel has contended in multiple of its proposed findings and in its post-trial brief, MRD tests are not the same as MCED tests. (*See* CCFF ¶¶ 155, 624–628, 731; CC Post-Trial Br. at 51–52, 54–55.)

2227. [redacted]

Response to Finding No. 2227:

[redacted]

[redacted]

Respondents also incorporate their responses to CCFF ¶¶ 2216–17 and 2222 herein.

2228. [redacted]

Response to Finding No. 2228:

[redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 2216–17 and 2222 herein.

2229. [redacted]

Response to Finding No. 2229:

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 2216–17 and 2222herein.

2230. [redacted]

Response to Finding No. 2230:

Respondents have no specific response.

2231. [redacted]

Response to Finding No. 2231:

[redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 2216–17 and 2222 herein.

2232. [redacted]

Response to Finding No. 2232:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2216–17 and 2222, which Respondents incorporate herein. The significance of this prior work is undermined by [redacted] (PFF ¶¶ 526.1–526.3.) [redacted] own public statements show that while [redacted] may have been focused on early detection around the time of its IPO, it clearly shifted its focus to MRD and has only recently turned its focus back to early detection: until its recent shift, [redacted] appears to have last mentioned its efforts in early detection in 2016 and 2017. [redacted] discussing exploring breast and ovarian cancer screening); RX3491 [redacted] at 18.

2233. [redacted]

Response to Finding No. 2233:

[redacted]

[redacted]

2234. [redacted]

Response to Finding No. 2234:

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 2216–17 and 2222 herein.

2235. [redacted]

Response to Finding No. 2235:

Respondents have no specific response.

2236. [redacted]

Response to Finding No. 2236:

[redacted]

[redacted]

Respondents also incorporate their responses to CCFF ¶¶ 2216–17 and 2222 herein.

2237. [redacted]

Response to Finding No. 2237:

[redacted]

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents also incorporate their responses to CCFF ¶¶ 2216–17 and 2222 herein.

2238. [redacted]

Response to Finding No. 2238:

[redacted]

(PFF ¶ 512–13 (RX3869 (Cote Expert Report) ¶ 228; [redacted] Therefore, there is no basis for the cited testimony and it should be discounted.

[redacted], even though [redacted] was served with a subpoena by both Complaint Counsel and Respondents. (RX5022-RX5023[redacted] Nor has Complaint Counsel identified such a document. Therefore, this cited testimony should be accorded little weight.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents also incorporate their responses to CCFF ¶¶ 2216–17 and 2222 herein.

2239. [redacted]

Response to Finding No. 2239:

[redacted]

Without having conducted any clinical trial or published the results of any study, [redacted] cannot know what the specificity and other performance metrics are of its putative MCED test. (PFF ¶ 512–13 (RX3869 (Cote Expert Report) ¶ 228; [redacted] Therefore, there is no basis for the cited testimony and it should be discounted.

[redacted], even though [redacted] was served with a subpoena by both Complaint Counsel and Respondents. (RX5022-RX5023 [redacted] Nor has Complaint Counsel identified such a document. [redacted] Therefore, this cited testimony should be accorded little weight.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents also incorporate their responses to CCFF ¶¶ 2216–17 and 2222 herein.

2240. [redacted]

[redacted]

Response to Finding No. 2240:

[redacted]

Respondents also incorporate their responses to CCFF ¶¶ 2216–17, 2222 and 2236–39 herein.

4. [redacted]

2241. [redacted]

Response to Finding No. 2241:

[redacted] even though [redacted] was served with a subpoena by both Complaint Counsel and Respondents. (RX5022-RX5023 [redacted] Nor has Complaint Counsel identified such a document. Therefore, this cited testimony should be accorded little weight.

2242. [redacted]

Response to Finding No. 2242:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2210, 2216–17, 2222 and 2236–39, which Respondents incorporate herein.

2243. [redacted]

Response to Finding No. 2243:

[redacted]

As Dr. Cote explained, "[t]he development of biomarkers for a particular cancer will not be adequate for other cancers. While there may be overlap, one still needs to go through all of the [development] steps. If . . . the test developer has made the decision that they've already undergone biomarker discovery with the assay that they have, they still need to go through the case-control verification to determine whether or not the assay has the performance characteristics needed . . . for the new target cancer, and then has to go through a prospective trial depending on which cancer is being targeted." (PFF ¶ 328.1.)

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2210, 2216–17, 2222 and 2236–39, which Respondents incorporate herein.

2244. [redacted]

Response to Finding No. 2244:

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 2210, 2216–17, 2222 and 2236–39 herein.

2245. [redacted]

Response to Finding No. 2245:

[redacted]

2246. [redacted]

Response to Finding No. 2246:

[redacted]

2247. [redacted]

Response to Finding No. 2247:

The proposed finding relates to irrelevant subject matter because [redacted] has no bearing on Natera's clinical development of its putative MCED test.

2248. [redacted]

Response to Finding No. 2248:

The proposed finding relates to irrelevant subject matter becaue it does not relate to any putative MCED test.

2249. [redacted]

Response to Finding No. 2249:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF CCFF ¶¶ 2210, 2216–17, 2222, 2236–39 and 2244, which Respondents incorporate herein. Respondents also note that to the extent the proposed finding and CCFF ¶ 2248 suggest that [redacted]

5. [redacted]

2250. [redacted]

Response to Finding No. 2250:

[redacted]

2251. [redacted]

Response to Finding No. 2251:

Respondents have no specific response.

2252. [redacted]

Response to Finding No. 2252:

Respondents have no specific response.

2253. [redacted]

Response to Finding No. 2253:

Respondents have no specific response.

2254. [redacted]

Response to Finding No. 2254:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2210, 2216–17, 2222, 2236–39 and 2244, which Respondents incorporate herein.

2255. [redacted]

Response to Finding No. 2255:

The proposed finding is incomplete and misleading as well as contradicted by the weight of the evidence. *First*, [redacted].

[redacted]

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2210, 2216–17, 2222, 2236–39 and 2244, which Respondents incorporate herein.

2256. [redacted]

Response to Finding No. 2256:

[redacted]

[redacted]. To the contrary, even once a company has developed a cancer screening test for a single cancer type, it does not become easier to add additional cancer types, because "[t]he development of biomarkers for a particular cancer will not be adequate for other cancers" and "[w]hile there may be overlap, one still needs to go through all of the [development] steps," including "go[ing] through the case-control verification to determine whether or not the assay has the performance characteristics needed . . . for the new target cancer," and "go[ing] through a prospective trial depending on which cancer is being targeted." . (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123; PFF ¶¶ 328–328.1.) Dr. Aravanis testified that GRAIL considered developing a single cancer screening test as a route to multicancer screening test but abandoned it because it would take far too long; building a multicancer test by developing single cancer tests seriatim could take four or five years for each cancer; to develop a 50-cancer test one cancer at a time a developer would need to do a research study, discovery study and collect relevant samples, determine the right technology, go into a new test development phase and clinical trials for each new cancer; GRAIL was able to develop a test capable of detecting 50 cancer types simultaneously directly by undergoing a much more intensive process to develop a test for 50 cancer types at the same time. (Aravanis (Illumina) Tr. 1895–97.)

6. [redacted]

C. GUARDANT HEALTH IS DEVELOPING AN MCED TEST CALLED LUNAR-2

1. Guardant Is An Established Oncology Test Developer

2257. Guardant—a publicly traded company—is headquartered in Redwood City, California. (PX0059 (Guardant) at 001 (Guardant Health FY 2019 Form 10-K)).

Response to Finding No. 2257:

Respondents have no specific response.

2258. Guardant is a clinical diagnostics company that is currently developing blood-based tests for oncology applications. (Chudova (Guardant) Tr. 1135).

Response to Finding No. 2258:

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. Today, Guardant commercially offers only therapy selection tests and MRD tests, and is developing a single-cancer screening test focused on colorectal cancer. (PFF ¶ 486–92.)

2259. Guardant's mission is "to conquer cancer with data." (Getty (Guardant) Tr. 2488).

Response to Finding No. 2259:

Respondents have no specific response, except to note that the proposed finding relates to irrelevant subject matter.

2260. Guardant's R&D efforts include three oncology related clinical applications: a therapy selection test, a minimal residual disease test, and a cancer screening test. (Chudova (Guardant)Tr. 1138-39). These three applications span the different phases of a cancer diagnosis, from an undiagnosed patient to patients currently undergoing various stages of treatment. (Chudova (Guardant) Tr. 1138-39).

Response to Finding No. 2260:

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. The cited testimony provides no relevant information as to the stage of development of each of the purported R&D efforts. According to Dr. Chudova's testimony, only Guardant's therapy selection test and minimal residual disease test are commercially available. (Chudova (Guardant) Tr. 1146–47.) The cited testimony provides no relevant information about

the development of Guardant's purported MCED test, and therefore, no relevant information about whether Guardant is presently a credible rival of GRAIL or is likely to become one in the foreseeable future.

2261. Guardant's flagship product, Guardant360, is a therapy selection test that helps clinicians choose the appropriate treatment for patients diagnosed with cancer based on an analysis of a blood sample. (Chudova (Guardant) Tr. 1146-47).

Response to Finding No. 2261:

Respondents have no specific response, except to note that the proposed finding relates to irrelevant subject matter because it concerns therapy selection tests, which are not multicancer screening tests.

2262. Guardant obtained breakthrough device status for Guardant 360 CDx on January 29, 2018. (PX8316 (Guardant) at 001 (Summary of Safety and Effectiveness Data (SSED), Dec. 21, 2020)).

Response to Finding No. 2262:

Respondents have no specific response, except to note that [redacted] This proposed finding also relates to irrelevant subject matter because it concerns therapy selection tests, which are not multicancer screening tests.

2263. [redacted] (*See* PX2046 (Illumina) (Email from P. Febbo, Illumina, to J. Leite, Illumina, et al, discussing Guardant 360 CDx FDA approval Cowen Press Release, Aug. 10, 2020) (*in camera*); RX3299 (FDA, Guardant360 CDx – P200010, https://www.fda.gov/medical-devices/recently-approved-devices/guardant360-cdx-p200010 (last visited Feb. 10, 2022)); PX7045 (Chudova (Guardant) IHT at 17-18)).

Response to Finding No. 2263:

Respondents have no specific response, except to note that the proposed finding relates to irrelevant subject matter because it concerns therapy selection tests, which are not multicancer screening tests.

2264. Guardant's therapy selection oncology application helps identify biomarkers that can be used to match cancer patients with relevant treatment options. (Chudova (Guardant) Tr. 1138-39).

Response to Finding No. 2264:

Respondents have no specific response, except to note that the proposed finding relates to irrelevant subject matter because it concerns therapy selection tests, which are not multicancer screening tests.

2265. LUNAR-1 is currently in clinical trials to obtain FDA approval. (PX7045 (Chudova (Guardant) IHT at 68-69)).

Response to Finding No. 2265:

Respondents have no specific response except to note that the proposed finding relates to irrelevant subject matter insofar as it concerns LUNAR-1, which is a minimal residual disease test, which is not a multicancer screening test.

2266. [redacted] (PX7040 (Getty (Guardant) IHT at 114) (*in camera*)).

Response to Finding No. 2266:

Respondents have no specific response except to note that the proposed finding relates to irrelevant subject matter because Guardant Reveal is "designed to detect minimal residual disease in colorectal cancer patients", and is not an MCED. (Chudova (Guardant) Tr. 1147.) Further, the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

2267. Dr. Chudova testified that Guardant plans to extend Guardant Reveal to detect additional cancers beyond colorectal and will launch a new version of the test with additional cancers shortly. (Chudova (Guardant) Tr. 1152).

Response to Finding No. 2267:

Respondents have no specific response except to note that the proposed finding relates to irrelevant subject matter because Guardant Reveal is not an MCED test: As Dr. Chudova notes, "[i]n the space of minimal residual disease or the Guardant Reveal test, the clinical setting is different" than that of an MCED. (Chudova (Guardant) Tr. 1150–51.)

2268. Guardant is developing early-stage cancer screening products with a current focus on screening for colorectal cancer. (PX7045 (Chudova (Guardant) IHT at 17-19)).

Response to Finding No. 2268:

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future.

The proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2269. At trial, Dr. Chudova described Guardant's development of a cancer screening test as a "big area of development at the moment" for the company. (Chudova (Guardant) Tr. 1152).

Response to Finding No. 2269:

Respondents have no specific response, except to state that the cited testimony confirms that Guardant's cancer screening test is merely "in development" and has not advanced sufficiently to show that Guardant is currently a credible rival for GRAIL or will be in the foreseeable future. (*See* PFF ¶¶ 476–85.)

2270. Each of Guardant's clinical tests in development uses NGS sequencing in its workflow. (Chudova (Guardant) Tr. 1139-40).

Response to Finding No. 2270:

The proposed finding is inaccurate, incomplete and misleading, including because it appears to suggest that an NGS platform is required for Guardant's putative development of cancer screening tests. To the contrary, many test developers are pursuing cancer screening tests for multiple cancers using other analytes. For example, StageZero's Aristotle test is a microarray-based liquid biopsy test that interrogates mRNA to detect 10 cancers and Genesys Biolabs' OneTest is a proteomics-based test that measures seven cancer protein biomarkers to screen for lung, liver, pancreatic, ovarian, prostate and colon cancers. (*See* PFF ¶¶ 691–696.) Protein biomarkers have also been used for many years for early stage cancer detection and screening. (*See* PFF ¶¶ 155–157.) An increasing number of companies are developing "multi-omic" tests which combine information from multiple analytes, including DNA (genome), RNA (transcriptome) and protein (proteome) for increased sensitivity in cancer detection. (*See* PFF ¶¶ 169–169.3.) Respondents incorporate their responses to CCFF ¶ 344 herein.

2271. Illumina is Guardant's sole supplier of sequencer instruments and the sole supplier of repair services for Guardant's sequencer instruments. (Getty (Guardant) Tr. 2683).

Response to Finding No. 2271:

The proposed finding is inaccurate, incomplete and misleading to the extent it suggests that only Illumina's sequencers and core consumables are suitable for Guardant's tests including its putative MCED test in development. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶¶ 341, 927–28, 940, 971, 980, 1115 and 1118 herein.

[redacted]

[redacted]

2. Guardant Is Developing an MCED Test Called LUNAR-2

2272. Guardant has spent several years developing a cancer screening test based on the technological platform used for its Guardant Reveal MRD test. (Chudova (Guardant) Tr. at 1152).

Response to Finding No. 2272:

Respondents note that the proposed finding is misleading to the extent that it implies the development of Guardant's cancer screening test is somehow complete. Dr. Chudova testified that "we're also working for a number of years now on extending that same technology platform . . . and that's another big area of development at the moment". (Chudova (Guardant) Tr. 1152 (emphasis added).) In particular, [redacted] (PFF ¶ 473; Chudova (Guardant) Tr. 1240, 1249; Getty (Guardant) Tr. 2580–82; RX3869 (Cote Expert Report) ¶ 201.).) Therefore, it has taken about [redacted] (PFF ¶ 474; RX3869 (Cote Expert Report) ¶ 201.)

2273. [redacted] (Getty, Tr. 2493-94; PX7100 (Chudova (Guardant) Dep. at 15-16); PX7045 (Chudova (Guardant) IHT at 17-19)).

Response to Finding No. 2273:

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future.

[redacted]

Guardant produced no data or publications for cancer signal of origin, has no publications on cancer screening beyond colorectal cancer screening, has no cancer screening studies registered at *clinicaltrials.gov* beyond colorectal and lung cancer, [redacted]

[redacted]

Accordingly, there is no evidence that Guardant will launch in the foreseeable future a cancer screening test that is a close substitute to the Galleri test. (PFF ¶¶ 476–92.) Respondents also incorporate PFF ¶¶ 476–92 and their responses to CCFF ¶¶ 426–438, 611, 684, 927 and 1231 herein.

Respondents also note that the proposed finding relies in part on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2274. [redacted] (PX7105 (Getty (Guardant) Dep. at 13-14) (*in camera*)).

Response to Finding No. 2274:

The proposed finding is contradicted by the weight of the evidence. In the same cited deposition, [redacted] In addition, there is no such thing as a "pan-cancer test" because there is no such thing as a universal cancer biomarker. (PFF ¶ 308; Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106.) Therefore, test development for a multi-cancer screening test cannot proceed as Mr. Getty suggests: full biomarker discovery is

required to identify a panel of biomarkers for each new cancer to ensure the accuracy, specificity and sensitivity needed for an early cancer screening test. (PFF ¶ 309; Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 106; *see also* Aravanis (Illumina) Tr. 1883, 1896–98.)

The proposed finding is also misleading to the extent it suggests that it is a viable option to convert from a single cancer screening test to a multi-cancer screening test. To the contrary, even once a company has developed a cancer screening test for a single cancer type, it does not become easier to add additional cancer types, because "[t]he development of biomarkers for a particular cancer will not be adequate for other cancers" and "[w]hile there may be overlap, one still needs to go through all of the [development] steps," including "go[ing] through the case-control verification to determine whether or not the assay has the performance characteristics needed . . . for the new target cancer," and "go[ing] through a prospective trial depending on which cancer is being targeted." . (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123; PFF ¶¶ 328–328.1.) To add new cancer types to an existing test is the same as if the test developer is starting over with a new test.

Respondents also incorporate their responses to CCFF ¶¶ 405 and 2273 herein.

2275. [redacted]
(Chudova (Guardant) Tr. 1243 (*in camera*)).

Response to Finding No. 2275:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74, which Respondents incorporate herein.

[redacted]

[redacted]

Respondents also note that Guardant has not yet finalized which biomarkers it will analyze as part of its putative MCED test, [redacted]

Respondents also incorporate their responses to CCFF ¶ 427 herein.

2276. [redacted]
(Chudova (Guardant) Tr. 1243 (*in camera*)).

Response to Finding No. 2276:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2275, which Respondents incorporate herein. [redacted]

[redacted] (Chudova (Guardant) Tr. 1270.)

The cited testimony also confirms that [redacted]

2277. Dr. Chudova testified at trial that she is "focused on developing technology that could be used for detection of multiple cancer indications or precancer indications, any cancer." (Chudova (Guardant) Tr. 1179).

Response to Finding No. 2277:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74 and 2278, which Respondents incorporate herein. Respondents also note that Dr. Chudova also testified that Guardant's "clinical trial for colorectal cancer and the product for colorectal cancer is in the most advanced phase" (Chudova (Guardant) Tr. 1179); [redacted]; Chudova (Guardant) Tr. 1154; [redacted]).

2278. Guardant's cancer screening test is suitable for multiple cancer types. (Chudova (Guardant) Tr. 1179).

Response to Finding No. 2278:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74 and 2277, which Respondents incorporate herein.

Further, the cited evidence does not support the proposed finding. Dr. Chudova claimed, without support, that "***the platform technology***" that Guardant has developed is suitable for multiple cancer types. (Chudova (Guardant) Tr. 1179 (emphasis added).) Neither Guardant's representatives nor Complaint Counsel have cited any evidence to suggest that Guardant has an operational cancer screening test, nor that it has been analytically or clinically validated to detect multiple types of cancer.

To the contrary, [redacted]

[redacted]

2279. Guardant's business strategy involves first creating a colorectal cancer ("CRC") test that will be rapidly adopted, then moving to a multi-cancer phase. (Getty (Guardant) Tr. 2495-96; *see* Chudova (Guardant) Tr. 1153-54 (stating that the initial version of Guardant's cancer screening test will screen for colorectal cancer)).

Response to Finding No. 2279:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74 and 2277–78, which Respondents incorporate herein. Respondents also note that Guardant's purported "business strategy" is untested because only the CRC indication is undergoing clinical trials at this time (*i.e.*, the Eclipse trial).

2280. Dr. Chudova testified that the benefit of prioritizing cancers with existing screening modalities is that "clinically it's established that screening for those indications is beneficial for the patients." (Chudova (Guardant) Tr. 1153-54).

Response to Finding No. 2280:

Respondents have no specific response except to note that the cited testimony confirms that GRAIL and Guardant are taking distinct approaches, suggesting that if Guardant's test comes to market, it will be a complement to GRAIL's Galleri test, rather than a substitute. Respondents also note that [redacted]

[redacted] Respondents also incorporate their responses to ¶¶ 2273–74 and 2277–78 herein.

2281. [redacted] (PX7090 (Sood (Guardant) Dep. at 108) (*in camera*)).

Response to Finding No. 2281:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74 and 2277–78, which Respondents incorporate herein. Respondents have no specific response, except to note that the cited testimony confirms the fact that [redacted] (Getty (Guardant) Tr. 2593, 2599; Chudova (Guardant) Tr. 1154, 1240.)

2282. For its MCED test, Guardant is initially focusing on cancers with existing screening modalities—including colorectal, lung, and breast cancer. (Chudova (Guardant) Tr. 1153-54; Getty (Guardant) Tr. 2499).

Response to Finding No. 2282:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2280–81, which Respondents incorporate herein.

2283. Dr. Chudova testified at trial that the benefits of prioritizing cancers with existing screening modalities is "clinically it's established that screening for those indications is beneficial for the patients." (Chudova (Guardant) Tr. 1153-54).

Response to Finding No. 2283:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2280–81, which Respondents incorporate herein.

2284. As Mr. Getty explained, starting with CRC makes "it a little bit easier to bring a test to market in a faster fashion," and Guardant's strategy of "pursuing a singular tumor and then adding on tumors is just a little bit of a different view of the same coin that Grail has." (PX7105 (Getty (Guardant) Dep. at 238)).

Response to Finding No. 2284:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2279, which Respondents incorporate herein.

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

2285. [redacted] (PX8503 (Guardant) at 066 [redacted] (*in camera*)).

Response to Finding No. 2285:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74 and 2277–78, which Respondents incorporate herein.

[redacted]

[redacted]

Further, Guardant's proposed approach means that Guardant's test will not be a potential substitute to Galleri in the foreseeable future, given that Guardant will need to start anew to add additional cancer types to its colorectal cancer screening test in development. [redacted]

2286. [redacted] (Getty (Guardant) Tr. 2565-66, 2569-70 (*in camera*)).

Response to Finding No. 2286:

Respondents have no specific response except to note that the cited testimony confirms that Guardant and GRAIL are adopting different approaches, suggesting that if Guardant's test comes to market, it will be a complement to GRAIL's Galleri test, rather than a substitute.

Respondents also note that there is typically a tradeoff between specificity and sensitivity. (PFF ¶ 180 (RX3869 (Cote Expert Report) ¶ 95).) Given the same conditions, a test applying cutoff thresholds that minimizes false positives, *i.e.*, higher specificity, may often have

a lower sensitivity than a test that results in a higher false positive rate. (PFF ¶ 180 (RX3869 (Cote Expert Report) ¶ 95).)

Despite Guardant's purported focus on sensitivity, however, Respondents also note that, In contrast, Galleri's current sensitivity rate for version 2 of its test (which is the version that is available as an LDT) is 51.5% for all cancer types across stages. (PFF ¶ 335.)

2287. Guardant plans to initiate MCED test clinical trials in the near future. (Getty (Guardant) Tr. 2497).

Response to Finding No. 2287:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74 and 2277–78, which Respondents incorporate herein.

Respondents also note that the cited testimony confirms the fact that (Getty (Guardant) Tr. 2593, 2599; Chudova (Guardant) Tr. 1154, 1240.)

2288. Guardant's primary customer for its MCED test will be the primary care physician, including OB/GYN physicians who function as the primary caregiver for women. (Getty (Guardant) Tr. 2502).

Response to Finding No. 2288:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74, 2277–78 and 2285, which Respondents incorporate herein.

2289. The initial version of Guardant's cancer screening test will screen for colorectal cancer ("CRC"). (Chudova (Guardant) Tr. 1153-54).

Response to Finding No. 2289:

Respondents have no specific response, except to note that the cited testimony confirms that Guardant's current test is a single-cancer, CRC-only test. Respondents also incorporate their responses to CCFF ¶¶ 2273–74 and 2277–78 herein.

2290. Guardant's business strategy involves first creating a CRC test that will be rapidly adopted, then moving to a multi-cancer phase. (Getty (Guardant) Tr. 2495-96).

Response to Finding No. 2290:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74, 2277–78 and 2285, which Respondents incorporate herein.

Respondents also note that the cited source also observes that Guardant has not yet commenced a clinical trial for any additional cancer types beyond CRC. (Getty (Guardant) Tr. 2593.)

2291. [redacted] (Getty (Guardant) Tr. 2625 (*in camera*)).

Response to Finding No. 2291:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74, 2277–78 and 2285, which Respondents incorporate herein.

Respondents also note that the cited testimony confirms that Guardant's current test is a single-cancer, CRC-only test.

2292. [redacted] (PX7100 (Chudova (Guardant) Dep. at 22-23) (*in camera*)).

Response to Finding No. 2292:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74 and 2277–78, which Respondents incorporate herein.

Respondents note that Guardant's 10-K warned its investors that "[t]here is no guarantee that the FDA will grant 510(k) clearance or a premarket approval of our products", that [t]he process of obtaining a PMA is a rigorous, costly, lengthy and uncertain process", and "[t]he FDA can delay, limit or delay clearance or approval of a device or approval of a device for many reasons". (PX0060 (Guardant) at 40.) Respondents also note that the cited testimony merely confirms the uncertain future of Guardant's potential MCED test: the high prevalence of CRC circulating tumor DNA in the bloodstream may make CRC easier to detect than other cancers. Accordingly, Guardant's ability to "add" more cancers to its test is highly contingent and uncertain.

2293. Guardant is currently conducting a clinical trial—called Eclipse—on the use of its screening test for colorectal cancer. (Chudova (Guardant) Tr. 1154-55).

Response to Finding No. 2293:

Respondents have no specific response, except to note that the proposed finding is evidence that [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 2273–74 and 2277–78 herein.

2294. [redacted] (PX7040 (Getty (Guardant) IHT at 149) (*in camera*)).

Response to Finding No. 2294:

Respondents have no specific response except to note that Guardant's 10-K warned its investors that "[t]here is no guarantee that the FDA will grant 510(k) clearance or a premarket approval of our products", that [t]he process of obtaining a PMA is a rigorous, costly, lengthy and uncertain process", and "[t]he FDA can delay, limit or delay clearance or approval of a device or approval of a device for many reasons". (PX0060 (Guardant) at 40.) Respondents also note that the cited testimony confirms that [redacted] Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine, it should be given no weight. Respondents also incorporate their responses to CCFF ¶¶ 2273–74 and 2277–78 herein.

a) Guardant's MCED Test Is Based off the Technological Platform Used with Guardant Reveal

2295. Guardant has spent several years developing its cancer screening test based on the technological platform used with its MRD test. (Chudova (Guardant) Tr. 1152).

Response to Finding No. 2295:

Respondents have no specific response, except to note that the several years of development resulted only in a single-cancer, CRC-only test. Respondents also incorporate their responses to CCFF ¶¶ 2272–74 and 2277–78 herein.

2296. [redacted] (PX7100 (Chudova (Guardant) Dep. at 23-24) (*in camera*)).

Response to Finding No. 2296:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74 and 2277–78, which Respondents incorporate herein.

Respondents have no specific response, except to note that the proposed finding is evidence of the fact that Guardant does not yet have a multicancer screening test; that Guardant's current test is a single-cancer, CRC-only test. In addition, there is no such thing as a "pan-cancer test" because there is no such thing as a universal cancer biomarker. (PFF ¶ 308; Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106.) Therefore, test development for a multi-cancer screening test cannot proceed as Dr. Chudova suggests: full biomarker discovery is required to identify a panel of biomarkers for each new cancer to ensure the accuracy, specificity and sensitivity needed for an early cancer screening test. (PFF ¶ 309; Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 106; *see also* Aravanis (Illumina) Tr. 1883, 1896–98.) To add new cancer types to an existing test is the same as if the test developer is starting over with a new test.

2297. [redacted] (Getty (Guardant) Tr. 2628 (*in camera*)).

Response to Finding No. 2297:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 435, 2273–74 and 2277–78, which Respondents incorporate herein.

[redacted]

[redacted]

2298. As Dr. Chudova explained, for LUNAR-2, "The platform in its foundation doesn't have anything specific for an individual cancer types other than the selection of the regions of the genomes that are most representative for that specific cancer. But that's a minor aspect of the technology, and it can be adapted to other cancer types." (PX7100 (Chudova (Guardant) Dep. at 24)).

Response to Finding No. 2298:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2296, which Respondents incorporate herein.

[redacted]

2299. [redacted] (PX7105 (Getty (Guardant) Dep. at 132-33) (*in camera*)).

Response to Finding No. 2299:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74, 2277–78 and 2296, which Respondents incorporate herein.

Respondents note that there is no such thing as a "pan-cancer test" because there is no such thing as a universal cancer biomarker. (PFF ¶ 308; Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106.) [redacted]

2300. Dr. Chudova testified that "Guardant has active plans to apply technology that we've developed for colorectal cancer to . . . multi-cancer screening context that involves cancers other than colorectal cancer." (PX7100 (Chudova (Guardant) Dep. at 23-24)).

Response to Finding No. 2300:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74, 2277–78, 2285 and 2296, which Respondents incorporate herein.

Respondents also note that the cited testimony confirms that Guardant has not yet ***actually*** translated its technology to a clinically-validated test for the detection of multiple cancers.

2301. [redacted] (PX7045 (Chudova (Guardant) IHT at 100) (*in camera*)).

Response to Finding No. 2301:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74, 2277–78 and 2296, which Respondents incorporate herein.

Respondents also note that the cited testimony confirms that [redacted]

2302. [redacted] (PX7100 (Chudova (Guardant) Dep. at 107) (*in camera*)).

Response to Finding No. 2302:

[redacted]

2303. [redacted] (PX7100 (Chudova (Guardant) Dep. at 139) (*in camera*)).

Response to Finding No. 2303:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74 and 2277–78, which Respondents incorporate herein.

[redacted]

2304. [redacted] (PX7105 (Getty (Guardant) Dep. at 199-200) (*in camera*)).

Response to Finding No. 2304:

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. Mr. Getty is not a physician and has no knowledge as to how primary care physicians will choose among putative MCED test providers. The proposed finding also

relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding is also incomplete and misleading. [redacted] Respondents also incorporate their responses to CCFF ¶ 699.

b) [redacted]

2305. [redacted] (PX7105 (Getty (Guardant) Dep. at 23); Chudova Tr. 1199-1200 (*in camera*); *see also* PX7100 (Chudova (Guardant) Dep. at 23-24, 147-48) (*in camera*)).

Response to Finding No. 2305:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74, 2277–78 and 2296, which Respondents incorporate herein.

[redacted]

2306. [redacted]

[redacted]
(Chudova (Guardant) Tr. 1200 (*in camera*)).

Response to Finding No. 2306:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74, 2277–78 and 2296, which Respondents incorporate herein. **Further,** [redacted]

2307. [redacted]
(Chudova (Guardant) Tr. 1201 (*in camera*)).

Response to Finding No. 2307:

The proposed finding is inaccurate, incomplete and misleading as well as contradicted by the weight of the evidence. [redacted] The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74 and 2277–78, which Respondents incorporate herein.

2308. [redacted]

(PX8503 (Guardant) at 066 [redacted]

Response to Finding No. 2308:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2285, which Respondents incorporate herein.

2309. [redacted]
(PX8503 (Guardant) at 066 [redacted] (*in camera*)).

Response to Finding No. 2309:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2285, which Respondents incorporate herein.

Respondents also note that there is typically a tradeoff between specificity and sensitivity. (PFF ¶ 180 (RX3869 (Cote Expert Report) ¶ 95).) Given the same conditions, a test applying cutoff thresholds that minimizes false positives, *i.e.*, higher specificity, may often have a lower sensitivity than a test that results in a higher false positive rate. (PFF ¶ 180 (RX3869 (Cote Expert Report) ¶ 95).) [redacted]

Despite Guardant's purported focus on sensitivity, however, Respondents also note that, [redacted] In contrast, Galleri's current sensitivity rate for version 2 of its test (which is the version that is available as an LDT) is 51.5% for all cancer types across stages. (PFF ¶ 335.)

Further, [redacted]

Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 64), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2310. [redacted] (Getty (Guardant) Tr. 2533, 2537 (*in camera*)).

Response to Finding No. 2310:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74 and 2277–78, which Respondents incorporate herein. Respondents also note that the proposed finding is evidence of differentiation between Guardant's proposed MCED test and GRAIL's Galleri test, suggesting that if Guardant's test comes to market, it will be a complement to GRAIL's Galleri test, rather than a substitute.

[redacted]

2311. [redacted] (Getty (Guardant) Tr. 2533-34 (*in camera*)).

Response to Finding No. 2311:

Respondents have no specific response.

2312. [redacted] (Chudova (Guardant) Tr. 1309-10 (*in camera*)).

Response to Finding No. 2312:

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74 and 2277–78, which Respondents incorporate herein.

[redacted]

[redacted]

2313. [redacted] (Chudova (Guardant) Tr. 1309-11 (*in camera*)).

Response to Finding No. 2313:

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74 and 2277–78, which Respondents incorporate herein.

[redacted]

[redacted]

2314. [redacted] (Chudova (Guardant) Tr. 1200-01 (*in camera*)).

Response to Finding No. 2314:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74, 2277–78 and 2296, which Respondents incorporate herein. [redacted]

2315. [redacted] (Chudova (Guardant) Tr. 1205 (*in camera*)).

Response to Finding No. 2315:

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74 and 2277–78, which Respondents incorporate herein.

The proposed finding is incomplete and misleading. [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶ 429 herein.

2316. [redacted] (PX7100 (Chudova (Guardant) Dep. at 150-51) (*in camera*)).

Response to Finding No. 2316:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2315, which Respondents incorporate herein.

Further, [redacted]

[redacted]

2317. Dr. Chudova testified at trial that Guardant's products "have been generating development data to [] date that suggests that [Guardant] will have a decent chance in being successful in this very, very complicated endeavor" of developing a cancer screening test. (Chudova (Guardant) Tr. 1154-55).

Response to Finding No. 2317:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74 and 2277–78, which Respondents incorporate herein. Respondents also note that Dr. Chudova's testimony confirms that Guardant has not generated sufficient external-facing, validated data—the kind of data required even to launch an LDT and that is acceptable to regulators and payors—to suggest it is likely to succeed; rather it has generated internal data indicative of only a "decent chance" of success. The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. Dr. Chudova cannot know that Guardant "will be successful" given Guardant's current state of development.

[redacted]

[redacted]

3. [redacted]

2318. [redacted] (Getty (Guardant) Tr. 2529 (*in camera*); PX7040 (Getty (Guardant) IHT at 149) (*in camera*)).

Response to Finding No. 2318:

Respondents have no specific response, except to note that the cited testimony confirms that Guardant plans to introduce a single-cancer screening test to the market. The cited testimony says nothing about Guardant's proposed MCED. Moreover the timing of this introduction remains uncertain in light of contradictory statements from Guardant's personnel and ordinary course documents. (*See, e.g.*, RRFF ¶ 2321.) Respondents also note that the cited testimony confirms [redacted]

Respondents also note that the proposed finding relies in part on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2319. [redacted] (PX8503 (Guardant) at 065 (*in camera*)); *see* PX7100 (Chudova (Guardant) Dep. at 137-38) (*in camera*)) [redacted]).

Response to Finding No. 2319:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2285, which Respondents incorporate herein.

The proposed finding is incomplete and misleading as well as contradicted by the weight of the evidence. [redacted]

Further, Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 64), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2320. [redacted] (*in camera*)).

Response to Finding No. 2320:

Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 59), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

Respondents have no further, specific response, except to note that the proposed finding is evidence that [redacted]

Accordingly, the cited testimony confirms that GRAIL and Guardant are taking distinct approaches, suggesting that if Guardant's test ultimately comes to market, it will be a complement to GRAIL's Galleri test, rather than a substitute. Respondents also incorporate their responses to CCFF ¶ 2318 herein.

2321. [redacted] (Getty (Guardant) Tr. 2505, 2529 (*in camera*)).

Response to Finding No. 2321:

Respondents have no specific response, except to note that the cited testimony confirms that Guardant plans to introduce a single-cancer screening test to the market. The cited testimony says nothing about Guardant's proposed MCED. Moreover the timing of this introduction remains uncertain in light of contradictory statements from Guardant's personnel and ordinary course documents. (*See, e.g.*, RRFF ¶ 2318.)

2322. [redacted] (PX8309 (Guardant) at 016 [redacted] (*in camera*)).

Response to Finding No. 2322:

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74 and 2277–78, which Respondents incorporate herein. Respondents also note that the proposed finding indicates that Guardant's best case projection does not suggest that Guardant is likely to receive approval for, let alone apply for approval of, its hypothetical MCED in the reasonably foreseeable future.

Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 59), and therefore, the

document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2323. [redacted] (Chudova (Guardant) Tr. 1206 (*in camera*)).

Response to Finding No. 2323:

The proposed finding is incomplete and misleading. [redacted] Respondents also incorporate their responses to CCFF ¶ 2278 herein.

2324. [redacted] (Chudova (Guardant) Tr. 1202 (*in camera*)).

Response to Finding No. 2324:

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74, 2277–78 and 2302, which Respondents incorporate herein. Further, [redacted]

Respondents note, however, that there is no such thing as a "pan-cancer test" because there is no such thing as a universal cancer biomarker. (PFF ¶ 308; Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106.)

4. Guardant Is Committed to Improving Its MCED Test Over Time

2325. [redacted] (Getty (Guardant) Tr. 2537-38 (*in camera*)).

Response to Finding No. 2325:

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74 and 2277–78, which Respondents incorporate herein. Further, there is no indication based on Guardant's work to date that [redacted]

2326. [redacted] (Getty (Guardant) Tr. 2539-40 (*in camera*)).

Response to Finding No. 2326:

Respondents have no specific response, except to note that the proposed finding is evidence that potential participants in the purported MCED market recognize the potential for differentiation as among putative MCED tests, resulting in the various offerings acting as complements to each other, rather than substitutes. Respondents also incorporate their responses to CCFF ¶¶ 2273–74 and 2277–78 herein.

2327. [redacted] (Getty (Guardant) Tr. 2540 (*in camera*)).

Response to Finding No. 2327:

Respondents have no specific response except to note that all agree that accelerating the adoption of a cancer screening test with save lives, the unrefuted evidence shows that reuniting Illumina and GRAIL will accelerate the adoption of the Galleri test. (PFF ¶¶ 476 (RX3869 (Cote Expert Report) ¶ 203), 1117.2-17.3 (*see e.g.* Conroy (Exact/Thrive) Tr. 1739; Chahine (Helio) Tr. 1132–33; [redacted] Fiedler (FMI) Tr. 4474; deSouza (Illumina) Tr. 2411; [redacted]

2328. Continually improving the performance of an MCED test will "catch more early stage disease" before it becomes aggressive and spreads, as well as "save [patients] the mental anguish of telling them they have a disease" when they do not. (PX7105 (Getty (Guardant) Dep. at 29-30)).

Response to Finding No. 2328:

Respondents have no specific response, except to note that the proposed finding supports the Respondents' arguments regarding GRAIL's lifesaving potential and incorporate their responses to CCFF ¶ 2327 herein.

2329. [redacted] (Getty, Tr. 2540 (*in camera*); PX7090 (Sood (Guardant) Dep. at 108); PX7100 (Chudova (Guardant) Dep. at 27)).

Response to Finding No. 2329:

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 433, 2273–74 and 2277–78, which Respondents incorporate herein. Further, there is no

indication based on Guardant's work to date that [redacted] (PFF ¶¶ 476–92.)

2330. [redacted] (Getty (Guardant) Tr. 2540 (*in camera*)).

Response to Finding No. 2330:

Respondents have no specific response, except to note that there is typically a tradeoff between specificity and sensitivity. (PFF ¶ 180 (RX3869 (Cote Expert Report) ¶ 95).) [redacted] Given the same conditions, a test applying cutoff thresholds that minimizes false positives, *i.e.*, higher specificity, may often have a lower sensitivity than a test that results in a higher false positive rate. (PFF ¶ 180 (RX3869 (Cote Expert Report) ¶ 95).) [redacted]

Despite Guardant's purported focus on sensitivity, however, Respondents also note that, [redacted]

[redacted] In contrast, Galleri's current sensitivity rate for version 2 of its test (which is the version that is available as an LDT) is 51.5% for all cancer types across stages. (PFF ¶ 335.)

2331. Mr. Getty testified regarding his expectation that a distributed model of cancer screening tests will be "important" and "oftentimes the preferred mode in certain markets, for certain customers." (PX7040 (Getty (Guardant) IHT at 162-163); *see* PX7105 (Getty (Guardant) Dep. at 246) (testifying a distributed model for its MCED test is "certainly something that we would have to explore at some point if the market conditions effectively pushed us in that direction.")).

Response to Finding No. 2331:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

[redacted]

The proposed finding is also misleading to the extent it implies that a distributed IVD model will be part of the pipeline in the foreseeable future for any putative MCED test. GRAIL has not expressed any intent to pursue a distributed IVD kit. (PFF ¶ 1417 (Goswami (Illumina) Tr. 3273).) Several features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (PFF ¶ 675; RX3869 (Cote Expert Report) ¶ 359.) The test developer's decision whether to proceed with an

IVD kit as opposed to a centralized model is an economic decision driven by test-specific factors. (Goswami (Illumina) Tr. 3197.) IVD kits are most suitable for tests that have precious samples, that present shipping challenges and require fast turnaround times. (Goswami (Illumina) Tr. 3196–3200; *see also* RX3869 (Cote Expert Report) § XI, ¶¶ 360–63.)

2332. Mr. Getty explained that Guardant "would need to work with Illumina" in order to obtain FDA approval to sell Guardant's MCED test as a distributed IVD test. (Getty (Guardant) Tr. 2689).

Response to Finding No. 2332:

The proposed finding is incomplete and misleading. *First*, as Ms. Berry testified, Illumina's role in test developers' obtaining regulatory approval is quite limited: Beyond supplying standard documentation about the sequencing technologies that a customer is using, Illumina does not provide any support to its customers in obtaining regulatory approval. (Berry (Illumina) Tr. 847–49.) *Second*, Illumina's Open Offer specifically addresses any concerns related to IVD development and documentation. For example, under the Open Offer, Illumina may not withhold support of documentation and information for FDA approval, even from a customer who is a cancer screening competitor. (Berry (Illumina) Tr. 914–16.) *See generally* PFF ¶ 1026–35. In addition, as noted, there is no indication based on Guardant's work to date that [redacted]. (*See* RRFF ¶¶ 2273–74 and 2277–78). *Third,* the proposed finding is misleading to the extent it implies that a distributed IVD model will be part of the pipeline in the foreseeable future for any putative MCED test. GRAIL has not expressed any intent to pursue a distributed IVD kit. (PFF ¶ 1417 (Goswami (Illumina) Tr. 3273).) Several features of sequencing instruments and pipeline multi-cancer

screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (PFF ¶ 675; RX3869 (Cote Expert Report) ¶ 359.) The test developer's decision whether to proceed with an IVD kit as opposed to a centralized model is an economic decision driven by test-specific factors. (Goswami (Illumina) Tr. 3197.) IVD kits are most suitable for tests that have precious samples, that present shipping challenges and require fast turnaround times. (Goswami (Illumina) Tr. 3196–3200; *see also* RX3869 (Cote Expert Report) § XI, ¶¶ 360–63.) Respondents also incorporate their response to CCFF ¶ 2965 herein.

5. [redacted]

2333. [redacted]

Response to Finding No. 2333:

Respondents have no specific response, except to note that the proposed finding is evidence that [redacted] Respondents also incorporate their responses to CCFF ¶¶ 2273–74 and 2277–78 herein.

2334. [redacted] (Chudova (Guardant) Tr. 1156; PX7100 (Chudova (Guardant) Dep. at 127-28) (*in camera*)).

Response to Finding No. 2334:

The proposed finding is incomplete and misleading. The ECLIPSE clinical trial's stated purpose is exclusively to clinically validate the LUNAR-2 colorectal cancer assay. (Chudova (Guardant) Tr. 1155.) There is no evidence to suggest an alternative purpose for the ECLIPSE data. Respondents also incorporate their responses to CCFF ¶¶ 2273–74 and 2277–78 herein.

2335. [redacted] (PX7100 (Chudova (Guardant) Dep. at 31-32, 131) (*in camera*)).

Response to Finding No. 2335:

The proposed finding is incomplete and misleading. [redacted]

2336. [redacted]

Response to Finding No. 2336:

The proposed finding is inaccurate and misleading because the cited testimony only states that Guardant plans to complete "enrollment" by 2022, not the trial itself. (Chudova (Guardant) Tr. 1154–55). [redacted]

2337. [redacted]

Response to Finding No. 2337:

Respondents have no specific response except to note that Guardant does not have a final enrollment for the ECLIPSE trial. (*See* Chudova (Guardant) Tr. 1155.)

2338. [redacted] (PX7100 (Chudova (Guardant) Dep. at 34) (*in camera*)).

Response to Finding No. 2338:

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2269, 2272, 2273–74, 2277–78 and 2285, incorporated herein.

[redacted]

2339. [redacted] (PX7100 (Chudova (Guardant) Dep. at 34) (*in camera*)).

Response to Finding No. 2339:

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2269, 2272, 2273–74, 2277–78 and 2285, incorporated herein.

[redacted]

2340. [redacted] (PX7100 (Chudova (Guardant) Dep. at 34-35) (*in camera*)).

Response to Finding No. 2340:

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2269, 2272, 2273–74, 2277–78 and 2285, incorporated herein.

Respondents also note that the proposed finding is evidence that Guardant has not yet initiated the requisite clinical trials to receive approval for and eventually launch a MCED test.

2341. [redacted] (Getty (Guardant) Tr. 2534-35 (*in camera*)).

Response to Finding No. 2341:

To the extent the proposed finding relies on Guardant's own internal approvals for a trial design, the proposed finding relates to irrelevant subject matter because there is no evidence that Guardant's internal criteria for a trial design will comport with the standards governing registrational clinical trials imposed by regulators, such as the FDA.

Respondents further note that the proposed finding is evidence that Guardant has not yet undertaken registrational clinical trials for any cancer types beyond CRC. Respondents also incorporate their responses to CCFF ¶¶ 2269, 2272, 2273–74, 2277–78 and 2285, herein.

2342. [redacted] (Chudova (Guardant) Tr. 1200 (*in camera*)).

Response to Finding No. 2342:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ ¶¶ 2269, 2272–74, 2277–78 and 2285, which Respondents incorporate herein.

[redacted]

(Chudova (Guardant) Tr. 1200 (*in camera*).)

[redacted]

[redacted]

2343. [redacted] (Chudova (Guardant) Tr. 1200 (*in camera*)).

Response to Finding No. 2343:

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2269, 2272–74, 2277–78, 2285, incorporated herein. Respondents also note that the proposed finding supports Respondents' proposition that Guardant has not yet commenced clinical trials to test the performance of LUNAR-2 with respect to any cancers other than CRC.

2344. [redacted] (Chudova (Guardant) Tr. 1154-55, 1201) (*in camera*)).

Response to Finding No. 2344:

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2269, 2272–74, 2277–78, 2285, incorporated herein. In addition, there is no evidence showing that Guardant actually started their clinical trials for other cancer types in Q4 2021. (PFF ¶ 485 [redacted]

Respondents also note that the proposed finding supports Respondents' proposition that Guardant has not yet commenced clinical trials to test the performance of LUNAR-2 with respect to any cancers other than CRC. [redacted] A test for three cancer types, particularly one that addresses only cancer types that have an existing standard of care screening test, is likely to be a complement to

GRAIL's Galleri test, not a substitute. (PFF ¶ 358 (RX0744 (GRAIL) at 76–90; [redacted] RX0867 (Clinical Overview Deck) at 15; PX7086 (Cance (ACS) Dep. at 50–53); [redacted] RX3869 (Cote Expert Report) ¶ 136.)

Respondents also note that [redacted]

2345. [redacted] (Chudova (Guardant) Tr. 1202 (*in camera*); PX7105 (Getty (Guardant) Dep. at 167) [redacted] (*in camera*)).

Response to Finding No. 2345:

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶ 2344, incorporated herein. In addition, there is no evidence showing that Guardant actually started their clinical trials for other cancer types in Q4 2021. (PFF ¶ 485 [redacted]

Respondents also note that the proposed finding is evidence that Guardant's hypothetical MCED test remains too ill-defined to be considered a competitor of GRAIL's Galleri.

Respondents further note that the proposed finding is evidence of differentiation between Guardant's proposed test and GRAIL's Galleri test, suggesting that if Guardant's test does come to market, it will be a complement to GRAIL's Galleri test, rather than a substitute.

2346. (Chudova (Guardant) Tr. 1204 (*in camera*)).

Response to Finding No. 2346:

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶ 2344, incorporated herein. In addition, there is no evidence showing that Guardant actually started their clinical trials for other cancer types in 2021. (PFF ¶ 485

Respondents also note that the proposed finding provides support for Respondents' proposition that Guardant has not yet commenced clinical trials to test the performance of LUNAR-2 with respect to any cancers other than CRC.

2347. (Chudova (Guardant) Tr. 1154-55).

Response to Finding No. 2347:

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶ 2344, incorporated herein. In addition, there is no evidence showing that Guardant actually started their clinical trials for other cancer types in Q4 2021. (PFF ¶ 485 [redacted]

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

2348. [redacted] (Chudova (Guardant) Tr. 1205-06 (*in camera*)).

Response to Finding No. 2348:

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶ 2344, incorporated herein. In addition, there is no evidence showing that Guardant actually started their clinical trials for other cancer types in Q4 2021. (PFF ¶ 485 [redacted]

[redacted]

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

2349. [redacted] (Chudova (Guardant) Tr. 1205-06 (*in camera*)).

Response to Finding No. 2349:

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶ 2344, incorporated herein. In addition, there is no evidence showing that Guardant actually started their clinical trials for other cancer types in Q4 2021. (PFF ¶ 485 [redacted]

Respondents also note that the proposed finding is evidence that Guardant's possible future clinical trials remain hypothetical, ill-defined and uncertain in outcome.

6. [redacted]

2350. [redacted] (PX7105 (Getty (Guardant) Dep. at 131-35) (*in camera*)).

Response to Finding No. 2350:

The proposed finding is incomplete and misleading.

2351. (Getty (Guardant) Tr. 2542 (*in camera*)).

Response to Finding No. 2351:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2350, which Respondents incorporate herein. Further, to the extent that

[redacted] *See* Getty (Guardant) Tr. 2542 (*in camera*); PFF ¶ 70 (PX0122 (Illumina) at 1).)

2352. [redacted] (PX8305 (Guardant) at 062 (Guardant Health Q3 2020 BOD Meeting, Nov. 2020) (*in camera*) [redacted] *see also* (PX7100 (Chudova (Guardant) Dep. at 27-28) (*in camera*)).

Response to Finding No. 2352:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2350, which Respondents incorporate herein. Further, to the extent that [redacted] (*See* PX8305 (Guardant) at 062 (Guardant Health Q3 2020 BOD Meeting, Nov. 2020) (*in camera*); PFF ¶ 70 (PX0122 (Illumina) at 1).)

7. [redacted]

D. FREENOME IS DEVELOPING AN MCED TEST AS AN EXPANSION OF ITS COLORECTAL CANCER SCREENING TEST

1. Background

2353. [redacted] (PX7055 (Otte (Freenome) IHT at 14) (*in camera*)).

Response to Finding No. 2353:

Respondents have no specific response.

2354. Freenome was founded in 2014. (PX7121 (Otte (Freenome) Dep. at 13)).

Response to Finding No. 2354:

Respondents have no specific response, [redacted]

2. Freenome's MCED Test Technological Platform Is Designed to Be Able to Host a Multi-Cancer Test

2355. [redacted] (PX7050 (Nolan (Freenome) IHT at 43-44) (*in camera*); PX7121 (Otte (Freenome) Dep. at 17-19) (*in camera*)).

Response to Finding No. 2355:

The proposed finding is incomplete and misleading without additional context including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. As noted, even once a company has developed a cancer screening test for a single cancer type (which Freenome has not yet completed), it does not become easier to add additional cancer types.

Mr. Nolan testified that [redacted] (PX7094 (Nolan (Freenome) Dep. at 307).) Freenome's putative multiomics platform also has not demonstrated the ability to screen for multiple cancers simultaneously. (PFF ¶¶ 459-70.) [redacted]

Mr. Otte, Freenome's former CEO, also testified that [redacted]

Further while Freenome may aspire to develop a multiomics platform that could support both an MCED and single cancer test, Freenome has not published any clinical data showing that it is remotely close to achieving this objective. [redacted] Respondents also incorporate their responses to CCFF ¶¶ 405, 439–440, 444, 666, 698, 801, 806, 945 and 1140 herein.

Accordingly, there is no indication based on Freenome's work to date that [redacted] (PFF ¶ 458 ([redacted]; RX3869 (Cote Expert Report) ¶ 193).)

Respondents also note that the proposed finding relies in part on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2356. [redacted] (Nolan (Freenome) Tr. 2748-49 (*in camera*)).

Response to Finding No. 2356:

The proposed finding is inaccurate, incomplete and misleading.

[redacted]

[redacted]

2357. [redacted] (Nolan (Freenome) Tr. 2748-49 (*in camera*)).

Response to Finding No. 2357:

The proposed finding is inaccurate, incomplete and misleading. [redacted]

[redacted]

2358. Freenome is developing cancer screening tests based on multiomics. (Nolan (Freenome) Tr. 2706).

Response to Finding No. 2358:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–57, which Respondents incorporate herein. While Freenome may be developing a single-cancer, blood-based CRC cancer screening test based on what it has termed its "multiomics platform", [redacted]

Respondents also note that the proposed finding provides support for Respondents' proposition that Freenome and GRAIL (which is using a targeted methylation approach) are adopting different approaches to the development of their respective tests, suggesting that if Freenome's test were to come to market, it would be a complement GRAIL's Galleri test, rather than a substitute.

2359. In general, multiomics describes a biological analysis approach that involves identifying and measuring "a range of analytes" such as DNA methylation, genomics, proteomics, and transcriptomics, among others. (Nolan (Freenome) Tr. 2710-11).

Response to Finding No. 2359:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–57, which Respondents incorporate herein.

Respondents also note that the proposed finding illustrates the breadth of potential analytes that ***may*** ultimately be included in Freenome's test. The proposed finding is evidence of

the highly uncertain nature of Freenome's hypothetical MCED test. Respondents also note that the proposed finding provides support for Respondents' proposition that Freenome and GRAIL (which is using a targeted methylation approach) are adopting different approaches to the development of their respective tests, suggesting that if Freenome's test were to come to market, it would be a complement GRAIL's Galleri test, rather than a substitute.

2360. [redacted] (PX7121 (Otte (Freenome) Dep. at 29-31) (*in camera*); PX7055 (Otte (Freenome) IHT at 44-47) (*in camera*); PX4048 (Grail) at 013 [redacted] (*in camera*)).

Response to Finding No. 2360:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–57, which Respondents incorporate herein. Respondents also note that the proposed finding provides support for Respondents' proposition that Freenome and GRAIL (which is using a targeted methylation approach) are adopting different approaches to the development of their respective tests, suggesting that if Freenome's test were to come to market, it would be a complement GRAIL's Galleri test, rather than a substitute.

2361. Freenome's multiomics platform is designed to detect tumor-derived biological signatures and non-tumor derived biological signatures. (Nolan (Freenome) Tr. 2712).

Response to Finding No. 2361:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–57, which Respondents incorporate herein.

Respondents have no specific response except to note that the proposed finding is evidence that Freenome and GRAIL are adopting different approaches to the development of

their respective tests, suggesting that if Freenome's putative MCED test were to come to market, it would be a complement GRAIL's Galleri test, rather than a substitute.

2362. [redacted] (PX8368 (Freenome) at 005 (Crossover Round Company Overview, 2020) (*in camera*)).

Response to Finding No. 2362:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–57, which Respondents incorporate herein. Further, [redacted]

a) Freenome Will Launch a Colorectal Cancer Screening Test First Before Expanding to an MCED Test

2363. Freenome's cancer screening test development has "start[ed] with [the] detection of colorectal cancer and advanced adenomas from a blood sample." (Nolan (Freenome) Tr. 2706).

Response to Finding No. 2363:

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–58 and 2379, which Respondents incorporate herein. [redacted]

[redacted]

The proposed finding is misleading the extent it suggests that it is a viable option to convert from a single cancer screening test to a multi-cancer screening test. To the contrary, even once a company has developed a cancer screening test for a single cancer type, it does not become easier to add additional cancer types, because "[t]he development of biomarkers for a particular cancer will not be adequate for other cancers" and "[w]hile there may be overlap, one still needs to go through all of the [development] steps," including "go[ing] through the case-control verification to determine whether or not the assay has the performance characteristics needed . . . for the new target cancer," and "go[ing] through a prospective trial depending on which cancer is being targeted." . (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123; PFF ¶¶ 328–328.1.) Dr. Aravanis testified that GRAIL considered developing a single cancer screening test as a route to multicancer screening test but abandoned it because it would take far too long; building a multicancer test by developing single cancer tests seriatim could take four or five years for each cancer; to develop a 50-cancer test one cancer at a time a developer would need to do a research study, discovery study and collect relevant samples, determine the right technology, go into a new test development phase and clinical trials for each new cancer; GRAIL was able to develop a test capable of detecting 50 cancer types simultaneously directly by

undergoing a much more intensive process to develop a test for 50 cancer types at the same time. (Aravanis (Illumina) Tr. 1895–97.)

2364. [redacted] (PX7055 (Otte (Freenome) IHT at 20-21) (*in camera*)).

Response to Finding No. 2364:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2363, which Respondents incorporate herein.

Respondents also note that the cited testimony confirms that [redacted]

Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2365. Freenome CEO, Michael Nolan testified at trial that "[Freenome] started [with a colorectal cancer screening test] because it is well-characterized. Physicians know when to order it. The reimbursement and medical policy frameworks are supportive in that the unmet need is very clear." (Nolan (Freenome) Tr. 2708).

Response to Finding No. 2365:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2363, which Respondents incorporate herein.

Respondents also note that the cited testimony confirms that Freenome's test is being designed for a single-cancer indication, and that the test is differentiated from Galleri insofar as it is designed solely to detect a cancer for which an existing screening methodology (colonoscopy) is already in place. The cited testimony confirms that Freenome and GRAIL are adopting different approaches to the development of their respective tests, suggesting that if Freenome's

test were to come to market, it would be a complement GRAIL's Galleri test, rather than a substitute.

2366. Freenome expects that focusing initially on developing a colorectal cancer screening test will [redacted] (Nolan (Freenome) Tr. 2760 (*in camera*)).

Response to Finding No. 2366:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2363, which Respondents incorporate herein.

Respondents also note that the cited testimony confirms that Freenome expects to launch its test as a single-cancer, CRC-only test, [redacted]

2367. [redacted] (Nolan (Freenome) Tr. 2761 (*in camera*)).

Response to Finding No. 2367:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2366, which Respondents incorporate herein.

2368. [redacted] (Nolan (Freenome) Tr. 2762 (*in camera*); PX7050 (Nolan (Freenome) IHT at 72) (*in camera*)).

Response to Finding No. 2368:

The proposed finding is incomplete and misleading including because the cited source also observes [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶ 2366 herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2369. [redacted] (Nolan (Freenome) Tr. 2765 (*in camera*)).

Response to Finding No. 2369:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2368, which Respondents incorporate herein. Further, the cited source also observes that [redacted]

2370. [redacted] (Nolan (Freenome) Tr. 2748 (*in camera*)).

Response to Finding No. 2370:

The proposed finding is incomplete and misleading. [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶ 2363 herein.

2371. [redacted] (PX7094 (Nolan (Freenome) Dep. at 26-28) (*in camera*)).

Response to Finding No. 2371:

The proposed finding is incomplete and misleading including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶ 2363, which Respondents incorporate herein.

The proposed finding also relates to irrelevant subject matter [redacted]. Respondents further note the proposed finding is evidence that Freenome and GRAIL are adopting different approaches to the development of their respective tests, suggesting that if Freenome's test were to come to market, it would be a complement GRAIL's Galleri test, rather than a substitute.

2372. [redacted] (PX7094 (Nolan (Freenome) Dep. at 26-27) (*in camera*)).

Response to Finding No. 2372:

The proposed finding is incomplete and misleading including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶ 2371, which Respondents incorporate herein.

b) [redacted]

2373. [redacted] (PX7121 (Otte (Freenome) Dep. at 17-18) (*in camera*)). At trial, Mr. Nolan testified that Freenome's multiomics platform is "built for the purpose of having application across a range of cancer types[.]" (Nolan (Freenome) Tr. 2709).

Response to Finding No. 2373:

The proposed finding is incomplete and misleading including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–58 and 2379, which Respondents incorporate herein. Respondents also note that [redacted] Accordingly, there is no indication based on Freenome's work to date that [redacted]

[redacted] (PFF ¶ 458 [redacted] RX3869 (Cote Expert Report) ¶ 193).)

2374. While developing its early detection colorectal cancer test, Freenome plans to "tak[e] a stepwise approach to get to other cancer types so that [Freenome] can deliver benefits of early detection across a range of different cancers." (Nolan (Freenome) Tr. 2706).

Response to Finding No. 2374:

The proposed finding is incomplete and misleading including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶ 2363, incorporated herein.

2375. [redacted] (Nolan (Freenome) Tr. 2751-52 (*in camera*)).

Response to Finding No. 2375:

The proposed finding is incomplete and misleading including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–58 and 2379, which Respondents incorporate herein. Respondents also note that [redacted]

[redacted] (PFF ¶ 458 [redacted]; RX3869 (Cote Expert Report) ¶ 193).)

2376. [redacted] (Nolan (Freenome) Tr. 2709; *see also* (Nolan (Freenome) Tr. 2747-48 (*in camera*)).

Response to Finding No. 2376:

The proposed finding is incomplete and misleading including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶ 2363, which Respondents incorporate herein.

[redacted]

[redacted]. (PFF ¶ 308; Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106.) [redacted]

[redacted]

2377. [redacted] (Nolan (Freenome) Tr. 2761 (*in camera*)). Freenome's CEO testified that Freenome is then able to [redacted] (Nolan (Freenome) Tr. 2761 (*in camera*)).

Response to Finding No. 2377:

The proposed finding is incomplete and misleading including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶ 2363, which Respondents incorporate herein.

[redacted]

2378. [redacted] (PX7121 (Otte (Freenome) Dep. at 22) (*in camera*)).

Response to Finding No. 2378:

The proposed finding is incomplete and misleading including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the

foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–58 and 2379, which Respondents incorporate herein. Respondents also state that [redacted] To the extent that Freenome actually started looking at seven cancer types, Freenome has made minimal progress over the past five years. Freenome has published data only relating to a single cancer, colorectal, and has commenced additional clinical trials only relating to colorectal cancer screening. (PFF ¶ 457; RX3869 (Cote Expert Report) ¶ 192; [redacted]

2379. Freenome has [redacted] (Nolan (Freenome) Tr. 2748-50 (*in camera*)).

Response to Finding No. 2379:

The proposed finding is incomplete and misleading including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–58 and 2379, which Respondents incorporate herein. [redacted]

Freenome also has not published any data relating to cancers other than colorectal cancer and has not even registered for any clinical trials for any other cancer. PFF ¶ 457. At trial, Mr.

Nolan could not even identify what all ten of the cancer types that Freenome purportedly detects actually are. PFF ¶ 2766.

To the extent that Mr. Nolan contends that Freenome has [redacted] even though Freenome was served with a subpoena by both Complaint Counsel and Respondents. (RX5012-RX5013 (Freenome)). Nor has Complaint Counsel identified such a document. Neither Mr. Nolan nor Mr. Otte [redacted] (*See* Nolan (Freenome) Tr. 2816, 2811; [redacted] Therefore, this cited testimony should be accorded little weight.

2380. Freenome CEO Michael Nolan testified that [redacted] (Nolan (Freenome) Tr. 2749-50 (*in camera*)).

Response to Finding No. 2380:

The proposed finding is incomplete and misleading including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶ 2379, which Respondents incorporate herein. [redacted]

[redacted]

2381. Mr. Nolan explained at trial that the [redacted] (Nolan (Freenome) Tr. 2749 (*in camera*)).

Response to Finding No. 2381:

The proposed finding is incomplete and misleading including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶ 2379, which Respondents incorporate herein. [redacted]

[redacted] Respondents also refer to PFF ¶¶ 465–70.

2382. Mr. Nolan further testified that Freenome [redacted] (Nolan (Freenome) Tr. 2748 (*in camera*); *see also* Nolan (Freenome) Tr. 2766-67 (*in camera*)).

Response to Finding No. 2382:

The proposed finding is incomplete and misleading including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–58 and 2379 and 2379, which Respondents incorporate herein. Respondents [redacted] This supports the proposition that Freenome's test is likely to be a complement to GRAIL's Galleri test.

2383. [redacted] (PX8368 (Freenome) at 014 (Crossover Round Company Overview, 2020) (*in camera*); *see* PX7121 (Otte (Freenome) Dep. at 168-69) (testifying that Freenome expects to launch a CRC screening test in 2022 and add additional cancers in 2023 and 2024)).

Response to Finding No. 2383:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–58 and 2379, which Respondents incorporate herein. Respondents also note that [redacted]

[redacted]

2384. Freenome CEO, Michael Nolan, testified that Freenome plans to [redacted] (Nolan (Freenome) Tr. 2751 (*in camera*)).

Response to Finding No. 2384:

The proposed finding is incomplete and misleading including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–58 and 2379, which Respondents incorporate herein. [redacted]

2385. [redacted] (Nolan (Freenome) Tr. 2769 (*in camera*)). At trial, Freenome CEO, Michael Nolan, explained that Freenome is [redacted] (Nolan (Freenome) Tr. 2852-53 (*in camera*)).

Response to Finding No. 2385:

The proposed finding is inaccurate, incomplete and misleading. [redacted] Respondents also incorporate their responses to CCFF ¶¶ 2355–58 and 2379 herein.

2386. [redacted] (Nolan (Freenome) Tr. 2772 (*in camera*)).

Response to Finding No. 2386:

The proposed finding is incomplete and misleading without further context, as well as irrelevant to the adjudication of this Transaction. [redacted] Respondents also incorporate their responses to CCFF ¶¶ 2355–58 and 2379 herein.

The proposed finding is also misleading to the extent it implies that a distributed IVD model will be part of the pipeline in the foreseeable future for any putative MCED test. Several features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (PFF ¶ 675; RX3869 (Cote Expert Report) PFF ¶ 359.) The test developer's decision whether to proceed with an IVD kit as opposed to a centralized model is an economic decision driven by test-specific factors. (Goswami (Illumina) Tr. 3197.) IVD kits are most suitable for tests that have precious samples, that present shipping challenges and require fast turnaround times. (Goswami (Illumina) Tr. 3196–3200; *see also* RX3869 (Cote Expert Report) § XI, PFF ¶¶ 360–63.)

2387. At trial, Mr. Nolan explained that Freenome plans to start by offering its tests as an LDT out of its own laboratory. (Nolan (Freenome) Tr. 2706-07). Then, Freenome plans to "take a stepwise approach to add additional sites for operation resilience and also for very specific country-level access and then evolve from there" to offering its test as a distributed IVD test. (Nolan (Freenome) Tr. 2706-07).

Response to Finding No. 2387:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2386, which Respondents incorporate herein. [redacted]

[redacted]

2388. [redacted] (Nolan (Freenome) Tr. 2772 (*in camera*)).

Response to Finding No. 2388:

The proposed finding is incomplete and misleading including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–58 and 2379, which Respondents incorporate herein. Respondents [redacted]

2389. [redacted] (Nolan (Freenome) Tr. 2769-70) (*in camera*)).

Response to Finding No. 2389:

The proposed finding is incomplete and misleading including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–58 and 2379, which Respondents incorporate herein.

2390. [redacted] (Nolan (Freenome) Tr. 2748 (*in camera*)).

Response to Finding No. 2390:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–58 and 2379, which Respondents incorporate herein.

[redacted]

2391. Freenome's CEO testified that Freenome plans on [redacted] (Nolan (Freenome) Tr. 2748 (*in camera*)).

Response to Finding No. 2391:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2390, which Respondents incorporate herein.

2392. Freenome is also [redacted] (Nolan (Freenome) Tr. 2709; *see also* Nolan (Freenome) Tr. 2766 (*in camera*)).

Response to Finding No. 2392:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–58 and 2379, which Respondents incorporate herein.

3. [redacted]

2393. [redacted] (PX7050 (Nolan (Freenome) IHT at 67-68, 72) (*in camera*)).

Response to Finding No. 2393:

Respondents have no specific response [redacted] Respondents also note that the cited testimony supports Respondents' proposition that Freenome has only progressed in developing a single-cancer screening test and incorporate their responses to CCFF ¶¶ 2355–58 and 2379 herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2394. [redacted] (PX7050 (Nolan (Freenome) IHT at 60-61)).

Response to Finding No. 2394:

Respondents have no specific response except to note that the cited testimony supports Respondents' proposition that Freenome has only progressed in developing a single-cancer screening test and incorporate their responses to CCFF ¶¶ 2355–58 and 2379 herein.

2395. [redacted] (Nolan (Freenome) Tr. 2799 (*in camera*)).

Response to Finding No. 2395:

Respondents have no specific response except to note that the cited testimony supports Respondents' proposition that Freenome has only progressed in developing a single-cancer screening test and incorporate their responses to CCFF ¶¶ 2355–58 and 2379 herein.

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

2396. [redacted] (Nolan (Freenome) Tr. 2761-62 (*in camera*)).

Response to Finding No. 2396:

Respondents have no specific response except to note that the cited testimony supports Respondents' proposition that Freenome has only progressed in developing a single-cancer screening test and incorporate their responses to CCFF ¶¶ 2355–58 and 2379 herein. In addition, there is no evidence that Freenome in fact completed its clinical trials of its colorectal cancer early detection test in early 2022. (*See* RX3869 (Cote Expert Report) ¶ 200 (Clinicaltrials.gov, *Prevention of Colorectal Cancer Through Multiomics Blood Testing (PREEMPT CRC)*, at https://clinicaltrials.gov/ct2/show/study/NCT04369053).)

Respondents also [redacted] Respondents incorporate PFF ¶¶ 328–29 herein.

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony

and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

2397. [redacted] (PX7055 (Otte (Freenome) IHT at 91) (*in camera*)).

Response to Finding No. 2397:

The proposed finding is incomplete and misleading including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–58 and 2379, which Respondents incorporate herein. [redacted] (*See* Nolan (Freenome) Tr. 2811.)

Further, [redacted]

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2398. [redacted] (PX8368 (Freenome) at 015 (Crossover Round Company Overview, 2020) (*in camera*)). [redacted]

(PX8368 (Freenome) at 015 (Crossover Round Company Overview, 2020) (*in camera*)).

Response to Finding No. 2398:

The proposed finding is incomplete and misleading including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–58 and 2379, which Respondents incorporate herein. Further,

The proposed finding is also incomplete and misleading because it suggests the ability to detect "all cancers", but there is no such thing as a universal or pan-cancer marker. (*See* RRFF ¶ 2416; PFF ¶¶ 308–309 (Cote Tr. 3787; Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106).)

The proposed finding is further misleading the extent it suggests that it is a viable option to convert from a single cancer screening test to a multi-cancer screening test. To the contrary, even once a company has developed a cancer screening test for a single cancer type, it does not become easier to add additional cancer types, because "[t]he development of biomarkers for a particular cancer will not be adequate for other cancers" and "[w]hile there may be overlap, one still needs to go through all of the [development] steps," including "go[ing] through the case-control verification to determine whether or not the assay has the performance characteristics needed . . . for the new target cancer," and "go[ing] through a prospective trial depending on which cancer is being targeted." (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123; PFF ¶¶ 328–328.1.) Dr. Aravanis testified that GRAIL considered developing a single cancer screening test as a route to multicancer screening test but abandoned it because it would take far too long; building a multicancer test by developing single cancer tests seriatim could take four or five years for each cancer; to develop a 50-cancer test one cancer at a time a developer would need to do a research study, discovery study and collect relevant samples, determine the right technology, go into a new test development phase and clinical trials for each new cancer; GRAIL was able to develop a test capable of detecting 50 cancer types simultaneously directly by undergoing a much more intensive process to develop a test for 50 cancer types at the same time. (Aravanis (Illumina) Tr. 1895–97.)

4. [redacted]

2399. [redacted] (PX7121 (Otte (Freenome) Dep. at 96) (*in camera*)).

Response to Finding No. 2399:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–58 and 2379, which Respondents incorporate herein.

2400. [redacted] (PX7055 (Otte (Freenome) IHT at 16) (*in camera*)).

Response to Finding No. 2400:

Respondents have no specific response.

5. [redacted]

See Complaint Counsel's Proposed Findings of Fact Section VII.B.3.a.3.

E. SINGLERA HAS ALREADY CONDUCTED A 100,000 SAMPLE TRIAL FOR ITS MCED TEST IN DEVELOPMENT—PANSEER

1. Background

2401. Singlera is headquartered in Shanghai, China and has U.S. offices in La Jolla, California. (Gao (Singlera) Tr. 2870; PX7042 (Gao (Singlera) IHT at 21)).

Response to Finding No. 2401:

Respondents have no specific response.

2402. Singlera currently operates four laboratories. (Gao (Singlera) Tr. 2870).

Response to Finding No. 2402:

Respondents have no specific response.

2403. Dr. Gary Gao and Professor Kun Zhang cofounded Singlera Genomics in 2014. (Gao (Singlera) Tr. 2865, 2869; PX7042 (Gao (Singlera) IHT at 15)).

Response to Finding No. 2403:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2404. Singlera is a test developer focused on early cancer detection using targeted DNA methylation technology for cell-free DNA. (Gao (Singlera) Tr. 2869-70).

Response to Finding No. 2404:

Respondents have no specific response except to note that though Singlera has been focusing on early cancer screening for seven years, it still views itself as "early in the run." (PX7102 (Gao (Singlera) Dep. at 17).) It appears that Singlera is in the research and development stage for a cancer screening test for five cancer types, and in the clinical stage for its ColonES colorectal cancer screening test. (RX3869 (Cote Expert Report) at ¶ 237.)

2405. "Based on next-generation sequencing platform, Singlera is a world leader on tissue and cfDNA methylation sequencing with patented proprietary technologies. Singlera has developed a series of methods for early screening, early-stage diagnosis and prevention of cancers, including lung cancer, colorectal cancer, gastric cancer, liver cancer, and esophageal cancer." (PX8517 (Singlera) at 001 (Company Overview)).

Response to Finding No. 2405:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 64), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2406. Dr. Gao testified that Singlera's "goal is to detect cancer early, all kinds of cancer." (PX7042 (Gao (Singlera) IHT at 21)).

Response to Finding No. 2406:

The proposed finding is incomplete and misleading. Although Singlera's "goal" may be to detect all kinds of cancer, Dr. Gao has also testified that Singlera is "far away" from starting

clinical trials for PanSeer in the United States, and that it is "still not in the really starting clinical trial state." (Gao (Singlera) Tr. 2926; PX7102 (Gao (Singlera) Dep. at 113–14, 81–82; PFF ¶ 536.1.) By Dr. Gao's own calculation, PanSeer is at least eight to ten years away from potential launch in the United States, and Singlera does not currently have any clinical trials relating to screening for multiple cancers listed on clinicaltrials.gov. (PFF ¶¶ 536.1-36.2.) Accordingly, [redacted] Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶¶ 447, 451 and 982 herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2407. Singlera ultimately has the "goal [] to improve health standards for all." (PX8517 (Singlera) at 001 (Company Overview)).

Response to Finding No. 2407:

Respondents have no specific response except to note that the proposed finding is irrelevant as it does not relate to MCED tests.

2408. Illumina considers Singlera as a "[p]rovider of non-invasive oncology and reproductive health tests using single cell sequencing, DNA methylation, and machine learning technology." (PX2780 (Illumina) at 001 (Singlera Genomics - Overview)).

Response to Finding No. 2408:

Respondents have no specific response except to note that the proposed finding is irrelevant as it does not relate to MCED tests.

2. Singlera's Single-Cancer Screening Tests

2409. Singlera is developing four single-cancer screening tests and one MCED test in the United States. (Gao (Singlera) Tr. 2873, 2914).

Response to Finding No. 2409:

The proposed finding is incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶ 2406, which Respondents incorporate herein. Further, there is evidence of only two single-cancer tests being developed by Singlera in the record: Singlera is also developing single cancer screening tests for colorectal cancer and likely lung cancer. (PFF ¶ 537; Gao (Singlera) Tr. 2872–73; RX3869 (Cote Expert Report) ¶ 243.)

The ColonES test that Singlera is currently developing has a specific focus on early detection of only colorectal cancer in asymptomatic patients; Singlera does not have any clinical trial evidence that ColonES can detect more than one cancer. (Gao (Singlera) Tr. 2914–15, 2917; 2917–18; 2926–27, 2942–43, 2949.) Despite these efforts with clinical trials in China, Singlera believes that it is "far from" starting FDA clinical trials for ColonES in the United States. (PFF ¶ 542; PX7102 (Gao (Singlera) Dep. at 113).) Singlera testified that it will need a three to four year study for at least 10,000 people for the trial. (PX7102 (Gao (Singlera) Dep. at 120–21); Gao (Singlera) Tr. 2923.) In addition, Singlera is considering a qPCR version—not NGS—of the ColonES test to be launched in China first. (PX7042 (Gao (Singlera) IHT at 90–91); Gao (Singlera) Tr. 2911–12.) Therefore, by its own admission, Singlera appears to

anywhere from three to seven years away from completing clinical trials for ColonES, and likely even longer. (RX3869 (Cote Expert Report) ¶ 246; Gao (Singlera) Tr. 2923.)

2410. Singlera is developing single-cancer early detection tests for colorectal cancer, lung cancer, pancreatic cancer, and throat cancer. (Gao (Singlera) Tr. 2873, 2914).

Response to Finding No. 2410:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2409, which Respondents incorporate herein. The proposed finding is also irrelevant because it does not relate to MCED tests.

2411. Singlera's single cancer tests for lung cancer, pancreatic cancer, and throat cancer use DNA methylation to detect cancer. (Gao (Singlera) Tr. 2914).

Response to Finding No. 2411:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2410, which Respondents incorporate herein.

2412. Singlera's ColonES test is a blood-based early detection test for colorectal cancer. (Gao (Singlera) Tr. 2873-74).

Response to Finding No. 2412:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2410, which Respondents incorporate herein.

2413. ColonES uses DNA methylation to detect colorectal cancer. (Gao (Singlera) Tr. 2873-74).

Response to Finding No. 2413:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2410, which Respondents incorporate herein.

2414. "ColonES is currently the only colorectal product that can detect early adenoma." (PX8517 (Singlera) at 001 (Company Overview)). "Detecting early adenoma is necessary for preventing colorectal cancer (CRC)[.]" (PX8517 (Singlera) at 001 (Company Overview)).

Response to Finding No. 2414:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2410, which Respondents incorporate herein.

Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 64), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2415. Singlera's ColonES test is "the same targeted DNA methylation analysis" as used with its pan-cancer test, PanSeer. (Gao (Singlera) Tr. 2915).

Response to Finding No. 2415:

Respondents have no specific response except to note that there is no such thing as a "pan-cancer test" because there is no such thing as a universal cancer biomarker. (PFF ¶ 308; Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106.)

2416. Dr. Gao explained that Singlera is starting with a colorectal cancer early detection test because "the complexity to get FDA approval and reimbursement is also much lower, so we use it as a kind of test case scenario." (PX7042 (Gao (Singlera) IHT at 119-20)).

Response to Finding No. 2416:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2409, which Respondents incorporate herein.

The proposed finding is misleading the extent it suggests that it is a viable option to convert from a single cancer screening test to a multi-cancer screening test. To the contrary, even once a company has developed a cancer screening test for a single cancer type, it does not become easier to add additional cancer types, because "[t]he development of biomarkers for a particular cancer will not be adequate for other cancers" and "[w]hile there may be overlap, one still needs to go through all of the [development] steps," including "go[ing] through the case-control verification to determine whether or not the assay has the performance characteristics

needed . . . for the new target cancer," and "go[ing] through a prospective trial depending on which cancer is being targeted." (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123; PFF ¶¶ 328–328.1.) Dr. Aravanis testified that GRAIL considered developing a single cancer screening test as a route to multicancer screening test but abandoned it because it would take far too long; building a multicancer test by developing single cancer tests seriatim could take four or five years for each cancer; to develop a 50-cancer test one cancer at a time a developer would need to do a research study, discovery study and collect relevant samples, determine the right technology, go into a new test development phase and clinical trials for each new cancer; GRAIL was able to develop a test capable of detecting 50 cancer types simultaneously directly by undergoing a much more intensive process to develop a test for 50 cancer types at the same time. (Aravanis (Illumina) Tr. 1895–97.)

3. Singlera is Developing an MCED Test—PanSeer

2417. Singlera is currently developing an MCED test referred to as PanSeer. (PX7102 (Gao (Singlera) Dep. at 23-24)).

Response to Finding No. 2417:

The proposed finding is incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2406 and 2416, which Respondents incorporate herein. No analytical or clinical data that Singlera has collected provides support for the proposition that PanSeer can detect more than 5 cancer types. (Gao (Singlera) Tr. 2917–18; RX3869 (Cote Expert Report) ¶ 241; [redacted]) Singlera does not currently have any clinical trials relating to screening for multiple cancers listed on clinicaltrials.gov. (RX3869 (Cote Expert Report) ¶ 242.); Gao (Singlera) Tr. 2926; [redacted]

Accordingly, there is no indication based on Singlera's work to date that [redacted]

2418. Singlera's PanSeer test is a blood-based early detection test designed to detect multiple cancers. (Gao (Singlera) Tr. 2876, 2881-82).

Response to Finding No. 2418:

The proposed finding is incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2406 and 2416–17, which Respondents incorporate herein.

2419. Singlera has developed "PanSeer" technology, which in theory works for any type of cancer. (PX7102 (Gao (Singlera) Dep. at 94-95)).

Response to Finding No. 2419:

The proposed finding is incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2406 and 2416–17, which Respondents incorporate herein.

2420. From a test development perspective, Dr. Gao explained that ColonES and PanSeer both use the same method for detecting cancer: "That's the beauty of the methylation technology platform. It's the same methylation analysis, assay and software and algorithm, but your target is different." (PX7042 (Gao (Singlera) IHT at 117, 119-20)).

Response to Finding No. 2420:

The proposed finding is incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the

foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2406 and 2416–17, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2421. Singlera's PanSeer test is designed to detect all kinds of cancer, and not just the five cancers used in the Taizhou Longitudinal Study. (Gao (Singlera) Tr. 2881). Dr. Gao testified that Singlera's "goal is pan-cancer" for the PanSeer test. (Gao (Singlera) Tr. 2881).

Response to Finding No. 2421:

The proposed finding is incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2406 and 2416–17, which Respondents incorporate herein. While Dr. Gao may testify that Singlera's goal is "pan-cancer", there is no such thing as a universal or pan-cancer marker. (*See* RRFF ¶ 2416; PFF ¶¶ 308–309 (Cote Tr. 3787; Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106).)

To date, Singlera has not shown in any publication or clinical trial the ability to detect more than five cancer types. (*See* PFF ¶ 532.) Singlera also has not registered for any clinical trials beyond colon and lung cancer. (*See* PFF ¶ 536.3–41.)

To the extent that Dr. Gao contends that Singlera has generated internal data relating to any additional cancer types, no such documentation or data was produced in this proceeding, even though Singlera was served with a subpoena by both Complaint Counsel and Respondents. (RX5035-RX5036 (Singlera)). Nor has Complaint Counsel identified such a document. Therefore, this cited testimony should be accorded little weight.

The characteristics of the PanSeer test in development are also far from being suitable for being used in a multi-cancer screening test. In a retrospective, observational study of 418 participants from part of the Taizhou Longitudinal Study with samples from 113 post-diagnosis cancer patients, 98 prediagnostic cancer patients, and 207 healthy individuals, PanSeer achieved a 96% specificity. (PFF ¶ 532; RX3637 (Singlera) at 1–6; Gao (Singlera) Tr. 2877–79.)

[redacted]

Consistent with their very early stage of development, Singlera testified that it is "far away" from starting clinical trials for PanSeer in the United States, and that it is "still not in the really starting clinical trial state." (PFF ¶ 536.1; Gao (Singlera) Tr. 2926; PX7102 (Gao (Singlera) Dep. at 113–14, 81–82.) By Dr. Gao's own calculation, PanSeer is at least eight to ten years away from potential launch in the United States. (PFF ¶ 536.2; Gao (Singlera) Tr. 2925–26; RX3869 (Cote Expert Report) ¶ 242.)

2422. PanSeer is the "[o]nly product in the [w]orld for multiple types of cancer early screening that was validated by healthy population studies." (PX8517 (Singlera) at 001 (Company Overview)).

Response to Finding No. 2422:

The proposed finding is incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2406, 2416–17 and 2421, which Respondents incorporate herein. The proposed finding is

also inaccurate because it seems to suggest that PanSeer is the purportedly validated by healthy population studies, and not only that, that it is the *only* product to be so validated. However, the only purported validation of the PanSeer test (which is not commercialized (PFF ¶ 536)) is a retrospective, observational study of 418 participants from part of the Taizhou Longitudinal Study with samples from 113 post-diagnosis cancer patients, 98 pre-diagnostic cancer patients, and 207 healthy individuals. (PFF ¶ 532; RX3637 (Singlera) at 1–6; Gao (Singlera) Tr. 2877–79.) This study is by no means population scale, involving only 300 or so "healthy" individuals. By contrast, Galleri is a product (and unlike PanSeer, Galleri is available commercially) that is validated by healthy population studies, such as the PATHFINDER study, which was used in 6,662 participants. (*See* PFF ¶¶ 394–402.) Further, given that Singlera is continuing to develop PanSeer, whatever the final version of the PanSeer product has not been validated in any study of any kind, involving healthy populations or otherwise. Singlera plans to further develop the PanSeer test design before seeking FDA approval. (Gao (Singlera) Tr. 2881).

Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 64), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2423. The PanSeer test can detect lung cancer, liver cancer, colorectal cancer, esophageal cancer, and gastric cancer. (PX8517 (Singlera) at 001 (Company Overview)).

Response to Finding No. 2423:

The proposed finding is incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2406, 2416–17 and 2421, which Respondents incorporate herein.

Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 64), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2424. PanSeer can detect lung cancer at a 93 percent sensitivity. (PX8517 (Singlera) at 001 (Company Overview)). PanSeer can detect liver cancer at a 94 percent sensitivity. (PX8517 (Singlera) at 001 (Company Overview)). PanSeer can detect colorectal cancer at 89 percent sensitivity. (PX8517 (Singlera) at 001 (Company Overview)). PanSeer can detect esophageal cancer at 89 percent sensitivity. (PX8517 (Singlera) at 001 (Company Overview)). PanSeer can detect gastric cancer at 70 percent sensitivity. (PX8517 (Singlera) at 001 (Company Overview)).

Response to Finding No. 2424:

The proposed finding is incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2406, 2416–17 and 2421, which Respondents incorporate herein.

Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 64), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2425. PanSeer "detects cancer [four] years earlier than conventional diagnoses." (PX8517 (Singlera) at 001 (Company Overview)).

Response to Finding No. 2425:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 64), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2426. The PanSeer test is also designed to detect tissue of origin. (Gao (Singlera) Tr. 2874).

Response to Finding No. 2426:

The proposed finding is inaccurate, incomplete and misleading. Singlera has not published any ability to identify a molecular cancer signal of origin. (RX3115 (Chen et al., 2020) at 6.) Singlera has stated that any patient testing positive on PanSeer would then undergo additional blood test and/or follow-up imaging to allow tissue of origin mapping. (RX3869 (Cote Expert Report) ¶ 239; RX3115 (Chen et al., 2020) at 6.) However, Singlera has not developed such a blood test. (RX3115 (Chen et al., 2020) at 6.)

2427. The PanSeer test uses targeted DNA methylation technology to analyze over 500 regions on a DNA sample. (Gao (Singlera) Tr. 2874-75; *see* PX7042 (Gao (Singlera) IHT at 21) (testifying that Singlera's "technology is based on analyzing DNA methylation pattern of cell-free ctDNA in the blood.”))

Response to Finding No. 2427:

Respondents have no specific response.

2428. PanSeer's technology can detect many types of cancer using methylation patterns as biomarkers. (PX7102 (Gao (Singlera) Dep. at 22-24)).

Response to Finding No. 2428:

The proposed finding is incomplete and misleading including insofar as it suggests that Singlera's PanSeer test has been shown to detect more than five types of cancer, or that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2406, 2416–17 and 2421, which Respondents incorporate herein.

2429. Dr. Gao testified that Singlera has spent between $60 million to $100 million on research and development efforts related to the PanSeer test. (Gao (Singlera) Tr. 2888-2889).

Response to Finding No. 2429:

Respondents have no specific response.

2430. While the PanSeer test is currently focused on screening for colorectal, lung, gastric, esophageal, and liver cancers, it may add more cancers prior to commercialization and

could end up detecting "any kind of cancer." (PX7042 (Gao (Singlera) IHT at 28-30); *see* Gao (Singlera) Tr. 2881).

Response to Finding No. 2430:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2406, 2416–17 and 2421, which Respondents incorporate herein.

2431. Dr. Gao testified that Singlera's "goal is pan-cancer" for the PanSeer test. (Gao (Singlera) Tr. 2881).

Response to Finding No. 2431:

The proposed finding is incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2406, 2416–17 and 2421, which Respondents incorporate herein. While Dr. Gao may testify that Singlera's goal is "pan-cancer", there is no such thing as a universal or pan-cancer marker. (*See* RRFF ¶ 2416; PFF ¶¶ 308–309 (Cote Tr. 3787; Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106).)

2432. Singlera plans to seek FDA approval for its PanSeer Test. (Gao (Singlera) Tr. 2881).

Response to Finding No. 2432:

The proposed finding is incomplete. Singlera testified that it is "far away" from starting clinical trials for PanSeer in the United States, and that it is "still not in the really starting clinical trial state." (Gao (Singlera) Tr. 2926; PX7102 (Gao (Singlera) Dep. at 113–14, 81–82.) For a pan-cancer trial, Singlera estimates that a clinical trial would need to be for 100,000 or 200,000 people, somewhere around eight or 10 years. (Gao (Singlera) Tr. 2925–26; PX7102 (Gao (Singlera) Dep. at 122–23).) Therefore, by Dr. Gao's own calculation, PanSeer is at least eight to ten years away from potential launch in the United States. (Gao (Singlera) Tr. 2925–26;

RX3869 (Cote Expert Report) ¶ 242.) Respondents also incorporate their responses to CCFF ¶¶ 2406, 2416–17 and 2421 herein.

2433. Singlera plans to further develop the PanSeer test design before seeking FDA approval. (Gao (Singlera) Tr. 2881).

Response to Finding No. 2433:

Respondents have no specific response.

a) Singlera Plans to Launch PanSeer Using a Distributed Model

2434. Singlera's business model is to offer the PanSeer test as a distributed test in order to differentiate it from single-site tests. (PX7042 (Gao (Singlera) IHT at 109)).

Response to Finding No. 2434:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2406, 2416–17, 2421 and 2432, which Respondents incorporate herein. Respondents also note that Singlera has testified that PanSeer is at least eight to ten years away from a potential launch in the United States.

The proposed finding is also misleading to the extent it implies that a distributed IVD model will be part of the pipeline in the foreseeable future for any putative MCED test. Several features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (PFF ¶ 675; RX3869 (Cote Expert Report) ¶ 359.) The test developer's decision whether to proceed with an IVD kit as opposed to a centralized model is an economic decision driven by test-specific factors. (Goswami (Illumina) Tr. 3197.) IVD kits are most suitable for tests that have precious samples, that present shipping challenges and require fast turnaround times. (Goswami (Illumina) Tr. 3196–3200; *see also* RX3869 (Cote Expert Report) § XI, ¶¶ 360–63.)

2435. To turn the PanSeer test into a distributed model, Singlera must follow the "FDA clinical trial study protocol" which means running "at least three sites." (PX7042 (Gao (Singlera) IHT at 109-10)).

Response to Finding No. 2435:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2434, which Respondents incorporate herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Dr. Gao also testified, "when we're going to talk to FDA[,] we have no experience as a young startup company about a regulatory pathway". (PX7101 (Gao (Singlera) Dep. at 47).) Singlera noted that the "[t]est will be sold to and performed at external CLIA labs," "[u]nlimited number of labs can sell test assuming they have equipment and personnel," "CLIA labs responsible for running assay, reporting results, billing patients, QC, QA, etc." Singlera "must provide complete kits" meaning they "are responsible for kit manufacturing, QC, supply agreements, supply chain management[,] [and] upload[ing] software to Illumina's cloud." The FDA trial for a distributed test "must be performed in 3 CLIA labs." (PX8518 (Singlera) at 009 (FDA Update: PMA vs 510k)).

2436. Singlera noted that the "[t]est will be sold to and performed at external CLIA labs," "[u]nlimited number of labs can sell test assuming they have equipment and personnel," "CLIA labs responsible for running assay, reporting results, billing patients, QC, QA, etc." Singlera "must provide complete kits" meaning they "are responsible for kit manufacturing, QC, supply agreements, supply chain management[,] [and] upload[ing] software to Illumina's cloud." The FDA trial for a distributed test "must be performed in 3 CLIA labs." (PX8518 (Singlera) at 009 (FDA Update: PMA vs 510k)).

Response to Finding No. 2436:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2435, which Respondents incorporate herein.

Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 64), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2437. Dr. Gao testified that an advantage of offering a distributed IVD test is that "you can quickly convince partner – you know, LabCorp, Quest [] to quickly adopt your system instead of you building your capacity up, scale up, like Exact Sciences." (PX7042 (Gao (Singlera) IHT at 110)).

Response to Finding No. 2437:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2434–35, which Respondents incorporate herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Dr. Gao admitted that he is not an expert witness in this proceeding. (Gao (Singlera) Tr. 2937).

2438. Dr. Gao testified that selling the PanSeer test as a distributed test would allow Singlera to "quickly scale up to sell." (PX7042 (Gao (Singlera) IHT at 110-11); *see* PX8518 (Singlera) at 011 (FDA Update: PMA vs 510k)).

Response to Finding No. 2438:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2437, which Respondents incorporate herein.

2439. Dr. Gao testified that the customers of a distributed IVD test would be the same as the customers of a single-site test because "the customer won't care [about] your business model, [] they only care about result." (PX7042 (Gao (Singlera) IHT at 111)).

Response to Finding No. 2439:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2437, which Respondents incorporate herein.

2440. In order for a non-Singlera lab to run a Singlera test on an Illumina sequencer, Illumina must authorize the use of its sequencer. (PX7042 (Gao (Singlera) IHT at 112-13)).

Response to Finding No. 2440:

The proposed finding is incomplete to the extent that Dr. Gao is referring to marketing a distributed version of a Singlera test using an Illumina sequencer. It is possible to run an IVD test on the RUO side of an Illumina instrument, instead of the Dx side, which would not require Illumina's authorization. (*See* PFF ¶ 678.2.) In any event, under the Open Offer, any oncology customer may enter into an IVD agreement with Illumina to develop a distributed version of its oncology test. (*See* PFF ¶¶ 1026–1035.3.)

2441. Dr. Gao testified that "a distributed model will have an advantage" for Singlera, and without a distributed model, Singlera would be at a competitive disadvantage to other pan-cancer screening companies that were authorized to sell a distributed IVD test. (PX7042 (Gao (Singlera) IHT at 114-15)).

Response to Finding No. 2441:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2437, which Respondents incorporate herein.

[redacted]

(*See, e.g.*, PFF ¶ 1736; Chahine (Helio) Tr. 1065-66).)

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

b) Singlera Hired Consulting Firm CSSi to Aid Its FDA and Commercial Development

2442. CSSi Life Sciences is a consulting company which helps its clients take a product from discovery to the clinical research and FDA review/approval stage of development. (*See* PX8656 (Singlera) at 002 (CSSi Life Sciences: Accelerating Discovery to Commercialization)).

Response to Finding No. 2442:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 68), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2443. Singlera contracted with CSSi in February 2019 for "regulatory, preclinical, CMC, clinical, CRO, and/or other services" relating to Singlera's "blood-based colon cancer in vitro diagnostic (IVD) that uses Next Generation Sequencing (NGS) for methylation haplotype analysis of cell-free DNA." (PX8657 (Singlera) at 001, 013 (CSSi Life Sciences Service Agreement, Feb. 1, 2019)).

Response to Finding No. 2443:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 68), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2444. Singlera hired CSSi because Singlera is "a small company [and] do[es] not have the expertise to go through [the] FDA [alone] for the first time." (PX7102 (Gao (Singlera) Dep. at 41)).

Response to Finding No. 2444:

The proposed finding is misleading to the extent it suggests that GRAIL could accelerate its FDA approval by hiring a vendor like CSSi. Contrary to Complaint Counsel's unproven contention, GRAIL could not achieve FDA approval by hiring additional personnel or outside consultants because the pool of individuals with such experience is limited and it can take a long time for consultants to get up to speed on the specific needs in a new area such as screening (PFF ¶¶ 1175.1–1175.2.4), and Illumina and GRAIL witnesses testified that they could not contract for these efficiencies if they were separate entities because Illumina does not provide such services

to any third party entities and doing so would require GRAIL to share its confidential information with Illumina (PFF ¶ 1175.3).

Respondents also note that Singlera's experience with CSSi was overall extremely negative. Dr. Gao testified that Singlera "spent a lot of money on . . . consultancy . . . to prepare documents to have an FDA pre-meeting", "hundreds of thousands of dollars already", and yet "are still not in in the . . . starting clinical trial state". (PX7102 (Gao (Singlera) Dep. at 81–82); *see generally id.* at 115–18 (explaining how Singlera's consultants failed to inform Singlera that a supply agreement was required for 510K clearance from the FDA, causing Singlera to miss their ColonES FDA approval timeline by at least a year).) In fact, as Dr. Gao testified, Singlera testified that it is "far away" from starting clinical trials for PanSeer in the United States, and that it is "still not in the really starting clinical trial state." (Gao (Singlera) Tr. 2926; PX7102 (Gao (Singlera) Dep. at 113–14, 81–82.) For a pan-cancer trial, Singlera estimates that a clinical trial would need to be for 100,000 or 200,000 people, somewhere around eight or 10 years. (Gao (Singlera) Tr. 2925–26; PX7102 (Gao (Singlera) Dep. at 122–23).) Therefore, by Dr. Gao's own calculation, PanSeer is at least eight to ten years away from potential launch in the United States. (Gao (Singlera) Tr. 2925–26; RX3869 (Cote Expert Report) ¶ 242.) By contrast, GRAIL expects that Illumina's assistance will accelerate the adoption and availability of the Galleri test by at least one year. (Febbo (Illumina) Tr. 4345–46, 4360.)

2445. CSSi helps reduce a product's "[t]ime to market and development costs" and "[r]isk for late-stage failures and post authorization action" while increasing "[c]ommercial success and early adoption" and "[s]takeholder value and return." (PX8656 (Singlera) at 004 (CSSi Life Sciences: Accelerating Discovery to Commercialization)).

Response to Finding No. 2445:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2444, which Respondents incorporate herein.

Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 68), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2446. Dr. Gao testified that CSSi was "very expensive" to use. (PX7102 (Gao (Singlera) Dep. at 41)). The hourly rate for CSSi's regulatory and clinical strategy personnel was $400. (PX8657 (Singlera) at 016 (CSSi Life Sciences Service Agreement, Feb. 1, 2019)).

Response to Finding No. 2446:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2444, which Respondents incorporate herein.

Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 68), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2447. CSSi "basically tell[s] [Singlera] what needs to be done, prepare documents, [] call a meeting with the FDA. So they are more like [a] consultancy." (PX7102 (Gao (Singlera) Dep. at 41)). In other words, CSSi walked Singlera through the FDA regulatory approval process. (PX7102 (Gao (Singlera) Dep. at 41-42) ("Q. Okay. So CSSi can walk the company like Singlera through the FDA regulatory approval process. Is that – did I understand that correctly? A. Yes. They are more hand-h[o]lding us through the jungle of regulatory, you know. So they will help out to coordinate study center, write up the plan, and communicate with FDA doing statistics. So that we call CIO.")).

Response to Finding No. 2447:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2444, which Respondents incorporate herein.

2448. As part of CSSi's "health authority interactions" services they assist a company with "FDA/EMA Advisory Committee and Panel preparation," "[o]ral explanation preparation," "[m]ilestone meetings," "[h]ealth authority responses to questions," "[r]esolution and response to safety issues," and "[r]epresentation with FDA and National Competent Authorities." (PX8656 (Singlera) at 018 (CSSi Life Sciences: Accelerating Discovery to Commercialization)).

Response to Finding No. 2448:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2444, which Respondents incorporate herein. Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 68), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2449. Dr. Gao explained that Singlera did not need to have its own in-house FDA expertise to go through the FDA regulatory process. Singlera instead hired CSSi. (PX7102 (Gao (Singlera) Dep. at 42)).

Response to Finding No. 2449:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2444, which Respondents incorporate herein.

4. Singlera's PanSeer Completed a 100,000 Sample Clinical Trial

2450. Singlera completed a proof-of-concept study of its PanSeer test in China on 100,000 people, identifying lung, esophageal, liver, colorectal, and gastric cancers at least four years before conventional diagnosis. (PX7042 (Gao (Singlera) IHT at 28-30)).

Response to Finding No. 2450:

The proposed finding is incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2406, 2416–17 and 2421, which Respondents incorporate herein. The proposed finding is also inaccurate because it states that PanSeer was studied in 100,000 people (RX3115 (Chen et al., 2020) at 4, Table 1); PanSeer was only studied in an retrospective, observational study of 418 participants. (PFF ¶ 534; RX3637 (Singlera) at 1–6; Gao (Singlera) Tr. 2877–79.)

2451. Singlera's PanSeer clinical study was called the Taizhou Longitudinal study. (Gao (Singlera) Tr. 2877-78).

Response to Finding No. 2451:

Respondents have no specific response.

2452. Singlera's PanSeer test detected a total of five different types of cancers four years before participants showed symptoms in the Taizhou study. (Gao (Singlera) Tr. 2878-79).

Response to Finding No. 2452:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2450, which Respondents incorporate herein.

2453. The PanSeer test demonstrated the ability to detect stomach cancer, esophageal cancer, liver cancer, colorectal cancer, and lung cancer in the Taizhou study. (Gao (Singlera) Tr. 2884).

Response to Finding No. 2453:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2406, 2416–17 and 2421, which Respondents incorporate herein.

2454. The Taizhou study demonstrated the PanSeer test has a sensitivity of "88 to 90 percent and [a] specificity of 96 percent" for the cancers used in the study. (Gao (Singlera) Tr. 2876).

Response to Finding No. 2454:

The proposed finding is incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2406, 2416–17 and 2421, which Respondents incorporate herein. [redacted]

[redacted]

2455. Singlera's Taizhou study took place in Taizhou, China. (Gao (Singlera) Tr. 2878).

Response to Finding No. 2455:

Respondents have no specific response.

2456. Singlera's Taizhou study involved 123,115 participants. (RX2717 (Singlera) at 001 (Non-invasive early detection of cancer four years before conventional diagnosis using a blood test, July 21, 2020)).

Response to Finding No. 2456:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2406, 2416–17 and 2421, which Respondents incorporate herein. The proposed finding is also inaccurate because it suggests that PanSeer was studied in 123,115 people (RX3115 (Chen et al., 2020) at 4, Table 1); PanSeer was only studied in an retrospective, observational study of 418 participants. (PFF ¶ 534; RX3637 (Singlera) at 1–6; Gao (Singlera) Tr. 2877–79.)

2457. "In the Taizhou Longitudinal Study (TZL), 123,115 healthy subjects provided plasma samples for long-term storage and were then monitored for cancer occurrence." (RX2717 (Singlera) at 001 (Non-invasive early detection of cancer four years before conventional diagnosis using a blood test, July 21, 2020)).

Response to Finding No. 2457:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2406, 2416–17 and 2421, which Respondents incorporate herein. The proposed finding is also inaccurate because it suggests that PanSeer was studied in 123,115 people (RX3115 (Chen et al., 2020) at 4, Table 1); PanSeer was only studied in an retrospective, observational study of 418 participants. (PFF ¶ 534; RX3637 (Singlera) at 1–6; Gao (Singlera) Tr. 2877–79.)

2458. Singlera published the results of the Taizhou study in the peer-reviewed Nature Communications Journal in 2020. (Gao (Singlera) Tr. 2879-80).

Response to Finding No. 2458:

Respondents have no specific response.

2459. At trial, Dr. Gao also explained that all data associated with the Taizhou study, including "all the original sequencing data [and] design data[,]" were made publicly available "so any statistician, biologist, any computer scientist can download, analyze themselves, to see if the results we published agree with the data." (Gao (Singlera) Tr. 2880).

Response to Finding No. 2459:

Respondents have no specific response.

2460. The Nature article reported "the preliminary results of PanSeer, a noninvasive blood test based on circulating tumor DNA methylation, on TZL plasma samples from 605 asymptomatic individuals, 191 of whom were later diagnosed with stomach, esophageal, colorectal, lung or liver cancer within four years of blood draw." (RX2717 (Singlera) at 001 (Non-invasive early detection of cancer four years before conventional diagnosis using a blood test, July 21, 2020)).

Response to Finding No. 2460:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2406, 2416–17 and 2421, which Respondents incorporate herein. Respondents also note that of the 605 TZL plasma samples, 414 were from health individuals, and only 98 of the pre-diagnosis samples were used for validation of the PanSeer test. (RX3115 (Chen et al., 2020) at 4, Table 1.)

2461. The five cancer types studied in Taizhou "account for 261,530 yearly cancer deaths in the US and 2.1 million yearly cancer deaths in China; early detection could greatly reduce deaths from these diseases." (RX2717 (Singlera) at 007 (Non-invasive early detection of cancer four years before conventional diagnosis using a blood test, July 21, 2020)).

Response to Finding No. 2461:

Respondents have no specific response.

2462. "The PanSeer assay was able to successfully detect five cancer types using a common set of methylation markers regardless of tissue-of-origin. As such, the genes included in the LR classifier represent a core epigenetic signature common to multiple cancer types."

(RX2717 (Singlera) at 005 (Non-invasive early detection of cancer four years before conventional diagnosis using a blood test, July 21, 2020)).

Response to Finding No. 2462:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2406, 2416–17 and 2421, which Respondents incorporate herein.

2463. The PanSeer "assay is most likely identifying patients who already have cancerous growths but who remain asymptomatic to current detection methods and standard of care, as many cancers do not cause the appearance of symptoms until late in disease development." (RX2717 (Singlera) at 006 (Non-invasive early detection of cancer four years before conventional diagnosis using a blood test, July 21, 2020)).

Response to Finding No. 2463:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2406, 2416–17 and 2421 herein.

2464. "The PanSeer assay was solely developed to detect cancer regardless of the tissue-of-origin by targeting a limited number of genomic regions that are commonly aberrantly methylated across different cancer types, allowing it to be used as a potential first-line inexpensive cancer screen; it also requires a comparatively small amount of input DNA (from only a single tube of blood)." (RX2717 (Singlera) at 006 (Non-invasive early detection of cancer four years before conventional diagnosis using a blood test, July 21, 2020)).

Response to Finding No. 2464:

The proposed finding is inaccurate, incomplete and misleading. Singlera has not published any ability to identify a molecular cancer signal of origin. (RX3115 (Chen et al., 2020) at 6.) Singlera has stated that any patient testing positive on PanSeer would then undergo additional blood test and/or follow-up imaging to allow tissue of origin mapping. (RX3869 (Cote Expert Report) ¶ 239; RX3115 (Chen et al., 2020) at 6.) However, Singlera has not developed such a blood test. (RX3115 (Chen et al., 2020) at 6.)

2465. "The PanSeer assay provides a preliminary demonstration of early detection of multiple cancer types four years prior to conventional diagnosis in a robust manner, and lays the foundation for a non-invasive blood test for early detection of cancer in a high-risk (or

average-risk in the future) population." (RX2717 (Singlera) at 006-007 (Non-invasive early detection of cancer four years before conventional diagnosis using a blood test, July 21, 2020)).

Response to Finding No. 2465:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2406, 2416–17 and 2421 herein.

2466. Dr. Gao testified at trial that Singlera has received recognition from industry publications for its PanSeer test after publishing the results of the Taizhou study. (Gao (Singlera) Tr. 2880).

Response to Finding No. 2466:

Respondents have no specific response.

2467. Singlera plans to showcase the PanSeer test's ability to detect more cancers than the five demonstrated in the Taizhou study. (Gao (Singlera) Tr. 2881-82).

Response to Finding No. 2467:

The proposed finding is incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2406, 2416–17 and 2421, which Respondents incorporate herein.

2468. Dr. Gao testified at trial that demonstrating the ability to detect additional cancers will require a prospective study. (Gao (Singlera) Tr. 2881).

Response to Finding No. 2468:

Respondents have no specific response.

2469. Singlera hopes to start its FDA trial for PanSeer in two to three years. (PX7042 (Gao (Singlera) IHT at 96)).

Response to Finding No. 2469:

Respondents have no specific response.

2470. Dr. Gao testified at trial that the study designs for the clinical studies conducted using Grail's Galleri test and PanSeer are different. (Gao (Singlera) Tr. 2885).

Response to Finding No. 2470:

The proposed finding is inaccurate, incomplete and misleading to the extent it suggests that GRAIL has not demonstrated the ability of the Galleri test to screen for 50 cancer types, while Singlera has shown the ability of the PanSeer test to screen for five cancer types. Unlike PanSeer, where an earlier version has been studied in a small retrospective study (*See* RRFF ¶¶ 2406, 2416–17 and 2421), Galleri has been studied in several, large prospective trials.

GRAIL's CCGA study is a *prospective*, multi-center, case-control, observational study with longitudinal follow-up of 15,254 participants. (PFF ¶ 370 (RX3409 (Klein 2021) at 2; (RX3430 (Liu 2020) at 1; Ofman (GRAIL) Tr. 3291–95; [redacted] RX0744 (GRAIL) at 47–48).) It is believed to be the largest case-control study that there has ever been for early detection. (Ofman (GRAIL) Tr. 3291.) The study was unique because the samples were prospectively collected. As Dr. Cote explained: "[The] case-control trial was actually prospectively collected, and it was done under a strict protocol for the collection of all of these samples. That makes it unique in terms of the case-control study, and . . . it was designed that way to provide sample collection under circumstances that would be similar to an actual clinical collection of samples." (Cote Tr. 3794–95.)

Respondents note that GRAIL's PATHFINDER study is a prospective, interventional study of 6,662 participants over the age of 50 with a cohort with additional risk of a positive cancer result (3695; ~55% of total enrollment), and another cohort containing participants without any heightened risk (2934). (PFF ¶¶ 394 (RX3044 (GRAIL) at 1–2), 399 (Ofman (GRAIL) Tr. 3293; RX0744 (GRAIL) at 73), 1290 (Aravanis (Illumina) Tr. 1891–92).) In February 2021, GRAIL released interim prospective interventional study (PATHFINDER) results that were positive and largely confirmed the previous studies. (Ofman (GRAIL) Tr.

3293; [redacted] The results also showed that Galleri detected three cancer types for which stage designation is not applicable (lymphoid leukemia, plasma cell neoplasm, and Waldenstrom macroglobulinemia), one recurrent cancer type at the "local" stage (prostate), and one cancer for which the stage was unknown (colon or rectum). (RX3041 at 005 (Thomasz Beer, Interim Results of Pathfinder, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, June 4, 2021).

Galleri has been shown to detect the largest number of cancer types in a prospective clinical trial.

Respondents further note that GRAIL's STRIVE study is a prospective, observational, longitudinal study of approximately 100,000 women undergoing mammography (PFF ¶ 403 (Ofman (GRAIL) Tr. 3293–95; RX0744 (GRAIL) at 71), GRAIL's SUMMIT study is a prospective, observational study of approximately 13,000 participants between the ages of 50–77 with a substantial smoking history (PFF ¶¶ 407–409 (RX3291 (GRAIL) at 1; RX0744 (GRAIL) at 46–47, 72), and [redacted] and a prospective, real-world, pragmatic, randomized clinical study in the U.K. with the NHS in 140,000 screening-eligible individuals (PFF ¶¶ 1603 (Ofman (GRAIL) Tr. 3291–300), 1648 (Freidin (GRAIL) Tr. 3008)).

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper

Lay Witness Opinion Testimony (Aug. 5, 2021).) Dr. Gao admitted that he is not an expert witness in this proceeding. (Gao (Singlera) Tr. 2937).

2471. At trial, Dr. Gao explained that Grail conducted a case control study on individuals already diagnosed with cancer, but Singlera conducted its Taizhou study on asymptomatic individuals. (Gao (Singlera) Tr. 2885-87).

Response to Finding No. 2471:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2470, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶¶ 2406, 2416–17 and 2421.

5. Singlera Has Invested Approximately $250 Million on PanSeer's Development

2472. Singlera has raised over $250 million from investors to date, including a $150M fundraising round in 2020. (PX7042 (Gao (Singlera) IHT at 22-24)).

Response to Finding No. 2472:

Respondents have no specific response except to note that the cited source confirms that investment has poured into cancer test development since the time that Illumina announced its agreement to acquire GRAIL. (PFF ¶ 929.) In December 2020, Singlera obtained $150 million in financing, which it planned to utilize "mainly to expand the company's early cancer screening product research and development pipeline and focus on promoting product registration and commercialization." (PFF ¶ 929.3; RX3633 (PR Newswire) at 1); [redacted]

[redacted]

2473. Dr. Gao testified that Singlera has spent between $60 million to $100 million on research and development efforts related to the PanSeer test. (Gao (Singlera) Tr. 2888-2889).

Response to Finding No. 2473:

Respondents have no specific response.

2474. Singlera is working to "reduce cost, improve accuracy, and improve convenience" of its test. (PX7042 (Gao (Singlera) IHT at 100)).

Response to Finding No. 2474:

Respondents have no specific response except to note that the proposed finding confirms that Singlera's development of its PanSeer test is only at the very early stages. Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6. Singlera Expects to Launch PanSeer in the U.S. in 2028 and Will Not Offer PanSeer as an LDT in the U.S.

2475. Singlera expects to launch PanSeer in the United States around 2028 as an FDA approved test. (PX7042 (Gao (Singlera) IHT at 96)).

Response to Finding No. 2475:

The proposed finding is inaccurate, incomplete and misleading. Dr. Gao subsequently testified at trial that Singlera is "far away" from starting clinical trials for PanSeer in the United States, and that it is "still not in the really starting clinical trial state." (PFF ¶ 536.1; Gao (Singlera) Tr. 2926; PX7102 (Gao (Singlera) Dep. at 113–14, 81–82.) For a pan-cancer trial, Singlera estimates that a clinical trial would need to be for 100,000 or 200,000 people, somewhere around eight or 10 years. (PFF ¶ 536.1; Gao (Singlera) Tr. 2925–26; PX7102 (Gao (Singlera) Dep. at 122–23).). Therefore, PanSeer would not be launched in the United States before 2029 at the earliest. (PFF ¶ 536.1; Gao (Singlera) Tr. 2925–26; PX7102 (Gao (Singlera) Dep. at 122–23).).

2476. Dr. Gao testified that it is "very possible [Singlera] will be able to market [the] PanSeer" test in the Chinese market as an LDT "in the next . . . two to three years." (Gao (Singlera) Tr. 2892).

Response to Finding No. 2476:

Respondents have no specific response except to note that the proposed finding is irrelevant because Complaint Counsel contends that the relevant market is the United States.

2477. Dr. Gao testified that he is not aware of any path under which the FDA would allow Singlera to market the "PanSeer in the U.S. without FDA approval." (Gao (Singlera) Tr. 2892).

Response to Finding No. 2477:

The proposed finding is inaccurate and misleading because test developers may market their tests in the United States under the LDT framework.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Dr. Gao admitted that he is not an expert witness in this proceeding. (Gao (Singlera) Tr. 2937).

7. Singlera and Grail Consider One Another Competitors in MCED

See Complaint Counsel's Proposed Findings of Fact Section VII.B.3.a.4.

F. HELIO HEALTH IS DEVELOPING ITS MCED TEST ON THE SAME PLATFORM AS ITS HELIOLIVER TEST

1. Background

2478. Helio Health, Inc. ("Helio") is a healthcare company focused on the early detection of cancer using blood specimens. (Chahine (Helio) Tr. 1000; PX7077 (Chahine (Helio) Dep. at 12)).

Response to Finding No. 2478:

Respondents have no specific response.

2479. Helio previously operated under the name Laboratory for Advanced Medicine ("LAM"). (Chahine (Helio) Tr. 1001-02).

Response to Finding No. 2479:

Respondents have no specific response.

2480. [redacted] (PX8655 (Helio) at 006 [redacted] (*in camera*)).

Response to Finding No. 2480:

Respondents have no specific response except to note that despite working in this area for more than seven years, [redacted]

2481. [redacted] (Chahine (Helio) Tr. 1058-59 (*in camera*)).

Response to Finding No. 2481:

Respondents have no specific response except to note that the cited testimony confirms that Helio has ambitions to create a multicancer test, but does not presently have a multicancer test. Dr. Chahine also testified that [redacted] (Chahine (Helio) Tr. 1090, 1092–93.) Further, Dr. Chahine testified that [redacted]

Accordingly, there is no indication based on Helio Health's [redacted] (PFF ¶ 498.) Respondents also incorporate their responses to CCFF ¶¶ 454–60, 774–75, 777 and 1177 herein.

2482. Dr. Chahine, Helio's former CEO, testified that Helio is "probably one of the earlier companies in the category." (Chahine (Helio) Tr. 1001).

Response to Finding No. 2482:

Respondents have no specific response, except to note that in this proposed finding, Complaint Counsel appear to concede, as Dr. Chahine and FTC expert Dr. Scott Morton both concede, that [redacted] (PX6090 (Scott Morton Expert Report) ¶¶ 118–119; PX7077 (Chahine (Helio) Dep. at 31) (*in camera*).)

2483. Helio has operations in the United States and China. (Chahine (Helio) Tr. 1025).

Response to Finding No. 2483:

Respondents have no specific response, except to note that Complaint Counsel concedes that Helio has operations in China, and accordingly Complaint Counsel's contention that BGI should be disregarded as a competing sequencing provider for Helio is baseless. Helio has partnered with Chinese collaborators in the past as part of its work to validate its liver test, further undermining Complaint Counsel's argument that Chinese competitors such as BGI are off-limits to potential MCED developers. (RX3308 (Helio) at 1.) Respondents incorporate their responses to CCFF ¶¶ 1269–1345 herein.

2484. [redacted] (*in camera*)).

Response to Finding No. 2484:

The proposed finding is not supported by the cited evidence. Page 20 of PX8655 lists an [redacted] as a [redacted] but neither of the cited pages of PX8655 identifies [redacted] (PX8655 (Helio) at 19, 20, 45 (*in camera*).)

2. HelioLiver Test

2485. [redacted] (Chahine (Helio) Tr. 1000-01, 1009-10; PX7077 (Chahine (Helio) Dep. 15-17) (*in camera*)).

Response to Finding No. 2485:

Respondents have no specific response except to note that the cited testimony confirms that Helio is developing a single-cancer screening test.

2486. When still operating as LAM, Helio used the name "IvyGene" for the liver cancer screening test now known as HelioLiver. (Chahine (Helio) Tr. 1001-02).

Response to Finding No. 2486:

Respondents have no specific response.

2487. [redacted] (Chahine (Helio) Tr. 1010-11; 1057-58 (*in camera*)); PX7077 (Chahine (Helio) Dep. at 15-16) (*in camera*)).

Response to Finding No. 2487:

Respondents have no specific response.

2488. [redacted] (Chahine (Helio) Tr. 1069 (*in camera*)).

Response to Finding No. 2488:

Respondents have no specific response.

2489. Helio currently performs the sequencing for the HelioLiver test at its own certified lab as well as third-party labs. (Chahine (Helio) Tr. 1011-12).

Response to Finding No. 2489:

Respondents have no specific response.

2490. Helio chose to develop a liver cancer screening test because of the large market opportunity in the United States and China, which has the largest number of liver cancer cases in the world. (Chahine (Helio) Tr. 1025).

Response to Finding No. 2490:

Respondents have no specific response except to note that the cited testimony confirms that Helio is developing a single-cancer screening test.

2491. [redacted] (PX6049 (Grail) at 038 (Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 2491:

Respondents have no specific response except to note that the cited testimony confirms that Helio is developing a single-cancer screening test, not an MCED test.

2492. [redacted] (PX7077 (Chahine (Helio) Dep. at 16-17) (*in camera*); Chahine (Helio) Tr. 1050 (*in camera*)).

Response to Finding No. 2492:

Respondents have no specific response except to note that the cited testimony confirms that Helio is developing a single-cancer screening test.

2493. [redacted] (Chahine (Helio) Tr. 1050 (*in camera*)).

Response to Finding No. 2493:

Respondents have no specific response except to note that the cited testimony confirms that Helio is developing a single-cancer screening test.

a) [redacted]

2494. [redacted] (Chahine (Helio) Tr. 1064-65 (*in camera*)).

Response to Finding No. 2494:

The proposed finding is incomplete and misleading, and is vague and ambiguous as to the meaning of the "tests" to which it refers. When asked at trial, [redacted] (Chahine (Helio) Tr. 1064 (*in camera*).) The proposed finding is also misleading to the extent it implies that a distributed IVD model will be part of the pipeline in the foreseeable future for any putative MCED test. Several features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (PFF ¶ 675; RX3869 (Cote Expert Report) ¶ 359.) The test developer's decision whether to proceed with an IVD kit as opposed to a centralized model is an economic decision driven by test-specific factors. (Goswami (Illumina) Tr. 3197.) IVD kits are most suitable for tests that have precious samples, that present shipping challenges and require fast turnaround times. (Goswami (Illumina) Tr. 3196–3200; *see also* RX3869 (Cote Expert Report) § XI, ¶¶ 360–63.)

2495. [redacted] (Chahine (Helio) Tr. 1065-66 (*in camera*)).

Response to Finding No. 2495:

Respondents have no specific response except incorporates their responses to CCFF ¶ 2494 herein.

2496. [redacted] (Chahine (Helio) Tr. 1066 (*in camera*)).

Response to Finding No. 2496:

Respondents have no specific response except incorporates their responses to CCFF ¶ 2494 herein.

2497. [redacted] (Chahine (Helio) Tr. 1064-65 (*in camera*)).

Response to Finding No. 2497:

Respondents have no specific response except incorporates their responses to CCFF ¶ 2494 herein.

2498. [redacted] (Chahine (Helio) Tr. 1050-51 (*in camera*)).

Response to Finding No. 2498:

The proposed finding is incomplete and misleading, and appears to be based on inadmissible speculation and hearsay. Dr. Chahine testified at trial that the referenced [redacted] (Chahine (Helio) Tr. 1050-52 (*in camera*).)

2499. [redacted] (Chahine (Helio) Tr. 1051-52 (*in camera*)).

Response to Finding No. 2499:

The proposed finding is incomplete and misleading, and appears to be based on inadmissible speculation and hearsay. Dr. Chahine testified at trial that he [redacted] (Chahine (Helio) Tr. 1052

(*in camera*) (emphasis added).) Respondents also incorporate their responses to CCFF ¶ 2498 herein.

2500. [redacted] (Chahine (Helio) Tr. 1052 (*in camera*)).

Response to Finding No. 2500:

The proposed finding is incomplete and misleading, and appears to be based on inadmissible speculation and hearsay. Dr. Chahine testified at trial that he [redacted] (Chahine (Helio) Tr. 1052 (*in camera*) (emphasis added).) Respondents also incorporate their responses to CCFF ¶¶ 2498–99 herein.

3. Helio Is Developing an MCED Test on the HelioLiver Technological Platform

2501. [redacted] (Chahine (Helio) Tr. 1057 (*in camera*)).

Response to Finding No. 2501:

The proposed finding is incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶ 2481, which Respondents incorporate herein. The proposed finding is also incomplete and misleading to the extent it suggests Helio has or is close to developing an "MCED test". In fact, Dr. Chahine and FTC expert Dr. Scott Morton conceded that [redacted] (PX6090 (Scott Morton Expert Report) ¶¶ 118–119; PX7077 (Chahine (Helio) Dep. at 31) (*in camera*).)

2502. Helio is researching additional cancers to add to the HelioLiver test platform. (Chahine (Helio) Tr. 1039).

Response to Finding No. 2502:

The proposed finding is not supported by the cited evidence. The proposed finding mischaracterizes the cited testimony, in which Dr. Chahine testified that Helio is "interested in" other cancers, not that Helio plans to add cancers to its liver test. (PX7077 (Chahine (Helio) Dep. at 15 ("Q. What blood-based cancer screening products is Helio currently developing? A. Our lead product is in liver, but we have a pipeline of other cancers that we're interested in, including colon, breast, lung.").) Further, the cited testimony confirms that Helio is only "interested in" other cancers but has not in fact developed a test that screens for multiple cancer types simultaneously. In the cited trial testimony Dr. Chahine referred to "many others [i.e., cancer types] that we have done, you know, very limited research on" and noted that "ovarian cancer is a huge killer" and "[e]sophageal cancer is another one" but did not refer to a "HelioLiver test platform" or specifically discuss adding those or other cancer types to any such platform. (Chahine (Helio) Tr. 1039.) Respondents also incorporate their responses to CCFF ¶¶ 455 and 2481 herein.

2503. [redacted] (Chahine (Helio) Tr. 1000-01). (PX8655 (Helio) at 019 [redacted] (*in camera*)).

Response to Finding No. 2503:

The proposed finding is incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2481 and 2502, which Respondents incorporate herein. The proposed finding is also not

supported by the cited evidence. In the cited trial testimony Dr. Chahine mentions Helio's [redacted] but does not state [redacted] and the cited portion of PX8655 [redacted] (Chahine (Helio) Tr. 1000-01; PX8655 (Helio) at 019) (*in camera*).) Further, as Dr. Chahine testified, Helio abandoned those earlier multi-cancer efforts by LAM on the IvyGene test. (PFF ¶ 501.1; PX7077 (Chahine (Helio) Dep. at 218); RX3417 (Helio); RX3263 (GenomeWeb) at 1; RX3869 (Cote Expert Report) n. 334.)

The proposed finding is also misleading to the extent it implies that Helio has any plans to launch a broad MCED test that would compete with Galleri. In fact, Dr. Chahine testified that Helio's intent is to proceed by [redacted] (PX7077 (Chahine (Helio) Dep. at 30–31) (*in camera*); Chahine (Helio) Tr. 1084 (*in camera*).) [redacted]

Dr. Chahine also testified that [redacted] 2504. [redacted] (Chahine (Helio) Tr. 1056-57 (*in camera*)).

Response to Finding No. 2504:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2503, which Respondents incorporate herein.

2505. [redacted] (Chahine (Helio) Tr. 1056-57 (*in camera*)).

Response to Finding No. 2505:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2503, which Respondents incorporate herein.

2506. [redacted] (Chahine (Helio) Tr. 1056-57 (*in camera*)).

Response to Finding No. 2506:

The proposed finding is incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2481 and 2502–03, which Respondents incorporate herein. In fact, Dr. Chahine and FTC expert Dr. Scott Morton conceded that [redacted] (PX6090 (Scott Morton Expert Report) ¶¶ 118–119; PX7077 (Chahine (Helio) Dep. at 31) (*in camera*).) Moreover, Dr. Chahine has testified that Helio's intent is to proceed by [redacted] (PX7077 (Chahine (Helio) Dep. at 30–31) (*in camera*); Chahine (Helio) Tr. 1084 (*in*

camera).) [redacted] (Chahine (Helio) Tr. 1090-93.)

The proposed finding is also misleading the extent it suggests that it is a viable option to convert from a single cancer screening test to a multi-cancer screening test. To the contrary, even once a company has developed a cancer screening test for a single cancer type, it does not become easier to add additional cancer types, because "[t]he development of biomarkers for a particular cancer will not be adequate for other cancers" and "[w]hile there may be overlap, one still needs to go through all of the [development] steps," including "go[ing] through the case-control verification to determine whether or not the assay has the performance characteristics needed . . . for the new target cancer," and "go[ing] through a prospective trial depending on which cancer is being targeted." (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123; PFF ¶¶ 328–328.1.) Dr. Aravanis testified that GRAIL considered developing a single cancer screening test as a route to multicancer screening test but abandoned it because it would take far too long; building a multicancer test by developing single cancer tests seriatim could take four or five years for each cancer; to develop a 50-cancer test one cancer at a time a developer would need to do a research study, discovery study and collect relevant samples, determine the right technology, go into a new test development phase and clinical trials for each new cancer; GRAIL was able to develop a test capable of detecting 50 cancer types simultaneously directly by undergoing a much more intensive process to develop a test for 50 cancer types at the same time. (Aravanis (Illumina) Tr. 1895–97.)

2507. [redacted] (PX7077 (Chahine (Helio) Dep. at 33-34 (*in camera*))).

Response to Finding No. 2507:

The proposed finding is not supported by the cited evidence. The quotation from the cited deposition testimony is accurate, but Dr. Chahine did not make reference in the cited deposition testimony [redacted] (PX7077 (Chahine (Helio) Dep. at 33-34) (*in camera*).) Respondents also incorporate their responses to CCFF ¶¶ 2481 and 2502–03 herein.

2508. [redacted] (PX7077 (Chahine (Helio) Dep. at 34 (*in camera*))).

Response to Finding No. 2508:

The proposed finding is not supported by the cited evidence. The quotations from the cited deposition testimony are accurate, but Dr. Chahine did not state in the cited deposition testimony [redacted] (PX7077 (Chahine (Helio) Dep. at 34) (*in camera*).)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

2509. [redacted] (Chahine (Helio) Tr. 1058-59 (*in camera*)).

Response to Finding No. 2509:

Respondents have no specific response.

2510. [redacted] (Chahine (Helio) Tr. 1057-58 (*in camera*)).

Response to Finding No. 2510:

The proposed finding is incomplete and not supported by the cited evidence. Dr. Chahine stated in the cited trial testimony that [redacted] but he did not state in the cited trial testimony [redacted] (Chahine (Helio) Tr. 1057-58 (*in camera*).) The proposed finding is also misleading to the extent that it suggests Helio has or is close to developing a MCED test that could compete with Galleri. In fact, Dr. Chahine and FTC expert Dr. Scott Morton both conceded that [redacted] (PX6090 (Scott Morton Expert Report) ¶¶ 118–119; PX7077 (Chahine (Helio) Dep. at 31) (*in camera*).) Respondents also incorporate their responses to CCFF ¶¶ 2481 and 2502–03 herein.

2511. When considering which cancers to add to HelioLiver, Helio has prioritized by reviewing the research conducted on other cancer types and the cost to conduct a clinical trial for each cancer. (Chahine (Helio) Tr. 1039-40). Helio also considers the prevalence of a cancer and the corresponding market size for a test that detects that cancer when considering what cancers to add to its screening test. (Chahine (Helio) Tr. 1040-41). In addition, Helio considers the lethality of a cancer when considering what cancers to add to its cancer screening test. (Chahine (Helio) Tr. 1041).

Response to Finding No. 2511:

The proposed finding is not supported by the cited evidence. The cited portions of Dr. Chahine's trial testimony do not discuss "add[ing]" cancers "to HelioLiver". (Chahine (Helio) Tr. 1039-41.) The proposed finding is also vague, ambiguous and misleading to the extent it refers vaguely to "other cancer types". Respondents also incorporate their responses to CCFF ¶¶ 2481 and 2502–03 herein.

2512. [redacted] (PX7077 (Chahine (Helio) Dep. at 15); PX8655 (Helio) at 013 [redacted] (*in camera*)).

Response to Finding No. 2512:

The proposed finding is incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2481 and 2502–03, which Respondents incorporate herein.

The proposed finding is also not supported by the cited evidence. Neither the cited portion of Dr. Chahine's deposition testimony nor the cited portion of PX8655 reflects [redacted] To the contrary, the cited portion of PX8655 [redacted] and Dr. Chahine stated in his deposition testimony that [redacted]. (PX7077 (Chahine (Helio) Dep. at 15); PX8655 (Helio) at 013 (*in camera*).)

2513. [redacted] (*in camera*)).

Response to Finding No. 2513:

The proposed finding is not supported by the cited evidence. Although the quotations from the [redacted] the file name of the [redacted]

[redacted] PX8655 (Helio) at 001, 027 (*in camera*).) Moreover, Helio's recent announcements, as well as its prior work on IvyGene, show that it has only ever studied breast, colon, liver, nasopharyngeal and lung cancers. (RX3302 (Hao et al., 2017); RX3308 (Helio) at 2); RX3616 (Roy et al., 2019).) Further, the cited source is outdated as it is from 2019. As Dr. Chahine testified, Helio abandoned those earlier multi-cancer efforts by LAM on the IvyGene test. (PFF ¶ 501.1; PX7077 (Chahine (Helio) Dep. at 218); RX3417 (Helio); RX3263 (GenomeWeb) at 1; RX3869 (Cote Expert Report) n. 334.) Since then, Dr. Chahine testified [redacted] (Chahine (Helio) Tr. 1085.) Respondents also incorporate their responses to CCFF ¶¶ 2481 and 2502–03 herein.

2514. Helio told its investors that Helio intends to develop an MCED test by adding additional cancers to its single-cancer HelioLiver test. (Chahine (Helio) Tr. 1037).

Response to Finding No. 2514:

The proposed finding is not supported by the cited evidence. The cited portion of Dr. Chahine's trial testimony does not discuss Helio "adding additional cancers to its single-cancer HelioLiver test." Instead, when asked at trial, "has Helio told investors that it's developing an MCED test?" Dr. Chahine testified, "It has" but clarified that "the strategy as I've communicated it to investors . . . is . . . that, you know, ultimately the category is going in this direction **but that we're choosing to, for the reasons I've mentioned, doing a single test first**." (Chahine (Helio) Tr. 1037 (emphasis added).)

2515. Per Dr. Chahine, Helio has not set a limit on the number of cancers it plans to include in its MCED test. (Chahine (Helio) Tr. 1043).

Response to Finding No. 2515:

Respondents have no specific response, except to note that Helio's recent announcements, as well as its prior work on IvyGene, show that it has only ever studied breast, colon, liver, nasopharyngeal and lung cancers. (RX3302 (Hao et al., 2017); RX3308 (Helio) at 2); RX3616 (Roy et al., 2019).) Further, as Dr. Chahine testified, Helio abandoned those earlier multi-cancer efforts by LAM on the IvyGene test. (PFF ¶ 501.1; PX7077 (Chahine (Helio) Dep. at 218); RX3417 (Helio); RX3263 (GenomeWeb) at 1; RX3869 (Cote Expert Report) n. 334.) Respondents also incorporate their responses to CCFF ¶¶ 2481 and 2502–03 herein.

2516. [redacted] (Chahine (Helio) Tr. 1069-70 (*in camera*)).

Response to Finding No. 2516:

The proposed finding is inaccurate and not supported by the cited evidence. Dr. Chahine testified at trial that, contrary to the [redacted] (Chahine (Helio) Tr. 1069-70 (*in camera*).)

2517. [redacted] (PX7077 (Chahine (Helio) Dep. at 15-16 (*in camera*))).

Response to Finding No. 2517:

The proposed finding is not supported by the cited evidence. In the cited deposition testimony Dr. Chahine testified that the [redacted] but the cited deposition testimony contained no discussion of [redacted] (PX7077 (Chahine (Helio) Dep. at 15-16) (*in camera*).)

2518. [redacted] (Chahine (Helio) Tr. 1058 (*in camera*)).

Response to Finding No. 2518:

The proposed finding is incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2481 and 2502–03, which Respondents incorporate herein.

2519. [redacted] (PX8655 (Helio) [redacted] (*in camera*)). (*See* PX8655 (Helio) at 045 [redacted] (*in camera*)).

Response to Finding No. 2519:

The proposed finding is incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2481 and 2502–03, which Respondents incorporate herein. Further, the cited source is outdated as it is from 2019. As Dr. Chahine testified, Helio abandoned those earlier multi-cancer efforts by LAM on the IvyGene test. (PFF ¶ 501.1; PX7077 (Chahine (Helio) Dep. at 218); RX3417 (Helio); RX3263 (GenomeWeb) at 1; RX3869 (Cote Expert Report) n. 334.) Since then, Dr. Chahine testified [redacted] (Chahine (Helio) Tr. 1085.)

Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 68), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2520. [redacted] (*in camera*)).

Response to Finding No. 2520:

The proposed finding is incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2481 and 2502–03, which Respondents incorporate herein.

Respondents also note that Helio's recent announcements, as well as its prior work on IvyGene, show that it has only ever studied breast, colon, liver, nasopharyngeal and lung cancers. (RX3302 (Hao et al., 2017); RX3308 (Helio) at 2); RX3616 (Roy et al., 2019).)

Further, the cited source is outdated as it is from 2019. As Dr. Chahine testified, Helio abandoned those earlier multi-cancer efforts by LAM on the IvyGene test. (PFF ¶ 501.1; PX7077 (Chahine (Helio) Dep. at 218); RX3417 (Helio); RX3263 (GenomeWeb) at 1; RX3869 (Cote Expert Report) n. 334.) Since then, Dr. Chahine testified [redacted] (Chahine (Helio) Tr. 1085.)

2521. [redacted] (*in camera*)).

Response to Finding No. 2521:

The proposed finding is incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2481 and 2502–03, which Respondents incorporate herein. Further, the cited source is outdated as it is from 2019. As Dr. Chahine testified, Helio abandoned those earlier multi-cancer efforts by LAM on the IvyGene test. (PFF ¶ 501.1; PX7077 (Chahine (Helio) Dep. at 218); RX3417 (Helio); RX3263 (GenomeWeb) at 1; RX3869 (Cote Expert Report) n. 334.) Since then, Dr. Chahine testified [redacted] (Chahine (Helio) Tr. 1085.)

2522. [redacted] (PX8655 (Helio) at 024 [redacted] (*in camera*)).

Response to Finding No. 2522:

The proposed finding is incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2481 and 2502–03, which Respondents incorporate herein. Further, the cited source is outdated as it is from 2019. As Dr. Chahine testified, Helio abandoned those earlier multi-cancer efforts by LAM on the IvyGene test. (PFF ¶ 501.1; PX7077 (Chahine (Helio) Dep. at 218); RX3417 (Helio); RX3263 (GenomeWeb) at 1; RX3869 (Cote Expert Report) n. 334.) Since then, Dr. Chahine testified [redacted]

[redacted] (Chahine (Helio) Tr. 1085.)

2523. [redacted] (RX0894 (Helio) at 015, 022 (Helio Health, May 31, 2021) (*in camera*)).

Response to Finding No. 2523:

The proposed finding is irrelevant because the [redacted] (RX0894 (Helio) at 015, 022 (*in camera*).)

2524. [redacted] (PX8655 (Helio) at 018 [redacted] (*in camera*)).

Response to Finding No. 2524:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2481 and 2502–03 herein.

2525. [redacted] (RX0894 (Helio) at 25 (Helio Health, May 31, 2021) (*in camera*)).

Response to Finding No. 2525:

The proposed finding is incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2481 and 2502–03, which Respondents incorporate herein. Further, the cited source is outdated as it is from 2019. As Dr. Chahine testified, Helio abandoned those earlier multi-cancer efforts by LAM on the IvyGene test. (PFF ¶ 501.1; PX7077 (Chahine (Helio) Dep. at 218);

RX3417 (Helio); RX3263 (GenomeWeb) at 1; RX3869 (Cote Expert Report) n. 334.) Since then, Dr. Chahine testified [redacted] (Chahine (Helio) Tr. 1085.)

2526. [redacted] (PX8655 (Helio) at 028 [redacted] (*in camera*)).

Response to Finding No. 2526:

The proposed finding is incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2481 and 2502–03, which Respondents incorporate herein. Further, the cited source is outdated as it is from 2019. As Dr. Chahine testified, Helio abandoned those earlier multi-cancer efforts by LAM on the IvyGene test. (PFF ¶ 501.1; PX7077 (Chahine (Helio) Dep. at 218); RX3417 (Helio); RX3263 (GenomeWeb) at 1; RX3869 (Cote Expert Report) n. 334.) Since then, Dr. Chahine testified [redacted] (Chahine (Helio) Tr. 1085.)

[redacted]

[redacted]

In addition, to the extent that Helio intends to launch a putative MCED test with these described features (which it does not), this test would have serious issues. *First*, the test does not report a specificity across different types of cancer. Further, [redacted]

[redacted]

).)

2527. [redacted] (RX0894 (Helio) at 19 (Helio Health, May 31, 2021) (*in camera*)).

Response to Finding No. 2527:

The proposed finding is incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2481, 2502–03 and 2526, which Respondents incorporate herein.

2528. [redacted] (*in camera*)).

Response to Finding No. 2528:

The proposed finding is misleading and contradicted by the weight of the evidence to the extent it suggests that [redacted]. For example, Dr. Chahine and FTC expert Dr. Scott Morton both conceded that [redacted] (PX6090 (Scott Morton Expert Report) ¶¶ 118–119; PX7077 (Chahine (Helio) Dep. at 31) (*in camera*).) Further, the cited source is outdated as it is from 2019. As Dr. Chahine testified, Helio abandoned those earlier multi-cancer efforts by LAM on the IvyGene test. (PFF ¶ 501.1; PX7077 (Chahine (Helio) Dep. at 218); RX3417 (Helio); RX3263 (GenomeWeb) at 1; RX3869 (Cote Expert Report) n. 334.) Since then, Dr. Chahine testified [redacted] (Chahine (Helio) Tr. 1085.) Respondents also incorporate their responses to CCFF ¶¶ 2481, 2502–03 and 2526 herein.

2529. [redacted] (*in camera*)). [redacted]

(PX8655 (Helio) at 038 (*in camera*)).

Response to Finding No. 2529:

Respondents have no specific response except to note that it appears that the first citation to PX8655 (Helio) should be to page 038, not page 031. Respondents also incorporate their responses to CCFF ¶¶ 2481, 2502–03 and 2526 herein.

2530. (PX8655 (Helio) at 039 (*in camera*)).

Response to Finding No. 2530:

Respondents have no specific response. Respondents also incorporate their responses to CCFF ¶¶ 2481, 2502–03 and 2526 herein.

a)

2531. (Chahine (Helio) Tr. 1061-62 (*in camera*)).

Response to Finding No. 2531:

The proposed finding is incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2481, 2502–03 and 2526, which Respondents incorporate herein.

[redacted]

2532. [redacted] (Chahine (Helio) Tr. 1061-63 (*in camera*)).

Response to Finding No. 2532:

The proposed finding is inaccurate and misleading. In the cited trial testimony Dr. Chahine testified about [redacted]

(Chahine (Helio) Tr. 1061-63 (*in camera*).)

2533. [redacted] (*in camera*)).

Response to Finding No. 2533:

Respondents have no specific response.

2534. [redacted] (Chahine (Helio) Tr. 999, 1061 (*in camera*)).

Response to Finding No. 2534:

Respondents have no specific response.

2535. [redacted] (PX8655 (Helio) at 031 (*in camera*)).

[redacted] (PX8655 (Helio) at 031 [redacted] (*in camera*)).

Response to Finding No. 2535:

The proposed finding is incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2481, 2502–03 and 2526, which Respondents incorporate herein.

Further, the cited source is outdated as it is from 2019. As Dr. Chahine testified, Helio abandoned those earlier multi-cancer efforts by LAM on the IvyGene test. (PFF ¶ 501.1; PX7077 (Chahine (Helio) Dep. at 218); RX3417 (Helio); RX3263 (GenomeWeb) at 1; RX3869 (Cote Expert Report) n. 334.) Since then, Dr. Chahine testified that [redacted] (Chahine (Helio) Tr. 1085.) Respondents also incorporate their responses to CCFF ¶¶ 2481, 2502–03 and 2526 herein.

2536. [redacted] (Chahine (Helio) Tr. 1061-62 (*in camera*)).

Response to Finding No. 2536:

The proposed finding is incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2481, 2502–03 and 2526, which Respondents incorporate herein.

[redacted]

2537. [redacted] (Chahine (Helio) Tr. 1062 (*in camera*)).

Response to Finding No. 2537:

Respondents have no specific response, except to note that in this proposed finding Complaint Counsel concedes that [redacted] Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) For example, Natera and BGI Genomics formed a partnership to commercialize Natera's Signatera NGS-based cancer monitoring test on BGI's DNBSEQ platform in China, and has now launched a version of the Signatera test in China "that incorporates MGI sequencing platforms." [redacted] RX3062 (BGI) at 1.)

BGI already has a commercially available NGS platform. (PFF ¶¶ 777–777.5.) BGI also markets its NGS technology in many other countries and is expected to enter the U.S. market in the near future. [redacted]

[redacted]

RX3869 (Cote Expert Report) ¶ 287; [redacted]**.)** BGI also recently won a jury verdict that held three of Illumina's patents to be invalid meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022). BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.) [redacted]

2538. [redacted] (Chahine (Helio) Tr. 1062-63 (*in camera*)).

Response to Finding No. 2538:

The proposed finding is incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2481, 2502–03 and 2526, which Respondents incorporate herein.

b) Helio's Definition of "Cancer Type" Is Narrower Than the One Grail Uses When Grail Claims It Can Detect 50 Cancers

2539. [redacted]

[redacted] (*in camera*)).

Response to Finding No. 2539:

The proposed finding is not supported by the cited evidence. Although the cited portion of PX8655 contains the quoted [redacted], and the cited portion of PX8655 contains no statement that [redacted]. (PX8655 (Helio) at 031 (*in camera*).) Helio's recent announcements, as well as its prior work on IvyGene, show that it has only ever studied breast, colon, liver, nasopharyngeal and lung cancers. (RX3302 (Hao et al., 2017); RX3308 (Helio) at 2); RX3616 (Roy et al., 2019).) Further, the cited source is outdated as it is from 2019. As Dr. Chahine testified, Helio abandoned those earlier multi-cancer efforts by LAM on the IvyGene test. (PFF ¶ 501.1; PX7077 (Chahine (Helio) Dep. at 218); RX3417 (Helio); RX3263 (GenomeWeb) at 1; RX3869 (Cote Expert Report) n. 334.) Since then, Dr. Chahine testified [redacted] (Chahine (Helio) Tr. 1085.)

The proposed finding is also incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2481, 2502–03 and 2526, which Respondents incorporate herein.

2540. Dr. Chahine testified at trial that "broadly in the category" people define cancer types based on the organ where the cancer is located but it's "far more complicated than that" because

"even within a certain organ you could have different cancer types and even different algorithms that would identify a certain cancer type or not." (Chahine (Helio) Tr. 1042).

Response to Finding No. 2540:

Respondents have no specific response.

2541. Grail uses the American Joint Committee on Cancer's definition of cancer types. (RX2770 (2021 ASCO CCGA Poster)).

Response to Finding No. 2541:

Respondents have no specific response.

2542. [redacted] (PX8655 (Helio) at 031 [redacted] (*in camera*)); RX2770 (2021 ASCO CCGA Poster); *see infra* Section X, Appendix B (Galleri Has Not Been Clinically Shown to Provide Early Detection of More Than 50 Cancers in an Asymptomatic Population)).

Response to Finding No. 2542:

The proposed finding is not supported by the cited evidence. PX8655 [redacted] . (PX8655 (Helio) at 031) (*in camera*); RX2770 (2021 ASCO CCGA Poster).) Helio's recent announcements, as well as its prior work on IvyGene, show that it has only ever studied breast, colon, liver, nasopharyngeal and lung cancers. (RX3302 (Hao et al., 2017); RX3308 (Helio) at 2); RX3616 (Roy et al., 2019).)

The proposed finding is also incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF

¶¶ 2481, 2502–03, 2526 and 2539, which Respondents incorporate herein. Further, the cited source is outdated as it is from 2019. As Dr. Chahine testified, Helio abandoned those earlier multi-cancer efforts by LAM on the IvyGene test. (PFF ¶ 501.1; PX7077 (Chahine (Helio) Dep. at 218); RX3417 (Helio); RX3263 (GenomeWeb) at 1; RX3869 (Cote Expert Report) n. 334.) Since then, Dr. Chahine testified [redacted] (Chahine (Helio) Tr. 1085.)

Respondents also note that Complaint Counsel chose not to discuss PX8655 at trial, (CC Exhibit Index at 68), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also incorporate their responses to CCFF ¶¶ 2562 and 2570–71 herein.

4. HelioLiver Is Undergoing an FDA Clinical Trial Now

2543. Helio is conducting one clinical trial on its HelioLiver test, which is available on ClinicalTrials.gov. (Chahine (Helio) Tr. 1031).

Response to Finding No. 2543:

Respondents have no specific response.

2544. [redacted] (PX7077 (Chahine (Helio) Depo at 16-17, 20) (*in camera*)).

Response to Finding No. 2544:

Respondents have no specific response.

2545. Helio is currently in the last phase of clinical development for its HelioLiver test with the FDA. (Chahine (Helio) Tr. 1020).

Response to Finding No. 2545:

Respondents have no specific response.

5. [redacted]

2546. Dr. Chahine testified at trial that the R&D process to develop a screening test is "extremely expensive," and the two major costs are "acquiring actual samples" to conduct the analysis and the sequencing the samples. (Chahine (Helio) Tr. 1035-36).

Response to Finding No. 2546:

Respondents have no specific response.

2547. [redacted] (PX7077 (Chahine (Helio) Dep. at 28-29) (*in camera*)).

Response to Finding No. 2547:

Respondents have no specific response.

2548. [redacted] (PX7077 (Chahine (Helio) Dep. at 40-41) (*in camera*)) [redacted]

Response to Finding No. 2548:

Respondents have no specific response.

2549. [redacted] (PX7077 (Chahine (Helio) Dep. at 33-34) (*in camera*)).

Response to Finding No. 2549:

The proposed finding is not supported by the cited evidence. In the cited deposition testimony Dr. Chahine was asked [redacted]

[redacted] (PX7077 (Chahine (Helio) Dep. at 33-34) (*in camera*).) Respondents also incorporate their responses to CCFF ¶¶ 2481, 2502–03, 2526, 2539 and 2542 herein.

6. [redacted]

2550. [redacted] (PX7077 (Chahine (Helio) Dep. at 16-17) (*in camera*)).

Response to Finding No. 2550:

Respondents have no specific response.

2551. [redacted] (PX7077 (Chahine (Helio) Dep. at 31) (*in camera*)).

Response to Finding No. 2551:

Respondents have no specific response, except to note that in this proposed finding Complaint Counsel concedes that [redacted] (PX7077 (Chahine (Helio) Dep. at 31) (*in camera*)). Respondents also incorporate their responses to CCFF ¶¶ 2481, 2502–03, 2526, 2539 and 2542 herein.

2552. [redacted] (Chahine (Helio) Tr. 1061 (*in camera*)).

Response to Finding No. 2552:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2481, 2502–03, 2526, 2539 and 2542 herein.

2553. [redacted] (Chahine (Helio) Tr. 1062-63 (*in camera*)).

Response to Finding No. 2553:

Respondents have no specific response, except to note that the quoted testimony reads [redacted] not [redacted]. (Chahine (Helio) Tr. 1062 (*in camera*).) Respondents also incorporate their responses to CCFF ¶¶ 2481, 2502–03, 2526, 2539 and 2542 herein.

2554. [redacted] (Chahine (Helio) Tr. 1063 (*in camera*)).

Response to Finding No. 2554:

Respondents have no specific response.

2555. [redacted] (Chahine (Helio) Tr. 1063 (*in camera*)).

Response to Finding No. 2555:

Respondents have no specific response except incorporate their responses to CCFF ¶¶ 2481, 2502–03, 2526, 2539 and 2542 herein.

2556. [redacted] (Chahine (Helio) Tr. 1061-62 (*in camera*)).

Response to Finding No. 2556:

The proposed finding is incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2481, 2502–03 and 2526, which Respondents incorporate herein.

[redacted]

1. [redacted]

G. [redacted]

1. [redacted]

2557. [redacted]

Response to Finding No. 2557:

2558. [redacted]

Response to Finding No. 2558:

Respondents have no specific response.

2559. [redacted]

Response to Finding No. 2559:

Respondents have no specific response.

2560. [redacted]

Response to Finding No. 2560:

Respondents have no specific response.

2561. [redacted]

Response to Finding No. 2561:

Respondents have no specific response.

2. [redacted]

2562. [redacted]

Response to Finding No. 2562:

The proposed finding is incomplete and misleading insofar as it suggests that [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 462–65, 807 and 1190 herein.

2563. [redacted]

Response to Finding No. 2563:

The proposed finding is misleading and incomplete. [redacted]

[redacted] RX3869 (Cote Expert Report) ¶ 191.)

2564. [redacted]

Response to Finding No. 2564:

The proposed finding is incomplete and misleading including insofar as it suggests that [redacted] including for the reasons explained in Respondents' responses to CCFF ¶ 2562, which Respondents incorporate herein.The proposed finding is also incomplete and misleading to the extent it suggests that there are certain universal cancer mutations or changes that are indicative of cancer; no such universal or pan-cancer markers exist. (PFF ¶¶ 308–309 (Cote Tr. 3787; Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106).)

2565. [redacted]

Response to Finding No. 2565:

Respondents have no specific response except to note that [redacted] Respondents also incorporate their responses to CCFF ¶ 2562 herein.

2566. [redacted]

Response to Finding No. 2566:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2562 and 2565 herein.

2567. [redacted]

Response to Finding No. 2567:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2562 and 2565 herein.

2568. [redacted]

Response to Finding No. 2568:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2562 and 2565 herein.

2569. [redacted]

Response to Finding No. 2569:

Respondents have no specific response except to note that [redacted] lacks personal knowledge to opine on what Illumina's motivations and incentives might

be. In addition, the record evidence shows that despite Illumina's competitive position vis-à-vis [redacted], Illumina has continued to support [redacted] for their working relationship. [redacted]

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2570. [redacted]

Response to Finding No. 2570:

The proposed finding is incomplete and misleading including insofar as it suggests that [redacted], including for the reasons explained in Respondents' responses to CCFF ¶ 2562, which Respondents incorporate herein.

Further, [redacted]

[redacted]

2571. [redacted]

Response to Finding No. 2571:

[redacted], including for the reasons explained in Respondents' responses to CCFF ¶¶ 2562 and 2570, which Respondents incorporate herein.

The proposed finding is also misleading the extent it suggests that it is a viable option to convert from a single cancer screening test to a multi-cancer screening test. To the contrary, even once a company has developed a cancer screening test for a single cancer type, it does not become easier to add additional cancer types, because "[t]he development of biomarkers for a particular cancer will not be adequate for other cancers" and "[w]hile there may be overlap, one still needs to go through all of the [development] steps," including "go[ing] through the case-control verification to determine whether or not the assay has the performance characteristics needed . . . for the new target cancer," and "go[ing] through a prospective trial depending on which cancer is being targeted." (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123; PFF ¶¶ 328–328.1.)

Dr. Aravanis testified that GRAIL considered developing a single cancer screening test as a route to multicancer screening test but abandoned it because it would take far too long; building a multicancer test by developing single cancer tests seriatim could take four or five

years for each cancer; to develop a 50-cancer test one cancer at a time a developer would need to do a research study, discovery study and collect relevant samples, determine the right technology, go into a new test development phase and clinical trials for each new cancer; GRAIL was able to develop a test capable of detecting 50 cancer types simultaneously directly by undergoing a much more intensive process to develop a test for 50 cancer types at the same time. (Aravanis (Illumina) Tr. 1895–97.)

2572. [redacted]

Response to Finding No. 2572:

[redacted], including for the reasons explained in Respondents' responses to CCFF ¶¶ 2562 and 2570–71, which Respondents incorporate herein.

2573. [redacted]

Response to Finding No. 2573:

The proposed finding is misleading and incomplete. [redacted]

[redacted], including for the reasons explained in Respondents' responses to CCFF ¶¶ 2562 and 2570–71, which Respondents incorporate herein.

2574. [redacted]

Response to Finding No. 2574:

The proposed finding is incomplete and misleading including insofar as it suggests that [redacted] including for the reasons explained in Respondents' responses to CCFF ¶¶ 2562 and 2570–71 herein.

2575. [redacted]

Response to Finding No. 2575:

Respondents have no specific response.

2576. [redacted]

Response to Finding No. 2576:

The proposed finding is inaccurate, incomplete and misleading to the extent it suggests that [redacted]

[redacted]

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 62), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also incorporate their responses to CCFF ¶¶ 2562 and 2570–71 herein.

3. [redacted] 2577. [redacted]

Response to Finding No. 2577:

The proposed finding is misleading and incomplete. [redacted] currently do not have any clinical trials relating to screening for multiple cancers listed on clinicaltrials.gov. (RX3869 (Cote Expert Report) ¶ 189.) Ms. Perettie also testified at her deposition that [redacted] Respondents also incorporate their responses to CCFF ¶¶ 2562 and 2570–71 herein.

2578. [redacted]

Response to Finding No. 2578:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2577, which Respondents incorporate herein.

2579. [redacted].

Response to Finding No. 2579:

Respondents have no specific response.

2580. [redacted]

Response to Finding No. 2580:

Respondents have no specific response.

2581. [redacted] (*in camera*)).

Response to Finding No. 2581:

The proposed finding is inaccurate, incomplete, misleading and contradicted by the weight of the evidence. [redacted]

[redacted]

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶¶ 2562 and 2570–71 herein.

2582. [redacted]

Response to Finding No. 2582:

The proposed finding is misleading and incomplete. [redacted] Respondents also incorporate their responses to CCFF ¶¶ 2562 and 2570–71 herein.

2583. [redacted]

Response to Finding No. 2583:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2562 and 2570–71 herein.

2584. [redacted]

Response to Finding No. 2584:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2562 and 2570–71 herein.

2585. [redacted]

Response to Finding No. 2585:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2562 and 2570–71 herein.

2586. [redacted]

Response to Finding No. 2586:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2562 and 2570–71 herein.

2587. [redacted]

Response to Finding No. 2587:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 2562 and 2570–71 herein.

2588. [redacted]

Response to Finding No. 2588:

Respondents have no specific response except to note that [redacted] Respondents also incorporate their responses to CCFF ¶¶ 2562 and 2570–71 herein.

2589. [redacted]

Response to Finding No. 2589:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2588.

2590. [redacted]

Response to Finding No. 2590:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2588.

2591. [redacted]

Response to Finding No. 2591:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 2588.

4. [redacted]

2592. [redacted]

Response to Finding No. 2592:

The proposed finding is inaccurate, incomplete, misleading and contradicted by the weight of the evidence. [redacted] Respondents also incorporate their responses to CCFF ¶¶ 2562, 2570–71, 2577 and 2588 herein.

2593. [redacted]

Response to Finding No. 2593:

The proposed finding is inaccurate, incomplete, misleading and contradicted by the weight of the evidence. With respect to its [redacted] RX3869 (Cote Expert Report) ¶ 185.) [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 2562, 2570–71, 2577 and 2588 herein.

2594. [redacted]

Response to Finding No. 2594:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2562, 2570–71, 2577 and 2588, which Respondents incorporate herein.

5. [redacted]

H. OTHER MCED TEST DEVELOPERS

1. [redacted]

2595. [redacted]

Response to Finding No. 2595:

[redacted]

[redacted]

[redacted].

2596. [redacted]

Response to Finding No. 2596:

[redacted]

[redacted].

[redacted] As numerous witnesses testified, GRAIL would not compete with a purported MCED test screened for few than ten cancers. (PFF ¶¶ 709–09.6.)

2597. [redacted]

Response to Finding No. 2597:

[redacted]

[redacted] The proposed finding is also misleading to the extent of its use of the term "Grail's intelligence" and relies entirely on unreliable speculation and hearsay. Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 38), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

[redacted], which are not reflective of, or generalizable to, the populations of United States, and thus is unlikely to be acceptable to the FDA as support for a PMA application.

In addition, there is no such thing as a "pan-cancer test" because there is no such thing as a universal cancer biomarker. (PFF ¶ 308; Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106.)

2598. [redacted]

Response to Finding No. 2598:

The proposed finding is irrelevant because it relates to a putative Chinese cancer test developer that Complaint Counsel has not shown will enter the U.S. market in the foreseeable future. The proposed finding is also misleading to the extent of its use of the term "Grail's

competitive intelligence" and relies entirely on unreliable speculation and hearsay. Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 38), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. [redacted] Respondents also note that [redacted] press release states that "In the future, [redacted] will continue to seek NMPA approvals for its IVD products based on NextSeq™ 550Dx *and other sequencing systems* to promote the implementation of tumor NGS products in hospitals and benefit more cancer patients." (*Id.* (emphasis added).) Respondents further note that BGI is a NGS sequencing system provider based in China. (PFF ¶ 587 (RX3060 (BGI) at 1).)

2599. [redacted] (PX4139 (Grail) at 002, 005 (Email from A. Tosti, Grail, to E. Mann, Grail, May 28, 2020, attaching press release, "2019 AACR Breakthrough in Application of Methylation Ultra-deep Sequencing in Liquid Biopsy for Early Lung Cancer Screening," Aug. 26, 2019).

Response to Finding No. 2599:

The proposed finding is irrelevant because it relates to a [redacted] The proposed finding is also misleading to the extent of its use of the term "Grail's

competitive intelligence" and relies entirely on unreliable speculation and hearsay. Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 38), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. [redacted]

The proposed finding is also inaccurate because Ms. Tosti indicated that one presentation would not be made until June 2022 and the presentations only mentioned lung cancer and ovarian cancer. (PX4139 (GRAIL) at 002.)

2600. [redacted] **(*in camera*)).**

Response to Finding No. 2600:

The proposed finding is irrelevant because it relates to a [redacted] The proposed finding is also incomplete and misleading. Respondents note that the cited presentation by Illumina is [redacted] (PX2163 (Illumina) at 008 (Project Valor, Aug. 4, 2020).)

2601. [redacted] (PX7085 (Harada (Exact) Dep. at 76, 227) (*in camera*)).

Response to Finding No. 2601:

The proposed finding is irrelevant because it relates to a putative Chinese cancer test developer that Complaint Counsel has not shown will enter the U.S. market in the foreseeable future. The proposed finding is also incomplete and misleading to the extent it seems to suggest that [redacted] (*See* PFF ¶¶ 418–421.) Respondents also incorporate their response to CCFF ¶ 1905. Respondents further note that [redacted] (PX7085 (Harada (Exact) Dep.) at 227.) [redacted]

Respondents also note that PX4139 shows that [redacted] appears to be pursuing, at best, a test for three cancer types, one of which is a cancer that has an existing cancer screening test. As numerous witnesses testified, GRAIL would not compete with a purported MCED test screened for few than ten cancers. (PFF ¶¶ 709–09.6.)

Complaint Counsel also did not mention [redacted] during discovery or at trial in this case. Complaint Counsel did not subpoena or notice any witnesses from [redacted]. Nor has [redacted] reached out to the Commission to address this Transaction. Therefore, the finding should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2602. [redacted]

Response to Finding No. 2602:

The proposed finding is irrelevant because it relates to a [redacted] (Cance (American Cancer Society) Tr. 611.) Further, Complaint Counsel has never even mentioned [redacted].

2. [redacted]

2603. [redacted] (PX7050 (Nolan (Freenome) IHT at 280-82) (*in camera*); PX7089 (Naclerio (Illumina) Dep. at 16); PX7094 (Nolan (Freenome) Dep. at 261) (*in camera*)).

Response to Finding No. 2603:

The proposed finding relies in part on on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) [redacted]

2604. [redacted] (PX7050 (Nolan (Freenome) IHT at 280-82) (*in camera*)).

Response to Finding No. 2604:

The proposed finding is misleading to the extent it suggests that [redacted] Respondents note that there is no indication based on Freenome's work to date that [redacted] (PFF ¶ 458 [redacted] RX3869 (Cote Expert Report) ¶ 193).) Respondents note that [redacted] (PFF ¶¶ 459-70.) Respondents also incorporate their response to CCFF ¶¶ 2355–62. Respondents also note that Mr. Nolan testified that [redacted] (PX7094 (Nolan (Freenome) Dep. at 307).)

Respondents also note that the proposed finding relies on speculation and inadmissible hearsay. Mr. Nolan testified that [redacted] (PX7094 (Nolan (Freenome) Dep.) at 261.)

The proposed finding relies in part on on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) [redacted]

[redacted]

2605. [redacted] (PX7094 (Nolan (Freenome) Dep. at 261) (*in camera*)).

Response to Finding No. 2605:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2604, which Respondents incorporate herein.

3. [redacted]

2606. [redacted]

Response to Finding No. 2606:

Respondents have no specific response except to note that Mr. Bishop was answering Complaint Counsel's question regarding companies he was aware of that are developing [redacted], not developing an MCED test. (PX7069 (Bishop (Grail) IHT) at 124–25.)

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Further, Complaint Counsel has never even mentioned the putative MCED test developer, Adaptive. Complaint Counsel did not subpoena or notice any witnesses from Adaptive. Nor has Adaptive reached out to the Commission to address this Transaction.

VII. THE PROPOSED MERGER WILL SUBSTANTIALLY LESSEN COMPETITION IN THE U.S. MCED TEST MARKET

A. ILLUMINA HAS THE ABILITY TO HARM GRAIL'S RIVALS

2607. As discussed in detail above in Section V., MCED test developers testified that they have no viable alternatives and that they need and rely on Illumina as their only NGS option.

Response to Finding No. 2607:

To the extent Complaint Counsel refers to the proposed findings in Section V,

Respondents hereby incorporate by reference their responses to those proposed findings.

1. Illumina Has the Ability to Identify and Discriminate Against MCED Test Developers Posing Competitive Threats to Grail's Galleri Test and the Tools to Foreclose or Reduce the Competitiveness of Grails' Rivals

a) Illumina Designs and Offers Products Tailored for Customers to Use in Certain Applications, Including Providing Custom Kits Not Just for Specific Applications but Also for Specific Customers

2608. Nicole Berry, Illumina's Senior Vice President and General Manager of the Americas Commercial Region, testified that Illumina classifies customers based on segments such as reproductive health, genetic disease testing, and oncology on the clinical side, and cell and molecular biology research, genetic disease research, cancer research, and microbiology on the research side. (PX7076 (Berry (Illumina) Dep. at 54-57); *see infra* Complaint Counsel's Proposed Findings of Fact ¶¶ 2694-2701 (identifying Illumina oncology customers as part of Illumina's post-transaction announcement outreach)).

Response to Finding No. 2608:

Respondents have no specific response.

2609. [redacted] (Berry (Illumina) Tr. 792-793) (*in camera*)). For example, Ms. Berry testified that [redacted] (Berry (Illumina) Tr. 795) (*in camera*)).

Response to Finding No. 2609:

Respondents have no specific response.

2610. [redacted] (Berry (Illumina) Tr. 795) (*in camera*)).

Response to Finding No. 2610:

Respondents have no specific response.

2611. Ms. Berry explained that Illumina offers "12 to 15 different kit configurations" for its NovaSeq sequencing instrument, so that it offers enough variety in reagents for "performance attributes that may be important to a particular customer." (Berry (Illumina) Tr. 827).

Response to Finding No. 2611:

The proposed finding is incomplete and misleading without additional context. Ms. Berry stated that those 12 to 15 different kit configurations were "general-purpose reagents, so we [Illumina] don't do custom versions of those kits". (Berry (Illumina) Tr. 827.) Illumina's reagent kits are thus designed to appeal to a majority of customers' needs. The use of the phrase "a particular customer", when read in light of the entire cited passage, does not mean "a specific, singular customer".

2612. Customers will provide Illumina with details on their tests so that Illumina can recommend which of its consumables the customers should purchase. (*See* PX7076 (Berry (Illumina) Dep. at 62-64)).

Response to Finding No. 2612:

The proposed finding is incomplete and misleading. In the ordinary course of business, Illumina's customers may volunteer high-level information about their tests to Illumina. Illumina does not require customers to report that information, and Illumina does not solicit detailed, technical information from its customers. As Ms. Berry explained, "we don't get into designing assays with customers." (Berry (Illumina) Tr. 845.)

Further, although Illumina may have an understanding of the types of applications a customer is developing or marketing, in many cases it does not know what specific tests are in its customers' development pipeline. (Berry (Illumina) Tr. 849–53.) For example, many of the putative MCED tests Complaint Counsel claims are in development are unknown to Illumina

even today—much less their specific attributes that would allow Illumina to predict with confidence whether any test will be a close substitute to Galleri, or, instead, a market-expanding complement, foreclosure of which would cause no material diversion to Galleri but would result in substantial lost upstream sales. (RX6000 (Carlton Trial Dep. at 24, 26–27).)

In any event, this information is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—including order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.)

Illumina also takes extensive precautions to protect the confidentiality of information it receives from developers including: (1) setting up confidentiality agreements with partners, (2) training staff and requiring them to sign confidentiality agreements, (3) separating teams who might work on similar products, (4) using document control processes and (5) providing legal guidance if individuals request access to protected documents. (PFF ¶¶ 1040–1040.5; Goswami (Illumina) Tr. 3227–30.) These practices are standard in the industry and generally accepted by companies that serve multiple clients in the same industry. (PFF ¶ 1040.8; Goswami (Illumina) Tr. 3228–29.)

The Open Offer requires that to the extent that Illumina has access to customer confidential information, Illumina shall not share such information with GRAIL, any GRAIL subsidiary or any employee who works within GRAIL. (PFF ¶ 1038; (Rabinowitz (Natera) Tr. 425; Berry (Illumina) Tr. 916–17; PX0064 (Illumina) at 9.)

Under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL.

(PFF ¶ 1039; [redacted] deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted].)

2613. Ms. Berry admitted at trial that Illumina sells custom library kits to its NGS sequencing customers. (Berry (Illumina) Tr. 928 (stating that Illumina "sell[s] some very specific SKUs that . . . are absolutely marketed and designed for customers to, you know, specify their own specific content that they want to interrogate" and that "we [Illumina] will make a product specific to a customer's request")).

Response to Finding No. 2613:

The proposed finding is irrelevant because it relates to library preparation kits and not NGS sequencing. Respondents note that liquid biopsy test developers do not use Illumina technology for library preparation. (Berry (Illumina) Tr. 815 (stating that the library preparation step "is very unique and specific to the particular test provider's sort of approach of methodology" and that there are "hundreds and hundreds of library preparation methods" and "potentially hundreds of providers of library preparation technology or kits").)

Further, while Illumina is willing to customize its library prep kits for use in an NGS workflow (Berry (Illumina) Tr. 928), this is a narrow application of customization, and a relatively rare practice. Ms. Berry testified that, in the Americas "customizing [a] product" is something that Illumina has "almost never, never done" and that she herself had "never personally been part of a discussion with a customer whereby [Illumina] w[as] creating a customized version of, say, a core consumable or an instrument for an Americas customer". (Berry (Illumina) Tr. 881–82; 844.)

2614. Guardant's Mr. Getty testified that Illumina provides Guardant with "customization and optimization of our reagents." (PX7105 (Getty (Guardant) Dep. at 60-62)).

Response to Finding No. 2614:

The proposed finding is inaccurate, incomplete and misleading. At trial, Mr. Getty admitted that he "would not be the person to answer technical questions about the sequencers

and reagents used by Guardant in its lab" and that he would "defer to Ms. Chudova on that". (Getty (Guardant) Tr. 2635.) [redacted]

2615. [redacted]
(PX2541 (Illumina) at 008 (Illumina, Interim Review K2-Grail (aka Grail "Pendragon"), Feb. 2, 2017) (*in camera*); s*ee infra* Section VII.D.3. (While Illumina Had Majority-Ownership, Grail Received Preferential Treatment)).

Response to Finding No. 2615:

The proposed finding relates to irrelevant subject matter because benefits that Illumina purportedly provided to GRAIL under its original supply agreement—when GRAIL was formed and controlled by Illumina—are irrelevant to evaluating the effects of the transaction on competition. At the time of GRAIL's formation, the objective of creating a cancer screening test was a moonshot concept, and Illumina believed that without a deep discount, it would be impossible for GRAIL to successfully develop a cancer test. *See* PFF ¶ 980. There was ***no one else*** pursuing the same goal as Illumina and GRAIL at that time: Because there were no rivals, any special pricing at that time could not have put any rivals at a disadvantage. *See* PFF ¶ 980.3.

The proposed finding is also misleading to the extent it suggests that GRAIL will receive access to sequencing instruments and core consumables, as well as associated services, that are unavailable to other putative MCED test developers. This is incorrect. Any customer that signs the Open Offer shall have the same access to services that GRAIL or any other For-Profit Entity has access to, at the same prices. (PFF ¶ 1004; [redacted]; Berry

(Illumina) Tr. 865–66; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.)). Similarly, the Open Offer provides customers the same access to purchase sequencing instruments and core consumables to which GRAIL has access. (PFF ¶ 1005; [redacted]; Berry (Illumina) Tr. 878–79; deSouza (Illumina) Tr. 2434–35, 2437–38; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) Further, the timing of the access to these services and sequencing products shall be the same for GRAIL as it is for its putative rivals: the Open Offer requires that "Customer shall have access to the Supplied Products for purchase that GRAIL . . . has access, within 5 days of when GRAIL . . . is offered such access (if not earlier) for purchase." (PFF ¶ 1005.1; RX3935 (Illumina) at 2.) Respondents also incorporate their responses to CCFF ¶¶ 23 and 47 herein.

(1) Illumina Has the Tools to Identify Customers That Develop MCED Tests Likely to Compete with Grail's Galleri Test

(a) Illumina Has a Variety of Means and Sources to Access Information about Its Customers' Products and Activities

(i) Illumina Learns about Its Customers' Products and Development Plans from Conversations with Its Customers

2616. Ms. Berry admitted at trial that Illumina identifies many customers that are buying its products for the purpose of developing or performing oncology tests through sales and service interactions with customers. (Berry (Illumina) Tr. 657-58).

Response to Finding No. 2616:

Respondents have no specific response, except to note that Illumina identifies such customers based on information that those customers voluntarily provide to Illumina.

2617. Ms. Berry explained that customers provide details about their tests to Illumina so that Illumina can recommend the appropriate consumables that they should purchase from Illumina. (PX7076 (Berry (Illumina) Dep. at 62-64)).

Response to Finding No. 2617:

The proposed finding is incomplete and misleading. At trial, Ms. Berry testified that the way that Illumina's sales team may help customers to figure out which of Illumina's products best suit their end use it to "talk to the customer about the various performance attributes . . . that [Illumina's] general-purpose reagents have, for example, or [Illumina's] sequencing instruments have". (Berry (Illumina) Tr. 658.) Information about performance attributes that a particular developer may require are not, as the proposed finding implies, specific "details" about the particulars of a given test. As Ms. Berry explained, "we don't get into designing assays with customers." (Berry (Illumina) Tr. 845.)

Further, although Illumina may have an understanding of the types of applications a customer is developing or marketing, in many cases it does not know what specific tests are in its customers' development pipeline. (Berry (Illumina) Tr. 849–53.) For example, many of the putative MCED tests Complaint Counsel claims are in development are unknown to Illumina even today—much less their specific attributes that would allow Illumina to predict with confidence whether any test will be a close substitute to Galleri, or, instead, a market-expanding complement, foreclosure of which would cause no material diversion to Galleri but would result in substantial lost upstream sales. (RX6000 (Carlton Trial Dep. at 24, 26–27).)

In any event, this information is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—including order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.)

Illumina also takes extensive precautions to protect the confidentiality of information it receives from developers including: (1) setting up confidentiality agreements with partners, (2) training staff and requiring them to sign confidentiality agreements, (3) separating teams who might work on similar products, (4) using document control processes and (5) providing legal guidance if individuals request access to protected documents. (PFF ¶¶ 1040–1040.5; Goswami (Illumina) Tr. 3227–30.) These practices are standard in the industry and generally accepted by companies that serve multiple clients in the same industry. (PFF ¶ 1040.8; Goswami (Illumina) Tr. 3228–29.)

The Open Offer requires that to the extent that Illumina has access to customer confidential information, Illumina shall not share such information with GRAIL, any GRAIL subsidiary or any employee who works within GRAIL. (PFF ¶ 1038; [redacted]; Berry (Illumina) Tr. 916–17; PX0064 (Illumina) at 9.)

Under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (PFF ¶ 1039; [redacted]; deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted]

2618. Ms. Berry described how customers may inform Illumina's sales team of their desired read length, analytes that they are detecting, and what platform they are using, among other things, to get input on which Illumina consumables meet their requirements. (PX7076 (Berry (Illumina) Dep. at 62-64)).

Response to Finding No. 2618:

The proposed finding is incomplete and misleading. In the ordinary course of business, Illumina's customers may volunteer high-level information about their tests to Illumina. Illumina does not require customers to report that information, and Illumina does not solicit

detailed, technical information from its customers. As Ms. Berry explained, "we don't get into designing assays with customers." (Berry (Illumina) Tr. 845.)

Further, this information is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—including order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.) Respondents also incorporate their responses to CCFF ¶¶ 2612 and 2617 herein.

2619. Ms. Berry testified that sometimes when troubleshooting sequencing problems for a customer, a customer will provide Illumina with context about what they are using the sequencer for. (PX7076 (Berry (Illumina) Dep. at 32-35)).

Response to Finding No. 2619:

The proposed finding is incomplete and misleading. In the ordinary course of business, Illumina's customers may volunteer high-level information about their tests to Illumina. Illumina does not require customers to report that information, and Illumina does not solicit detailed, technical information from its customers. As Ms. Berry explained, "we don't get into designing assays with customers." (Berry (Illumina) Tr. 845.)

Further, this information is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—including order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.) Respondents also incorporate their responses to CCFF ¶¶ 2612 and 2617 herein.

2620. Illumina can learn information about tests from sources other than the test developer itself, such as lab customers, which can provide Illumina with information about the tests that lab customers are running. (*See* PX7049 (Bailey (PGDx) IHT at 175-76) (explaining that PGDx's lab customers buy NGS products directly from Illumina, and testifying, "I do know examples of where [lab customers] have provided [the specific test] information. And because there is a lack of IVD kits on the market outside of ours it is not hard to figure out.

I mean, if they need the Dx reagents there is nothing else right now really that would require that so I think it's sort of understood when they are ordering those.")).

Response to Finding No. 2620:

The proposed finding is incomplete and misleading. Though Illumina may have an understanding of the *applications* a customer is developing or marketing, in most cases it does not know the specific *tests* that customers are developing. (Berry (Illumina) Tr. 849–53.) Illumina is unaware of many of the tests to which Complaint Counsel has referred in this proceeding, let alone the technical characteristics of those tests. (RX6000 (Carlton Trial Dep.) at 24, 26–27.) The weight of the evidence suggests that it is uncommon for Illumina to learn information about tests—much less the kind of detailed technical information that would allow it to assess competitive potential—from sources other than developers.

Further, although Illumina may have an understanding of the types of applications a customer is developing or marketing, in many cases it does not know what specific tests are in its customers' development pipeline. (Berry (Illumina) Tr. 849–53.) For example, many of the MCED tests Complaint Counsel claims are in development are unknown to Illumina even today—much less their specific attributes that would allow Illumina to predict with confidence whether any test will be a close substitute to Galleri, or, instead, a market-expanding complement, foreclosure of which would cause no material diversion to Galleri but would result in substantial lost upstream sales. (RX6000 (Carlton Trial Dep. at 24, 26–27).)

In any event, this information is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—including order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.)

Illumina also takes extensive precautions to protect the confidentiality of information it receives from developers including: (1) setting up confidentiality agreements with partners, (2) training staff and requiring them to sign confidentiality agreements, (3) separating teams who might work on similar products, (4) using document control processes and (5) providing legal guidance if individuals request access to protected documents. (PFF ¶¶ 1040–1040.5; Goswami (Illumina) Tr. 3227–30.) These practices are standard in the industry and generally accepted by companies that serve multiple clients in the same industry. (PFF ¶ 1040.8; Goswami (Illumina) Tr. 3228–29.)

The Open Offer requires that to the extent that Illumina has access to customer confidential information, Illumina shall not share such information with GRAIL, any GRAIL subsidiary or any employee who works within GRAIL. (PFF ¶ 1038; Berry (Illumina) Tr. 916–17; PX0064 (Illumina) at 9.)

Under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (PFF ¶ 1039; ; deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10;

2621. (PX7056 (Silvis (Tempus) IHT at 91-94) (*in camera*)). (PX7056 (Silvis (Tempus) IHT at 91-94) (*in camera*)).

Response to Finding No. 2621:

The proposed finding is irrelevant because Complaint Counsel does not even allege that Tempus is a putative MCED test developer. (*See* CC's Posthearing Br. at 18–23.)

The proposed finding is inaccurate and misleading. In the ordinary course of business, Illumina's customers may volunteer high-level information about their tests to Illumina. Illumina does not require customers to report that information, and Illumina does not solicit detailed, technical information from its customers. As Ms. Berry explained, "we don't get into designing assays with customers." (Berry (Illumina) Tr. 845.)

Further, this information is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—including order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.) Respondents also incorporate their responses to CCFF ¶¶ 2612 and 2617 herein.

[redacted] The Open Offer requires that to the extent that Illumina has access to customer confidential information, Illumina shall not share such information with GRAIL, any GRAIL subsidiary or any employee who works within GRAIL. (PFF ¶ 1038; [redacted] Berry (Illumina) Tr. 916–17; PX0064 (Illumina) at 9.)

Under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (PFF ¶ 1039; [redacted] deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted]

The proposed finding relies on IH testimony, which respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2622. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 134-35) (*in camera*)).

Response to Finding No. 2622:

The proposed finding is incomplete and misleading without additional context.

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 2612 and 2617 herein.

The proposed finding relies on IH testimony, which respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2623. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 136-38) (*in camera*)).

Response to Finding No. 2623:

The proposed finding is incomplete and misleading without additional context.

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 2612, 2617 and 2622 herein.

The proposed finding relies on IH testimony, which respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2624. [redacted] (PX7085 (Harada (Exact) Dep. at 218) (*in camera*)).

Response to Finding No. 2624:

The proposed finding is inaccurate and misleading. In the ordinary course of business, Illumina's customers may volunteer high-level information about their tests to Illumina. Illumina does not require customers to report that information, and Illumina does not solicit detailed, technical information from its customers. As Ms. Berry explained, "we don't get into designing assays with customers." (Berry (Illumina) Tr. 845.)

Further, this information is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—including order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.) Respondents also incorporate their responses to CCFF ¶¶ 2612 and 2617 herein.

2625. Mr. Getty testified that Guardant works with Illumina to optimize Illumina reagents for the applications Guardant is using the reagents for. (PX7040 (Getty (Guardant) IHT at 59-61)).

Response to Finding No. 2625:

The proposed finding is inaccurate, incomplete and misleading. At trial, Mr. Getty admitted that he "would not be the person to answer technical questions about the sequencers and reagents used by Guardant in its lab" and that he would "defer to Ms. Chudova on that". (Getty (Guardant) Tr. 2635.) [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 2614 and 2685 herein.

2626. As Illumina CEO Mr. deSouza told investors, Illumina works with their liquid biopsy customers to help plan the customers' "path to a regulated [product] offering." (PX2544 (Illumina) at 019 (Email from T. Peterson, JP Morgan, to F. deSouza, Illumina, attaching JPM Life Sciences CEO Conference Call Transcript, Sept. 5, 2019)).

Response to Finding No. 2626:

The proposed finding is incomplete and misleading. Illumina's role in helping customers is extremely limited. For example, Illumina does not provide market access and regulatory consulting services to its customers. (Febbo (Illumina) Tr. 4371.) Beyond supplying standard documentation about the sequencing technologies that a customer is using, Illumina does not provide any support to its customers in obtaining regulatory approval. (Berry (Illumina) Tr. 847–49.)

Further, this information is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—including order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.)

In any event, Illumina takes extensive precautions to protect the confidentiality of information it receives from developers including: (1) setting up confidentiality agreements with partners, (2) training staff and requiring them to sign confidentiality agreements, (3) separating teams who might work on similar products, (4) using document control processes and (5) providing legal guidance if individuals request access to protected documents. (PFF ¶¶ 1040–1040.5; Goswami (Illumina) Tr. 3227–30.) These practices are standard in the industry and

generally accepted by companies that serve multiple clients in the same industry. (PFF ¶ 1040.8; Goswami (Illumina) Tr. 3228–29.)

The Open Offer requires that to the extent that Illumina has access to customer confidential information, Illumina shall not share such information with GRAIL, any GRAIL subsidiary or any employee who works within GRAIL. (PFF ¶ 1038; [redacted]; Berry (Illumina) Tr. 916–17; PX0064 (Illumina) at 9.)

Under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (PFF ¶ 1039; [redacted] deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted]

The Open Offer requires Illumina, on a customer's request, to enter into a separate agreement with the customer based on standardized terms to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33; [redacted] deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; PX0087 (Illumina); PX0088 (Illumina); PX0089 (Illumina); [redacted] These requirements in the Open Offer prevent Illumina from withholding support as putative MCED test developers seek FDA approval. (PFF ¶ 1035; RX6002 (Guerin-Calvert Trial Dep. at 74).)

2627. Illumina CEO Mr. deSouza explained to investors that Illumina made structural changes to its operations to facilitate Illumina's ability to "catalyze [] clinical opportunity" for its customers. (PX2544 (Illumina) at 019-020 (Email from T. Peterson, JP Morgan, to F. deSouza, Illumina, attaching JPM Life Sciences CEO Conference Call Transcript, Sept. 5, 2019)). Mr. deSouza remarked during his investor call discussion with JP Morgan's Tycho Peterson that the Illumina clinical group has "no commercial components" but rather is designed to assist Illumina customers' "clinical enablement." (PX2544 (Illumina) at 020 (Email from T. Peterson, JP Morgan, to F. deSouza, Illumina, attaching JPM Life Sciences CEO Conference Call Transcript, Sept. 5, 2019)). Illumina's clinical group works with Illumina's clinical affairs, medical affairs, and regulatory teams. (PX2544 (Illumina) at 021 (Email from T. Peterson, JP Morgan, to F. deSouza, Illumina, attaching JPM Life Sciences CEO Conference Call Transcript, Sept. 5, 2019)).

Response to Finding No. 2627:

The proposed finding is incomplete and misleading. Mr. deSouza's comments are referring to *indirect* forms of assistance to customers: "enablement functions to drive clinical markets going forward and to engage as peers into the medical community". (PX2544 (Illumina) at -021 (Email from T. Peterson, JP Morgan to F. deSouza, Illumina, attaching JPM Life Sciences CEO Conference Call Transcript, Sept. 5, 2019).) "Enablement functions" refers to efforts by Illumina to engage with various stakeholders in the clinical market to increase the uptake and use of lifesaving clinical genomics technologies. Encouraging stakeholders' acceptance for applications of genetic sequencing technology in the clinic benefits ***all*** Illumina clinical customers who leverage Illumina's platform to design tests and therapies. (*See, e.g.*, Febbo (Illumina) Tr. 4354–55 ("So we have really set the stage for the UK to be aggressive with next-generation sequencing, and I believe strongly that their familiarity with our technology probably played very—was weighted heavily in the success that GRAIL found.").)

(ii) When Illumina Negotiates Supply Agreements and Offers Prices to Customers, It Examines Customers' Applications, Industry Segments, and Product Developments

2628. Nicole Berry testified at trial that Illumina typically "talk[s] to the customer about the various performance attributes that . . . our general-purpose reagents have . . . or our sequencing instruments have, and . . . that conversation could lead to an outcome whereby a particular instrument platform or sequencing kit could be identified as likely to be best suited to their needs." (Berry (Illumina) Tr. 658).

Response to Finding No. 2628:

Respondents have no specific response, except to note that the proposed finding is evidence that Illumina does not solicit information about developers' prospective tests; rather,

Illumina offers information about *its own products' performance attributes* in order to find the best match vis-à-vis a customer's specific needs.

2629. In her deposition, Ms. Berry testified that Illumina learns of customers' goals from supply agreement negotiations. (PX7076 (Berry (Illumina) Dep. at 52-55)).

Response to Finding No. 2629:

The proposed finding is misleading to the extent it suggests that a customer's high-level goals are sensitive information. To the contrary, virtually every contract negotiation involves some degree of agreement about the parties' mutual goals. Respondents note that the proposed finding merely supports the proposition that in the ordinary course of business, customers volunteer information about their goals to Illumina. Respondents further note that a company's goals are typically public information and are unlikely to incorporate competitively sensitive information. (*See, e.g.*, RX3748 (Guardant form 10-K) at 2 (explaining high level goal of developing blood-based screening test) ("We are also developing screening tests from our LUNAR-2 program intended for early detection of cancer.").)

Indeed, GRAIL acting alone—in fact, any test developer—can use public information, including public announcements and publications to glean information about other test developers' progress in developing putative MCED tests. Thus, Illumina has no special advantage in obtaining this information about GRAIL's putative rivals.

Further, although Illumina may have an understanding of the types of applications a customer is developing or marketing, in many cases it does not know what specific tests are in its customers' development pipeline. (Berry (Illumina) Tr. 849–53.) For example, many of the MCED tests Complaint Counsel claims are in development are unknown to Illumina even today—much less their specific attributes that would allow Illumina to predict with confidence whether any test will be a close substitute to Galleri, or, instead, a market-expanding

complement, foreclosure of which would cause no material diversion to Galleri but would result in substantial lost upstream sales. (RX6000 (Carlton Trial Dep. at 24, 26–27).)

In any event, this information is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—including order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.) Respondents also incorporate their responses to CCFF ¶¶ 2612 and 2617 herein.

2630. [redacted] (PX7060 (Naclerio (Illumina) IHT at 126-27) (*in camera*)).

Response to Finding No. 2630:

The proposed finding is inaccurate, incomplete and misleading. Although Dr. Naclerio left Illumina in 2016, the proposed finding appears to suggest that, even today, six years later, Illumina applies the same approach. This is incorrect.

[redacted]

Further, because the proposed finding relates to [redacted] the proposed finding relates to irrelevant subject matter because Illumina has subsequently committed to an Open Offer, the terms of which expressly address this issue. The terms of the Open Offer require that Illumina treat customers equitably relative to GRAIL and any other for-profit entity in terms of pricing. (deSouza (Illumina) Tr. 2402–03; PX0064 (Illumina) at 7–8.) Respondents also refer to PFF ¶¶ 1013–25. Under this universal pricing grid, customers receive most-favored-nations (MFN) pricing protections, which ensure that the customer has access to volume-based prices "that are no less favorable (i.e., the same or better) than" those provided to GRAIL. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 5, 7–8.) GRAIL also receives pricing under a universal pricing grid. (PFF ¶ 1016.5; Berry (Illumina) Tr. 894.)

The Open Offer also applies to "*all fields of use*, specifically excluding any use that (i) is not in accordance with the product's specifications or documentation (it being understood that specifications and documentation shall not undermine or limit Customer's rights under this Supply Agreement), (ii) is a reuse of a previously used consumable, (iii) is the disassembling, reverse-engineering, reverse-compiling, or reverse-assembling of the Supplied Product, (iv) is the separation, extraction, or isolation of components of consumables or other unauthorized analysis of the consumables, (v) gains access to or determines the methods of operation of the Supplied Product, or (vi) is the transfer to a third party of, or sub-licensing of, software or third-party software." (PX0064 (Illumina) at 3 (emphasis added).)

In any event, Respondents also note that the described pricing practice followed the standard market approach in the industry. [redacted]

[redacted] In his deposition, Dr. Naclerio similarly testified that "all supply agreements have some definition of a field of use in them. It is not uncommon to." (PX7060 (Naclerio Dep. 226).) Dr. Goswami testified that "field definition" is "very standard for any kind of contract . . . because it identifies what is allowable within a field"; "if there are any exclusions, they are called out as well, so each party knows exactly what it is getting as part of that contract". (Goswami (Illumina) Tr. 3234.)

The proposed finding relies on IH testimony, which respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2631. Dr. Naclerio testified that Illumina has included "field of use" restrictions in its supply agreements to "reserve the right to charge a higher test fee" in future markets that may develop with tests that "would be priced at a much higher price." (PX7060 (Naclerio (Illumina) IHT at 137)).

Response to Finding No. 2631:

The proposed finding is incomplete and misleading. Although Dr. Naclerio left Illumina in 2016, the proposed finding appears to suggest that, even today, six years later, Illumina applies the same approach. This is incorrect. Respondents incorporate their responses to CCFF ¶ 2630 herein.

The proposed finding relies on IH testimony, which respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2632. [redacted] (PX7057 (Flatley (Illumina) IHT at 95) (*in camera*); PX2241 (Illumina) at 001 [redacted]

Response to Finding No. 2632:

The proposed finding is incomplete and misleading. Although this letter dates to 2014, the proposed finding appears to suggest that, even today, eight years later, Illumina applies the same approach. This is incorrect. Respondents incorporate their responses to CCFF ¶¶ 2630–31 herein.

Respondents further note that Illumina's activity in the NIPT space had decidedly procompetitive effects in that market. Respondents also refer to Resps.' Post-Trial Br. at § II.F.1.

The proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2633. [redacted] (PX7060 (Naclerio (Illumina) IHT at 119-20, 186) (*in camera*)).

Response to Finding No. 2633:

The proposed finding is incomplete and misleading. Although Dr. Naclerio left Illumina in 2016, the proposed finding appears to suggest that, even today, six years later, Illumina applies the same approach. This is incorrect.

Specifically, [redacted]

[redacted]

[redacted] Respondents incorporate their responses to CCFF ¶¶ 2630–31 herein.

The proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2634. [redacted] (PX7060 (Naclerio (Illumina) IHT at 121) (*in camera*)).

Response to Finding No. 2634:

The proposed finding is incomplete and misleading. Although Dr. Naclerio left Illumina in 2016, the proposed finding appears to suggest that, even today, six years later, Illumina applies the same approach. This is incorrect.

[redacted] Respondents incorporate their responses to CCFF ¶¶ 2630–31 and 2633 herein.

Further, to the extent that the proposed finding relates to [redacted], the proposed finding relates to irrelevant subject matter because Illumina has subsequently committed to an Open Offer, the terms of which expressly address this issue. The terms of the Open Offer require that Illumina treat customers equitably relative to GRAIL and any other for-profit entity in terms of pricing. [redacted]; PX0064 (Illumina) at 7–8.) Respondents also refer to PFF ¶¶ 1013–25.

The proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2635. During supply agreement negotiations with [redacted] (*See* PX7076 (Berry (Illumina) Dep. at 258-66) (*in camera*); PX2301 (Illumina) at 001 [redacted] (*in camera*)).

Response to Finding No. 2635:

The proposed finding is incomplete and misleading without additional context. [redacted]

[redacted] Respondents also incorporate their response to CCFF ¶ 1089 herein.

In any event, while Mr. Elliott volunteered the above information, this information is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—including order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.)

Illumina also takes extensive precautions to protect the confidentiality of information it receives from developers including: (1) setting up confidentiality agreements with partners, (2)

training staff and requiring them to sign confidentiality agreements, (3) separating teams who might work on similar products, (4) using document control processes and (5) providing legal guidance if individuals request access to protected documents. (PFF ¶¶ 1040–1040.5; Goswami (Illumina) Tr. 3227–30.) These practices are standard in the industry and generally accepted by companies that serve multiple clients in the same industry. (PFF ¶ 1040.8; Goswami (Illumina) Tr. 3228–29.)

The Open Offer requires that to the extent that Illumina has access to customer confidential information, Illumina shall not share such information with GRAIL, any GRAIL subsidiary or any employee who works within GRAIL. (PFF ¶ 1038; [redacted]; Berry (Illumina) Tr. 916–17; PX0064 (Illumina) at 9.)

Under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (PFF ¶ 1039; [redacted] deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted] Respondents also incorporate their responses to CCFF ¶¶ 1089 and 2612 herein.

The terms of the Open Offer require that Illumina treat customers equitably relative to GRAIL and any other for-profit entity in terms of pricing. (deSouza (Illumina) Tr. 2402–03; PX0064 (Illumina) at 7–8.) Respondents also refer to PFF ¶¶ 1013–25. Under this universal pricing grid, customers receive most-favored-nations (MFN) pricing protections, which ensure that the customer has access to volume-based prices "that are no less favorable (i.e., the same or better) than" those provided to GRAIL. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 5, 7–8.) GRAIL also receives pricing under a universal pricing grid. (PFF ¶ 1016.5; Berry (Illumina) Tr. 894.)

The Open Offer also applies to "*all fields of use*, specifically excluding any use that (i) is not in accordance with the product's specifications or documentation (it being understood that specifications and documentation shall not undermine or limit Customer's rights under this Supply Agreement), (ii) is a reuse of a previously used consumable, (iii) is the disassembling, reverse-engineering, reverse-compiling, or reverse-assembling of the Supplied Product, (iv) is the separation, extraction, or isolation of components of consumables or other unauthorized analysis of the consumables, (v) gains access to or determines the methods of operation of the Supplied Product, or (vi) is the transfer to a third party of, or sub-licensing of, software or third-party software." (PX0064 (Illumina) at 3 (emphasis added).)

2636. [redacted] (Berry (Illumina) Tr. 771-73) (*in camera*)).

Response to Finding No. 2636:

The proposed finding is incomplete and misleading. [redacted]

In any event, [redacted] Respondents also refer to RRFF ¶ 2633.

Further, to the extent that the proposed finding relates to [redacted] the proposed finding relates to irrelevant subject matter because Illumina has subsequently committed to an Open Offer, the terms of which expressly address this issue.. The terms of the Open Offer require that Illumina treat customers equitably relative to GRAIL and any other for-profit entity in terms of pricing. (deSouza (Illumina) Tr. 2402–03; PX0064 (Illumina) at 7–8.) Respondents also refer to PFF ¶¶ 1013–25. Under this universal pricing grid, customers receive most-favored-nations (MFN) pricing protections, which ensure that the customer has access to volume-based prices "that are no less favorable (i.e., the same or better) than" those provided to GRAIL. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 5, 7–8.) GRAIL also receives pricing under a universal pricing grid. (PFF ¶ 1016.5; Berry (Illumina) Tr. 894.)

Respondents incorporate their responses to CCFF ¶¶ 1089, 2612, 2630–31 and 2633 herein.

2637. [redacted] (PX8387 (Exact) at 001 [redacted] (*in camera*)).

Response to Finding No. 2637:

Respondents have no specific response, except to note that the cited source provides support for the proposition that *Exact*, not *Illumina*, sought to obtain special discounts that were product-specific. Respondents incorporate their responses to CCFF ¶¶ 1089 and 2636 herein.

Further, because the proposed finding relates to [redacted], the proposed finding relates to irrelevant subject matter because Illumina has subsequently committed to an Open Offer, the terms of which expressly address this issue. The terms of the Open Offer require that Illumina treat customers equitably relative to GRAIL and any other for-profit entity in terms of pricing. (deSouza (Illumina) Tr. 2402–03; PX0064 (Illumina) at 7–8.) Respondents also refer to PFF ¶¶ 1013–25. Respondents also refer to PFF ¶¶ 1013–25. Under this universal pricing grid, customers receive most-favored-nations (MFN) pricing protections, which ensure that the customer has access to volume-based prices "that are no less favorable (i.e., the same or better) than" those provided to GRAIL. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 5, 7–8.) GRAIL also receives pricing under a universal pricing grid. (PFF ¶ 1016.5; Berry (Illumina) Tr. 894.)

2638. [redacted] (PX7058 (Conroy (Exact) IHT at 229-30) (*in camera*)).

Response to Finding No. 2638:

Respondents have no specific response, except to note that the the Open Offer requires Illumina, on a customer's request, to enter into a separate agreement with the customer based on standardized terms to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33; [redacted] deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; PX0087 (Illumina); PX0088 (Illumina); PX0089 (Illumina); [redacted]) These requirements in the Open Offer prevent Illumina from withholding support as putative MCED test developers seek FDA approval. (PFF ¶ 1035; RX6002 (Guerin-Calvert Trial Dep. at 74).)

Dr. Goswami testified that an IVD kit offering is extremely rare; due to the burdens associated with IVD kits, developers tend to stay with an LDT model instead of seeking to provide an IVD kit. For example, Exact Sciences' Cologuard test has not been offered as an IVD kit. (Goswami (Illumina) Tr. 3196.)

Respondents also note that features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (PFF ¶¶ 675–678.5 (RX3869 (Cote Expert Report) ¶¶ 359–363; Goswami (Illumina) Tr. 3189–92, 3194–95).) Respondents also incorporate their responses to CCFF ¶¶ 1089, 2612, 2617, 2620 and 2636 herein.

The proposed finding relies on IH testimony, which respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2639. [redacted]

(PX7076 (Berry (Illumina) Dep. at 260-61) (*in camera*)).

Response to Finding No. 2639:

The proposed finding is incomplete and misleading. [redacted]

Second, [redacted] Respondents incorporate their responses to CCFF ¶¶ 1089, 2630 and 2636 herein.

Further, because the proposed finding relates to [redacted] the proposed finding relates to irrelevant subject matter because Illumina has subsequently committed to an Open Offer, the terms of which expressly address this issue. The terms of the Open Offer require that Illumina treat customers equitably relative to GRAIL and any other for-profit entity in terms of pricing. (deSouza (Illumina) Tr. 2402–03; PX0064 (Illumina) at 7–8.) Respondents also refer to PFF ¶¶ 1013–25. Under this universal pricing grid, customers receive most-favored-nations (MFN) pricing protections, which ensure that the customer has access to volume-based prices "that are no less favorable (i.e., the same or better) than" those provided to GRAIL. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 5, 7–8.) GRAIL also receives pricing under a universal pricing grid. (PFF ¶ 1016.5; Berry (Illumina) Tr. 894.)

2640. Singlera's Dr. Gao explained that Singlera had to tell Illumina about its PanSeer test while negotiating a contract: "We – in order to do this negotiation [with Illumina], we had to tell them what we are using it for, so they understand the customer need." (PX7042 (Gao (Singlera) IHT at 81)).

Response to Finding No. 2640:

The proposed finding is incomplete and misleading, and contradicted by the weight of the evidence. In the portion of his IH cited here, Dr. Gao testified to facts that indicate that his characterization of Singlera's relationship with Illumina has no basis. For example, Dr. Gao testified that once Singlera seriously began pursuing a supply agreement with Illumina, Illumina "quickly turn[ed] around a draft proposal of [a] supply agreement", which was a "standard boilerplate" agreement. (PX7042 (Gao (Singlera) IHT at 74–75).) Dr. Gao testified that Singlera was "happy" to receive a standardized agreement because Singlera's "only request [was] to have a standard supply agreement". (PX7042 (Gao (Singlera) IHT at 75).) Finally, Dr. Gao admitted that Illumina "provided us with [a draft supply agreement], expect[ed] us to negotiate I'm sure, but we never went back" to negotiate with Illumina. (PX7042 (Gao (Singlera) IHT at 87).) Thus, Dr. Gao's testimony shows that, after Singlera proposed entering a supply agreement with Illumina, Illumina sent a boilerplate agreement, which was exactly what Singlera wanted, and yet Singlera refused to even engage with Illumina on the draft agreement. Therefore, Dr. Gao's recounting of his negotiations with Illumina are unreliable and should be accorded no weight.

As Ms. Berry explained, Illumina supplies "general-purpose reagents that enable a sample that's prepared in an infinite number, hundreds and hundreds and hundreds, of different ways to be read by our sequencer." (Berry (Illumina) Tr. 845.) But, as Berry explained, "we don't get into designing assays with customers." (Berry (Illumina) Tr. 845.)

Further, although Illumina may have an understanding of the types of applications a customer is developing or marketing, in many cases it does not know what specific tests are in its customers' development pipeline. (Berry (Illumina) Tr. 849–53.) For example, many of the

MCED tests Complaint Counsel claims are in development are unknown to Illumina even today—much less their specific attributes that would allow Illumina to predict with confidence whether any test will be a close substitute to Galleri, or, instead, a market-expanding complement, foreclosure of which would cause no material diversion to Galleri but would result in substantial lost upstream sales. (RX6000 (Carlton Trial Dep. at 24, 26–27).)

In any event, this information is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—including order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.)

Illumina also takes extensive precautions to protect the confidentiality of information it receives from developers including: (1) setting up confidentiality agreements with partners, (2) training staff and requiring them to sign confidentiality agreements, (3) separating teams who might work on similar products, (4) using document control processes and (5) providing legal guidance if individuals request access to protected documents. (PFF ¶¶ 1040–1040.5; Goswami (Illumina) Tr. 3227–30.) These practices are standard in the industry and generally accepted by companies that serve multiple clients in the same industry. (PFF ¶ 1040.8; Goswami (Illumina) Tr. 3228–29.)

The Open Offer requires that to the extent that Illumina has access to customer confidential information, Illumina shall not share such information with GRAIL, any GRAIL subsidiary or any employee who works within GRAIL. (PFF ¶ 1038; [redacted]; Berry (Illumina) Tr. 916–17; PX0064 (Illumina) at 9.)

Under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (PFF ¶ 1039; [redacted] deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted])

The proposed finding relies on IH testimony, which respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2641. Singlera's Dr. Gao explained that as part of supply agreement negotiations, Singlera told Illumina that Singlera planned to seek FDA approval for its ColonES test. (PX7042 (Gao (Singlera) IHT at 81-82)).

Response to Finding No. 2641:

The proposed finding is incomplete and misleading, and contradicted by the weight of the evidence. In the portion of his IH cited here, Dr. Gao testified to facts that indicate that his characterization of Singlera's relationship with Illumina has no basis. For example, Dr. Gao testified that once Singlera seriously began pursuing a supply agreement with Illumina, Illumina "quickly turn[ed] around a draft proposal of [a] supply agreement", which was a "standard boilerplate" agreement. (PX7042 (Gao (Singlera) IHT at 74–75).) Dr. Gao testified that Singlera was "happy" to receive a standardized agreement because Singlera's "only request [was] to have a standard supply agreement". (PX7042 (Gao (Singlera) IHT at 75).) Finally, Dr. Gao admitted that Illumina "provided us with [a draft supply agreement], expect[ed] us to negotiate I'm sure, but we never went back" to negotiate with Illumina. (PX7042 (Gao (Singlera) IHT at 87).) Thus, Dr. Gao's testimony shows that, after Singlera proposed entering a supply agreement with Illumina, Illumina sent a boilerplate agreement, which was exactly what Singlera wanted, and yet Singlera refused to even engage with Illumina on the draft agreement.

Therefore, Dr. Gao's recounting of his negotiations with Illumina are unreliable and should be accorded no weight.

The proposed finding is also misleading to the extent it suggests that Illumina requires information from Singlera about its products to enter into a supply agreement. In the ordinary course of business, Illumina's customers may volunteer high-level information about their tests to Illumina. Illumina does not require customers to report that information, and Illumina does not solicit detailed, technical information from its customers. Respondents also incorporate their responses to CCFF ¶¶ 1174, 2617, 2620 and 2640 herein.

The proposed finding relies on IH testimony, which respondents had no opportunity to cross examine, and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

2642. Singlera's Dr. Gao testified that in supply agreement negotiations with Illumina, Illumina proposed different fees for Singlera's different uses of Illumina sequencers. For example, Illumina proposed a cap of $4 million in market access fees relating to colorectal cancer tests, but a cap of $10 million in market access fees relating to pan-cancer testing. (PX7042 (Gao (Singlera) IHT at 78-80)).

Response to Finding No. 2642:

The proposed finding is incomplete and misleading, and contradicted by the weight of the evidence. In the portion of his IH cited here, Dr. Gao testified to facts that indicate that his characterization of Singlera's relationship with Illumina has no basis. For example, Dr. Gao testified that once Singlera seriously began pursuing a supply agreement with Illumina, Illumina "quickly turn[ed] around a draft proposal of [a] supply agreement", which was a "standard boilerplate" agreement. (PX7042 (Gao (Singlera) IHT at 74–75).) Dr. Gao testified that Singlera was "happy" to receive a standardized agreement because Singlera's "only request [was] to have a standard supply agreement". (PX7042 (Gao (Singlera) IHT at 75).) Finally, Dr. Gao admitted that Illumina "provided us with [a draft supply agreement], expect[ed] us to

negotiate I'm sure, but we never went back" to negotiate with Illumina. (PX7042 (Gao (Singlera) IHT at 87).) Thus, Dr. Gao's testimony shows that, after Singlera proposed entering a supply agreement with Illumina, Illumina sent a boilerplate agreement, which was exactly what Singlera wanted, and yet Singlera refused to even engage with Illumina on the draft agreement. Therefore, Dr. Gao's recounting of his negotiations with Illumina are unreliable and should be accorded no weight.

Dr. Gao's testimony is unsubstantiated as he does not explain what products he is referring to or what prices, or even what timeframe he is describing. In any event, the practices articulated in Dr. Gao's testimony, to the extent they existed, have been preempted by the Open Offer.

Illumina does not charge market access fees for colorectal cancer tests or for tests for pan-cancer testing and has never charged such fees. (*See, e.g.*, PX7093 (Young (Illumina) Dep.) at 31–32 (explaining distinct, oncology customer fee structure applicable to IVD agreements).**)** The Open Offer does not describe any such fees. (PX0064 (Illumina).). To the contrary, the Open Offer applies a universal grid under which all customers, regardless of application, pays the same price for sequencing. (PX0064 (Illumina) 6–7.) Respondents also incorporate their responses to CCFF ¶ 2640 herein.

The proposed finding relies on IH testimony, which respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2643. [redacted] (PX7040 (Getty (Guardant) IHT at 88-89) (*in camera*)).

Response to Finding No. 2643:

The proposed finding relates to irrelevant subject matter because the concerns articulated in the cited testimony have been preempted by the terms of the Open Offer.

The Open Offer requires Illumina, on a customer's request, to enter into a separate agreement with the customer based on standardized terms to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33; [redacted] deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; PX0087 (Illumina); PX0088 (Illumina); PX0089 (Illumina); [redacted] These requirements in the Open Offer prevent Illumina from withholding support as putative MCED test developers seek FDA approval. (PFF ¶ 1035; RX6002 (Guerin-Calvert Trial Dep. at 74).)

The proposed finding relies on IH testimony, which respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2644. Mr. Getty testified that if Guardant were to order 10 new sequencers from Illumina, it would give Illumina a "very clear perspective[] that [Guardant was] expanding [its] business." (PX7105 (Getty (Guardant) Dep. at 97-99)).

Response to Finding No. 2644:

The proposed finding is incomplete and misleading. The purchase of additional sequencers does not, by itself, conclusively evidence an intention to expand a business. Moreover, Complaint Counsel has adduced no evidence that Illumina has or would analyze such information systematically.

Further, this information is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—including order history, pending purchase orders and order forecasts—including employee

training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.) Respondents also incorporate their responses to CCFF ¶ 1612 herein.

2645. Invitae's CEO Sean George testified that Illumina seeks different prices for its products depending on what Invitae intends to use Illumina's sequencers for. (PX7046 (George (Invitae) IHT at 67-73, 121)).

Response to Finding No. 2645:

The proposed finding is incomplete and misleading. The proposed finding is incomplete and misleading. Mr. George's testimony is unsubstantiated as he does not explain what products he is referring to or what prices, or even what timeframe he is describing. (PX7046 (George (Invitae) IHT) at 67–73; 121.) Moreover, Mr. George conceded that "most companies" differentiate price "in the context of geographies or channels or cost of doing business in a given area". (PX7046 (George (Invitae) IHT) at 71.) In any event, the practices articulated in Mr. George's testimony, to the extent they existed, have been preempted by the Open Offer.

Further, because the proposed finding relates to [redacted] the proposed finding relates to irrelevant subject matter because Illumina has subsequently committed to an Open Offer, the terms of which expressly address this issue. The terms of the Open Offer require that Illumina treat customers equitably relative to GRAIL and any other for-profit entity in terms of pricing. (deSouza (Illumina) Tr. 2402–03; PX0064 (Illumina) at 7–8.) Respondents also refer to PFF ¶¶ 1013–25. Under this universal pricing grid, customers receive most-favored-nations (MFN) pricing protections, which ensure that the customer has access to volume-based prices "that are no less favorable (i.e., the same or better) than" those provided to GRAIL. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 5, 7–8.) GRAIL also receives pricing under a universal pricing grid. (PFF ¶ 1016.5; Berry (Illumina) Tr. 894.)

The proposed finding relies on IH testimony, which respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2646. Invitae's Megan Bailey testified that Illumina requires Invitae to provide information on its development plans to Illumina as part of Invitae's IVD agreement, including "the scope of [Invitae's] studies, . . . the number of samples, what data parameters [Invitae] will look at, [and] some aspects of the study protocols needed to validate the kit." (PX7049 (Bailey (Invitae) IHT at 130-31)).

Response to Finding No. 2646:

The proposed finding is inaccurate and misleading, including because it states that Megan Bailey is affiliated with Invitae. Megan Bailey is the CEO of PGDx. Respondents will respond to CCFF as if it referred to PGDx.

The proposed finding is also irrelevant. [redacted] (RX3869 (Cote Expert Report) ¶¶ 359–363; Goswami (Illumina) Tr. 3189–92, 3194–95).)

Even if Ms. Bailey's testimony related to an IVD for a distributed kit version of an MCED test, which is not part of any putative MCED test developer's plan for the foreseeable future, it appears to relate to standard terms that are used by all IVD platform developers and is not limited to Illumina. [redacted]

[redacted] Such information is necessary for Illumina to ensure that a given test is compatible with its FDA-approved sequencers and that support is available. (Goswami (Illumina) Tr. 3219–20, 3226–27.) For example, if a given test developer is seeking to develop a test with capabilities that Illumina's NextSeqDx does not have, Illumina will need to let the test developer know so that the test developer can pursue its options with either a different test or with a different sequencing platform that can meet their needs.

In any event, Illumina takes extensive precautions to protect the confidentiality of information it receives from developers including: (1) setting up confidentiality agreements with partners, (2) training staff and requiring them to sign confidentiality agreements, (3) separating teams who might work on similar products, (4) using document control processes and (5) providing legal guidance if individuals request access to protected documents. (PFF ¶¶ 1040–1040.5; Goswami (Illumina) Tr. 3227–30.) These practices are standard in the industry and generally accepted by companies that serve multiple clients in the same industry. (PFF ¶ 1040.8; Goswami (Illumina) Tr. 3228–29.)

The Open Offer requires that to the extent that Illumina has access to customer confidential information, Illumina shall not share such information with GRAIL, any GRAIL subsidiary or any employee who works within GRAIL. (PFF ¶ 1038; (Rabinowitz (Natera) Tr. 425; Berry (Illumina) Tr. 916–17; PX0064 (Illumina) at 9.)

Under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (PFF ¶ 1039; [redacted] deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted]

The proposed finding relies on IH testimony, which respondents had no opportunity to cross examine, and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

2647. Invitae's Megan Bailey testified that revenue share reporting requirements in Invitae's IVD agreement with Illumina could provide Illumina the opportunity to extrapolate Invitae's pricing strategy. (PX7049 (Bailey (Invitae) IHT at 132-33)).

Response to Finding No. 2647:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2647, which Respondents incorporate herein.

The proposed finding relies on IH testimony, which respondents had no opportunity to cross examine, and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

2648. Kenneth Chahine, former Ancestry Executive VP, testified that when Ancestry sought to launch a health business, it informed Illumina of the change and requested to have Illumina perform NGS processing on Ancestry's health-related samples, similar to the way Illumina already processed Ancestry's genealogy samples on microarrays. (PX7077 (Chahine (Helio) Dep. at 72)). Illumina refused to process Ancestry's health-related samples on NGS because of a conflict with Illumina's relationship with another company, Helix. (PX7077 (Chahine (Helio) Dep. at 72-74)).

Response to Finding No. 2648:

The proposed finding is incomplete and misleading. [redacted] Accordingly, the concerns cited by Complaint Counsel were time-limited and were not borne out by subsequent developments.

The proposed finding relies on IH testimony, which respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(iii) Illumina Learns about Its Customers' Products and Development Plans from Public Information

2649. Ken Song, former CEO of Ariosa Diagnostics, testified that Ariosa provided Illumina with "a fair amount of detail" regarding Ariosa's operations, in part because Illumina was an "important strategic supplier" for Ariosa's NIPT business. (PX7071 (Song (Omniome) IHT at 65)). During meetings where Ariosa provided Illumina with "confidential update[s] on [Ariosa's] progress, what [Ariosa] thought about putting in the tests, the cost structure, launch plans, [and] future product development plans," the Illumina personnel responsible for negotiating Ariosa's supply agreement were present. (PX7071 (Song (Omniome) IHT at 71-72)).

Response to Finding No. 2649:

The proposed finding is inaccurate and misleading. In the ordinary course of business, Illumina's customers may volunteer high-level information about their tests to Illumina. Illumina does not require customers to report that information, and Illumina does not solicit detailed, technical information from its customers. As Ms. Berry explained, "we don't get into designing assays with customers." (Berry (Illumina) Tr. 845.) Respondents also incorporate their responses to CCFF ¶¶ 2612, 2617 and 2620 herein.

Further, although Illumina may have an understanding of the types of applications a customer is developing or marketing, in many cases it does not know what specific tests are in its customers' development pipeline. (Berry (Illumina) Tr. 849–53.) For example, many of the MCED tests Complaint Counsel claims are in development are unknown to Illumina even today—much less their specific attributes that would allow Illumina to predict with confidence whether any test will be a close substitute to Galleri, or, instead, a market-expanding complement, foreclosure of which would cause no material diversion to Galleri but would result in substantial lost upstream sales. (RX6000 (Carlton Trial Dep. at 24, 26–27).)

In any event, this information is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—including order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.)

Illumina also takes extensive precautions to protect the confidentiality of information it receives from developers including: (1) setting up confidentiality agreements with partners, (2) training staff and requiring them to sign confidentiality agreements, (3) separating teams who might work on similar products, (4) using document control processes and (5) providing legal guidance if individuals request access to protected documents. (PFF ¶¶ 1040–1040.5; Goswami (Illumina) Tr. 3227–30.) These practices are standard in the industry and generally accepted by companies that serve multiple clients in the same industry. (PFF ¶ 1040.8; Goswami (Illumina) Tr. 3228–29.)

The Open Offer requires that to the extent that Illumina has access to customer confidential information, Illumina shall not share such information with GRAIL, any GRAIL subsidiary or any employee who works within GRAIL. (PFF ¶ 1038; [redacted] Berry (Illumina) Tr. 916–17; PX0064 (Illumina) at 9.)

Under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (PFF ¶ 1039; [redacted]; deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted].)

The proposed finding relies on IH testimony, which respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2650. Dr. Song testified that during negotiations relating to Ariosa's supply agreement with Illumina, Ariosa and Illumina discussed the specific allowable uses of Ariosa's NIPT offerings. (PX7071 (Song (Omniome) IHT at 73-77)).

Response to Finding No. 2650:

The proposed finding is inaccurate, incomplete, and misleading. Although Dr. Song worked at Ariosa until 2015 (at which point Ariosa was acquired by Roche) and the negotiations that he refers to took place in 2013-2014, the proposed finding appears to suggest that, even today, seven years later, Illumina applies the same approach. This is incorrect.

At the time that Ariosa negotiated the supply agreement, there was a lot of uncertainty about whether Illumina would be permitted to sell sequencing instruments and core consumables for clinical uses. (*See* PX7060 (Naclerio (Illumina) Dep. at 150–52).) Specifically, NIPT was the first clinical area which used Illumina's sequencing instruments and core consumables, and there was uncertainty about whether the same research-use only products could be used for clinical uses or whether Illumina would need to develop higher quality reagents for clinical applications. (*See* PX7060 (Naclerio (Illumina) Dep. at 150–52).) To avoid running afoul of the FDA regulations, in these early agreements, Illumina restricted the potential fields of use in early agreements. Respondents also incorporate their responses to RRFF ¶¶ 2630–32 herein.

Further, because the proposed finding relates to [redacted] the proposed finding relates to irrelevant subject matter because Illumina has subsequently committed to an Open Offer, the terms of which expressly address this issue. The terms of the Open Offer require that Illumina treat customers equitably relative to GRAIL and any other for-profit entity in terms of pricing. (deSouza (Illumina) Tr. 2402–03; PX0064 (Illumina) at 7–8.) Respondents also refer to PFF ¶¶ 1013–25. Under this universal pricing grid, customers receive most-favored-nations (MFN) pricing protections, which ensure that the customer has access to

volume-based prices "that are no less favorable (i.e., the same or better) than" those provided to GRAIL. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 5, 7–8.) GRAIL also receives pricing under a universal pricing grid. (PFF ¶ 1016.5; Berry (Illumina) Tr. 894.)

The proposed finding relies on IH testimony, which respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2651. Ms. Berry testified that Illumina learns of customers' activities from customers' public disclosures. (PX7076 (Berry (Illumina) Dep. at 54-55, 57-58)).

Response to Finding No. 2651:

Respondents have no specific response except to state that the cited testimony shows that Illumina learns information about its customers through widely distributed, public-facing material. Respondents further note that the proposed finding does not evidence any particular ability to identify and/or discriminate against alleged rivals.

In any event, GRAIL acting alone—in fact, any test developer—can use public information, including public announcements and publications to glean information about other test developers' progress in developing putative MCED tests. Thus, Illumina has no special advantage in obtaining this information about GRAIL's putative rivals. Respondents also incorporate their responses to CCFF ¶ 2612 herein.

2652. Illumina identifies many of its customers that are buying its products for the purpose of developing or performing oncology tests through public information. (Berry (Illumina) Tr. 655-56). For example, Illumina reviews company websites and regulatory filings to gather this information. (Berry (Illumina) Tr. 655-56).

Response to Finding No. 2652:

Respondents have no specific response except to state that the cited testimony shows that Illumina may learn information about its customers through widely distributed, public-facing

material. Respondents further note that the proposed finding does not evidence any particular ability to identify and/or discriminate against alleged rivals.

In any event, GRAIL acting alone—in fact, any test developer—can use public information, including company websites and regulatory information to glean information about other test developers' progress in developing putative MCED tests. Thus, Illumina has no special advantage in obtaining this information about GRAIL's putative rivals. Respondents also incorporate their responses to CCFF ¶ 2612 herein.

2653. Ms. Berry testified that she's aware of which companies purchase Illumina products for use with oncology tests based on public information as well as her interactions with customers. (PX7063 (Berry (Illumina) IHT at 34-35)).

Response to Finding No. 2653:

The proposed finding is incomplete and misleading. In the ordinary course of business, Illumina's customers may volunteer high-level information about their tests to Illumina. Illumina does not require customers to report that information, and Illumina does not solicit detailed, technical information from its customers. As Ms. Berry explained, "we don't get into designing assays with customers." (Berry (Illumina) Tr. 845.) Respondents also incorporate their responses to CCFF ¶¶ 2612, 2617 and 2620 herein.

Respondents further note that the proposed finding does not evidence any particular ability to identify and/or discriminate against alleged rivals.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2654. Illumina CEO Francis deSouza testified at trial that Illumina tracks investment activity in MCED testing companies. (deSouza (Illumina) Tr. 2392).

Response to Finding No. 2654:

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted] Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–06) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Respondents also state that the cited testimony shows that Illumina may learn information about putative cancer screening test developers using widely available, public-facing material. Respondents further note that the proposed finding does not evidence any particular ability to identify and/or discriminate against alleged rivals. Respondents also incorporate their responses to CCFF ¶¶ 2612 and 4201 herein.

2655. [redacted] (deSouza (Illumina) Tr. 2429; PX7072 (deSouza (Illumina) IHT at 243-44) (*in camera*)).

Response to Finding No. 2655:

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future**.** [redacted]

[redacted] and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Respondents also note that [redacted] In the ordinary course of business, Illumina's customers may volunteer high-level information about their tests to Illumina. Illumina does not require customers to report that information, and Illumina does not solicit detailed, technical information from its customers. As Ms. Berry explained, "we don't get into designing assays with customers." (Berry (Illumina) Tr. 845.)

Further, although Illumina may have an understanding of the types of applications a customer is developing or marketing, in many cases it does not know what specific tests are in its customers' development pipeline. (Berry (Illumina) Tr. 849–53.) For example, many of the MCED tests Complaint Counsel claims are in development are unknown to Illumina even today—much less their specific attributes that would allow Illumina to predict with confidence whether any test will be a close substitute to Galleri, or, instead, a market-expanding complement, foreclosure of which would cause no material diversion to Galleri but would result in substantial lost upstream sales. (RX6000 (Carlton Trial Dep. at 24, 26–27).)

In any event, this information is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—including order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.)

Respondents also incorporate their responses to CCFF ¶¶ 2612 and 4201 herein.

2656. [redacted] (PX7072 (deSouza (Illumina) IHT at 125-26) (*in camera*)).

Response to Finding No. 2656:

Respondents have no specific response except to state that cited testimony shows that Illumina may learn information about potential MCED tests using widely available, public-facing material. Respondents further note that the proposed finding does not evidence any particular ability to identify and/or discriminate against alleged rivals.

In any event, GRAIL acting alone—in fact, any test developer—can use public information, including company websites and regulatory information to glean information about other test developers' progress in developing putative MCED tests. Thus, Illumina has no special advantage in obtaining this information about GRAIL's putative rivals. Respondents also incorporate their responses to CCFF ¶¶ 2612, 2655 and 4201 herein.

2657. [redacted] (PX7059 (Scagnetti (Illumina) IHT at 70-71) (*in camera*); PX5030 (Illumina) at 012 [redacted] (*in camera*)).

Response to Finding No. 2657:

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. [redacted] and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Respondents also states that the cited testimony shows that Illumina learns information about putative cancer screening test developers using widely available, public-facing material. Respondents further note that the proposed finding does not evidence any particular ability to identify and/or discriminate against alleged rivals.

In any event, GRAIL acting alone—in fact, any test developer—can use public information, including company websites and regulatory information to glean information about other test developers' progress in developing putative MCED tests. Thus, Illumina has no special advantage in obtaining this information about GRAIL's putative rivals. Respondents also incorporate their responses to CCFF ¶¶ 2612, 2655 and 4201 herein.

2658. [redacted] (PX7050 (Nolan (Freenome) IHT at 293-295) (*in camera*)).

Response to Finding No. 2658:

The proposed finding is inaccurate and misleading to the extent it suggests that a putative MCED test developer can begin clinical studies on a test *before* posting a clinical trial is posted to clinicaltrials.gov. To the extent there is any delay, it would be only a matter of days.

To the extent this unproven contention is true, it merely suggests that Illumina may learn some information about Freenome from public sources that Freenome itself has publicized. This is irrelevant and does not evidence any particular ability to identify and/or discriminate against alleged rivals.

In any event, GRAIL acting alone—in fact, any test developer—can use public information, including company websites and regulatory information to glean information about other test developers' progress in developing putative MCED tests. Thus, Illumina has no special advantage in obtaining this information about GRAIL's putative rivals. Respondents also incorporate their responses to CCFF ¶¶ 2612 and 4201 herein.

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Respondents also incorporate CCFF ¶¶ 405, 439–440, 444, 666, 698, 801, 806, 945, 1140, and 2355–2400 herein.

2659. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 92-93) (*in camera*)).

Response to Finding No. 2659:

Respondents have no specific response except to state that the proposed finding merely suggests that Illumina may learn some information about Thrive from public sources that Thrive

itself has publicized. This is irrelevant and does not evidence any particular ability to identify and/or discriminate against rivals.

In any event, GRAIL acting alone—in fact, any test developer—can use public information, including company websites and regulatory information to glean information about other test developers' progress in developing putative MCED tests. Thus, Illumina has no special advantage in obtaining this information about GRAIL's putative rivals. Respondents also incorporate their responses to CCFF ¶¶ 2612, 2655 and 4201 herein.

The proposed finding relies on IH testimony, which respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2660. [redacted]

Response to Finding No. 2660:

Respondents have no specific response except to state that the proposed finding is evidence that GRAIL learns information about putative MCED test developers using widely available, public-facing material. Respondents further note that the proposed finding does not evidence any particular ability to identify and/or discriminate against rivals. To the extent that Complaint Counsel relies on its proposed findings in Sections §§ III.C.5.c & VII.B.3.b (CCFF ¶¶ 792–95, 3389–3468), Respondents incorporate their responses to those Proposed Findings herein.

In any event, GRAIL acting alone—in fact, any test developer—can use public information, including company websites and regulatory information to glean information about other test developers' progress in developing putative MCED tests. Thus, Illumina has no

special advantage in obtaining this information about GRAIL's putative rivals. Respondents also incorporate their responses to CCFF ¶¶ 2612, 2655 and 4201 herein.

The proposed finding is also incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. [redacted] and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

(2) Illumina Has Tools to Track How Customers Use Illumina NGS Products and for What Downstream Product

(a) Illumina Learns about Its Customers' Products and Development Plans from Customers' Purchase History

2661. [redacted] (PX6056 (*in camera*)).

Response to Finding No. 2661:

The proposed finding is incomplete and misleading. While Illumina may request forecasting information, Ms. Berry testified that this is not required: order forecasting information is retained only for those customers who choose to disclose it. (Berry (Illumina) Tr. 849–50.)

Further, although Illumina may have an understanding of the types of applications a customer is developing or marketing, in many cases it does not know what specific tests are in its

customers' development pipeline. (Berry (Illumina) Tr. 849–53.) For example, many of the MCED tests Complaint Counsel claims are in development are unknown to Illumina even today—much less their specific attributes that would allow Illumina to predict with confidence whether any test will be a close substitute to Galleri, or, instead, a market-expanding complement, foreclosure of which would cause no material diversion to Galleri but would result in substantial lost upstream sales. (RX6000 (Carlton Trial Dep. at 24, 26–27).) Moreover, Illumina's instruments and consumables are multi-use products that can be and often are used by Illumina customers for a variety of sequencing applications. (PFF ¶¶ 6–11.)

In any event, this information is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—including order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.)

Illumina also takes extensive precautions to protect the confidentiality of information it receives from developers including: (1) setting up confidentiality agreements with partners, (2) training staff and requiring them to sign confidentiality agreements, (3) separating teams who might work on similar products, (4) using document control processes and (5) providing legal guidance if individuals request access to protected documents. (PFF ¶¶ 1040–1040.5; Goswami (Illumina) Tr. 3227–30.) These practices are standard in the industry and generally accepted by companies that serve multiple clients in the same industry. (PFF ¶ 1040.8; Goswami (Illumina) Tr. 3228–29.)

The Open Offer requires that to the extent that Illumina has access to customer confidential information, Illumina shall not share such information with GRAIL, any GRAIL

subsidiary or any employee who works within GRAIL. (PFF ¶ 1038; [redacted] (Illumina) Tr. 916–17; PX0064 (Illumina) at 9.)

Under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (PFF ¶ 1039; [redacted] deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted].)

2662. [redacted] (PX6056 (Illumina) at 050 [redacted] (*in camera*)).

Response to Finding No. 2662:

The proposed finding is incomplete and misleading without additional context. While Illumina may request forecasting information, Ms. Berry testified that this is not required: order forecasting information is retained only for those customers who choose to disclose it. (Berry (Illumina) Tr. 849–50.) Respondents also incorporate their responses to CCFF ¶ 2661 herein.

2663. Ms. Berry testified that Illumina can learn customers' end uses from their purchase history. (PX7076 (Berry (Illumina) Dep. at 54-57)).

Response to Finding No. 2663:

The proposed finding is incomplete and misleading For example, at trial, Ms. Berry testified as follows [redacted]

[redacted] (Berry (Illumina) Tr. 785–86.) Respondents also incorporate their responses to CCFF ¶¶ 2612 and 2661 herein.

2664. Illumina is able to learn its customers' end uses from purchase history because certain Illumina consumables are better suited for certain applications. (PX7076 (Berry (Illumina) Dep. at 54-57); PX7063 (Berry (Illumina) IHT at 220-221)).

Response to Finding No. 2664:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2612, 2661 and 2663, which Respondents incorporate herein.

2665. Ms. Berry testified that Illumina's relationships with its customers give Illumina insight into how its customers are using Illumina products. (*See* PX7076 (Berry (Illumina) Dep. at 54-57); PX6056 (Illumina) at 051 [redacted]).

Response to Finding No. 2665:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2612, 2661 and 2663, which Respondents incorporate herein.

2666. Ms. Berry testified that the volume of samples a customer requires and therefore the volume of reagents purchased could increase if the customer is pursuing a clinical trial or commercializing a product. (Berry (Illumina) Tr. 664-65; PX7076 (Berry (Illumina) Dep. at 24)).

Response to Finding No. 2666:

Respondents have no specific response, except to note that a clinical trial or intended commercialization are not the only reasons that a customer might purchase a higher volume of reagents. Accordingly, this information would support at most a conjectural assessment of

another test developer's progress. . Respondents also incorporate their responses to CCFF ¶¶ 2612, 2661 and 2663 herein.

2667. [redacted] (*See* PX7076 (Berry (Illumina) Dep. at 24); PX7072 (deSouza (Illumina) IHT at 125-26) (*in camera*); PX2386 (Illumina) at 004 (Email from G. Shariat, Illumina, to N. Berry, Illumina, attaching Invitae 2020 NovaSeq Run Rate, Dec. 1, 2020) (*in camera*) ([redacted]).

Response to Finding No. 2667:

The proposed finding is incomplete and misleading. *First*, GRAIL acting alone—in fact, any test developer—can use public information, including public announcements and publications to glean information about other test developers' progress in developing MCED tests. Thus, Illumina has no special advantage in obtaining his information about GRAIL's putative rivals.

And, while Illumina may request forecasting information, Ms. Berry testified that this is not required: order forecasting information is retained only for those customers who choose to disclose it. (Berry (Illumina) Tr. 849–50.)

Second although Illumina may have an understanding of the types of applications a customer is developing or marketing, in many cases it does not know what specific tests are in its customers' development pipeline. (Berry (Illumina) Tr. 849–53.) For example, many of the MCED tests Complaint Counsel claims are in development are unknown to Illumina even today—much less their specific attributes that would allow Illumina to predict with confidence whether any test will be a close substitute to Galleri, or, instead, a market-expanding complement, foreclosure of which would cause no material diversion to Galleri but would result in substantial lost upstream sales. (RX6000 (Carlton Trial Dep. at 24, 26–27).) Moreover,

Illumina's instruments and consumables are multi-use products that can be and often are used by Illumina customers for a variety of sequencing applications. (PFF ¶¶ 6–11.)

Third, this information is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—including order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.)

Illumina also takes extensive precautions to protect the confidentiality of information it receives from developers including: (1) setting up confidentiality agreements with partners, (2) training staff and requiring them to sign confidentiality agreements, (3) separating teams who might work on similar products, (4) using document control processes and (5) providing legal guidance if individuals request access to protected documents. (PFF ¶¶ 1040–1040.5; Goswami (Illumina) Tr. 3227–30.) These practices are standard in the industry and generally accepted by companies that serve multiple clients in the same industry. (PFF ¶ 1040.8; Goswami (Illumina) Tr. 3228–29.)

The Open Offer requires that to the extent that Illumina has access to customer confidential information, Illumina shall not share such information with GRAIL, any GRAIL subsidiary or any employee who works within GRAIL. (PFF ¶ 1038; [redacted] Berry (Illumina) Tr. 916–17; PX0064 (Illumina) at 9.)

Under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (PFF ¶ 1039; [redacted] deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted]

Accordingly, even if Illumina could access sufficiently detailed information about GRAIL's putative rivals (it cannot without the consent of the putative rival's consent), Illumina is prohibited from disclosing that information to GRAIL.

The proposed finding is also irrelevant. [redacted] (Stahl (Invitae) Dep. at 22, 44, [redacted])

Respondents also incorporate their responses to CCFF ¶¶ 2612, 2661 and 2663 herein.

2668. [redacted] (PX2314 (Illumina) at 002 (Email from C. Jennings, Illumina, to N. Berry, Illumina, Dec. 17, 2020 (*in camera*))).

Response to Finding No. 2668:

The proposed finding is incomplete and misleading.

[redacted]

[redacted] Therefore, it is improper to attempt to extrapolate from this email from a settlement agreement to Illumina's actions with respect to ordinary course purchases for sequencing instruments and consumables. Respondents also incorporate their responses to CCFF ¶¶ 2612, 2661 and 2663 herein.

2669. [redacted] (PX7063 (Berry (Illumina) IHT at 219) (*in camera*)).

Response to Finding No. 2669:

The proposed finding is incomplete and misleading. For example, at trial, Ms. Berry testified as follows [redacted] (Berry (Illumina) Tr. 785–86.) In any event, Complaint Counsel refers to an example relating to NIPT consumables, which are irrelevant to any determinations made by Illumina with respect to oncology or screening consumables. Respondents further note that the proposed finding does not evidence any particular ability to identify and/or discriminate against alleged rivals. Respondents also incorporate their responses to CCFF ¶¶ 2612, 2661 and 2663 herein.

The proposed finding relies on IH testimony, which respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2670. [redacted]

[redacted] (PX2227 (Illumina) at 006 (Email from J. Flatley, Illumina, to A. Pierce, Illumina, attaching NIPT Update, Jan. 24, 2014) (*in camera*) (*see* inset); *see also infra* Section VII.D.3. (Illumina Identified and Used Similar Tools in the NIPT Market)).

[redacted]

Response to Finding No. 2670:

The proposed finding is incomplete and misleading. The information shown in PX2227 is not from "selling the instrument consumable and service information Illumina kept as part of its customer sales." [redacted] (PX7079 (Flatley (Illumina) Dep. at 190–92); PX7089 (Naclerio (Illumina) Dep. at 58–59).) [redacted] (PX7089 (Naclerio (Illumina) Dep.) at 63–65.) Given that Illumina does not collect any test fee from any oncology test developer,

Illumina does not track the type of information shown in PX2227 for oncology customers and the proposed finding should be accorded little weight. (*See, e.g.*, PX7093 (Young (Illumina) Dep.) at 31–32 (explaining distinct, oncology customer fee structure applicable to IVD agreements).) Respondents further note that the proposed finding does not evidence any particular ability to identify and/or discriminate against alleged rivals. Respondents also incorporate their responses to CCFF ¶¶ 2612, 2661 and 2663 herein.

Complaint Counsel also did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 34), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

To the extent that Complaint Counsel relies on its Proposed Findings in Section VII.D.3 (CCFF ¶¶ 4081–4164), Respondents incorporate their responses to those Proposed Findings herein.

2671. [redacted] (PX7109 (Daly (Singular Genomics) Dep. at 59) (*in camera*)).

Response to Finding No. 2671:

The proposed finding is vague, incomplete and misleading. *First*, the cited testimony does not state what Illumina [redacted] It merely suggests that Illumina would know the volume of sequencing consumables and instruments that Thrive is purchasing, which is information that Illumina would come to know subsequently when Thrive made its next purchase. [redacted] Respondents

further note that the proposed finding does not evidence any particular ability to identify and/or discriminate against alleged rivals. Respondents also incorporate their responses to CCFF ¶¶ 2612, 2661 and 2663 herein.

Second, as noted in CCFF ¶ 2667, which Respondents incorporate herein, even if Illumina could access sufficiently detailed information about GRAIL's putative rivals (it cannot without the consent of the putative rival's consent), Illumina is prohibited from disclosing that information to GRAIL.

2672. [redacted] (PX7109 (Daly (Singular Genomics) Dep. at 58) (*in camera*)). [redacted] (PX7109 (Daly (Singular Genomics) Dep. at 58-59) (*in camera*)).

Response to Finding No. 2672:

The proposed finding is vague, incomplete and misleading. *First*, the cited testimony does not state what purported [redacted] Illumina would learn. It merely suggests that Illumina would know the volume of sequencing consumables and instruments that Thrive is purchasing, which is information that Illumina would come to know subsequently when Thrive made its next purchase. Respondents further note that the proposed finding does not evidence any particular ability to identify and/or discriminate against alleged rivals. Respondents also incorporate their responses to CCFF ¶¶ 2612, 2661 and 2663 herein.

Second, as noted in CCFF ¶ 2667, which Respondents incorporate herein, even if Illumina could access sufficiently detailed information about GRAIL's putative rivals (it cannot

without the consent of the putative rival's consent), Illumina is prohibited from disclosing that information to GRAIL.

Third, given that all oncology test developers are now receiving pricing under universal grid in the Open Offer (unless they have grandfathered pricing, which Thrive does not), all oncology test developers and members of the public have the same knowledge of their pricing structure that Illumina does. (PFF ¶ 1014; Berry (Illumina) Tr. 892; PX0064 (Illumina) at 7.) In addition, GRAIL also purchases instruments and consumables under the same universal grid in the Open Offer. (PX0064 (Illumina) at 8.)

(b) Illumina Learns about Its Customers' Products through Embedded Software in Its NGS Platforms

2673. Illumina CEO Mr. deSouza testified at trial that some Illumina customers' sequencers connect to Illumina via the internet to monitor the instrument or connect to Illumina's cloud-based data storage service. (deSouza (Illumina) Tr. 2383-85).

Response to Finding No. 2673:

The proposed finding is incomplete and misleading. Mr. deSouza was unequivocal in testifying that customers could run their sequencers with an "airgap"—that is, they can "completely just run it on their own and don't have any connection to the Internet at all." (deSouza (Illumina) Tr. 2383–84.) The Proactive monitoring service and the cloud storage services are both voluntary, opt-in programs for customers. (*See also* PX7076 (Berry (Illumina) Dep. at 30.) Respondents also note that it is "an important bright line" for Illumina to "never access or look at or review any customer's genomic data", which customers do not provide to Illumina even if they are connected to the Proactive service. (deSouza (Illumina) Tr. 2385.) Respondents also incorporate their responses to CCFF ¶¶ 2612 and 2678 herein.

2674. Mr. deSouza testified that customers' Illumina sequencers can connect to Illumina remotely in two ways. The instrument can connect to Illumina to provide Illumina instrumentation metrics and for Illumina to "monitor the health of the instrument and

proactively let [the customer] know if something is looking off." A customer also can connect its sequencers to Illumina's cloud-based data storage service. (deSouza (Illumina) Tr. 2383-85).

Response to Finding No. 2674:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2673, which Respondents incorporate herein. Respondents also note that it is "an important bright line" for Illumina to "never access or look at or review any customer's genomic data", which customers do not provide to Illumina even if they are connected to the Proactive service. (deSouza (Illumina) Tr. 2385.) Respondents also incorporate their responses to CCFF ¶¶ 2612 and 2678 herein.

2675. Ms. Berry explained that Illumina's customers can choose to turn on "Proactive," a data sharing software embedded in Illumina's instruments. (PX7076 (Berry (Illumina) Dep. at 30)).

Response to Finding No. 2675:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2673, which Respondents incorporate herein. Respondents also note that the cited testimony is evidence that the Proactive solution is a voluntary option, which customers are not required to use in order to reap the benefits of Illumina's technology. . Respondents also note that it is "an important bright line" for Illumina to "never access or look at or review any customer's genomic data", which customers do not provide to Illumina even if they are connected to the Proactive service. (deSouza (Illumina) Tr. 2385.) Respondents also incorporate their responses to CCFF ¶¶ 2612 and 2678 herein.

2676. By turning on Illumina's data-sharing Proactive software, a customer receives improved service from Illumina. (PX7076 (Berry (Illumina) Dep. at 36-37)).

Response to Finding No. 2676:

The proposed finding is incomplete and misleading without additional context. The extent of the "improved service" that a customer receives from using Proactive is the Proactive service itself. Proactive "allows Illumina to have visibility into specific instrument sort of physical states to try to understand when an instrument is likely to requires service." (Berry (Illumina) Tr. 850–852.) The only added service benefit to the Proactive user is a notice from Illumina that its machines are likely to require service. Respondents also note that it is "an important bright line" for Illumina to "never access or look at or review any customer's genomic data", which customers do not provide to Illumina even if they are connected to the Proactive service. (deSouza (Illumina) Tr. 2385.) Respondents also incorporate their responses to CCFF ¶ 2678 herein.

The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2612 and 2673, which Respondents incorporate herein.

2677. Ms. Berry testified that about 68 to 70 percent of Illumina instruments capable of connecting to Proactive are connected to the service. (Berry (Illumina) Tr. 853).

Response to Finding No. 2677:

Respondents have no specific response, except to note that the cited testimony is evidence that the Proactive service is voluntary and that customers opt-in to the information sharing service at a relatively high rate. Respondents also incorporate their responses to CCFF ¶ 2673 herein. Respondents note that this testimony, in turn, supports an inference that customers do not perceive significant privacy concerns arising out of the use of the Proactive service. Respondents also note that it is "an important bright line" for Illumina to "never access or look at or review any customer's genomic data", which customers do not provide to Illumina

even if they are connected to the Proactive service. (deSouza (Illumina) Tr. 2385.) Respondents also incorporate their responses to CCFF ¶¶ 2612 and 2678 herein.

2678. [redacted] (*See* PX7076 (Berry (Illumina) Dep. at 38-39); PX2386 (Illumina) at 004 (Email from G. Shariat, Illumina, to N. Berry, Illumina, attaching Invitae 2020 NovaSeq Run Rate, Dec. 1, 2020) (*in camera*) [redacted]

Response to Finding No. 2678:

The proposed finding is incomplete and misleading. Illumina collects three different types of instrument performance data as part of its Proactive program. The first category is "Run Performance data" which is "Q-scores, error rates and instrument operational logs". This category of data is used for "failure risk prediction" and "failure detection". The second category is "Instrument configuration data", which is "instrument serial number, [and] software version". This category of data is used for "run troubleshooting". The last category is "Run configuration data", which is "run parameters, reagent and flow cell lot numbers, primary analysis set-up and configuration". This category of data is used for "run troubleshooting". (RX1478 (Illumina) at 002 (Illumina Proactive Technical Note).) Respondents also note that it is "an important bright line" for Illumina to "never access or look at or review any customer's genomic data", which customers do not provide to Illumina even if they are connected to the Proactive service. (deSouza (Illumina) Tr. 2385.)

The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2612 and 2673, which Respondents incorporate herein.

2679. [redacted] (PX7055 (Otte (Freenome) IHT at 77) (*in camera*)).

Response to Finding No. 2679:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2673, which Respondents incorporate herein. In particular, if Mr. Otte contends [redacted], this shows that Freenome has *voluntarily and affirmatively* elected to use the Proactive service.

Respondents also note that it is "an important bright line" for Illumina to "never access or look at or review any customer's genomic data", which customers do not provide to Illumina even if they are connected to the Proactive service. (deSouza (Illumina) Tr. 2385.) Respondents also incorporate their responses to CCFF ¶¶ 2612 and 2678 herein.

2680. [redacted] (PX7109 (Daly (Singular Genomics) Dep. at 59-60) (*in camera*)).

Response to Finding No. 2680:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2673, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention, Illumina does not offer a [redacted] Illumina's Proactive tool collects a limited amount of data, none of which is reveals the genomic information or specific experiments that customers are conducting. Respondents also incorporate their responses to CCFF ¶¶ 2612 and 2678 herein.

2681. [redacted] (PX7109 (Daly (Singular Genomics) Dep. at 59-60) (*in camera*)).

Response to Finding No. 2681:

The proposed finding is inaccurate, incomplete and misleading. Proactive is a complimentary monitoring tool that customers can opt-in to using on their Illumina sequencers. Using Proactive does not result in discounts to customers. To the contrary, under the Open Offer, there is no purchase or status requirement to receive access to pricing under the universal grid. Under this universal pricing grid, customers receive most-favored-nations (MFN) pricing protections, which ensure that the customer has access to volume-based prices "that are no less favorable (i.e., the same or better) than" those provided to GRAIL. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 7–8.) For a customer who signs the Open Offer, if Illumina granted a discretionary discount to an equivalent customer or to GRAIL, "Illumina would be obliged to reduce the price to the [Open Offer signatory] to match the price that was offered to either GRAIL or an equivalent customer." (Berry (Illumina) Tr. 894.) The universal grid does not provide any discounts to customers for using Proactive. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 7–8.)

Contrary to Mr. Daly's unsubstantiated testimony, Respondents also note that it is "an important bright line" for Illumina to "never access or look at or review any customer's genomic data", which customers do not provide to Illumina even if they are connected to the Proactive service. (deSouza (Illumina) Tr. 2385.) As stated, the data to which Illumina has access is only instrument physical state data—things like the temperature of the instrument or the laser power, which is not competitively sensitive. Respondents also incorporate their responses to CCFF ¶¶ 2612 and 2678 herein.

2682. [redacted] (PX7109 (Daly (Singular Genomics) Dep. at 60-61) (*in camera*)).

Response to Finding No. 2682:

The proposed finding relates to irrelevant subject matter because a particular test developer's beliefs—founded on completely inaccurate factual assumptions about Illumina's Proactive feature—say nothing about whether Illumina could share sensitive sequencing data with GRAIL.

The extent of the "improved service" that a customer receives from using Proactive is the Proactive service itself. Proactive "allows Illumina to have visibility into specific instrument sort of physical states to try to understand when an instrument is likely to requires service." (Berry (Illumina) Tr. 850–852.) The only added service benefit to the Proactive user is a notice from Illumina that its machines are likely to require service. In any event, putative test developers are welcome to voluntarily opt-out of the Proactive system. Respondents incorporate their responses to CCFF ¶¶ 2612, 2673, 2676 and 2678 herein.

(c) Illumina Learns about Its Customers' Products and Development Plans from Servicing Its Customers

2683. [redacted] (PX7076 (Berry (Illumina) Dep. at 32-34) (*in camera*)).

Response to Finding No. 2683:

Respondents have no specific response, except to note that customers are not requires to supply specific, technical information to Illumina in the course of troubleshooting. Respondents further note that Illumina treats information relating to troubleshooting and "quality records" as confidential information. (Berry (Illumina) Tr. 850.) Accordingly, that data is subject to Illumina's rigorous data privacy restrictions, which include regular training and supervision by management, but also a need-to-know limitation on accessing data outside the purview of an

individual's role. (Berry (Illumina) Tr. 853–55.) Respondents also note that it is "an important bright line" for Illumina to "never access or look at or review any customer's genomic data", which customers do not provide to Illumina even if they are connected to the Proactive service. (deSouza (Illumina) Tr. 2385.)

Specifically, Illumina takes extensive precautions to protect the confidentiality of information it receives from developers including: (1) setting up confidentiality agreements with partners, (2) training staff and requiring them to sign confidentiality agreements, (3) separating teams who might work on similar products, (4) using document control processes and (5) providing legal guidance if individuals request access to protected documents. (PFF ¶¶ 1040–1040.5; Goswami (Illumina) Tr. 3227–30.) These practices are standard in the industry and generally accepted by companies that serve multiple clients in the same industry. (PFF ¶ 1040.8; Goswami (Illumina) Tr. 3228–29.)

The Open Offer requires that to the extent that Illumina has access to customer confidential information, Illumina shall not share such information with GRAIL, any GRAIL subsidiary or any employee who works within GRAIL. (PFF ¶ 1038; [redacted] Berry (Illumina) Tr. 916–17; PX0064 (Illumina) at 9.)

Under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (PFF ¶ 1039; [redacted]; deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted]) Respondents incorporate their responses to CCFF ¶¶ 2612, 2673, 2676 and 2678 herein.

2684. Ms. Berry testified that Illumina "may learn about . . . the market segment that the customer is wishing to use our products for, in a service and support interaction. It could be tech support . . . we may ask them some questions about, you know, what performance attributes

are important to you, and you know, the customer may or may not disclose to us specifics about their intended use." (PX7063 (Berry (Illumina) IHT at 35-36)).

Response to Finding No. 2684:

The proposed finding is incomplete and misleading. In the ordinary course of business, Illumina's customers may volunteer high-level information about their tests to Illumina. Illumina does not require customers to report that information, and Illumina does not solicit detailed, technical information from its customers. As Ms. Berry explained, "we don't get into designing assays with customers." (Berry (Illumina) Tr. 845.) The cited testimony also confirms that some customer choose not to disclose specifics about their intended use, which does not change Illumina's approach to that customer. (*See* (Berry (Illumina) Tr. 785–86 [redacted].)

Further, this information is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—including order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.) Respondents incorporate their responses to CCFF ¶¶ 2612, 2673, 2676 and 2678 herein.

2685. Ms. Berry testified at trial that Illumina also provides "troubleshooting" help to customers for issues with NGS instruments and "chemistry problem[s]." (Berry (Illumina) Tr. 846). Ms. Berry explained, "So, yeah, we -- we support the customer with respect to the pieces of the workflow whereby they're using, you know -- that are absolutely dependent on the Illumina -- the parts of the workflow that we provide essentially, so the core sequencing piece primarily." (Berry (Illumina) Tr. 846).

Response to Finding No. 2685:

The proposed finding is misleading.

First, the cited testimony confirms that Illumina's support to customers is cabined to the "core sequencing" activities, and that other activities are kept totally secret from Illumina. In particular all the parts of the workflow except for core sequencing are not provided by Illumina. (*See* Berry (Illumina) Tr. 814 (Illumina not used for blood or fluid sample collection), 815 (library preparation). 821–22 (analysis to identify the presence of cancer or other clinically relevant conclusion)). For example, Ms. Berry testified that in the commercial space, information about specific biomarkers is "very proprietary and secret, so we don't get into that, that type of support with customers in the commercial space typically". (Berry (Illumina) Tr. 846–47.)

Second, the proposed finding is misleading to the extent it suggests that customers always use Illumina for their core sequencing needs. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.)

2686. Guardant relies on Illumina for service and support, as well as for "customization and optimization of our reagents." (PX7105 (Getty (Guardant) Dep. at 60-62) ("Illumina provides support to us as a partner in sequencing" and "we rely on [Illumina] as we advance our technology. So more forward-looking technology aspects versus the day-to-day, you know, if we have, let's say, reagent X and reagent X needs to be customized, maybe in the future state, you know, reagent Y could be created through a partnership with Illumina.").

Response to Finding No. 2686:

The proposed finding is inaccurate, incomplete and misleading. At trial, Mr. Getty admitted that he "would not be the person to answer technical questions about the sequencers and reagents used by Guardant in its lab" and that he would "defer to Ms. Chudova on that". (Getty (Guardant) Tr. 2635.) [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 2614 and 2685 herein.

2687. [redacted] (PX7105 (Getty (Guardant) Dep. at 61-62) (*in camera*) [redacted]; PX7094 (Nolan (Freenome) Dep. at 156-157) (*in camera*) ([redacted])).

Response to Finding No. 2687:

Respondents have no specific response except to note that the Open Offer ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; [redacted]; Berry (Illumina) Tr. 865–66; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) The Open Offer also requires Illumina to provide customers with the same access to services that GRAIL or any other For-Profit Entity has access to, and at the same prices. (PFF ¶ 1004; [redacted] Berry (Illumina) Tr. 865–66; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.)

As Ms. Berry testified, "the open offer obligates Illumina to provide access to a customer to not only the same [product and support] services for which the customer had before the transaction but also any [product and support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.).

2688. [redacted] (PX7056 (Silvis (Tempus) IHT at 91-94) (*in camera*)).

Response to Finding No. 2688:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2621, which Respondents incorporate herein.

In the ordinary course of business, Illumina's customers may volunteer high-level information about their tests to Illumina. Illumina does not require customers to report that information, and Illumina does not solicit detailed, technical information from its customers. As Ms. Berry explained, "we don't get into designing assays with customers." (Berry (Illumina) Tr. 845.)

Further, although Illumina may have an understanding of the types of applications a customer is developing or marketing, in many cases it does not know what specific tests are in its customers' development pipeline. (Berry (Illumina) Tr. 849–53.) For example, many of the MCED tests Complaint Counsel claims are in development are unknown to Illumina even today—much less their specific attributes that would allow Illumina to predict with confidence whether any test will be a close substitute to Galleri, or, instead, a market-expanding complement, foreclosure of which would cause no material diversion to Galleri but would result in substantial lost upstream sales. (RX6000 (Carlton Trial Dep. at 24, 26–27).) Moreover, Illumina's instruments and consumables are multi-use products that can be and often are used by Illumina customers for a variety of sequencing applications. (PFF ¶¶ 6–11.)

Respondents also incorporate their responses to CCFF ¶¶ 2612, 2663 and 2684 herein.

The proposed finding relies on IH testimony, which respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(3) Illumina Has Used Its Tools to Identify MCED Test Customers

(a) Illumina's Customer Database and Supply Terms Classify Customers into Segments, Including Ones Related to MCED and Cancer Screening

2689. Illumina tracks every product that its customers order using databases containing customer order and shipment history, and prices. (Berry (Illumina) Tr. 647). Illumina also tracks the services that it provides to customers. (Berry (Illumina) Tr. 647).

Response to Finding No. 2689:

Respondents have no specific response, except to note that this information is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—including order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.)

Respondents also note that the proposed finding is irrelevant and does not evidence any particular ability to identify and/or discriminate against alleged rivals. Further, although Illumina may have an understanding of the types of applications a customer is developing or marketing, in many cases it does not know what specific tests are in its customers' development pipeline. (Berry (Illumina) Tr. 849–53.) For example, many of the MCED tests Complaint Counsel claims are in development are unknown to Illumina even today—much less their specific attributes that would allow Illumina to predict with confidence whether any test will be a close substitute to Galleri, or, instead, a market-expanding complement, foreclosure of which would cause no material diversion to Galleri but would result in substantial lost upstream sales. (RX6000 (Carlton Trial Dep. at 24, 26–27).) Moreover, Illumina's instruments and consumables are multi-use products that can be and often are used by Illumina customers for a variety of sequencing applications. (PFF ¶¶ 6–11.)

In any event, Illumina takes extensive precautions to protect the confidentiality of information it receives from developers including: (1) setting up confidentiality agreements with partners, (2) training staff and requiring them to sign confidentiality agreements, (3) separating teams who might work on similar products, (4) using document control processes and (5) providing legal guidance if individuals request access to protected documents. (PFF ¶¶ 1040–1040.5; Goswami (Illumina) Tr. 3227–30.) These practices are standard in the industry and generally accepted by companies that serve multiple clients in the same industry. (PFF ¶ 1040.8; Goswami (Illumina) Tr. 3228–29.)

The Open Offer requires that to the extent that Illumina has access to customer confidential information, Illumina shall not share such information with GRAIL, any GRAIL subsidiary or any employee who works within GRAIL. (PFF ¶ 1038; (Rabinowitz (Natera) Tr. 425; Berry (Illumina) Tr. 916–17; PX0064 (Illumina) at 9.)

Under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (PFF ¶ 1039; [redacted] deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted].) Respondents also incorporate their responses to CCFF ¶¶ 2612 herein.

2690. Illumina utilizes Salesforce.com, a customer relationship management database, to store customer contact information, track sales opportunities, and generate price quotes. (Berry (Illumina) Tr. 659-660).

Response to Finding No. 2690:

Respondents have no specific response, except to note that Salesforce is a widely used customer relationship management database, and that the information enumerated in the proposed finding would likely be of little benefit to a putative competitor. Respondents also note

that the proposed finding is irrelevant and does not evidence any particular ability to identify and/or discriminate against alleged rivals. Respondents also incorporate their responses to CCFF ¶¶ 2612 and 2689 herein.

2691. Illumina's customer database classifies customers based on the market segments in which they participate. (Berry (Illumina) Tr. 660-61; PX7076 (Berry (Illumina) Dep. at 54-57)). Illumina classifies customers in "approximately 10 or 12 segments," including oncology testing. (Berry (Illumina) Tr. 660-61).

Response to Finding No. 2691:

The proposed finding is irrelevant and does not evidence any particular ability to identify and/or discriminate against alleged rivals. In particular, oncology testing is an extremely broad category, and attempting to target all oncology testing customers would have a significant negative impact on Illumina's bottom line. Although Illumina may have an understanding of the types of applications a customer is developing or marketing, in many cases it does not know what specific tests are in its customers' development pipeline. (Berry (Illumina) Tr. 849–53.) For example, many of the MCED tests Complaint Counsel claims are in development are unknown to Illumina even today—much less their specific attributes that would allow Illumina to predict with confidence whether any test will be a close substitute to Galleri, or, instead, a market-expanding complement, foreclosure of which would cause no material diversion to Galleri but would result in substantial lost upstream sales. (RX6000 (Carlton Trial Dep. at 24, 26–27).)

Respondents also note that the information described in Ms. Berry's testimony is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—including order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored

in the databases (Berry (Illumina) Tr. 853–55.) Respondents also incorporate their responses to CCFF ¶¶ 2612 and 2689 herein.

2692. Ms. Berry explained that Illumina classifies customers based on segments such as reproductive health, genetic disease testing, and oncology testing on the clinical side, and cell and molecular biology research, genetic disease research, cancer research, and microbiology on the research side. (PX7076 (Berry (Illumina) Dep. at 54-57)).

Response to Finding No. 2692:

The proposed finding is irrelevant for the reasons explained in Respondents' responses to CCFF ¶ 2691, which Respondents incorporate herein.

2693. Illumina's Ms. Berry testified that, "I'm not familiar with all of the companies that offer oncology tests, but I'm, you know, familiar with the companies that purchase products from Illumina for the purposes of offering oncology tests." (PX7063 (Berry (Illumina) IHT at 30-31)).

Response to Finding No. 2693:

The proposed finding is irrelevant for the reasons explained in Respondents' responses to CCFF ¶ 2691, which Respondents incorporate herein.

(b) Revealing Its Knowledge of Its MCED Customers [redacted]

2694. After the announcement of the Acquisition, Illumina decided to contact its "largest onc[ology] testing customers or those specifically participating in the early detection space" to inform them of the Acquisition and offer them long-term supply agreements, in an attempt to alleviate their concerns about the transaction. (PX2302 (Illumina) at 001 (Email from N. Berry, Illumina, to C. Fideler, M. Gallad, et al., Illumina, Sept. 21, 2020)).

Response to Finding No. 2694:

The proposed finding is incomplete and misleading to the extent it suggests that Illumina identified customers specifically because they were MCED developers. [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶ 2612 herein.

2695. [redacted] (Berry (Illumina) Tr. 752-53 (*in camera*)).

Response to Finding No. 2695:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2694, which Respondents incorporate herein.

2696. [redacted] (Berry (Illumina) Tr. 753 (*in camera*)).

Response to Finding No. 2696:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2694, which Respondents incorporate herein. [redacted]

[redacted]

2697. [redacted] (Berry (Illumina) Tr. 938 (*in camera*)).

Response to Finding No. 2697:

The proposed finding is incomplete and misleading. [redacted] Respondents also incorporate their responses to CCFF ¶ 2694 herein.

2698. [redacted] (Berry (Illumina) Tr. 750-51 (*in camera*)).

Response to Finding No. 2698:

The proposed finding is irrelevant and does not evidence any particular ability to identify and/or discriminate against alleged rivals. Although Illumina may have an understanding of the

types of applications a customer is developing or marketing, in many cases it does not know what specific tests are in its customers' development pipeline. (Berry (Illumina) Tr. 849–53.) For example, many of the MCED tests Complaint Counsel claims are in development are unknown to Illumina even today—much less their specific attributes that would allow Illumina to predict with confidence whether any test will be a close substitute to Galleri, or, instead, a market-expanding complement, foreclosure of which would cause no material diversion to Galleri but would result in substantial lost upstream sales. (RX6000 (Carlton Trial Dep. at 24, 26–27).) Respondents also incorporate their responses to CCFF ¶ 2694 herein.

2699. [redacted] (Berry (Illumina) Tr. 753-55 (*in camera*)).

Response to Finding No. 2699:

Respondents have no specific response.

2700. Mr. deSouza's comments at the Cowen Liquid Biopsy Summit on September 24, 2020 revealed that Illumina analyzed which of its customers a combined Illumina/Grail would compete with: "[A]bout 20 [Illumina] customers out of about 6,600 have said that they have an interest in exploring [the early detection of cancer] space. Those 20 customers represent roughly about 2% of our revenue." (PX2575 (Illumina) at 065 (Email from T. Friedman, Illumina, to J. Cunningham, Illumina, attaching Edited Transcript, ILMN.OQ – Illumina Inc at Cowen Liquid Biopsy Summit (Virtual), Sept. 29, 2020); *see also* deSouza (Illumina) Tr. 2220-22). Mr. deSouza confirmed that those 20 customers include Guardant, Roche, Freenome, Singlera, Exact/Thrive, and Grail. (deSouza (Illumina) Tr. 2220-23; PX2575 (Illumina) at 065 (Email from T. Friedman, Illumina, to J. Cunningham, Illumina, attaching Edited Transcript, ILMN.OQ – Illumina Inc at Cowen Liquid Biopsy Summit (Virtual), Sept. 29, 2020); PX2031 (Illumina) at 005 n.2 (Illumina, Cowen Liquid Biopsy Summit with Francis deSouza, Sept. 24, 2020) (listing Guardant, Thrive, Freenome, Singlera, Exact, and Grail)).

Response to Finding No. 2700:

The proposed finding is incomplete and misleading. The 20 customers representing roughly 2% of revenue is a reflection of Illumina's *historical* business with those test developers,

and Illumina's NGS profits from clinical testing lie largely in the future. (PFF ¶ 857.) The proposed finding is also misleading to the extent it describes [redacted] (RX3869 (Cote Expert Report ¶¶ 174 (Exact/Thrive), 184 ([redacted]), 193 (Freenome), 202 (Guardant), 217 (Helio), 227 ([redacted], 238 (Singlera)).) [redacted] Respondents also incorporate their responses to CCFF ¶¶ 2612, 2649–2660 and 2694.

2701. In a text message dated September 16, 2020, four days prior to the announcement of Illumina's proposed acquisition of Grail, Ms. Berry stated in an exchange with Jeremy Preston, Illumina's Vice President of Global Regional Marketing, that she thought that Illumina's acquisition of Grail would result in Illumina being perceived as competing with their customers in the same segment, including Guardant, Thrive, Freenome, Natera, Tempus, and FMI. (PX2158 (Illumina) at 001 (Mobile text chain between N. Berry, Illumina, and J. Preston, Illumina, Sept. 16, 2020) ("[Preston:] "Do you think grail will be perceived as competing with our customers? [Berry:] Yes for those that are in the same segment [Preston:] Guardant, Thrive, Freenome, Natera, Tempus, FMI. . . [Berry:] Yes exactly"); *see also* (Berry (Illumina) Tr. 743-44 (*in camera*))). Ms. Berry texted that "[w]e've already gotten some WTF emails from customers." (PX2158 (Illumina) at 001 (Text message between N. Berry, Illumina, and J. Preston, Illumina, Sept. 16, 2020)).

Response to Finding No. 2701:

The proposed finding is incomplete and misleading. *First*, [redacted]

[redacted] (Berry (Illumina) Tr. 749.)

The proposed finding is also misleading to the extent it describes [redacted] (RX3869 (Cote Expert Report ¶¶ 174 (Exact/Thrive), 184 (FMI/Roche), 193 (Freenome), 202 (Guardant), 217 (Helio), 227 (Natera), 238 (Singlera)).) [redacted]

2. Illumina Has a Multitude of Tools to Foreclose or Reduce the Competitiveness of Grail's MCED Test Rivals

2702. Illumina knows that "[s]creening represents the largest market opportunity within the broader ctDNA market, but the key bottleneck to market development is the cost of sequencing." (PX2712 (Illumina) at 029 (Email from P. Scagnetti, Illumina, to M. Nguyen, Illumina, attaching Python: A Revolution in Early Cancer Detection Presentation, Dec. 3, 2019)).

Response to Finding No. 2702:

The proposed finding is incomplete and misleading. Although the email chain cited in this proposed finding is from 2019, the quoted attachment is from December of 2015. (PX2712 (Illumina) at 1.) As Illumina's contemporaneous internal documents noted, in 2015, Illumina believed that "no customer has the ability to implement a pan-cancer screening test responsibly and economically anytime in the next 5 years"; therefore, to accelerate the growth of the

segment, Illumina "felt an imperative to organize an entity" focused on that moon-shot mission. (PFF ¶ 980.2; RX1088 (Illumina) at 7; (Flatley (Illumina) Dep. at 111–12).) These considerations from the time of GRAIL's formation no longer exist for many reasons, including because the cost of sequencing has come down substantially since 2015. (PFF ¶¶ 21, 981.)

Indeed, contrary to Complaint Counsel's unproven contention, the only evidence in the record on NGS costs as a percentage of future downstream MCED revenues and margins shows that NGS costs will be a very small percentage of MCED test revenues and margins in the future. (PFF ¶ 884; RX6000 (Carlton Trial Dep.) at 30–31.)

2703. As documented in Section V. above, each MCED witness testified that they only have one option for NGS supplier—Illumina.

Response to Finding No. 2703:

Respondents have no specific response. To the extent Complaint Counsel relies on its Proposed Findings in Section V, paragraphs 1053–1200, Respondents incorporate their responses to those Proposed Findings herein.

a) Illumina Can Increase Prices of Its Instruments and Reagents

2704. [redacted] (*See* PX7051 (Lengauer (Third Rock Ventures) IHT at 127-28) (*in camera*); PX7047 (Cooper (Progenity) IHT at 54)).

Response to Finding No. 2704:

The proposed finding is inaccurate, incomplete and misleading. Contrary to Complaint Counsel's unproven contention, the only evidence in the record on NGS costs as a percentage of future downstream MCED revenues and margins shows that NGS costs will be a very small percentage of MCED test revenues and margins in the future. (PFF ¶ 884; RX6000 (Carlton Trial Dep.) at 30–31.)

To the extent Complaint Counsel relies on its Proposed Findings in Section V.C.3, Respondents incorporate their responses to those Proposed Findings herein.

2705. [redacted] (PX6090 (Scott Morton Report) ¶ 178 (*in camera*)).

Response to Finding No. 2705:

The proposed finding is incomplete and misleading on both counts: [redacted]

First, [redacted] in light of the Open Offer, Illumina cannot increase prices it charges to putative GRAIL rivals. Specifically, "there's a provision in the open offer that prevents Illumina from raising prices over the term of the agreement beyond those that would be allowable relative to inflation adjustments or cost of goods sold". (Berry (Illumina) Tr. 899; *see also* PFF ¶ 1021; [redacted] Conroy (Exact/Thrive) Tr. 1731; PX0064 (Illumina) at 7; [redacted].) "[T]he impact [of this provision] would be that customers are essentially protected against price increases over the term" of the Open Offer. (Berry (Illumina) Tr. 900.) According to economic expert Ms. Guerin-Calvert, "taken in their totality with regard to shorter term, medium term, and longer term" concerns, the Open Offer's pricing provisions "provide[] [customers] fair treatment . . . across customers" and give customers "fair treatment in terms of advance knowledge and information" about pricing. (RX6002 (Guerin-Calvert Trial Dep. at 53).)

Second, the proposed finding is incomplete and misleading with respect to the statement that [redacted]. Contrary to Complaint Counsel's unproven

contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.)

For example, Natera and BGI Genomics formed a partnership to commercialize Natera's Signatera NGS-based cancer monitoring test on BGI's DNBSEQ platform in China, and has now launched a version of the Signatera test in China "that incorporates MGI sequencing platforms." [redacted] RX3062 (BGI) at 1.)

BGI already has a commercially available NGS platform. (PFF ¶¶ 777–777.5.) [redacted] BGI also recently won a jury verdict that held three of Illumina's patents to be invalid, meaning that these patents do not prevent BGI from launching its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022). BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.)

[redacted]. (PFF ¶¶ 778–778.2; 2085.) Thermo Fisher's Ion Torrent sequencers are suitable for certain MCED tests. (RX3869 (Cote Expert Report) ¶ 285.) [redacted]

[redacted]

Oxford Nanopore is also a viable alternative for putative MCED test developers. (RX3521 (NCM) at 50-51; RX3869 (Cote Expert Report) ¶¶ 293, 295-98.) Oxford Nanopore's instruments reportedly will compete with Illumina on throughput, accuracy and cost. Oxford Nanopore states that its highest throughput instrument, PromethION, has a higher throughput than the highest performance instrument and flow cell currently offered by Illumina, the NovaSeq 6000 with the S4 flow cell. (RX3543 (ONT); RX1205 (Illumina): RX3869 (Cote Expert Report) ¶ 294.) Oxford Nanopore states that its instruments have similar accuracy to Illumina. (*Compare* RX3541 (ONT) at 1 *with* RX3368 (Illumina).)

Singular commercially launched the G4 NGS sequencer at the end of 2021 and will begin shipping the G4 NGS systems in the first half of 2022. (PFF ¶ 607; Velarde (Singular) Tr. 4515–16, 4522; *see also* PX8561 (Singular) at 1–2; [redacted] (PFF ¶ 609-609.6.)

Respondents also note that several other sequencers that are capable of supporting MCED development are arriving in the near future. [redacted]

[redacted] (PX7119 (Lauer (Ultima) Dep. at 49–50); [redacted]

Omniome, which was acquired by PacBio for $800 million in July 2021, is developing a NGS sequencer. (RX3533 (Omniome).) Omniome expects that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72)**;** [redacted]

Roche expects to bring to market an NGS nanopore sequencer by the 2024 time frame. (RX3614 (Roche).)

Dr. Aravanis testified that GRAIL considered BGI, Thermo Fisher, Oxford Nanopore and Genapsys NGS sequencers for GRAIL's Galleri test, and determined that many of them would be a viable alternative. (PFF ¶ 1311 (Aravanis (Illumina) Tr. 1862–63).) Dr. Aravanis also

testified that BGI's systems are used for liquid biopsy applications; BGI has an NGS sequencing product that could be used for multicancer screening; BGI competes with Illumina for liquid biopsy applications in the countries in which it operates; BGI markets its NGS offerings as an alternative to Illumina. (PFF ¶ 1306 (Aravanis (Illumina) Tr. 1852–54).) Dr. Aravanis also testified that Thermo Fisher's Ion Torrent can be us as an alternative for many Illumina applications; that the Ion Torrent platform is adequate in terms of the type of sequencing data it produces, the accuracy and the cost and that Thermo Fisher markets the Ion Torrent as an alternative to Illumina. (PFF ¶ 1305 (Aravanis (Illumina) Tr. 1848–52).) Dr. Aravanis further testified that it is possible to do short-read sequencing on Oxford Nanopore's platforms at very low cost; the Oxford Nanopore platform is a very high-output sequencing platform; the amount of data and cost per data is comparable to the high-end Illumina systems; Oxford Nanopore's NGS sequencing product can be used and have been for liquid biopsy oncology testing; Oxford Nanopore markets its NGS offering as an alternative to Illumina and Illumina views Oxford Nanopore as a competitor in NGS sequencing. (PFF ¶ 1308 (Aravanis (Illumina) Tr. 1856–59).) (*See also* PFF ¶¶ 1304–1310.)

Purported MCED test developers treat these NGS platforms as viable substitutes for Illumina's NGS platform. (PFF ¶ 780.) Dr. Vogelstein, a founder of Thrive, stated, [redacted]

[redacted] Dr. Gao of Singlera testified that the PanSeer test can be run using Thermo Fisher equipment. (PFF ¶ 780.4.) [redacted] Dr. Chudova also stated that Guardant could use alternative sequencing platforms for its LUNAR-2 screening test in development that meet the throughput, error, time, and sequencing cost requirements. (PX7045 (Chudova (Guardant) IHT at 44–47.) [redacted]

Mr. Stahl of Invitae also recognized that Thermo Fisher (along with Oxford Nanopore, BGI, and PacBio) is a participant in the NGS field and that there would be "no way to predict" which NGS company would be successful over the next five or ten years. (PX7075 (Stahl (Invitae) Dep. at 43).) Mr. Stahl also testified that BGI's and Illumina's technologies are "very similar". (PX7075 (Stahl (Invitae) Dep. at 75.)

The proposed finding also relies on improper expert testimony. Dr. Scott Morton lacks the expertise to opine on scientific, technical, regulatory and reimbursement issues, rendering her opinions unreliable. (*See* Resps.' Post-Trial Br. at 261–62.)

2706. All pricing programs must be approved by Illumina's Pricing Committee. (PX6056 (Illumina) at 038 (Illumina, Narrative Response to Second Request, Mar. 1, 2021); PX7072 (deSouza (Illumina) IHT at 13-14 (*in camera*)).

Response to Finding No. 2706:

Respondents have no specific response.

2707. [redacted] (PX7123 (Fellis (Illumina) Dep. at 18) (*in camera*)).

Response to Finding No. 2707:

Respondents incorporate their response to CCFF ¶ 2706 herein.

2708. The pricing committee approves Illumina's pricing strategy. "As product managers in the product management function develop[] a pricing strategy around a given set of products, that would go to the pricing committee for review and approval." (PX7123 (Fellis (Illumina) Dep. at 20)). With very few exceptions, the pricing committee approves all pricing strategies provided by product managers. (PX7123 (Fellis (Illumina) Dep. at 20)).

Response to Finding No. 2708:

Respondents incorporate their response to CCFF ¶ 2706 herein.

2709. [redacted] PX7072 (deSouza (Illumina) IHT at 15) (*in camera*)).

Response to Finding No. 2709:

Respondents incorporate their response to CCFF ¶ 2706 herein.

2710. [redacted] PX6056 (Illumina) at 038 (Illumina, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 2710:

Respondents incorporate their response to CCFF ¶ 2706 herein.

2711. [redacted] (PX7072 (deSouza (Illumina) IHT at 14) (*in camera*)). [redacted] (PX7072 (deSouza (Illumina) IHT at 15) (*in camera*)).

Response to Finding No. 2711:

Respondents incorporate their response to CCFF ¶ 2706 herein.

2712. [redacted] (PX7072 (deSouza (Illumina) IHT at 17) (*in camera*)); PX7123 (Fellis (Illumina) Dep. at 24-25) (*in camera*)).

Response to Finding No. 2712:

Respondents incorporate their response to CCFF ¶ 2706 herein.

2713. [redacted] (PX7123 (Fellis (Illumina), Dep. at 21, 30 (*in camera*) [redacted]

Response to Finding No. 2713:

Respondents incorporate their response to CCFF ¶ 2706 herein.

2714. [redacted] (PX7123 (Fellis (Illumina), Dep. at 22) (*in camera*) [redacted] .

Response to Finding No. 2714:

Respondents incorporate their response to CCFF ¶ 2706 herein.

2715. Guardant's Mr. Getty testified that "whatever terms, conditions, and pricing they [Illumina] want to put forward, they can do so. And they can use their monopoly power in order to . . . drive to whatever conclusion they'd like." (PX7105 (Getty (Guardant) Dep. at 67-68)).

Response to Finding No. 2715:

The proposed finding is incomplete and misleading. Specifically, contrary to Mr. Getty's testimony, Illumina cannot use any alleged "monopoly power" to impose conditions on Guardant or any other customer because customers who were unhappy with proposed conditions could switch to one of Illumina's competitors in the NGS space. (*See* PFF ¶¶ 578–674; *see also* RRFF ¶ 2705.) Thus, as Mr. deSouza testified, [redacted]

Further, [redacted] (*See* Berry (Illumina) Tr. 938–43.) [redacted] (Berry (Illumina) Tr. 938.) [redacted] As Mr. Getty testified, the [redacted] This would not have been the case if Guardant had very little leverage in negotiating with Illumina.

[redacted]

[redacted] Guardant attached the amended supply agreement to its 2020 10–K because the amended agreement represented a material and

important contract for Guardant. (PFF ¶ 1075.4; Getty (Guardant) Tr. 2668–69; PX0060 (Guardant) at 151.)

Finally, the public availability of the Open Offer increases Guardant's (and other customers') negotiating power, which, as outlined above, was already significant. As economist and President of the Center for Healthcare Economics and Policy and Senior Managing Director at FTI Consulting, Margaret Guerin-Calvert, explained, "by providing customers and the marketplace with increased information on the contracting provisions that Illumina is willing to negotiate with regard to pricing, access, technology and other terms, the Open Offer changes bargaining dynamics in favor of third parties [like Guardant] after the Transaction." (RX3865 (Guerin-Calvert Expert Report) ¶ 44.)

Respondents also incorporate their responses to CCFF ¶¶ 927, 1115, 1118, 1129 and 1139 herein.

2716. [redacted] (Getty (Guardant) Tr. 2524, 2629-30 (*in camera*)).

Response to Finding No. 2716:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2715, which Respondents incorporate herein.

2717. Guardant's CEO testified that, "as customer for Illumina, we are an important customer, but we do not drive, you know, a significant portion of their revenue such that, you know, they would be dependent on Guardant." (Getty (Guardant) Tr. 2524).

Response to Finding No. 2717:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2715, which Respondents incorporate herein. Respondents also note that Mr. Getty is not Guardant's CEO. Mr. Getty is the senior vice president of commercial for the Screening Division at Guardant. (Getty (Guardant) Tr. 2482.)

While Respondents served a subpoena on Guardant's CEO, Helmy Eltouky, he declined to testify.

2718. [redacted] (PX7110 (Conroy (Exact) Dep. at 182-83) (*in camera*)).

Response to Finding No. 2718:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1084 and 1089, which Respondents incorporate herein.

[redacted] After Illumina announced its agreement to reacquire GRAIL, Exact entered into an agreement to acquire Thrive for $2.1 billion. (PFF ¶ 929.1.) [redacted]

[redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 4338–99.

2719. Dr. Gao testified that in negotiations with Illumina, "their [Illumina's] way is my way or the highway. If you gave [Illumina] that profit margin, well, [Illumina] -- you know, [Illumina] can allow you to survive. If not, you just die." (PX7042 (Gao (Singlera) IHT at 87-88)).

Response to Finding No. 2719:

The proposed finding is incomplete and misleading, and contradicted by the weight of the evidence. In the portion of his IH cited here, Dr. Gao testified to facts that indicate that his characterization of Singlera's relationship with Illumina has no basis. For example, Dr. Gao testified that once Singlera seriously began pursuing a supply agreement with Illumina, Illumina "quickly turn[ed] around a draft proposal of [a] supply agreement", which was a "standard boilerplate" agreement. (PX7042 (Gao (Singlera) IHT at 74–75).) Dr. Gao testified that Singlera was "happy" to receive a standardized agreement because Singlera's "only request [was] to have a standard supply agreement". (PX7042 (Gao (Singlera) IHT at 75).) Finally, Dr. Gao admitted that Illumina "provided us with [a draft supply agreement], expect[ed] us to negotiate I'm sure, but we never went back" to negotiate with Illumina. (PX7042 (Gao (Singlera) IHT at 87).) Thus, Dr. Gao's testimony shows that, after Singlera proposed entering a supply agreement with Illumina, Illumina sent a boilerplate agreement, which was exactly what Singlera wanted, and yet Singlera refused to even engage with Illumina on the draft agreement.

Further, even though Singlera stopped engaging with Illumina on a supply agreement, Illumina extended the Open Offer to Singlera (as well as all U.S. oncology customers). (*See* PX0064 (Illumina) at 1, 3.) The Open Offer specifically addresses the concerns identified in the

portion of Dr. Gao's IH in which he discussed Singlera's desire for a supply agreement. In his IH, Dr. Gao identified two primary reasons why Singlera sought a supply agreement with Illumina: (1) to ensure that "Illumina will [not] discontinue the product line" that Singlera uses and (2) to ensure that Illumina does not increase the costs of sequencing equipment for Singlera. (PX7042 (Gao (Singlera) IHT at 71–72).) The Open Offer addresses each of these concerns. *First*, Illumina is prohibited from discontinuing products that any oncology customer has purchased in the prior year. (PFF ¶ 1011; [redacted] Berry (Illumina) Tr. 883; PX0064 (Illumina) at 6; [redacted] *Second*, the Open Offer expressly forbids Illumina from raising prices over the entire 12-year term and affirmatively requires Illumina to lower the price of sequencing by at least 43% by 2025. (PFF ¶ ¶ 1021 –23; [redacted] Berry (Illumina) Tr. 899, 901 –04; Conroy (Exact/Thrive) Tr. 1731 –32; deSouza (Illumina) Tr. 2403; PX0064 (Illumina) at 7; [redacted] Even though Dr. Gao claimed these concerns drove Singlera's requests for a supply agreement, Dr. Gao testified at trial that he was "*not even aware of the first open – open offer* until [his] lawyer told [him]", let alone the amended version, which provides even greater protections. (Gao (Singlera) Tr. 2952 (emphasis added).) Respondents also incorporate their responses to CCFF ¶¶ 1174 and 2642 herein.

Respondents also note that the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2720. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 180-81) (*in camera*)).

Response to Finding No. 2720:

The proposed finding is incomplete and misleading.

[redacted] Illumina is not the sole supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.) [redacted]

[redacted]

Further, Dr. Vogelstein, the founder of Thrive stated, [redacted]

[redacted] The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928 and 2833, which Respondents incorporate herein.

Third, "there's a provision in the open offer that prevents Illumina from raising prices over the term of the agreement beyond those that would be allowable relative to inflation adjustments or cost of goods sold". (Berry (Illumina) Tr. 899; *see also* PFF ¶ 1021; [redacted] Conroy (Exact/Thrive) Tr. 1731; PX0064 (Illumina) at 7; [redacted].) "[T]he impact [of this provision] would be

that customers are essentially protected against price increases over the term" of the Open Offer. (Berry (Illumina) Tr. 900.) [redacted]

Fourth, The proposed finding is incomplete and misleading insofar as it suggests that Exact is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future for the reasons explained in Respondents' responses to CCFF ¶¶ 414 and 418, which Respondents incorporate herein. Respondents note that CancerSEEK is still under development (PFF ¶ 417 (Lengauer (Exact/Thrive) Tr. 158)), that [redacted] (Conroy (Exact) Tr. 1717), and that CancerSEEK is combined with a whole-body PET-CT, which [redacted] (*See*, *e.g.*, Lengauer (Exact/Thrive) Tr. 248; RX3419 (Lennon et al., 2020) at 3; Lengauer (Exact/Thrive) Tr. 226–27; PFF ¶¶ 419, [redacted] 739, 760, [redacted], 841.3, [redacted], 1723–24.) Respondents also note that [redacted] (Conroy (Exact) Tr. 1621.)

[redacted] Exact/Thrive also admitted that, based on the DETECT-A trial, "[a]t present, we cannot be certain that the DETECT-A blood test"—the CancerSEEK test—"helped any participant." (RX3419 at 11.)

Finally, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2721. In an internal Grail e-mail, Grail's Research Operations Manager Minyong Chung wrote with regard to price negotiations with Illumina that "[n]egotiating with ILMN alone is very tricky because of their unique market position (basically a monopoly) . . . ." (PX4019 (Grail) (Email from M. Chung, Grail, to J. Wong, Grail, Sept. 29, 2018)).

Response to Finding No. 2721:

The proposed finding is inaccurate, incomplete and misleading with respect to the statement that [redacted]. Contrary to Complaint Counsel's unproven contention that all MCED tests use Illumina's NGS platforms, there are several other NGS platforms that can support putative MCED tests in development. (PPF ¶¶ 776–781.) Respondents also incorporate their responses to CCFF ¶ 2705 herein.

Complaint Counsel also did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 34), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Further, neither individual in the cited email was a witness in this case and was not subject to cross examination regarding their knowledge of Illumina's market position or customers' ability to negotiate with Illumina. Moreover, Complaint Counsel has done nothing to establish that Minyong Chung, who is a *Research Operations Manager* at GRAIL, has any personal knowledge of Illumina's pricing negotiations with its customers. Thus, there is no foundation for Mr. Chung's statements about such negotiations. Therefore, this statement and the cited source should be given little weight.

(1) [redacted]

2722. [redacted] (PX2608 (Illumina) at 001, 003 [redacted] (*in camera*); *see* PX7123 (Fellis (Illumina) Dep. at 72-73) (*in camera*)).

Response to Finding No. 2722:

The proposed finding is incomplete and misleading. [redacted]

2723. [redacted] (PX2608 (Illumina) at 003 [redacted] (*in camera*)).

Response to Finding No. 2723:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2722, which Respondents incorporate herein.

2724. [redacted] (PX2608 (Illumina) at 001, 004 [redacted] (*in camera*)).

Response to Finding No. 2724:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2722, which Respondents incorporate herein.

(a) Illumina Offers Customers Discretionary Discounts Outside of Its Supply Agreements and Pricing Grids

2725. [redacted] (*See e.g.*, PX2306 (Illumina) at 011 [redacted] (*in camera*); see PX2387 (Illumina) at 002 (Email from WF-BATCH, Illumina, to N. Berry, Illumina, Apr. 19, 2018) (*in camera*) [redacted].

Response to Finding No. 2725:

The proposed finding is incomplete and misleading without additional context. [redacted] (PX2306 (Illumina) at 11.) Thus, the discounts referred to in the amended supply agreement are based on standardized considerations and are aimed at achieving overall commercial terms that are substantially similar across similarly situated customers. Moreover, as Ms. Berry testified, under the Open Offer, if GRAIL or an equivalent customer "gets a discretionary discount", "Illumina would be obliged to reduce the price to [other customers] under this agreement to match the price that was offered to either GRAIL or an equivalent customer." (Berry (Illumina) Tr. 893–94.)

2726. [redacted] (PX7076 (Berry (Illumina) Dep. at 115-116, 169-170) (*in camera*); *see* PX7123 (Fellis (Illumina) Dep. at 53-54) (*in camera*)).

Response to Finding No. 2726:

The proposed finding is incomplete and misleading without additional context for the reasons explained in Respondents' response to CCFF ¶ 2725, which Respondents incorporate herein.

2727. [redacted] (PX7076 (Berry (Illumina) Dep. at 172-173, 177) (*in camera*).

Response to Finding No. 2727:

The proposed finding is incomplete and misleading without additional context for the reasons explained in Respondents' response to CCFF ¶ 2725, which Respondents incorporate herein. Under the Open Offer, discounts do not vary based on the customer's application. (*See* PX0064 (Illumina) at 6–7, 12–14.)

2728. [redacted] (PX6056 (Illumina) at 022 [redacted] (*in camera*)).

Response to Finding No. 2728:

The proposed finding is incomplete and misleading without additional context for the reasons explained in Respondents' response to CCFF ¶ 2725, which Respondents incorporate herein.

Respondents also note that for a customer who signs the Open Offer, if Illumina granted a discretionary discount to an equivalent customer or to GRAIL, "Illumina would be obliged to reduce the price to the [Open Offer signatory] to match the price that was offered to either GRAIL or an equivalent customer." (Berry (Illumina) Tr. 894.)

2729. [redacted] (*in camera*)).

Response to Finding No. 2729:

The proposed finding is incomplete and misleading without additional context for the reasons explained in Respondents' responses to CCFF ¶ 2728, which Respondents incorporate herein.

Respondents also note that for a customer who signs the Open Offer, if Illumina granted a discretionary discount to an equivalent customer or to GRAIL (including, [redacted], "Illumina would be obliged to reduce the price to the [Open Offer signatory] to match the price that was offered to either GRAIL or an equivalent customer." (Berry (Illumina) Tr. 894.)

2730. [redacted] (*in camera*)).

Response to Finding No. 2730:

The proposed finding is incomplete and misleading without additional context for the reasons explained in Respondents' responses to CCFF ¶ 2728, which Respondents incorporate herein.

For a customer who signs the Open Offer, if Illumina granted a discretionary discount to an equivalent customer or to GRAIL (including customer-level discounts), "Illumina would be obliged to reduce the price to the [Open Offer signatory] to match the price that was offered to either GRAIL or an equivalent customer." (Berry (Illumina) Tr. 894.)

2731. [redacted] (Berry (Illumina) Tr. 774) (*in camera*).

Response to Finding No. 2731:

The proposed finding is incomplete and misleading without additional context for the reasons explained in Respondents' responses to CCFF ¶ 2728, which Respondents incorporate herein.

2732. [redacted] (Berry (Illumina) Tr. 775-76) (*in camera*).

Response to Finding No. 2732:

The proposed finding is incomplete and misleading without additional context for the reasons explained in Respondents' responses to CCFF ¶ 2728, which Respondents incorporate herein.

For a customer who signs the Open Offer, if Illumina granted a discretionary discount to an equivalent customer or to GRAIL (including discounts for whether customers paid in advance), "Illumina would be obliged to reduce the price to the [Open Offer signatory] to match the price that was offered to either GRAIL or an equivalent customer." (Berry (Illumina) Tr. 894.)

Under this universal pricing grid in the Open Offer, customers receive most-favored-nations (MFN) pricing protections, which ensure that the customer has access to volume-based prices "that are no less favorable (i.e., the same or better) than" those provided to GRAIL or an equivalent customer. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 7–8.)

2733. [redacted] (Berry (Illumina) Tr. 776) (*in camera)*.

Response to Finding No. 2733:

The proposed finding is incomplete and misleading without additional context for the reasons explained in Respondents' responses to CCFF ¶ 2728, which Respondents incorporate herein.

For a customer who signs the Open Offer, if Illumina granted a discretionary discount to an equivalent customer or to GRAIL, "Illumina would be obliged to reduce the price to the [Open Offer signatory] to match the price that was offered to either GRAIL or an equivalent customer." (Berry (Illumina) Tr. 894.)

2734. [redacted] (PX2688 (Illumina) at 001 (Email from WF-BATCH, Illumina, to R. Graff, Illumina, attaching Quote Approval Request, Feb. 1, 2018) (*in camera*)).

Response to Finding No. 2734:

The proposed finding is incomplete and misleading without additional context for the reasons explained in Respondents' responses to CCFF ¶ 2728, which Respondents incorporate herein.

Customers who sign the Open Offer can choose (for each product purchased) to use the pricing they had before the Transaction or to use pricing under the same universal grid that GRAIL uses. (PFF ¶ 1014; Berry (Illumina) Tr. 892; PX0064 (Illumina) at 7.) Since Freenome received as 12 percent discount in 2018, which is before the Transaction, Freenome can keep their 12 percent discount. (PFF ¶ 1014; Berry (Illumina) Tr. 892; PX0064 (Illumina) at 7.)

Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 28), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2735. [redacted] (Berry (Illumina) Tr. 780) (*in camera*). [redacted] PX7076 (Berry (Illumina) Dep. at 115-119); *see also* PX7123 (Fellis (Illumina) Dep. at 58-59) (*in camera*)).

Response to Finding No. 2735:

The proposed finding is incomplete and misleading without additional context for the reasons explained in Respondents' responses to CCFF ¶ 2728, which Respondents incorporate herein.

For a customer who signs the Open Offer, if Illumina granted a discretionary discount to an equivalent customer or to GRAIL (including those for "qualitative reasons"), "Illumina would be obliged to reduce the price to the [Open Offer signatory] to match the price that was offered to either GRAIL or an equivalent customer." (Berry (Illumina) Tr. 894.)

2736. Illumina often provides the customer with [redacted] (PX7076 (Berry (Illumina) Dep. at 155-156) (*in camera*)). [redacted] (PX2631 (Illumina) at 001 (Quote Approval Request, Feb. 26, 2018) (*in camera*)).

Response to Finding No. 2736:

The proposed finding is incomplete and misleading without additional context for the reasons explained in Respondents' responses to CCFF ¶ 2728, which Respondents incorporate herein.

For a customer who signs the Open Offer, if Illumina granted a discretionary discount to an equivalent customer or to GRAIL, "Illumina would be obliged to reduce the price to the [Open Offer signatory] to match the price that was offered to either GRAIL or an equivalent customer." (Berry (Illumina) Tr. 894.)

2737. [redacted] PX2379 (Illumina) at 001 (Email from N. Berry, Illumina, to D. Blevins et al., Illumina, attaching Quote Approval Request, Feb. 14, 2019) (*in camera*) [redacted]); PX2631 (Illumina) at 001 (Email from WF-BATCH, Illumina, to N. Berry, Illumina, attaching Quote Approval Request, Feb. 26, 2018) (*in camera*) [redacted]).

Response to Finding No. 2737:

The proposed finding is incomplete and misleading without additional context for the reasons explained in Respondents' responses to CCFF ¶ 2728, which Respondents incorporate herein.

For a customer who signs the Open Offer, if Illumina granted a discretionary discount to an equivalent customer or to GRAIL (including those for "upgrad[ing] to new Illumina technology"), "Illumina would be obliged to reduce the price to the [Open Offer signatory] to match the price that was offered to either GRAIL or an equivalent customer." (Berry (Illumina) Tr. 894.)

2738. [redacted] (PX2377 (Illumina) at 001 (Email from WF-BATCH, Illumina, to N. Berry, Illumina, attaching Quote Approval Request, Oct. 17, 2018) (*in camera*)).

Response to Finding No. 2738:

The pricing in the Open Offer is not contingent on the customer purchasing any other products: any customer buying sequencing reagents for use with a cancer screening test will pay the Open Offer price, regardless of whether that customer is also buying another product. (PX0064 (Illumina) at 6–7, 12–27; Berry (Illumina) Tr. 864:16-865:6.)

For a customer who signs the Open Offer, if Illumina granted a discretionary discount to an equivalent customer or to GRAIL (including those for "bundl[ing] multiple products"), "Illumina would be obliged to reduce the price to the [Open Offer signatory] to match the price

that was offered to either GRAIL or an equivalent customer"—even if the customer *did not* purchase the "bundled product". (Berry (Illumina) Tr. 894.) Additionally, the pricing in the Open Offer is standardized and is not contingent on a customer purchasing any other products: any customer buying a Supplied Product will pay the Open Offer price, regardless of whether that customer is also buying the Galleri test. (PX0064 (Illumina) at 6–7, 12–27; Berry (Illumina) Tr. 864–65.)

Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 17), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents further incorporate their response to CCFF ¶ 2728 herein.

2739. [redacted] (PX2378 (Illumina) at 001-02 (Email from WF-BATCH, Illumina, to N. Berry, Illumina, attaching Quote Approval Request, Dec. 27, 2018) (*in camera*)).

Response to Finding No. 2739:

The proposed finding is incomplete and misleading without additional context for the reasons explained in Respondents' responses to CCFF ¶ 2728, which Respondents incorporate herein.

For a customer who signs the Open Offer, if Illumina granted a discretionary discount to an equivalent customer or to GRAIL (including those for "hiring a full-time on-site Illumina service engineer"), "Illumina would be obliged to reduce the price to the [Open Offer signatory] to match the price that was offered to either GRAIL or an equivalent customer"—even if the customer *did not* hire the full-time service engineer. (Berry (Illumina) Tr. 894.)

2740. [redacted] (Berry (Illumina) Tr. 779) (*in camera*)). [redacted] (Berry (Illumina) Tr. 779) (*in camera*)).

Response to Finding No. 2740:

Respondents have no specific response. Respondents also incorporate their response to CCFF ¶ 2728 herein.

2741. [redacted] (Berry (Illumina) Tr. 779) (*in camera*)).

Response to Finding No. 2741:

Respondents have no specific response. Respondents also incorporate their response to CCFF ¶ 2728 herein.

2742. [redacted] (PX7076 (Berry (Illumina) Dep. at 174) (*in camera*)).

Response to Finding No. 2742:

The proposed finding is incomplete and misleading without additional context for the reasons explained in Respondents' responses to CCFF ¶ 2728, which Respondents incorporate herein.

2743. As detailed below in Section VII.D.2.c.4.a.iii., [redacted]

Response to Finding No. 2743:

The pricing in the Open Offer is not contingent on the customer purchasing any other products: any customer buying sequencing reagents for use with a cancer screening test will pay the Open Offer price, regardless of whether that customer is also buying another product, such as TSO-500. (PX0064 (Illumina) at 6–7, 12–27; Berry (Illumina) Tr. 864:16-865:6.)

For a customer who signs the Open Offer, if Illumina granted a discretionary discount to an equivalent customer or to GRAIL (including those for "bundl[ing] multiple products"), "Illumina would be obliged to reduce the price to the [Open Offer signatory] to match the price that was offered to either GRAIL or an equivalent customer"—even if the customer *did not* purchase the TSO-500 therapy selection test. (Berry (Illumina) Tr. 894.)

To the extent Complaint Counsel relies on its Proposed Findings in Section VII.D.2.c.4.a.iii, paragraphs 4044–50, Respondents incorporate their responses to those Proposed Findings herein. Respondents also incorporate their response to CCFF ¶ 2728 herein.

(b) [redacted]

2744. [redacted] (Berry (Illumina) Tr. 789-790) (*in camera*); PX7076 (Berry (Illumina) Dep. at 177) (*in camera*)).

Response to Finding No. 2744:

Respondents have no specific response.

2745. [redacted] (PX7076 (Berry (Illumina) Dep. at 177) (*in camera*) [redacted]; PX7076 (Berry (Illumina) Dep. at 174) (*in camera*) [redacted]

Response to Finding No. 2745:

The proposed finding is incomplete and misleading without additional context. In the portion of Ms. Berry's testimony immediately before that cited, Ms. Berry explained that [redacted]

[redacted]

In any event, Illumina's pricing for oncology customers is constrained by the Open Offer which allows customers to choose (for each product purchased) to use the pricing they had before the GRAIL acquisition or to use pricing under a universal grid. (PFF ¶ 1014; Berry (Illumina) Tr. 892; PX0064 (Illumina) at 7.) Pricing for segments other than oncology is irrelevant to this case, which is about Illumina's alleged ability to foreclose putative GRAIL rivals.

In addition, Respondents note that the pricing that oncology customers receive is for all of their sequencing purchases; if they use their purchases for a different application, they will still receive the same price. Specifically, The Open Offer applies to "*all fields of use*, specifically excluding any use that (i) is not in accordance with the product's specifications or documentation (it being understood that specifications and documentation shall not undermine or limit Customer's rights under this Supply Agreement), (ii) is a reuse of a previously used consumable, (iii) is the disassembling, reverse-engineering, reverse-compiling, or reverse-assembling of the Supplied Product, (iv) is the separation, extraction, or isolation of components of consumables or other unauthorized analysis of the consumables, (v) gains access to or determines the methods of operation of the Supplied Product, or (vi) is the transfer to a third party of, or sub-licensing of, software or third-party software." (PX0064 (Illumina) at 3 (emphasis added).)

2746. [redacted]

[redacted] (PX7076 (Berry (Illumina) Dep. at 177) (*in camera*)).

Response to Finding No. 2746:

The proposed finding is incomplete and misleading without additional context for the reasons explained in Respondents' responses to CCFF ¶ 2745, which Respondents incorporate herein.

2747. Illumina uses the different price sensitivities of different segments in determining how to price its products. (PX7076 (Berry (Illumina) Dep. at 174).

Response to Finding No. 2747:

The proposed finding is incomplete and misleading without additional context for the reasons explained in Respondents' responses to CCFF ¶¶ 2728 and 2745, which Respondents incorporate herein.

2748. [redacted] (PX7076 (Berry (Illumina) Dep. at 173-74)); (Berry (Illumina) Tr. 784-85) (*in camera*).

Response to Finding No. 2748:

The proposed finding is incomplete and misleading without additional context for the reasons explained in Respondents' responses to CCFF ¶¶ 2728 and 2745, which Respondents incorporate herein.

2749. [redacted] (PX2391 (Illumina) at 001 (Email from N. Berry, Illumina, to P. Dueppen, Illumina, Jan. 29, 2021) (*in camera*)).

Response to Finding No. 2749:

Respondents have no specific response except to note that pricing for segments other than oncology is irrelevant to this case, which is about Illumina's alleged ability to foreclose potential

GRAIL rivals. Respondents also note that this January 2021 email was prepared before the Open Offer went into effect and therefore is irrelevant in interpreting how the Open Offer will be administered.

(c) Illumina and Illumina's Oncology Customers Confirm Illumina Uses Different Pricing and Discounting Based on Its Customers' Product Lines, Including Pricing MCED Tests Differently from Single-cancer Tests

2750. Sean George, CEO of Invitae, a customer of Illumina, testified that Illumina charges "different pricing or price tiers or price volume tiers, depending on what we're doing." (PX7081 (George (Invitae) Dep. at 82-85)). Mr. George testified that "there's always been a kind of differential pricing for that – the core components of the Illumina sequencing based on what the application was, based on what you were using the sequencing for." (PX7081 (George (Invitae) Dep. at 82-85)).

Response to Finding No. 2750:

Respondents have no specific response except to note that customers who sign the Open Offer can choose (for each product purchased) to use the pricing they had before Illumina's acquisition of GRAIL or to use pricing under a universal grid. (PFF ¶ 1014; Berry (Illumina) Tr. 892; PX0064 (Illumina) at 7.) Under the universal pricing grid, customers receive most-favored-nations (MFN) pricing protections, which ensure that the customer has access to volume-based prices "that are no less favorable (i.e., the same or better) than" those provided to GRAIL. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 7–8.)

Further, Respondents note that Sean George, the CEO of Invitae stated that Illumina is a "trusted partner" of Invite and that "Invitae does not oppose Illumina's transaction to acquire GRAIL and looks forward to Illumina's continued role as a partner in developing NGS-applications including oncology-focused tests." (RX1100 (Invitae) ¶¶ 6, 17.)

2751. Matthew Cooper, Chief Scientific Officer at Progenity, a customer of Illumina, testified that "we have to buy the fancy reagents in a different-colored box to run an NIPT versus

cheap reagents for research use in doing [product] discovery purposes." (PX7082 (Cooper (Progenity) Dep. at 124-25)).

Response to Finding No. 2751:

The proposed finding is incomplete and misleading. At the time that Progenity negotiated the supply agreement, there was a lot of uncertainty about whether Illumina would be permitted to sell sequencing instruments and core consumables for clinical uses. (*See* PX7060 (Naclerio (Illumina) Dep. at 150–52).) Specifically, NIPT was the first clinical area which used Illumina's sequencing instruments and core consumables, and there was uncertainty about whether the same research-use only products could be used for clinical uses or whether Illumina would need to develop higher quality reagents for clinical applications. (*See* PX7060 (Naclerio (Illumina) Dep. at 150–52).) To avoid running afoul of the FDA regulations, Illumina restricted the potential fields of use and required NIPT customers to buy clinical grade reagents and core consumables rather than research use products. (*See* PX7060 (Naclerio (Illumina) Dep. at 150–52).)

2752. [redacted] (PX7076 (Berry (Illumina) Dep. at 260-61) (*in camera*)).

Response to Finding No. 2752:

The proposed finding is incomplete and misleading without additional context for the reasons explained in Respondents' responses to CCFF ¶¶ 2728 and 2745, which Respondents incorporate herein.

2753. [redacted] (*See* PX7076 (Berry (Illumina) Dep. at 260-61) (*in camera*)).

Response to Finding No. 2753:

The proposed finding is incomplete and misleading. *First*, the proposed finding makes no sense because Cologuard is a PCR-based test. (PFF ¶¶ 162, 1743; RX3869 (Cote Expert Report) ¶ 81; Lengauer (Exact/Thrive) Tr. 238–40.) Therefore, there is no reason whatsoever for Exact receiving access to pricing for *sequencing* to include Cologuard.

Second, [redacted] Respondents incorporate their responses to CCFF ¶¶ 1089, 2630, 2636 and 2639 herein.

Further, because the proposed finding relates to [redacted] the proposed finding relates to irrelevant subject matter because Illumina has subsequently committed to an Open Offer, the terms of which expressly address this issue. In any event, under the Open Offer, [redacted] discounts are based on a customer's volume of purchases of sequencing consumables and instruments and do not vary based on the specific tests in development by the customer. (*See* PX0064 (Illumina) at 12, 14.)

2754. [redacted]

[redacted].

Response to Finding No. 2754:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2753, which Respondents incorporate herein.

2755. Illumina sent Singlera a draft IVD rights term sheet, which included a $40 per sample "Market Access Fee" (in addition to other fees and a 10 percent revenue share). (PX7042 (Gao (Singlera) IHT at 78-80); *see* PX8516 (Singlera) at 006 (Singlera, Email attaching Singlera-Illumina Draft IVD NextSeqDX Term Sheet, June 20, 2020)).

Response to Finding No. 2755:

The proposed finding is incomplete and misleading. At trial, Mr. Leite, the former vice president of clinical business development at Illumina, testified that Illumina included upfront fees for IVD agreements based on "a combination of a number of factors. One, there was a recognition and quantification of the value that our own Dx platforms created, and we wanted to participate in that value creation. There was significant monetary investment from Illumina in the developments and the FDA approval of those systems that we wanted to recoup. And there was a potential for downside risk that we needed to offset through some financial consideration." (Leite (Illumina) Tr. 2163.)

Further, because the proposed finding relates to [redacted] the proposed finding relates to irrelevant subject matter because Illumina has subsequently committed to an Open Offer, the terms of which expressly address this issue. The Open Offer requires Illumina, on a customer's request, to enter into a separate agreement with the customer based on standardized terms to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33; [redacted] deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; PX0087 (Illumina); PX0088 (Illumina); PX0089 (Illumina); [redacted]

[redacted] Those standard terms in the IVD Agreements *do not* include a $40 per sample "Market Access Fee" and do not include a 10 percent revenue share. (PX0064 (Illumina) at 29–30; PX0087 (Illumina) at 21; PX0088 (Illumina) at 18; PX0089 (Illumina) at 18.)

Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2756. Illumina's "Market Access Fee" distinguished between a single-cancer test like Singlera's ColonES and a pan-cancer test like Singlera's PanSeer. (PX7042 (Gao (Singlera) IHT at 78-80); *see* PX8516 (Singlera) at 006 (Email from J. Leite, Illumina, to G. Gao, Singlera, attaching Singlera-Illumina Draft IVD NextSeqDX Term Sheet, June 20, 2020) (assigning a payment structure for each cancer indication, capping "pan-cancer Class III claims" at $10 million)).

Response to Finding No. 2756:

The proposed finding is incomplete and misleading. Under the Open Offer, customers interested in entering an IVD agreement can choose from three template agreements—an All-Platforms Agreement, a NextSeq Agreement or a NovaSeq Agreement. (Goswami (Illumina) Tr. 3208; PX0064 (Illumina) at 28–40; PX0087 (Illumina); PX0088 (Illumina); PX0089 (Illumina).) The financial terms (and other terms) for each agreement are consistent and do not vary based on the type of test a customer is developing. (*See* PFF ¶ 1032; Goswami (Illumina) Tr. 3212–13; PX0064 (Illumina) at 29–30; PX0087 (Illumina) at 20–22; PX0088 (Illumina) at 18–19; PX0089 (Illumina) at 18–19.) Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2757. Under Illumina's proposed terms to Singlera, a "pan-cancer" test would cost 2.5 times more than a single-cancer test. (PX7042 (Gao (Singlera) IHT at 78-81); *see* PX8516 (Singlera) at 006 (Email from J. Leite, Illumina, to G. Gao, Singlera, attaching Singlera-Illumina Draft IVD NextSeqDX Term Sheet, June 20, 2020) (assigning a payment structure for each indication, capping "pan-cancer Class III claims" at $10 million)).

Response to Finding No. 2757:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2756, which Respondents incorporate herein.

Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(d) Illumina Can Target MCED Customers Via Field-of-use Restrictions that Illumina Includes in Its Agreements with Customers.

2758. [redacted] (Felton Tr. 2062 (*in camera*).

Response to Finding No. 2758:

The proposed finding is inaccurate, incomplete and misleading because it relies on testimony from Dr. Felton, an employee of Thermo Fisher, to attempt to opine about field of use restrictions for Illumina contracts. Specifically, the proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. In any event, the cited testimony shows that the described pricing practice followed the standard market approach in the industry.

Further, the proposed finding relates to irrelevant subject matter because Illumina has committed to an Open Offer, the terms of which expressly address this issue. The terms of the Open Offer require that Illumina treat customers equitably relative to GRAIL and any other for-profit entity in terms of pricing. (deSouza (Illumina) Tr. 2402–03; PX0064 (Illumina) at 7–8.) Respondents also refer to PFF ¶¶ 1013–25. Under this universal pricing grid, customers receive most-favored-nations (MFN) pricing protections, which ensure that the customer has access to volume-based prices "that are no less favorable (i.e., the same or better) than" those provided to

GRAIL. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 5, 7–8.) GRAIL also receives pricing under a universal pricing grid. (PFF ¶ 1016.5; Berry (Illumina) Tr. 894.)

The Open Offer applies to "*all fields of use*, specifically excluding any use that (i) is not in accordance with the product's specifications or documentation (it being understood that specifications and documentation shall not undermine or limit Customer's rights under this Supply Agreement), (ii) is a reuse of a previously used consumable, (iii) is the disassembling, reverse-engineering, reverse-compiling, or reverse-assembling of the Supplied Product, (iv) is the separation, extraction, or isolation of components of consumables or other unauthorized analysis of the consumables, (v) gains access to or determines the methods of operation of the Supplied Product, or (vi) is the transfer to a third party of, or sub-licensing of, software or third-party software." (PX0064 (Illumina) at 3 (emphasis added).) Respondents also incorporate their responses to CCFF ¶¶ 2630–31 herein.

2759. [redacted] (PX7079 (Flatley (Illumina) Dep. at 127) (*in camera*)).

Response to Finding No. 2759:

The proposed finding is incomplete and misleading. Although Mr. Flatley stepped down as CEO, the proposed finding appears to suggest that, even today, six years later, Illumina applies the same approach. This is incorrect.

As Ms. Berry testified at trial, [redacted]

Respondents incorporate their response to CCFF ¶ 2758 herein.

2760. [redacted] (PX7053 (Fesko (Natera) IHT at 57-58) (*in camera*)).

Response to Finding No. 2760:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 27, which Respondents incorporate herein.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2761. Mr. Flatley explained that Illumina has invoked the field of use clause when Illumina was [redacted] (PX7079 (Flatley (Illumina) Dep. at 127) (*in camera*)).

Response to Finding No. 2761:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2758, which Respondents incorporate herein. Although Mr. Flatley stepped down as CEO, the proposed finding appears to suggest that, even today, six years later, Illumina applies the same approach. This is incorrect.

For a customer who signs the Open Offer, if Illumina granted a discretionary discount to an equivalent customer or to GRAIL (for example, an "unusual discount"), "Illumina would be obliged to reduce the price to the [Open Offer signatory] to match the price that was offered to either GRAIL or an equivalent customer." (Berry (Illumina) Tr. 894.)

(i) Illumina Has Previously Used Field-of-Use Restrictions to Limit Discounts to Product Lines that Did Not Compete with an Illumina Business Line

2762. [redacted] (PX7060 (Naclerio (Illumina) IHT at 126-28) (*in camera*)).

Response to Finding No. 2762:

The proposed finding is incomplete and misleading. Although Dr. Naclerio left Illumina in 2016, the proposed finding appears to suggest that, even today, six years later, Illumina applies the same approach. This is incorrect. Respondents incorporate their responses to CCFF ¶¶ 2630–31 herein.

As Ms. Berry testified at trial, [redacted] finding relates to irrelevant subject matter because Illumina has subsequently committed to an Open Offer, the terms of which expressly address this issue. The terms of the Open Offer require that Illumina treat customers equitably relative to GRAIL and any other for-profit entity in terms of pricing. (deSouza (Illumina) Tr. 2402–03; PX0064 (Illumina) at 7–8.) Respondents also refer to PFF ¶¶ 1013–25. Under this universal pricing grid, customers receive most-favored-nations (MFN) pricing protections, which ensure that the customer has access to volume-based prices "that are no less favorable (i.e., the same or better) than" those provided to

GRAIL. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 5, 7–8.) GRAIL also receives pricing under a universal pricing grid. (PFF ¶ 1016.5; Berry (Illumina) Tr. 894.)

The Open Offer applies to "*all fields of use*, specifically excluding any use that (i) is not in accordance with the product's specifications or documentation (it being understood that specifications and documentation shall not undermine or limit Customer's rights under this Supply Agreement), (ii) is a reuse of a previously used consumable, (iii) is the disassembling, reverse-engineering, reverse-compiling, or reverse-assembling of the Supplied Product, (iv) is the separation, extraction, or isolation of components of consumables or other unauthorized analysis of the consumables, (v) gains access to or determines the methods of operation of the Supplied Product, or (vi) is the transfer to a third party of, or sub-licensing of, software or third-party software." (PX0064 (Illumina) at 3 (emphasis added).)

In any event, Respondents also note that the described pricing practice followed the standard market approach in the industry. [redacted] As Dr. Goswami testified, "field definition is . . . very standard for any kind of contract . . . because it identifies what is allowable within a field." (Goswami (Illumina) Tr. 3234.) [redacted] (PX7060 (Naclerio (Illumina) Dep. at 125).)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their response to CCFF ¶ 2758 herein.

2763. [redacted] (PX7076 (Berry (Illumina) Dep. at 216-17) (*in camera*)).

Response to Finding No. 2763:

The proposed finding is irrelevant, incomplete and misleading. In NIPT, unlike in oncology, Illumina settled Verinata's litigation with Sequenom, and as part of that settlement, Illumina and Sequenom created a patent pool, where NIPT competitors could pay a single test fee and practice the key IP for NIPT from five different entities. [redacted]; PX7089 (Naclerio (Illumina) Dep. at 58–59).) Illumina is responsible for collecting the test fees and administering the patent pool agreement. (*See* deSouza (Illumina) Tr. 2470–71.)

Further, because the proposed finding relates to [redacted] the proposed finding relates to irrelevant subject matter because Illumina has subsequently committed to an Open Offer, the terms of which expressly address this issue. Specifically, Illumina's oncology supply agreements are not restricted to specific substantive fields of use. As noted in Respondents' responses to CCFF ¶ 2762, which Respondents incorporate herein, customers under the Open Offer may purchase sequencing instruments and core consumables for "all fields of use".

Respondents further note that the proposed finding does not evidence any particular ability to identify and/or discriminate against alleged rivals. Respondents also incorporate their responses to CCFF ¶¶ 2612, 2661, 2663 and 2758 herein.

2764. [redacted] (PX2441 (Illumina) at 003 (Email from N. Naclerio, Illumina, to M. Rabinowitz, Natera, et al. attaching Natera NIPT Supply Agreement Terms, May 4, 2013)) (*in camera*)).

Response to Finding No. 2764:

The proposed finding is irrelevant, incomplete and misleading. At the time that Natera negotiated the supply agreement in 2013, there was a lot of uncertainty about whether Illumina would be permitted to sell sequencing instruments and core consumables for clinical uses. (*See* PX7060 (Naclerio (Illumina) Dep. at 150–52).) Specifically, NIPT was the first clinical area which used Illumina's sequencing instruments and core consumables, and there was uncertainty about whether the same research-use only products could be used for clinical uses or whether Illumina would need to develop higher quality reagents for clinical applications. (*See* PX7060 (Naclerio (Illumina) Dep. at 150–52).) To avoid running afoul of the FDA regulations, Illumina restricted the potential fields of use and required NIPT customers to buy clinical grade reagents and core consumables rather than research use products. (*See* PX7060 (Naclerio (Illumina) Dep. at 150–52).)

In addition, as noted in Respondents' responses to CCFF ¶ 2763, which Respondents incorporate herein, Illumina is responsible for administering the test fee as part of the NIPT Patent Pool Agreement, which requires tracking the field of use for NIPT customers.

Further, because the proposed finding relates to [redacted] the proposed finding relates to irrelevant subject matter because Illumina has subsequently committed to an Open Offer, the terms of which expressly address this issue. Specifically, Illumina's oncology supply agreements are not restricted to specific substantive fields of use. As noted in Respondents' responses to CCFF ¶ 2762, which Respondents incorporate herein, customers

under the Open Offer may purchase sequencing instruments and core consumables for "all fields of use".

Respondents also incorporate their responses to CCFF ¶¶ 2630–31 and 2650 herein.

2765. [redacted] (PX7113 (Rabinowitz (Natera) Dep. at 114) (*in camera*)).

Response to Finding No. 2765:

The proposed finding is irrelevant, inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2762–64, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶¶ 2630–31 and 2650 herein.

2766. [redacted] (*in camera*)). [redacted] (PX8379 (Natera) at 023 [redacted] (*in camera*)).

Response to Finding No. 2766:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2762–64, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶¶ 2630–31 and 2650 herein.

2767. [redacted] (RX1899 (Illumina) at 003 [redacted]; PX2241 (Illumina) at 001 (Letter from C. Moehle, Illumina, to K. Song, Ariosa, Jan. 10, 2014)).

Response to Finding No. 2767:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2650, 2762–64, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶¶ 2630–31 and 2650 herein.

2768. According to Illumina, the Customer Field of Use provisions in Ariosa's supply agreement prohibited Ariosa from performing fetal gender determination using Illumina products. (PX2241 (Illumina) at 001 (Letter from C. Moehle, Illumina, to K. Song, Ariosa, Jan. 10, 2014)). On January 10, 2014, Illumina sent a breach letter to Ariosa alleging, among other things, that Ariosa's sale of a sequencing-based prenatal test that reported fetal gender represented a breach of its Sale and Supply Agreement with Illumina. (PX2241 (Illumina) at 001 (Letter from C. Moehle, Illumina, to K. Song, Ariosa, Jan. 10, 2014)).

Response to Finding No. 2768:

The proposed finding is irrelevant, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2650, 2762–64, which Respondents incorporate herein. Although the agreement and the breach letter date to 2014, the proposed finding appears to suggest that, even today, eight years later, Illumina applies the same approach. This is incorrect.

At the time that Ariosa negotiated the supply agreement, there was a lot of uncertainty about whether Illumina would be permitted to sell sequencing instruments and core consumables for clinical uses. (*See* PX7060 (Naclerio (Illumina) Dep. at 51–53).) [redacted] (*See* RX1899 (Illumina) at 2.) Despite these representations, [redacted] (*See* PX7057 (Flatley (Illumina) IHT at 95).) Respondents also incorporate their responses to CCFF ¶¶ 2630–32 herein.

Further, because the proposed finding relates to prior pricing practices, the proposed finding relates to irrelevant subject matter because Illumina has subsequently committed to an

Open Offer, the terms of which expressly address this issue. Specifically, Illumina's oncology supply agreements are not restricted to specific substantive fields of use. As noted in Respondents' responses to CCFF ¶ 2762, which Respondents incorporate herein, customers under the Open Offer may purchase sequencing instruments and core consumables for "all fields of use".

2769. [redacted]

Response to Finding No. 2769:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2758 and 2770, which Respondents incorporate herein. Further, Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 9), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

In any event, Respondents also note that the described pricing practice followed the standard market approach in the industry. [redacted] As Dr. Goswami testified, "field definition is . . . very standard for any kind of

contract . . . because it identifies what is allowable within a field." (Goswami (Illumina) Tr. 3234.) Dr. Naclerio similarly testified that "field of use" is "a standard term of art that's in practically I think every license or supply agreement". (PX7060 (Naclerio (Illumina) Dep. at 125).)

2770. [redacted] PX2200 (Illumina) at 002 (Email from J. Leite, Illumina, to M. Van Oene et al., Illumina, Nov. 3, 2020) [redacted]

Response to Finding No. 2770:

The proposed finding is irrelevant, incomplete and misleading.

First, the proposed finding is also irrelevant because it relates to distributed IVD kits for therapy selection, which do not relate to the availability of sequencing instruments and core consumables for oncology testing.

Second, the proposed finding is incomplete and misleading to the extent it suggests that Illumina restricted certain rights for distributed IVD kits for therapy selection because of competition concerns. To the contrary, at trial, Mr. Leite, the former vice president of clinical business development at Illumina, explained that [redacted]

[redacted]

Third, Illumina's oncology supply agreements are not restricted to specific substantive fields of use. As noted in Respondents' responses to CCFF ¶ 2762, which Respondents incorporate herein, customers under the Open Offer may purchase sequencing instruments and core consumables for "all fields of use".

The Open Offer also requires Illumina, on a customer's request, to enter into a separate agreement with the customer based on standardized terms to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33; Rabinowitz (Natera) Tr. 423–24; deSouza (Illumina) Tr.

2404; PX0064 (Illumina) at 8; PX0087 (Illumina); PX0088 (Illumina); PX0089 (Illumina);

[redacted]

Specifically, the standardized IVD agreements under the Open Offer provide the ability of oncology test developers to pursue distributed IVD kits (also known as "IVD test kits") for "genetic testing of human samples in the field of oncology, including risk assessment, predisposition, *screening*, diagnosis, stating, prognosis, prediction, monitoring, and treatment selection". (PX0087 (Illumina) at 4; PX0088 (Illumina) at 3; PX0089 (Illumina) at 3; Goswami (Illumina) Tr. 3234.)

Respondents also note that features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (PFF ¶¶ 675–678.5 (RX3869 (Cote Expert Report) ¶¶ 359–363; Goswami (Illumina) Tr. 3189–92, 3194–95).)

Finally, Complaint Counsel did not present the Guardant draft term sheet (PX2134) cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 9), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

In any event, Respondents also note that the described pricing practice followed the standard market approach in the industry. [redacted]

[redacted] As Dr. Goswami testified, "field definition is . . . very standard for any kind of contract . . . because it identifies what is allowable within a field." (Goswami (Illumina) Tr. 3234.) Dr. Naclerio similarly testified that "field of use" is "a standard term of art that's in practically I think every license or supply agreement". (PX7060 (Naclerio (Illumina) Dep. at 125).)

2771. [redacted]

PX2200 (Illumina) at 002 (Email from J. Leite, Illumina, to M. Van Oene, Illumina, Nov. 3, 2020) [redacted]

Response to Finding No. 2771:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2770, which Respondents incorporate herein.

2772. As explained in detail below in Sections VII.D.2. (Illumina Identified and Used Similar Tools in the Oncology Therapy Selection Market**)** and VII.D.3. (Illumina Identified and Used Similar Tools in the NIPT Market), when vertically integrated, Illumina has used many tools to inhibit its NGS customers that also compete with Illumina's clinical product portfolio.

Response to Finding No. 2772:

The proposed finding is improper because it treats Complaint Counsel's inaccurate, misleading and argumentative headers as purported facts. To the extent Complaint Counsel relies on its Proposed Findings in Sections VII.D.2 and VII.D.3, ¶¶ 3749–4164, Respondents incorporate their responses to those Proposed Findings herein.

(2) Illumina's Pricing Strategy Gives It the Ability to Increase Prices Anywhere along the Value Chain—from the Sale of Instruments and Consumables to the Provision of Services—and Target Specific Applications or Customers by Altering the Discounts it Offers

2773. [redacted] (PX7123 (Fellis (Illumina) Dep. at 27-28, 29, 30, 35) (*in camera*)).

Response to Finding No. 2773:

The proposed finding relates to [redacted] and therefore relates to irrelevant subject matter because Illumina has subsequently committed to an Open Offer, which includes extensive pricing terms. The Open Offer includes a list of standardized prices for Illumina's sequencing instruments and core consumables. (PX0064 (Illumina) at 15–27.) The terms of the Open Offer require that Illumina treat customers equitably relative to GRAIL and any other for-profit entity in terms of pricing. (deSouza (Illumina) Tr. 2402–03; PX0064 (Illumina) at 7–8.) Respondents also refer to PFF ¶¶ 1013–25. Under this universal pricing grid, customers receive most-favored-nations (MFN) pricing protections, which ensure that the customer has access to volume-based prices "that are no less favorable (i.e., the same or better) than" those provided to GRAIL. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 5, 7–8.) GRAIL also receives pricing under a universal pricing grid. (PFF ¶ 1016.5; Berry (Illumina) Tr. 894.)

2774. [redacted] (*See e.g.*, PX2306 (Illumina) at 011-12 [redacted] (*in camera*)).

Response to Finding No. 2774:

The proposed finding is directed to irrelevant subject matter, including for the reasons identified in the response to CCFF ¶ 2773, which Respondents incorporate herein.

2775. [redacted] (PX7089 (Naclerio (Illumina) Dep. at 196-197) (*in camera*)).

Response to Finding No. 2775:

The proposed finding is incomplete and misleading. Although Dr. Naclerio left Illumina in 2016, the proposed finding appears to suggest that, even today, six years later, Illumina applies the same approach. This is incorrect. As discussed in Respondents responses to CCFF ¶¶ 2630–31, which Respondents incorporate herein, Illumina does not charge a premium for using Illumina's sequencing platform in a commercial clinical setting. Instead, as discussed below, the universal pricing grid applies.

Further, because the proposed finding relates to [redacted] the proposed finding relates to irrelevant subject matter because Illumina has subsequently committed to an Open Offer, the terms of which expressly address this issue. The terms of the Open Offer require that Illumina treat customers equitably relative to GRAIL and any other for-profit entity in terms of pricing. (deSouza (Illumina) Tr. 2402–03; PX0064 (Illumina) at 7–8.) Respondents also refer to PFF ¶¶ 1013–25. Under this universal pricing grid, customers receive most-favored-nations (MFN) pricing protections, which ensure that the customer has access to volume-based prices "that are no less favorable (i.e., the same or better) than" those provided to GRAIL. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 5, 7–8.) GRAIL also receives pricing under a universal pricing grid. (PFF ¶ 1016.5; Berry (Illumina) Tr. 894.)

2776. [redacted] (PX7089 (Naclerio (Illumina) Dep. at 199-200) (*in camera*)).

Response to Finding No. 2776:

The proposed finding is incomplete and misleading. Although Dr. Naclerio left Illumina in 2016, the proposed finding appears to suggest that, even today, six years later, Illumina

applies the same approach. This is incorrect. As discussed in Respondents responses to CCFF ¶¶ 2630–31, which Respondents incorporate herein, Illumina does not charge a premium for using Illumina's sequencing platform in a commercial clinical setting. Instead, as discussed below, the universal pricing grid applies.

Further, because the proposed finding relates to [redacted], the proposed finding relates to irrelevant subject matter because Illumina has subsequently committed to an Open Offer, the terms of which expressly address this issue. The terms of the Open Offer require that Illumina treat customers equitably relative to GRAIL and any other for-profit entity in terms of pricing. (deSouza (Illumina) Tr. 2402–03; PX0064 (Illumina) at 7–8.) Respondents also refer to PFF ¶¶ 1013–25. Under this universal pricing grid, customers receive most-favored-nations (MFN) pricing protections, which ensure that the customer has access to volume-based prices "that are no less favorable (i.e., the same or better) than" those provided to GRAIL. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 5, 7–8.) GRAIL also receives pricing under a universal pricing grid. (PFF ¶ 1016.5; Berry (Illumina) Tr. 894.)

2777. [redacted]
(*See, e.g.*, PX7042 (Gao (Singlera) IHT at 76-77) (noting Illumina's "technology access fee of $3 million"); PX7049 (Bailey (PGDx) IHT at 121-125) (*in camera*) [redacted]).

Response to Finding No. 2777:

The proposed finding is incomplete and misleading. At trial, Mr. Leite, the former vice president of clinical business development at Illumina, testified that Illumina included upfront fees for IVD agreements based on "a combination of a number of factors. One, there was a recognition and quantification of the value that our own Dx platforms created, and we wanted to participate in that value creation. There was significant monetary investment from Illumina in

the developments and the FDA approval of those systems that we wanted to recoup. And there was a potential for downside risk that we needed to offset through some financial consideration." (Leite (Illumina) Tr. 2163.)

The Open Offer requires Illumina, on a customer's request, to enter into a separate agreement with the customer based on standardized terms to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33; Rabinowitz (Natera) Tr. 423–24; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; PX0087 (Illumina); PX0088 (Illumina); PX0089 (Illumina); [redacted] Those standard terms include a "Tech Access Fee", fees for certain development milestones and a 6% revenue share. Contrary to Complaint Counsel's unproven contention, the standard terms *do not* include fees for different diagnostic claims. (*See* PX0087 (Illumina) at 20–22; PX0088 (Illumina) at 18–19; PX0089 (Illumina) at 18–19.)

In any event, Respondents also note that the described pricing practice followed the standard market approach in the industry. [redacted] As Dr. Goswami testified, "field definition is . . . very standard for any kind of contract . . . because it identifies what is allowable within a field." (Goswami (Illumina) Tr. 3234.) Dr. Naclerio similarly testified that "field of use" is "a standard term of art that's in

practically I think every license or supply agreement". (PX7060 (Naclerio (Illumina) Dep. at 125).)

Respondents also note that the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2778. As described in Sections VII.D.2. (Illumina Identified and Used Similar Tools in the Oncology Therapy Selection Market**)** and VII.D.3. (Illumina Identified and Used Similar Tools in the NIPT Market), Illumina has previously used fees—in various forms—when vertically integrated in the therapy selection and NIPT markets to control and customize the price of its instruments, consumables, and services.

Response to Finding No. 2778:

The proposed finding is improper because it treats Complaint Counsel's inaccurate, misleading and argumentative headers as purported facts. To the extent Complaint Counsel relies on its Proposed Findings in Section VII.D.2 and VII.D.3, paragraphs 3749–4164, Respondents incorporate their responses to those Proposed Findings herein.

2779. [redacted]

(PX6090 (Scott Morton Report) ¶ 182 (*in camera*)).

Response to Finding No. 2779:

The proposed finding is incomplete and misleading. Contrary to Dr. Scott Morton's conclusion, the weight of the evidence shows that, post-acquisition, customers are protected from Illumina increasing input costs in a way that materially disadvantages their test development efforts. As Margaret Guerin-Calvert testified, "[t]he open offer[‘s pricing section] has a number of provisions that specifically address to me, as an economist, the conditions that keep prices from being increased" for customers. (RX6002 (Guerin-Calvert Trial Dep. at 34).) Ms. Guerin-Calvert explained that Dr. Scott Morton's opinion on Illumina's ability to use pricing to increase potential GRAIL rivals' costs is flawed because "it really didn't take into consideration an evaluation of all of the aspects" of the Open Offer that "specifically address Illumina's ability to raise price or to price in such a way across its products to . . . competitively disadvantage rivals". (RX6002 (Guerin-Calvert Trial Dep. at 39).) For example, the Open Offer provides that the prices that a customer has access to "will not be changed or increased, other than by inflation adjustment, for the 12 years [of the Open Offer agreement]. So that is a straightforward limitation on price change." (RX6002 (Guerin-Calvert Trial Dep. at 35).) Additionally, customers "if they choose, can stay with the prices that they have premerger", meaning that their prices will not increase relative to the premerger status quo. (RX6002 (Guerin-Calvert Trial Dep. at 35–36).)

Furthermore, the evidence shows that NGS costs will be a very small part of any commercialized MCED test's revenues. (PFF ¶ 884 (RX6000 (Carlton Trial Dep.) at 30–31).)

The proposed finding is also incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. [redacted]

[redacted] (PFF ¶¶ 701–06) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

(3) With Its Price Control, Illumina Could Offer Less Favorable Terms to MCED Test Developers, Affecting Their Profitability and Competitiveness, and Harming Innovation

2780. Dr. William Cance, Chief Medical and Scientific Officer at American Cancer Society, stated in a Declaration, "If development costs increase, companies that would otherwise have worked towards developing these tests may struggle to carry their ideas forward to where they can become a reality for doctors and patients." (PX8398 (Cance (American Cancer Society) Decl. at ¶ 12)).

Response to Finding No. 2780:

Respondents have no specific response except to note that the Open Offer, which Illumina extended to all of its U.S. oncology customers, "prevents Illumina from being able to raise prices over the term of the agreement of any of the existing products" and further protects customers "from being charged higher prices for new versions of sequencing products or instruments or consumables". (Berry (Illumina) Tr. 901–02; *see also* PFF ¶ 1021–22.)

Furthermore, the evidence shows that NGS costs will be a very small part of any commercialized MCED test's revenues. (PFF ¶ 884 (RX6000 (Carlton Trial Dep.) at 30–31).) Respondents also incorporate their responses to CCFF ¶ 2779 herein.

2781. William Getty, Senior Vice President of the Commercial Screening Division at Guardant, testified that Illumina has the ability to act so that "profitability is squeezed for other manufacturers such that over time, those manufacturers are rendered nonexistent. And ultimately then innovation slows down because there's no advantage for Illumina to

advance their technology" and "patients will be negatively impacted." (PX7105 (Getty (Guardant) Dep. at 74-76)).

Response to Finding No. 2781:

The proposed finding is incomplete and misleading. The Open Offer, which Illumina extended to all of its U.S. oncology customers, [redacted] "prevents Illumina from being able to raise prices over the term of the agreement of any of the existing products" and further protects customers "from being charged higher prices for new versions of sequencing products or instruments or consumables". (Berry (Illumina) Tr. 901–02; *see also* PFF ¶ 1021–22.)

Furthermore, the evidence shows that NGS costs will be a very small part of any commercialized MCED test's revenues. (PFF ¶ 884 (RX6000 (Carlton Trial Dep.) at 30–31).) Respondents also incorporate their responses to CCFF ¶ 2779 herein.

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. As a Guardant executive, Mr. Getty has no basis to know about Illumina's incentive to advance its technology. To the contrary, Illumina has developed its reputation by investing substantial amounts into innovation and dramatically lowering sequencing costs over time. (PFF ¶ 855; Aravanis (Illumina) Tr. 1922; (RX1100 (George (Invitae) Decl. ¶ 8).) Today, Illumina's brand is synonymous with innovative, low-cost sequencing systems. (PFF ¶ 855.1; s*ee* Berry (Illumina) Tr. 811–12.) Illumina has cultivated a reputation as a trusted supplier of NGS technology. (PFF ¶ 853; *see* PX7101 (Vogelstein (Johns Hopkins) Dep. at 57–58) ("Illumina makes fantastic instruments. I mean, they are unbelievably good . . . it's amazing what they've done.").)

2782. [redacted] (PX7105 (Getty (Guardant) Dep. at 72-73) (*in camera*)).

Response to Finding No. 2782:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2781, which Respondents incorporate herein.

2783. Mr. Getty explained that "as a public company . . . profitability is critical to our shareholders. And very quickly we would find it very difficult to invest in the R&D necessary or the commercialization necessary to make, you know, improvements and impact patients' lives." (PX7105 (Getty (Guardant) Dep. at 32-33)).

Response to Finding No. 2783:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2781, which Respondents incorporate herein.

2784. [redacted] (PX7055 (Otte (Freenome) IHT at 110) (*in camera*)).

Response to Finding No. 2784:

The proposed finding is incomplete and misleading. The Open Offer, which Illumina extended to all of its U.S. oncology customers, [redacted] "prevents Illumina from being able to raise prices over the term of the agreement of any of the existing products" and further protects customers "from being charged higher prices for new versions of sequencing products or instruments or consumables". (Berry (Illumina) Tr. 901–02; *see also* PFF ¶ 1021–22.)

Furthermore, the evidence shows that NGS costs will be a very small part of any commercialized MCED test's revenues. (PFF ¶ 884 (RX6000 (Carlton Trial Dep.) at 30–31).) Respondents also incorporate their responses to CCFF ¶ 2779 herein.

Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2785. Dr. Gary Gao, Co-Founder and Scientific Advisor for Singlera, expressed that "Illumina can jack up the price of [its] reagent or machine . . . and then we will not be able to compete." (PX7042 (Gao (Singlera) IHT at 130)).

Response to Finding No. 2785:

The proposed finding is incomplete and misleading. The Open Offer, which Illumina extended to all of its U.S. oncology customers, including Singlera (*see* deSouza (Illumina) Tr. 2338), "prevents Illumina from being able to raise prices over the term of the agreement of any of the existing products" and further protects customers "from being charged higher prices for new versions of sequencing products or instruments or consumables". (Berry (Illumina) Tr. 901–02; *see also* PFF ¶ 1021–22.)

Furthermore, the evidence shows that NGS costs will be a very small part of any commercialized MCED test's revenues. (PFF ¶ 884 (RX6000 (Carlton Trial Dep.) at 30–31).) Respondents also incorporate their responses to CCFF ¶ 2779 herein.

Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2786. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 194) (*in camera*)).

Response to Finding No. 2786:

The proposed finding is misleading. [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶ 977 herein.

The proposed finding is also incomplete and misleading with respect to Exact/Thrive's purported reliance on Illumina's NGS systems. Dr. Lengauer testified at trial that [redacted] (Lengauer (Exact/Thrive) Tr. 238–40.)

[redacted]

[redacted]

[redacted] The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 928–29, 1532, 1536 and 2833, which Respondents incorporate herein.

2787. [redacted] (PX8324 (Roche) at 003 [redacted] (*in camera*)).

Response to Finding No. 2787:

The proposed finding is incomplete and misleading. The Open Offer, which Illumina extended to all of its U.S. oncology customers, [redacted] "prevents Illumina from being able to raise prices over the term of the agreement of any of

the existing products" and further protects customers "from being charged higher prices for new versions of sequencing products or instruments or consumables". (Berry (Illumina) Tr. 901–02; *see also* PFF ¶ 1021–22.)

On March 4, 2021, after Roche submitted this set of objections to the FTC, Dr. Severin Schwan, the CEO of Roche stated in a letter that [redacted]

Further, Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 59), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2788. [redacted] (*in camera*)).

Response to Finding No. 2788:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2787, which Respondents incorporate herein.

Further, Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 59), and

therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

2789. [redacted] (*in camera*)).

Response to Finding No. 2789:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2787, which Respondents incorporate herein.

Further, Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 59), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

b) Illumina Can Delay or Foreclose MCED Rivals' Access to New NGS Technology and Favor and Advantage Grail to the Exclusion and Disadvantage of Grail's MCED Rivals

(1) Illumina Regularly Releases New Sequencers, Reagents, and Upgrades to its NGS Technology

2790. Illumina continuously makes improvements and updates to the performance and feature set of its existing platforms:

> JUDGE CHAPPELL: Do you know if there are frequent – I'm not sure of the terminology – but software updates or something that would need to be added to make the machine perform properly?
>
> THE WITNESS [Nicole Berry, Illumina Senior Vice President and General Manager of the Americas Commercial Region]: Sure. So we are continuously seeking to improve performance and, you know, the feature set of our instruments and user friendliness as it relates to things like software. So, yes, software updates are something that we would typically provide and make part of our continuous sort of update and improvement process.

> Those oftentimes could be actually administered remotely. If the customer opted into sort of, you know, a remote connectivity, we could potentially just push an update to the customer's instrument without having to actually go into the lab and, you know, sit at it and put disks in a hard drive, you know, the old-fashioned way.

(Berry (Illumina) Tr. 675-76).

Response to Finding No. 2790:

Respondents have no specific response.

2791. Illumina's Ms. Berry testified about Illumina's "track record in terms of our technology innovation and new product introduction process," stating that Illumina has introduced new instrument platforms and new chemistries within instrument platforms "on a very regular basis." (Berry (Illumina) Tr. 714).

Response to Finding No. 2791:

Respondents have no specific response.

2792. [redacted] (PX7072 (deSouza (Illumina) IHT at 247) (*in camera*)).

Response to Finding No. 2792:

Respondents have no specific response.

2793. Illumina updates its sequencers' software from time to time. (deSouza (Illumina) Tr. 2383).

Response to Finding No. 2793:

Respondents have no specific response.

2794. [redacted] (*See* PX2169 (Illumina) at 024 (Illumina Strategic Plan 2021-2025: Board Discussion Document, Oct. 23, 2020) (*in camera*)).

Response to Finding No. 2794:

Respondents have no specific response.

2795. [redacted] (*See* PX7107 (deSouza (Illumina) Dep. at 271) (*in camera*)). [redacted] (PX2558 (Illumina) at 005-06 (Email from E. Milsovic, Illumina, to F. deSouza, Illumina, attaching Board of Directors Executive Session, Feb. 9, 2021) (*in camera*); *see also* PX2560 (Illumina) at 007 [redacted] (*in camera*); PX7067 (Blanchett (Illumina) IHT at 194-95) (*in camera*)).

Response to Finding No. 2795:

Respondents have no specific response.

2796. [redacted] (RX1994 (Illumina) at 023 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching Illumina 2021-2025 Strategic Plan Presentation, Nov. 5, 2020) (*in camera*)).

Response to Finding No. 2796:

Respondents have no specific response.

2797. [redacted] (deSouza (Illumina) Tr. 2277 (*in camera*)).

Response to Finding No. 2797:

Respondents have no specific response.

2798. [redacted] (deSouza (Illumina) Tr. 2269 (*in camera*)).

Response to Finding No. 2798:

Respondents have no specific response.

2799. As detailed above in Section V.G.4. (Even if Another NGS Platform Entered the U.S. Market Comparable to Illumina's Current Platform, Illumina Plans to Continue to Improve its Existing Platform), [redacted]

Response to Finding No. 2799:

The proposed finding is improper because it treats Complaint Counsel's inaccurate, misleading and argumentative headers as purported facts. To the extent Complaint Counsel

relies on its Proposed Findings in Section V.G.4, Respondents incorporate their responses to those Proposed Findings herein.

2800. [redacted] (RX1994 (Illumina) at 025 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching Illumina 2021-2025 Strategic Plan Presentation, Nov. 5, 2020) (*in camera*)).

[redacted]

Response to Finding No. 2800:

Respondents have no specific response.

2801. [redacted] (RX1994 (Illumina) at 029 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching Illumina 2021-2025 Strategic Plan Presentation, Nov. 5, 2020) (*in camera*)). [redacted] (RX1994 (Illumina) at 029 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching Illumina 2021-2025 Strategic Plan Presentation, Nov. 5, 2020) (*in camera*)).

Response to Finding No. 2801:

Respondents have no specific response.

2802. [redacted] (RX1994 (Illumina) at 029 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching Illumina 2021-2025 Strategic Plan Presentation, Nov. 5, 2020) (*in camera*)).

Response to Finding No. 2802:

Respondents have no specific response.

2803. [redacted] (RX1994 (Illumina) at 037 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching Illumina 2021-2025 Strategic Plan Presentation, Nov. 5, 2020) (*in camera*)).

Response to Finding No. 2803:

Respondents have no specific response.

2804. [redacted] (*See* PX7076 (Berry (Illumina) Dep. at 211-212) (*in camera*)).

Response to Finding No. 2804:

Respondents have no specific response.

(2) When Illumina Releases New NGS Equipment, MCED Customers Rely on Illumina for Installation, Technical Support, and Product Development

2805. When customers seek to upgrade their NGS instruments, Illumina will send a technician to get the new instruments "up and running and to assist in troubleshooting matters." (PX7082 (Cooper (Progenity) Dep. at 87)).

Response to Finding No. 2805:

Respondents have no specific response.

2806. Illumina's Nicole Berry testified that Illumina "work[s] with a customer to confirm that the instrument is performing to spec and the general purpose reagents, the sequencing kits that they buy from us to sequence samples using their assay, are performing to our specifications." (PX7076 (Berry (Illumina) Dep. at 151-152)).

Response to Finding No. 2806:

Respondents have no specific response.

2807. When Illumina releases a new product, Illumina provides customers with support for "how to validate" the new product's functionality. (PX7080 (Silvis (Tempus) Dep. at 131)). Tempus's Lauren Silvis testified, "it could be very difficult to run a successful validation if there were questions we couldn't figure out or troubleshoot on our own and . . . [Illumina]

wouldn't answer questions about what the issues might be or how to solve them." (PX7080 (Silvis (Tempus) Dep. at 131)).

Response to Finding No. 2807:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2808, which Respondents incorporate herein.

2808. [redacted] (PX7076 (Berry (Illumina) Dep. 154) (*in camera*)).

Response to Finding No. 2808:

The proposed finding is incomplete and misleading. In the portion of Ms. Berry's deposition cited here, Ms. Berry explained that [redacted]

2809. At trial, Illumina CEO Mr. deSouza referred to helping customers with installing machines as a frequent issue. (deSouza (Illumina) Tr. 2442).

Response to Finding No. 2809:

Respondents have no specific response.

(3) Illumina Can Delay or Foreclose MCED Rivals' Access to New Technology to Advantage Grail and Disadvantage Grail's Rivals

2810. Illumina's Nicole Berry testified that Section 4(c) of the Open Offer does not prevent Grail from having knowledge of Illumina's new technology before other companies developing oncology tests. (Berry (Illumina) Tr. 708).

Response to Finding No. 2810:

The proposed finding is incomplete and misleading. Although section 4(c) of the Open Offer does not provide customers with protections relating to access to information, section 4(f) does. Specifically, section 4(f) of the Open Offer requires Illumina to provide customers, within 5 days, with the same information that GRAIL receives about final product specifications of any sequencing instruments or core consumables. (PFF ¶ 1006; RX3935 (Illumina) at 2; deSouza (Illumina) Tr. 2405–06.) Respondents also incorporate their responses to CCFF ¶ 2811 herein.

2811. Under the Open Offer, Grail can learn the specifications of new Illumina sequencers before its rival MCED test developers. (Berry (Illumina) Tr. 708).

Response to Finding No. 2811:

The proposed finding is incomplete and misleading. In the portion of Ms. Berry's testimony cited here, Ms. Berry provided context for this answer: She testified that it "clearly is not [Illumina's] intent" to provide specifications to GRAIL before potential GRAIL rivals and that Illumina's "intent with this offer is to, you know, create a level playing field" between customers. (Berry (Illumina) Tr. 708.) Moreover, the cited portion of Ms. Berry's testimony is from August 26, 2021, but the Open Offer was amended to provide additional protections on September 8, 2021. (*See* PFF ¶ 996; RX3935 (Illumina) at 1; deSouza (Illumina) Tr. 2405–06.) These additional protections included section 4(f) of the Open Offer, which requires Illumina to provide customers, within 5 days, with the same information that GRAIL receives about final

product specifications of any sequencing instruments or core consumables. (PFF ¶ 1006; RX3935 (Illumina) at 2.)

2812. As discussed below in Section VIII.A.3. (Illumina's Open Offer Fails to Remedy Anticompetitive Harm from the Merger), [redacted] (Getty (Guardant) Tr. 2552-53 (*in camera*)).

Response to Finding No. 2812:

The proposed finding is improper because it treats Complaint Counsel's inaccurate, misleading and argumentative headers as purported facts. To the extent Complaint Counsel relies on its Proposed Findings in Section VII.A.3, Respondents incorporate their responses to those Proposed Findings herein.

2813. Dr. Bert Vogelstein testified that advanced knowledge of "future product developments and refinements" from Illumina "could substantially alter research and development in the field and the nature of the test products that are eventually produced." (PX8400 (Vogelstein (John Hopkins University) Decl. ¶ 9)).

Response to Finding No. 2813:

Respondents have no specific response except to note that the Open Offer requires Illumina to provide customers, within 5 days, with the same information that GRAIL receives about final product specifications of any sequencing instruments or core consumables. (PFF ¶ 1006; RX3935 (Illumina) at 2.)

2814. Guardant's Bill Getty testified that "it is not any bit speculative" that Illumina could provide new technology to Grail to aid Grail's test over its rivals:

> [S]o it is not any bit speculative to believe to that as Illumina continues to advance their technology, that they would advance that technology and allow for a subsidiary or partner, however it's structured, in GRAIL access to that technology, which may convey a benefit to them around their testing in terms of sensitivity and specificity, which their advancements in sequencing have done over time.
>
> So there is largely a precedent there for their advancement. And so giving early access to an organization that you are tied up with translates into a highly-advantaged test in the marketplace, thus, you know, patient and potentially --

> not potentially -- but physician preference -- potentially patient preference, I should say, and therefore you maintain further your competitive advantage as Illumina.

(PX7105 (Getty (Guardant) Dep. at 73-74)).

Response to Finding No. 2814:

The proposed finding is inaccurate, incomplete and misleading. Contrary to Mr. Getty's testimony, under the Open Offer [redacted] Illumina cannot favor GRAIL in developing new products. As Mr. deSouza testified: "[I]n this offer letter we're saying that any product that's available for GRAIL will be available for everyone. So we're not allowed to make a product only for GRAIL. . . . JUDGE CHAPPELL: All right, thank you. And I think you told me earlier, do you make specific products with your sequencers today? Do you make specific products for your customers? THE WITNESS: No, we do not. We sell to everyone the same portfolio." (deSouza (Illumina) Tr. 2434–35.)

Further, even though Illumina typically has not provided support in the development or commercialization of customers' products, to provide additional benefits to customers, the Open Offer requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶ 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.) This not only prevents Illumina from disadvantaging putative GRAIL rivals, but also requires Illumina to act in a particular way to support rivals developing their own products. (PFF ¶ 1010.9; RX6002 (Guerin-Calvert Trial Dep. at 68).)

2815. Bill Getty of Guardant testified that Illumina could "provide favored status or development opportunities to their internal partners in Grail, which would convey potentially a lack of opportunity for us to advance our technology at a faster rate, and . . . thus hurt us competitively." (PX7105 (Getty (Guardant) Dep. at 69-71)).

Response to Finding No. 2815:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2814, which Respondents incorporate herein.

2816. Guardant's Bill Getty testified that without access to Illumina's latest technology, Guardant will not be able to offer patients the best performing or the lowest cost test. (PX7105 (Getty (Guardant) Dep. at 74-75)).

Response to Finding No. 2816:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2814, which Respondents incorporate herein.

2817. Mr. Getty described the scenario where "the profitability is squeezed for other manufacturers such that over time, those manufacturers are rendered nonexistent. And ultimately then innovation slows down because there's no advantage for Illumina to advance their technology such that patients will be negatively impacted." (PX7105 (Getty (Guardant) Dep. at 74-76)).

Response to Finding No. 2817:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2781, which Respondents incorporate herein.

2818. [redacted] (Getty (Guardant) Tr. 2543 (*in camera*)).

Response to Finding No. 2818:

The proposed finding is incomplete and misleading. Specifically, the Open Offer requires Illumina to provide customers with access to new products within 5 days of GRAIL receiving access. (PFF ¶ 1007; Berry (Illumina) Tr. 878–79; deSouza (Illumina) Tr. 2434–35, 2437–38; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) The Open Offer's access provisions specifically address the concern that Illumina could delay access to products because they level the playing field and prevent individual customers from lagging behind in terms of the products available to them. (PFF ¶ 1009.4; RX6002 (Guerin-Calvert Trial Dep. at 61–62).)

2819. One of Mr. Getty's concerns about the Proposed Acquisition is that advanced notice of information about a new sequencer in development from Illumina could give Grail a "significant head start" on developing the next version of its MCED assay. (Getty (Guardant) Tr. 2518-19).

Response to Finding No. 2819:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2814 and 2818, which Respondents incorporate herein.

2820. [redacted] (PX7058 (Conroy (Exact) IHT at 241-242) (*in camera*)).

Response to Finding No. 2820:

Respondents incorporate their response to CCFF ¶ 2813 herein. [redacted] Finally, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2821. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 88-89) (*in camera*)).

Response to Finding No. 2821:

The proposed finding is incomplete and misleading without additional context. Specifically, under the Open Offer, [redacted] Illumina is prohibited from discontinuing products that any oncology customer has purchased in the prior year. (PFF ¶ 1011; [redacted] Berry (Illumina)

Tr. 883; PX0064 (Illumina) at 6; [redacted].) This provision adequately addresses the concern that Illumina could advantage GRAIL by simply no longer providing a product and ensures that customers as "certainly no worse off than in the current world". (PFF ¶¶ 1011.7–.8; RX6002 (Guerin-Calvert Trial Dep. at 71–73).)

Additionally, the Open Offer requires Illumina to provide customers, within 5 days, with the same information that GRAIL receives about final product specifications of any sequencing instruments or core consumables. (PFF ¶ 1006; RX3935 (Illumina) at 2.) Further, even though Illumina typically has not provided support in the development or commercialization of customers' products, to provide additional benefits to customers, the Open Offer requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶ 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.) This not only prevents Illumina from disadvantaging putative GRAIL rivals, but also requires Illumina to act in a particular way to support rivals developing their own products. (PFF ¶ 1010.9; RX6002 (Guerin-Calvert Trial Dep. at 68).)

Finally, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2822. [redacted]

Response to Finding No. 2822:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2821, which Respondents incorporate herein.

[redacted]

(Lengauer (Third Rock Ventures) Tr. 197-98 (*in camera*)).

2823. [redacted] (PX7085 (Harada (Exact) Dep. at 204-205) (*in camera*)).

Response to Finding No. 2823:

The proposed finding is incomplete and misleading. Specifically, the Open Offer [redacted] requires Illumina to provide customers with access to new products within 5 days of GRAIL receiving access. (PFF ¶ 1007; Berry (Illumina) Tr. 878–79; deSouza (Illumina) Tr. 2434–35, 2437–38; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) The Open Offer's access provisions specifically address the concern that Illumina could delay access to products because they level the playing field and prevent individual customers from lagging behind in terms of the products available to them. (PFF ¶ 1009.4; RX6002 (Guerin-Calvert Trial Dep. at 61–62).) Respondents also incorporate their responses to CCFF ¶ 2821 herein.

2824. [redacted] (PX2598 (Illumina) at 002 (Email from D. Daly, Illumina, to L. Leigh, Illumina, et al., Apr. 11, 2018) (*in camera*)).

Response to Finding No. 2824:

The proposed finding is incomplete and misleading. Specifically, the Open Offer [redacted] requires Illumina to provide customers with access to new products within 5 days of GRAIL receiving access. (PFF

¶ 1007; Berry (Illumina) Tr. 878–79; deSouza (Illumina) Tr. 2434–35, 2437–38; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) The Open Offer's access provisions specifically address the concern that Illumina could delay access to products because they level the playing field and prevent individual customers from lagging behind in terms of the products available to them. (PFF ¶ 1009.4; RX6002 (Guerin-Calvert Trial Dep. at 61–62).) Respondents also incorporate their responses to CCFF ¶¶ 2814 and 2818 herein.

2825. [redacted] (PX2152 (Illumina) at 001 (Text message from S. Tousi, Illumina, Apr. 23, 2020) (*in camera*)).

Response to Finding No. 2825:

The proposed finding is incomplete and misleading. When shown this document at his IH, Dr. Goswami, Illumina's Senior Vice President of Corporate Development and Strategic Planning—who is the text recipient—disagreed with Complaint Counsel's suggestion that this email indicated that Illumina could provide preferential technology to GRAIL, describing it as "patently wrong." (PX7064 (Goswami (Illumina) IH at 215).) He explained that "working with GRAIL will help us improve our technology", but that any improved technology will be "available to all our customers across the RUO and clinical spectrum, and that will include GRAIL's competitors as well." (PX7064 (Goswami (Illumina) IH at 215).) He also testified that "if we want to improve and bring innovations, we don't choose who we bring that innovation to . . . [and] we have all the incentives to bring those innovations as quickly as possible to market." (PX7064 (Goswami (Illumina) IH at 225).)

Further, under the Open Offer, Illumina cannot favor GRAIL in product improvements. As Mr. deSouza testified at trial: "[I]n this offer letter we're saying that any product that's

available for GRAIL will be available for everyone. So we're not allowed to make a product only for GRAIL. . . . JUDGE CHAPPELL: All right, thank you. And I think you told me earlier, do you make specific products with your sequencers today? Do you make specific products for your customers? THE WITNESS: No, we do not. We sell to everyone the same portfolio." (deSouza (Illumina) Tr. 2434–35.)

To the extent that Complaint Counsel attempts to use this proposed finding to suggest that Mr. deSouza's testimony cited in CCFF ¶ 2826 is untrue, this is attempt is misguided. In the portion of Mr. deSouza's testimony cited in CCFF ¶ 2826, Mr. deSouza was asked, "[I]f you made one of these improvements [to Illumina's sequencing equipment]] to time, throughput, or reducing cost, is there any way to limit that to one particular user or customer?" (deSouza (Illumina) Tr. 2446.) Mr. deSouza responded in relevant part that "contractually we're committing [that] [a]nything that GRAIL gets, the entire market will get." (deSouza (Illumina) Tr. 2447.) That is, in light of the Open Offer, even if Illumina wanted to develop products specifically for GRAIL, it would be required to make them available to all Open Offer customers. It supersedes whatever statement Ms. Tousi made in 2020—which was before the Illumina even decided to acquire GRAIL.

Further, even though Illumina typically has not provided support in the development or commercialization of customers' products, to provide additional benefits to customers, the Open Offer requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶ 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.) This not only prevents Illumina from disadvantaging putative GRAIL rivals, but also requires Illumina to act in a

particular way to support rivals developing their own products. (PFF ¶ 1010.9; RX6002 (Guerin-Calvert Trial Dep. at 68).)

2826. Illumina's CEO told the Court at trial that Illumina cannot, and will not, make improvements to technology specifically geared toward Grail. (deSouza (Illumina) Tr. 2443-44; 2446-47).

Response to Finding No. 2826:

Respondents have no specific response.

2827. [redacted] (PX2541 (Illumina) at 008 (Illumina, Interim Review K2-Grail (aka Grail "Pendragon"), Feb. 2, 2017) (*in camera*)).

Response to Finding No. 2827:

The proposed finding is incomplete and misleading.

[redacted] (PX7107 (deSouza (Illumina) Dep. at 243–44.) Complaint Counsel nonetheless chose not to ask Mr. Aravanis or any other witness about that document.

[redacted]

[redacted] (PX7065 (Aravanis (Illumina) IHT at 56–60).) Dr. Aravanis also explained that, to achieve those operational efficiencies, Illumina made "some minor alterations to the reagents for the purposes of developing this assay", and ultimately, "the discussion about the K2/Napa activity was a very minor, minor part of the R&D activities at GRAIL and a very minor, minor part of the R&D activities at Illumina when put in context of the overall R&D activities and overall activities of the company almost – again, kind of a very early, minor activity in the company's history . . . ." (PX7065 (Aravanis (Illumina) IHT 61–62).)

Third, there is nothing anticompetitive about Illumina collaborating with GRAIL in ways it has not and would not with an arm's-length customer; to the contrary, that is an efficiency of vertical integration that benefits competition and consumers. To the extent the proposed finding is meant to suggest otherwise, it is wrong. Further, under the Open Offer, upon customer request, Illumina must enter into a development agreement on commercially reasonable terms relating to the design or modification of sequencing products to optimize interoperability with the customer's tests. (*See* PFF ¶¶ 1005, 1008, 1010.) Illumina has not historically collaborated with customers on such optimization, and so, in this regard, customers who see value in optimization are better off under the Open Offer than they were under the pre-Transaction status quo. (Berry (Illumina) Tr. 844.)

2828. As discussed below in Sections VII.A.2.e. (Illumina Can Alter its NGS Products to Disadvantage Grail's MCED Rivals), VIII.A.3.c.1. (Illumina Can Customize Its Consumables to Favor Grail), and VII.A.3.n.1. (Rather Than Refusing to Sell MCED Test Developer Reagents Outright, Illumina Can Gradually Optimize Its Reagents to Work Best on Galleri Without Optimizing Its Reagents for Other MCED Tests), MCED customers testified that Illumina may develop new NGS products that favor Grail and harm its rivals.

Response to Finding No. 2828:

The proposed finding is improper because it treats Complaint Counsel's inaccurate, misleading and argumentative headers as purported facts. To the extent Complaint Counsel relies on its Proposed Findings in Sections VII.A.2.e, VIII.A.3.c.1 and VII.A.3.n.1, Respondents incorporate their responses to those Proposed Findings herein.

c) Illumina Can Reduce the Quality of its Supply, Support, and Service to Grail's Rivals

(1) MCED Test Developers Rely on Illumina as a Partner from Product Development through Commercialization

2829. Illumina's Nicole Berry, Senior Vice President and General Manager for Illumina's Americas Commercial Region [redacted] (PX7076 (Berry (Illumina) Dep. at 179-181) (*in camera*)).

Response to Finding No. 2829:

Respondents have no specific response except to note that the proposed finding is misleading to the extent it implies that Illumina takes an active role in customers' test development. In the cited testimony, Ms. Berry observed that [redacted] This testimony confirms that Illumina is interested in seeing its customers succeed. It does not, however, suggest that Illumina takes an active role in customers' development efforts. To the contrary, Illumina typically does not provide support in the development or commercialization of customers' products. (PFF ¶¶ 1010.4–1010.7; Berry (Illumina) Tr. 844–47.); *see also* PFF ¶¶ 1735, 1879 [redacted].) For example, [redacted]

[redacted]

[redacted] Likewise, Mr. Getty of Guardant admitted that Illumina did not help Guardant develop the LUNAR-2 assay and did not brainstorm with Guardant on how it could improve the LUNAR-2 assay. (Getty (Guardant) Tr. 2645–46.)

2830. [redacted] (PX7058 (Conroy (Exact) IHT at 174-177) (*in camera*)).

Response to Finding No. 2830:

The proposed finding is inaccurate, incomplete and misleading. As Mr. Conroy admitted,

[redacted]

[redacted] Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2831. [redacted]

(PX7058 (Conroy (Exact) IHT at 221-22) (*in camera*); *see* PX8387 (Exact) at 001 [redacted] (*in camera*)).

Response to Finding No. 2831:

The proposed finding is inaccurate, incomplete and misleading. The cited testimony confirms that Illumina's role in Exact's is limited to that of a "consistent supplier". For example, as Mr. Conroy acknowledged, [redacted]

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2832. [redacted]

[redacted]

(Conroy (Exact) Tr. 1588-89 (*in camera*)).

Response to Finding No. 2832:

The proposed finding is inaccurate, incomplete and misleading. The Open [redacted] requires Illumina to allocate supply in an equitable manner among its customers in the event of a supply shortage. (PFF ¶ 1012; Berry (Illumina) Tr. 885–86; PX0064 (Illumina) at 9.) The Open Offer specifically ensures that customers with the greatest need—those whose lots are expiring earliest—will receive allocations of short supply first. (PFF ¶ 1012.4; RX6002 (Guerin-Calvert Trial Dep. at 77).) Further, [redacted] (*See* PX7058 (Conroy (Exact/Thrive) IHT at 65; PX7051 (Lengauer (Exact/Thrive) IHT at 120–22).)

2833. [redacted] (Conroy (Exact) Tr. 1596 (*in camera*)).

Response to Finding No. 2833:

The proposed finding is inaccurate, incomplete and misleading. Illumina is not the sole supplier of NGS [redacted] and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674; 1704.) Respondents also incorporate their response to CCFF ¶ 2830 herein.

2834. [redacted]

[redacted] (Conroy (Exact) Tr. 1596-97 (*in camera*)).

Response to Finding No. 2834:

The proposed finding is inaccurate, incomplete and misleading. While Mr. Conroy testified [redacted] Respondents also incorporate their responses to CCFF ¶ 1089, incorporated herein.

[redacted] In any event, Exact/Thrive can sign the Open Offer at any time and thereby have a supply agreement for the next twelve years with Illumina. Even though Exact has received a copy of the Open Offer ([redacted]; Conroy (Exact) Tr. 1724 25), at trial, Mr. Conroy had not actually read the Open Offer, and so his

testimony should be given little weight. (PFF ¶¶ 1073, 1073.2; Conroy (Exact/Thrive) Tr. 1725–27.)

2835. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 201) (*in camera*)).

Response to Finding No. 2835:

The proposed finding is incomplete and misleading without additional context. In the portion of Dr. Lengauer's testimony immediately after the cited portion, Dr. Lengauer explained that [redacted] Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2836. Helio's former CEO, Dr. Chahine, testified that he envisioned "a million different ways" that Illumina and Helio could have strategically collaborated "to work as a partner to try to solve the consumer's products and not have to be guarded about your plans and your strategy and your consumer data and your physician data and things like that." He also testified that if the Illumina-Grail transaction closed, "this is obvious – I'd just have to be more guarded." (PX7077 (Chahine (Helio) Dep. at 65-67)).

Response to Finding No. 2836:

The proposed finding is misleading to the extent that it implies that Illumina has an active role in development of customers' products. Illumina typically does not provide support in the development or commercialization of customers' products. (PFF ¶¶ 1010.4–1010.7; Berry (Illumina) Tr. 844–47.) Dr. Chahine's testimony is entirely hypothetical: Illumina and Helio have never, in fact, collaborated on any projects. [redacted] Further, to the extent that the proposed finding suggests that Illumina would use customers' confidential information to disadvantage putative GRAIL rivals, it fails to take account of the Open Offer's confidentiality protections, which prevent such use of confidential information. (*See* PFF ¶¶ 1038–42.)

(2) MCED Test Developers Testified that Illumina Controls the NGS Supply Chain, and Developers' Reliance on Illumina Creates Continuing Business Risk

2837. [redacted] (PX7109 (Daly (Singular Genomics) Dep. at 56) (*in camera*)).

Response to Finding No. 2837:

The proposed finding is inaccurate, incomplete and misleading. The Open Offer expressly prohibits Illumina from favoring GRAIL in a supply shortage and requires Illumina instead to allocate short supply equitably across customers, including GRAIL. (PFF ¶ 1012; Berry (Illumina) 885–87; PX0064 (Illumina) at 9.) The Open Offer specifically ensures that

customers with the greatest need—those whose lots are expiring earliest—will receive allocations of short supply first. (PFF ¶ 1012.4; RX6002 (Guerin-Calvert Trial Dep. at 77).)

2838. [redacted] (PX7090 (Sood (Guardant) Dep. at 119-21) (*in camera*)).

Response to Finding No. 2838:

Respondents have no specific response except to note that [redacted]

2839. William Getty, Guardant's Senior Vice President of Commercial, Cancer Screening Core, expressed that if Illumina stopped supplying Guardant, or failed to supply products in a timely manner, then Guardant's business "would be nonexistent." (PX7105 (Getty (Guardant) Dep. at 58)).

Response to Finding No. 2839:

The proposed finding is inaccurate, incomplete and misleading. Illumina is not the sole supplier of NGS equipment [redacted] and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674, 1823.)

The proposed finding is misleading to the extent it suggests that only Illumina's NovaSeq instrument is suitable for supporting Guardant's putative MCED test. [redacted] Dr.

Chudova also stated that Guardant could use alternative sequencing platforms for its LUNAR-2 screening test in development that meet the throughput, error, time, and sequencing cost requirements. (PX7045 (Chudova (Guardant) IHT at 44–47.) Respondents also incorporate their responses to CCFF ¶ 927 herein.

Additionally, [redacted]

Further, the cited testimony fails to take account of the protections of the Open Offer [redacted] The Open Offer ensures consistent supply of Illumina's products and prohibits Illumina from refusing to supply its sequencing products to cancer screening customers in a timely manner. (*See* PFF ¶¶ 1005, 1007–08, 1011–12.) As Ms. Berry testified, "if Illumina deliberately delayed fulfilling a purchase order for a customer or somehow, you know, monkeyed with supply", "Illumina would be in breach of the [Open Offer] agreement". (Berry (Illumina) Tr. 878–79.)

2840. Mr. Getty testified that any disruption in Guardant's relationship with Illumina could adversely affect Guardant's ability to conduct its business and generate revenue. (Getty (Guardant) Tr. 2684).

Response to Finding No. 2840:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2839, which Respondents incorporate herein.

2841. [redacted] (PX7045 (Chudova (Guardant) IHT at 105-109) (*in camera*)).

Response to Finding No. 2841:

The proposed finding is incomplete and misleading. [redacted] requires Illumina to consistently supply its customers with reagents at a consistent level of quality. (PFF ¶¶ 1005, 1007, 1009.4; RX6002 (Guerin-Calvert Trial Dep. at 61–62).) As Ms. Berry testified, "we are not permitted to [supply lower-quality reagents to customers] under the open offer." (Berry (Illumina) Tr. 878.)

Finally, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2842. [redacted] (PX7100 (Chudova (Guardant) Dep. at 85) (*in camera*)). [redacted] (PX7100 (Chudova (Guardant) Dep. at 85-87) (*in camera*)). [redacted] (PX7100 (Chudova (Guardant) Dep. at 86-87) (*in camera*)). [redacted]

[redacted] (PX7100 (Chudova (Guardant) Dep. at 87) (*in camera*)).

Response to Finding No. 2842:

The proposed finding is inaccurate, incomplete and misleading, the Open Offer [redacted] prohibits Illumina from providing customers with lower quality instruments or consumables. (PFF ¶ 1092.1; Berry (Illumina) Tr. 878–79.) As Ms. Berry testified, "we are not permitted to [supply lower-quality reagents to customers] under the open offer." (Berry (Illumina) Tr. 878.) The Open Offer ensures that MCED test developers will have a consistent quality of supply because, as new, higher quality products are released, they must be made available to all customers. (PFF ¶ 1009.3; RX6002 (Guerin-Calvert Trial Dep. at 61).) In addition, Complaint Counsel's example relates to therapy selection and describes an incident that allegedly happened long before the announcement of the Transaction and is therefore irrelevant. Respondents also incorporate their response to CCFF ¶ 2844 herein.

2843. Mr. Getty explained that Guardant's dependence on Illumina creates business risk "[b]ecause Illumina is a sole supplier for us and our business rests on our ability to sequence and leverage [Illumina's] services in order to maintain those sequencers." (Getty (Guardant) Tr. 2684-85).

Response to Finding No. 2843:

The proposed finding is incomplete and misleading without additional context. Illumina is not the sole supplier of NGS equipment [redacted] and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674, 1823.)

The proposed finding is misleading to the extent it suggests that only Illumina's NovaSeq instrument is suitable for supporting Guardant's putative MCED test. [redacted]

[redacted] Dr. Chudova also stated that Guardant could use alternative sequencing platforms for its LUNAR-2 screening test in development that meet the throughput, error, time, and sequencing cost requirements. (PX7045 (Chudova (Guardant) IHT at 44–47.) Respondents also incorporate their responses to CCFF ¶ 927 herein.

Further, [redacted]

Additionally, the Open Offer [redacted] ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; [redacted] Berry (Illumina) Tr. 865–66; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) The Open Offer requires Illumina to provide customers with the same access to services that GRAIL or any other For-Profit Entity has access to, and at the same prices. (PFF ¶ 1004; [redacted]; Berry (Illumina) Tr. 865–66; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) As Ms. Berry, the senior vice president and general manager of the Americas commercial team at Illumina, testified, "the open offer obligates Illumina to provide

access to a customer to not only the same [product and support] services for which the customer had before the transaction but also any [product and support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.)

2844. Mr. Getty expressed that Illumina is "in a position where they could take significant advantage by kneecapping our ability to run our lab, which would of course flow through to our inability to compete." (PX7105 (Getty (Guardant) Dep. at 68-69)).

Response to Finding No. 2844:

The proposed finding is incomplete and misleading because it fails to take into account to protections of the Open Offer [redacted]

[redacted] Guardant attached the amended supply agreement to its 2020 10-K because the amended agreement represented a material and important contract for Guardant. (PFF ¶ 1075.4; Getty (Guardant) Tr. 2668–69; PX0060 (Guardant) at 151.) And during its negotiations with Illumina, Guardant never indicated to Illumina that Guardant viewed its amended supply agreement as unenforceable or worthless. (Getty (Guardant) Tr. 2669.)

Finally, the Open Offer [redacted] provides for [redacted] as well as additional protections relating to various topics such as pricing for similarly situated customers and access to information about new products. (*See* PFF ¶¶ 1000–57; PX0064 (Illumina); RX3935 (Illumina).). The Open Offer also requires Illumina to provide customers with a consistent source of supply of sequencing instruments and core consumables. (*See* PFF ¶¶ 1000, 1005, 1007, 1009, 1011, 1037; [redacted]; Berry (Illumina) Tr. 690–91, 864, 878–79, 883; Conroy (Exact/Thrive) 1725; deSouza (Illumina) Tr. 2402, 2434–35, 2437–38; PX0064 (Illumina) at 5–6, 9; RX3935 (Illumina) at 2; RX6002 (Guerin-Calvert Trial Dep. at 59–60, 77–79.). As Ms. Berry testified, "if Illumina deliberately delated fulfilling a purchase order for a customer or somehow . . . monkeyed with supply", "Illumina would be in breach of the agreement". (Berry (Illumina) Tr. 878-79.) As economist and President of the Center for Healthcare Economics and Policy and Senior Managing Director at FTI Consulting, Margaret

Guerin-Calvert, explained, the Open Offer provides the economically necessary terms to prevent the alleged anticompetitive harms from the transaction in both the short term and the long term. (RX6002 (Guerin-Calvert Trial Dep. at 21–22).) The Open Offer also represents an improvement for customers over the premerger status quo. (RX6002 (Guerin-Calvert Trial Dep. at 37, 52–53, 57).)

2845. [redacted] (PX7040 (Getty (Guardant) IHT 88 (*in camera*))).

Response to Finding No. 2845:

The proposed finding is inaccurate, incomplete and misleading. Mr. Getty's testimony that Guardant cannot develop a distributable kit without Illumina is incorrect, as Illumina is not the sole supplier of NGS equipment [redacted] and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674, 1823.) Respondents also incorporate their responses to CCFF ¶ 927 herein.

The proposed finding is incomplete and misleading without additional context. Specifically, in the portion of Mr. Getty's testimony immediately after the cited portion, Mr. Getty provided context for this answer: Mr. Getty explained that, in the regulatory process, Guardant relies on Illumina "as a manufacturer" to provide information on Illumina's products. (Getty (Guardant) Tr. 2515.) Further, Mr. Getty admitted that Illumina did not have a role in developing Guardant's LUNAR-2 assay and has not been involved in any FDA review or consideration of the LUNAR-2 assay. (Getty (Guardant) Tr. 2645.)

Additionally, the Open Offer requires Illumina to provide to provide documentation to assist customers with FDA approval or marketing authorization to sell a for-profit, clinical test

using Illumina's sequencing instruments and core consumables. (PFF ¶ 1027; PX0064 (Illumina) at 8; PX0087 (Illumina) at 23; PX0088 (Illumina) at 20; PX0089 (Illumina) at 20; PX7093 (Young (Illumina) Dep. at 68).) The Open Offer includes a right of reference to any relevant Illumina regulatory documentation for Illumina's IVD partners. (PFF ¶ 1027.2; Leite (Illumina/InterVenn) Tr. 2156; PX0064 (Illumina) at 39; PX0087 (Illumina) at 23; PX0088 (Illumina) at 20; PX0089 (Illumina) at 20; [redacted] Under this right, a partner developing on Illumina systems may reference Illumina's files in their regulatory submission. (PFF ¶ 1027.2; PX0064 (Illumina) at 39; PX0087 (Illumina) at 23; PX0088 (Illumina) at 20; PX0089 (Illumina) at 20; [redacted]

Respondents also note that features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (PFF ¶¶ 675–678.5 (RX3869 (Cote Expert Report) ¶¶ 359–363; Goswami (Illumina) Tr. 3189–92, 3194–95).) The test developer's decision whether to proceed with an IVD kit as opposed to a centralized model is an economic decision driven by test-specific factors. (Goswami (Illumina) Tr. 3197.) IVD kits are most suitable for tests that have precious samples, that present shipping challenges and require fast turnaround times. (Goswami (Illumina) Tr. 3196–3200; *see also* RX3869 (Cote Expert Report) § XI, ¶¶ 360–63.) Respondents also note that Illumina's NovaSeq is not yet available as Dx instrument. (Goswami (Illumina) Tr. 3194.)

Finally, the proposed finding relies on impermissible lay opinion testimony. Mr. Getty was not called as an expert witness on the FDA approval process and his opinion on that process should be disregarded.

2846. In its annual report, Guardant identified Illumina as its "sole supplier of sequencers and as the sole provider of maintenance and repair services for these sequencers," and indicated that "[a]ny disruption in operations of Illumina . . . could materially and adversely impact our supply chain and laboratory operations of our precision oncology platform and thus our ability to conduct our business and generate revenue." (PX0153 at 47 (Guardant 2020 Form 10-K, Feb. 25, 2021)).

Response to Finding No. 2846:

Respondents have no specific response except to note that Illumina is not the sole supplier of NGS equipment**,** as Mr. Getty of Guardant acknowledged (Getty (Guardant) Tr. 2642), and faces stiff competition from current and future NGS providers**.** (*See* PFF ¶¶ 578–674, 1823; *see also* PFF ¶ 1812; [redacted].)

[redacted] Dr. Chudova also stated that Guardant could use alternative sequencing platforms for its LUNAR-2 screening test in development that meet the throughput, error, time, and sequencing cost requirements. (PX7045 (Chudova (Guardant) IHT at 44–47.) BGI also markets its NGS technology in many other countries and is expected to enter the U.S. market in the near future. [redacted]; RX3869 (Cote Expert Report) ¶ 287; [redacted]**.)** BGI also recently won a jury verdict that held three of Illumina's patents to be invalid such that BGI can legally launch its sequencing instruments and related reagents in the United States. Jury Verdict at 14–16, ECF No. 407, *Complete Genomics, Inc. v. Illumina, Inc.*, No. CV-19-970 (MN) (D. Del. May 6, 2022). BGI may enter the United States market as soon as August 2022. (PFF ¶¶ 777-777.3.) Respondents also incorporate their responses to CCFF ¶¶ 927–28 herein.

2847. [redacted] (Conroy (Exact) Tr. 1585 (*in camera*)).

Response to Finding No. 2847:

The proposed finding is incomplete and misleading. Illumina is not the sole supplier of NGS equipment, [redacted] and faces stiff competition from other NGS providers. (*See* PFF ¶¶ 578–674, 1704–05.) [redacted] Respondents also incorporate their responses to CCFF ¶¶ 928–29 herein.

2848. [redacted] (Conroy (Exact) Tr. 1585 (*in camera*)).

Response to Finding No. 2848:

The proposed finding is inaccurate, incomplete and misleading. The Open Offer [redacted] requires Illumina to provide customers with a consistent source of supply of sequencing instruments and core consumables. (*See* PFF ¶¶ 1000, 1005, 1007, 1009, 1011, 1037; [redacted]; Berry

(Illumina) Tr. 690–91, 864, 878–79, 883; Conroy (Exact/Thrive) 1725; deSouza (Illumina) Tr. 2402, 2434–35, 2437–38; PX0064 (Illumina) at 5–6, 9; RX3935 (Illumina) at 2; RX6002 (Guerin-Calvert Trial Dep. at 59–60, 77–79.). As Ms. Berry testified, "if Illumina deliberately delated fulfilling a purchase order for a customer or somehow . . . monkeyed with supply", "Illumina would be in breach of the agreement". (Berry (Illumina) Tr. 878-79.)

2849. Dr. Gao testified that Illumina is "obviously the 800-pound gorilla in the room." (Gao (Singlera) Tr. 2947-48). Dr. Gao explained, "Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies, too. So I don't think I'm alone in this -- seeing this 800-pound gorilla." (Gao (Singlera) Tr. 2947-48, 2951).

Response to Finding No. 2849:

The proposed finding is inaccurate, incomplete and misleading. Illumina is not the only supplier of NGS equipment and faces stiff competition from other NGS providers. (*See* PFF ¶¶ 578–674.) Dr. Gao admitted, for example, that Singlera's PanSeer test was not designed to solely on Illumina equipment and it is compatible with Thermo Fisher's NGS systems, including the Ion Torrent S5. (PFF ¶ 1893; Gao (Singlera) Tr. 2928; *see also* RX3637 (Singlera) at 5; RX3869 (Cote Expert Report) ¶ 239.)

[redacted]. (PFF ¶¶ 778–778.2; 2085.) Thermo Fisher's Ion Torrent sequencers are suitable for certain MCED tests. (RX3869 (Cote Expert Report) ¶ 285.) [redacted]

Respondents also incorporate their responses to CCFF ¶ 1171 herein.

2850. Dr. Gao explained his concerns related to Illumina's "control" of the supply chain:

> [T]he problem is . . . cost is very essential for any -- basically marketing any product or any investor. Illumina can choose the price, set the price of the sequencer, and also the reagent, but Grail is a -- if it's part of the Illumina public company, they can lose on the reagent and Grail can still charge whatever -- Illumina can charge them a high price. They don't care. They are one company. But for us, we cannot have another cost center to transfer the cost, so we have to eat the high reagent and equipment cost. We -- you know, we cannot decrease our price or we will lose.

(Gao (Singlera) Tr. 2951).

Response to Finding No. 2850:

The proposed finding is inaccurate, incomplete and misleading. *First*, the Open Offer, which Singlera had an opportunity to sign (*see* deSouza (Illumina) Tr. 2338), prohibits Illumina from raising the price of its sequencing products beyond inflation for the Open Offer's 12-year term. (PFF ¶¶ 1021–22.) Further, the Open Offer requires Illumina to reduce the price of sequencing by at least 43% by 2025. (PFF ¶ 1023; Berry (Illumina) Tr. 712–13, 897, 903–04; PX0064 (Illumina) at 7).)

Second, contrary to Complaint Counsel's unproven contention, the only evidence in the record on NGS costs as a percentage of future downstream MCED revenues and margins shows that NGS costs will be a very small percentage of MCED test revenues and margins in the future. (PFF ¶ 884; RX6000 (Carlton Trial Dep.) at 30–31.)

2851. Dr. Gao testified that "Grail [is] doing something similar in direct competition with [Singlera and] Illumina is supplying . . . all essential equipment and reagents. [Illumina] could potentially . . . prevent us from develop[ing the PanSeer test] and delivering a cost-effective product." (Gao (Singlera) Tr. 2901-02).

Response to Finding No. 2851:

The proposed finding is inaccurate, incomplete and misleading. Dr. Gao's testimony disregards the fact that the Open Offer, which Singlera had an opportunity to sign (*see* deSouza (Illumina) Tr. 2338), prevents Illumina from interfering with customers' test development. (PFF ¶ 997; RX6002 (Guerin-Calvert Trial Dep. at 21–22).) The Open Offer requires Illumina to

provide customers with a consistent source of supply of sequencing instruments and core consumables. (*See* PFF ¶¶ 1000, 1005, 1007, 1009, 1011, 1037; [redacted]; Berry (Illumina) Tr. 690–91, 864, 878–79, 883; Conroy (Exact/Thrive) 1725; deSouza (Illumina) Tr. 2402, 2434–35, 2437–38; PX0064 (Illumina) at 5–6, 9; RX3935 (Illumina) at 2; RX6002 (Guerin-Calvert Trial Dep. at 59–60, 77–79.) As Ms. Berry testified, "if Illumina deliberately delated fulfilling a purchase order for a customer or somehow . . . monkeyed with supply", "Illumina would be in breach of the agreement". (Berry (Illumina) Tr. 878-79.)

Further, Dr. Gao admitted that Singlera's PanSeer test was not designed to solely on Illumina equipment and it is compatible with Thermo Fisher's NGS systems, including the Ion Torrent S5. (PFF ¶ 1893; Gao (Singlera) Tr. 2928; *see also* RX3637 (Singlera) at 5; RX3869 (Cote Expert Report) ¶ 239.)

2852. [redacted] (Fiedler (FMI) Tr. 4498 (*in camera*)).

Response to Finding No. 2852:

The proposed finding is misleading and incomplete without additional context. Dr. Fiedler also testified that FMI, which competes with Illumina's TSO500 product, has never had any concerns in its relationship with Illumina. (PFF ¶ 1749; Fiedler (FMI) Tr. 4469–70.) He testified that: FMI has been a customer of Illumina since FMI was started; FMI's first supply agreement with Illumina was signed in 2013; since 2019, FMI has purchased well over a hundred million, probably 140 million, in NGS products from Illumina; and during the time that FMI has been an Illumina customer FMI has had no issues or problems with Illumina servicing the Illumina instruments that FMI uses. (PFF ¶ 1749; Fiedler (FMI) Tr. 4470.) Dr. Fiedler has never known Illumina to delay providing services or replacement parts to FMI; Illumina has

acted in good faith with respect to its obligations under the 2013 supply agreement; Illumina has never "monkeyed with supply"; Illumina has never interrupted supply to FMI because it claimed FMI had infringed on Illumina's intellectual property; Illumina has never reneged on a commitment it made to FMI; FMI is a satisfied customer and FMI trusts Illumina to abide by its commitments. (PFF ¶ 1749; Fiedler (FMI) Tr. 4471–72.)

Dr. Fielder also testified that [redacted]

2853. In its annual report, Natera expressed, "Illumina is currently the sole supplier of our sequencers and related reagents for [our tests]. . . . Without sequencers and the related reagents, we would be unable to run our tests and commercialize our products." (PX0155 at 39 (Natera 10-K, Feb. 25, 2021)).

Response to Finding No. 2853:

Respondents have no specific response except to note that Illumina is not the sole supplier of NGS equipment and faces stiff competition from other NGS providers. (See PFF ¶¶ 578–674.) For example, Natera's Signatera test was initially validated on Illumina's HiSeq 2500 NGS platform but now uses BGI's DNBSEQ Platform in China. (PFF ¶ 652; RX3499 (Natera) at 6; [redacted]; RX3062 (BGI) at 1.)

2854. In its annual report, Natera acknowledged that Illumina's acquisition of Grail might add to the risks associated with Illumina being its sole supplier of sequencers and reagents. (PX0155 at 40 (Natera 10-K, Feb. 25, 2021)).

Response to Finding No. 2854:

The proposed finding is incomplete and misleading without additional context. The Open Offer [redacted] addresses any potential concerns that Illumina would disadvantage Natera or other customers after the acquisition and, in fact, represents an improvement for customers over the pre-merger status quo. (*See* PFF ¶¶ 997–99.) For example, the Open Offer [redacted] ensures a continued source of supply for sequencing instruments and core consumables. (*See* [redacted] PX0064 (Illumina) at 9.)

(3) MCED Customers Rely on Illumina for Assistance, Service, and Support of Illumina's NGS Products

2855. [redacted] (Conroy (Exact) Tr. 1583-84 (*in camera*)).

Response to Finding No. 2855:

Respondents have no specific response except to note that Illumina has service engineers who perform any necessary maintenance on Illumina's products, and that the Open Offer [redacted] requires that Illumina provide customers with the same access to services that GRAIL or any other For-Profit Entity has access to, at the same prices. (PFF 1004; Berry (Illumina) Tr. 668–69, 865–66; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.)

2856. [redacted] (Conroy (Exact) Tr. 1583-84 (*in camera*)).

Response to Finding No. 2856:

Respondents have no specific response except to note that the Open Offer [redacted] requires that Illumina provide customers with the same access to services that GRAIL or any other For-Profit Entity has access to, at the same prices. (PFF 1004; Berry (Illumina) Tr. 668–69, 865–66; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.)

2857. Pre-Acquisition, when there was an issue with a customer's purchase or supply, Illumina claims to "do our best to resolve customer issues quickly." (PX7076 (Berry (Illumina) Dep. at 83-84)).

Response to Finding No. 2857:

The proposed finding is incomplete and misleading without additional context. While Illumina worked to resolve customer issues quickly pre-acquisition, Illumina will *continue* to resolve customer issues quickly post-acquisition both because failure to do so would place Illumina in breach of the Open Offer and because failing to service instruments as necessary would be bad for Illumina's business. (PFF ¶ 1004.7; Berry (Illumina) Tr. 871–72, 879.) As Ms. Berry testified, "if Illumina deliberately delayed or even refused to service an instrument that belonged to a test developer who signed the open offer", "we'd be in breach of the agreement." (Berry (Illumina) Tr. 871.) Further, Ms. Berry explained that, both before and after the acquisition, "when instruments are down, customers aren't buying kits from us . . . so there's absolutely a disincentive" for Illumina to delay service. (Berry (Illumina) Tr. 872.)

In order to ensure that it satisfies its obligations when a customer orders a service SKU, Illumina measures its customer support using key performance indicators (KPIs). (PFF ¶ 1004.6; Berry (Illumina) Tr. 867–68.) These KPIs include metrics like instrument downtime or the

length of time between when a case is opened to when it is closed. (PFF ¶ 1004.6; Berry (Illumina) Tr. 867–68.) These KPIs enable Illumina to compare how it performs in terms of service and support across individual customers or groups of customers. (PFF ¶ 1004.6; Berry (Illumina) Tr. 868.)

As economist and President of the Center for Healthcare Economics and Policy and Senior Managing Director at FTI Consulting, Ms. Guerin-Calvert, explained, the Open Offer's equal-services commitment ensures that customers will receive at least the same level of service that they did before the merger. (PFF ¶ 1004.9; RX6002 (Guerin-Calvert Trial Dep. at 58).)

2858. Pre-Acquisition, Illumina tried to assist customers by making sure that products get to its customers when they want them. (PX7076 (Berry (Illumina) Dep. at 85-86); *see e.g.*, PX2601 (Illumina) at 002-004 (Email exchange between J. Gripp, Illumina, S. Verbeek, Illumina, T. Curti, Illumina, et al., Nov. 13, 2021) (*in camera*) ([redacted]).

Response to Finding No. 2858:

The proposed finding is incomplete and misleading without additional context because, post-Transaction, Illumina will continue to provide its products to customers as quickly as possible. Specifically, the Open Offer requires Illumina to provide customers with a consistent source of supply of sequencing instruments and core consumables. (*See* PFF ¶¶ 1000, 1005, 1007, 1009, 1011, 1037; [redacted]; Berry (Illumina) Tr. 690–91, 864, 878–79, 883; Conroy (Exact/Thrive) 1725; deSouza (Illumina) Tr. 2402, 2434–35, 2437–38; PX0064 (Illumina) at 5–6, 9; RX3935 (Illumina) at 2; RX6002 (Guerin-Calvert Trial Dep. at 59–60, 77–79.) As Ms. Berry testified, "if Illumina deliberately delated fulfilling a purchase order for a customer or somehow . . . monkeyed with supply", "Illumina would be in breach of the agreement". (Berry (Illumina) Tr. 878-79.)

Further, Respondents note that [redacted]

2859. Mr. Getty testified that a portion of Guardant's product "portfolio is dependent on Illumina and their sequencers and reagents, service." (Getty (Guardant) Tr. 2517).

Response to Finding No. 2859:

Respondents have no specific response except to note that the Open Offer [redacted] requires Illumina to continue to provide customers with the same access to products and services that they had prior to the Transaction, and that the Open Offer requires Illumina to provide customers with the same access to products and services to which GRAIL or any other For-Profit Entity has access. (See PFF ¶¶ 1004–09, 1011–12; Berry (Illumina) Tr. 865–72, 878–86; PX0064 (Illumina) at 6, 9; RX3935 (Illumina) at 2.) Respondents also note that [redacted] Respondents further incorporate their response to CCFF ¶ 2844 herein.

(a) MCED Test Developers Testified that the Speed and Quality of Illumina's Customer, Technical, Product Development, and Regulatory Support Can Alter the Quality, Development, and Delivery of Developers' Products

(i) Illumina Testimony and Ordinary Course Documents Show that Illumina's Customer, Technical, and Regulatory Support Can Alter the Speed, Quality, Development, and Delivery of Developers' Products

2860. Illumina's service and support team installs Illumina's equipment in customers' laboratories. (Berry (Illumina) Tr. 646).

Response to Finding No. 2860:

Respondents have no specific response.

2861. Illumina services Illumina equipment that customers purchase. (Berry (Illumina) Tr. 646).

Response to Finding No. 2861:

Respondents have no specific response.

2862. Illumina provides customers with technical support to resolve any problems with Illumina products. (Berry (Illumina) Tr. 646).

Response to Finding No. 2862:

Respondents have no specific response.

2863. Illumina provides customers with field application scientists who administer "training to enable the customer to successfully use" Illumina instruments. (Berry (Illumina) Tr. 670).

Response to Finding No. 2863:

Respondents have no specific response.

2864. Illumina's field application scientists train customers after a customer purchases an Illumina instrument and subsequently upon a customer's request. (Berry (Illumina) Tr. 669-70).

Response to Finding No. 2864:

Respondents have no specific response.

2865. Illumina provides customers with field service engineers to perform routine maintenance and repair customers' instruments. (Berry (Illumina) Tr. 668-69).

Response to Finding No. 2865:

Respondents have no specific response.

2866. Illumina's Nicole Berry testified that Illumina's field service engineers service a customer's NovaSeq 6000 once a month on average. (Berry (Illumina) Tr. 675).

Response to Finding No. 2866:

Respondents have no specific response.

2867. Illumina provides customers with field service engineers to perform "break/fix service" when instruments experience a failure that prevents customers from operating the instruments. (Berry (Illumina) Tr. 668).

Response to Finding No. 2867:

Respondents have no specific response.

2868. [redacted] (PX2378 (Illumina) at 003 (Illumina, Quote Approval Request, Dec. 27, 2018) (*in camera*); Berry (Illumina) Tr. 682-83).

Response to Finding No. 2868:

Respondents have no specific response except to note that the Open Offer requires Illumina to continue to provide customers with the same access to the services that they had prior to the Transaction, and that the Open Offer requires Illumina to provide customers with the same access to services to which GRAIL or any other For-Profit Entity has access. (See PFF 1004; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2; Berry (Illumina) Tr. 865–66; RX6002 (Guerin-Calvert Trial Dep. at 57–59).) Additionally, the Open Offer requires that customers receive access to the same pricing to which GRAIL has access for the equivalent level of service, or to which the customer had access before the Transaction, at the customer's option. (PFF ¶ 1004.2; RX3935 (Illumina) at 2.) Also, under the Open Offer, any discounts received by a customer,

must be extended to all Equivalent customers. (PFF ¶ 1017.4; Berry (Illumina) Tr. 893–94; RX6002 (Guerin-Calvert Trial Dep. at 38–39).)

2869. Ms. Berry testified that some Illumina customers have Illumina service engineers working full time at the customers' labs:

> We have got some customers that are very large and with many, many, many instruments, and the economics and also just the practical reality of what it takes to support very large fleets lends itself oftentimes to not only an onsite but an onsite with multiple FTEs, or full-time equivalents, for -- to provide the labor.

(Berry (Illumina) Tr. 682-83).

Response to Finding No. 2869:

Respondents have no specific response.

2870. [redacted] (*See, e.g.*, PX2598 (Illumina) at 002-003 (Email from D. Krebbel, Illumina, to D. Daly, Illumina, et al., Apr. 13, 2018) (*in camera*) ([redacted]); PX2602 (Illumina) at 009 (Email from T. Trinh, Illumina, to ILMN-Com-Instrument Service, Nov. 16, 2020) (*in camera*) ([redacted]); PX7063 (Berry (Illumina) IHT at 108-109) (*in camera*); PX7105 (Getty (Guardant) Dep. at 6)).

Response to Finding No. 2870:

The proposed finding is incomplete and misleading without additional context. Specifically, the proposed finding fails to acknowledge that the Open Offer requires consistent treatment of customers, including in terms of access to existing and new Illumina products and access to equivalent pricing. (*See* PFF ¶¶ 1005–20.)

2871. Illumina's internal documents show that [redacted] (*See, e.g.*, PX2599 (Illumina) at 003 (Email from L. Leigh, Illumina, to M. Gallina, Illumina, et al., Oct. 9, 2020) (*in camera*) [redacted]

[redacted]); PX2597 (Illumina) (Email from W. Caceres, Illumina, to E. Chen, Illumina, et al., Mar. 25, 2018) (discussing Illumina's assistance with the installation of sequencers); PX2603 (Illumina) (Email from G. Nunn, Illumina, to L. Tonkin, Illumina, et al., May 11, 2016) (*in camera*) [redacted].

Response to Finding No. 2871:

The proposed finding is incomplete and misleading without additional context. Complaint Counsel did not present the exhibits cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 25), and therefore should not be entitled to rely on them to establish anything beyond the words on the page. Further, the Open Offer ensures that putative GRAIL rivals will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; Berry (Illumina) Tr. 865–66; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) As Ms. Berry testified, "the open offer obligates Illumina to provide access to a customer to not only the same [product and support] services for which the customer had before the transaction but also any [product and support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.)

(ii) MCED Test Developers Testified that the Speed and Quality of Illumina's Customer and Technical Support can Alter the Quality, Development, and Delivery of Developers' Products

2872. [redacted] (PX7105 (Getty (Guardant) Dep. at 55-56); PX2599 (Illumina) at 003 (Email from L. Leigh, Illumina, to M. Gallina, Illumina, et al., Oct. 9, 2020) (*in camera*); PX2597(Illumina) (Email from W. Caceres, Illumina, to E. Chen, Illumina, Mar. 25, 2018); PX2603 (Illumina) (Email from G. Nunn, Illumina, to L. Tonkin, Illumina, et al., May 11, 2016) (*in camera*)).

Response to Finding No. 2872:

The proposed finding is incomplete and misleading without additional context. Complaint Counsel did not present the exhibits cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 25), and therefore should not be entitled to rely on them to establish anything beyond the words on the page. Further, the Open Offer ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; Berry (Illumina) Tr. 865–66; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) As Ms. Berry testified, "the open offer obligates Illumina to provide access to a customer to not only the same [product and support] services for which the customer had before the transaction but also any [product and support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.)

2873. MCED witnesses also testified that they rely on Illumina for service and support. (PX7105 (Getty (Guardant) Dep. at 61-62) (explaining that Guardant relies on Illumina for service and support on a daily basis). For example, Guardant relies upon Illumina to service its sequencers. (Getty (Guardant) Tr. 2509).

Response to Finding No. 2873:

Respondents have no specific response except to note that the Open Offer [redacted] ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; Berry (Illumina) Tr. 865–66; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) As Ms. Berry testified, "the open offer obligates Illumina to provide access to a customer to not only the same [product and support] services for which the customer had before the transaction but also any [product and

support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.)

Further, [redacted]

2874. Guardant relies on Illumina for servicing of machines, regulatory support, and the "development and finetuning of our technology." (Getty (Guardant) Tr. 2509)

Response to Finding No. 2874:

The proposed finding is inaccurate, incomplete and misleading without additional context. Illumina has a "minimal role" in a customer receiving regulatory approval of their products and typically does not provide support in developing or commercializing customers' products. (PFF ¶¶ 1010.4–1010.7, 1415; Goswami (Illumina) Tr. 3188–91; Berry (Illumina) Tr. 844–47.) Mr. Getty admitted that Illumina did not help Guardant develop the LUNAR-2 assay, did not contribute to the scientific effort Guardant undertook in connection with the LUNAR-2 assay, and did not brainstorm with Guardant on how it could improve the LUNAR-2 assay; Illumina has not been involved in any FDA review or consideration of the LUNAR-2 assay; and Guardant will be the sponsor of a PMA application for the LUNAR-2 assay as a sole-source laboratory. (PFF ¶ 1824; Getty (Guardant) Tr. 2645–46.)

2875. Ms. Berry testified that when a customer orders "a new instrument… [Illumina] would provide normal assistance, you know, support,…installation of the instrument, customer training." (PX7076 (Berry (Illumina) Dep. at 149)).

Response to Finding No. 2875:

Respondents have no specific response.

2876. Guardant's Bill Getty testified that Illumina technicians come to Guardant's lab to work on sequencers on a regular basis, probably weekly. (Getty (Guardant) Tr. 2514).

Response to Finding No. 2876:

Respondents have no specific response except to note that the Open Offer [redacted] ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (See PFF ¶¶ 1004.1, 1004.9; (PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) Further, [redacted]

2877. Guardant relies on Illumina in its product development and the fine-tuning of Guardant's technology. (Getty (Guardant) Tr. 2509, 2514).

Response to Finding No. 2877:

The proposed finding is inaccurate, incomplete and misleading without additional context. Respondents incorporate their responses to CCFF ¶¶ 2845 and 2874 herein.

2878. Mr. Getty explained that Illumina's instruments are "highly tuned machines," so "in order for us to maximize the value of those, we certainly need to know from Illumina representatives how those might be best deployed." (Getty (Guardant) Tr. 2514).

Response to Finding No. 2878:

Respondents have no specific response except to note that the Open Offer [redacted] ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; Berry (Illumina) Tr. 865–66; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) As Ms. Berry testified, "the open offer obligates Illumina to provide access to a customer to not only the same [product and support] services for which the customer had before the transaction but also any [product and support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.)

Further, [redacted]

2879. Mr. Getty explained that "without [Illumina's] sequencers [and] without the service that Illumina provides to keep them in good working order, [Guardant] would be unable to run [blood samples of patients] and deliver the final product to patients." (Getty (Guardant) Tr. 2685-86).

Response to Finding No. 2879:

Respondents have no specific response except to note that the Open Offer [redacted] ensures that customers will

continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; Berry (Illumina) Tr. 865–66; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) As Ms. Berry testified, "the open offer obligates Illumina to provide access to a customer to not only the same [product and support] services for which the customer had before the transaction but also any [product and support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.)

Further, [redacted]

2880. "[T]here's a symbiotic relationship between Guardant Health and our activity and Illumina's activities in terms of making sure we're maximizing the value of the products they have delivered to us." (Getty (Guardant) Tr. 2509).

Response to Finding No. 2880:

Respondents have no specific response except to note that the Open Offer [redacted] ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; Berry (Illumina) Tr. 865–66; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) As Ms. Berry testified, "the open

offer obligates Illumina to provide access to a customer to not only the same [product and support] services for which the customer had before the transaction but also any [product and support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.)

Further, [redacted]

Respondents also incorporate their response to CCFF ¶ 2845 herein.

2881. [redacted]

Response to Finding No. 2881:

Respondents have no specific response except to note that the Open Offer [redacted] ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; Berry (Illumina) Tr. 865–66; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) As Ms. Berry testified, "the open offer obligates Illumina to provide access to a customer to not only the same [product and

support] services for which the customer had before the transaction but also any [product and support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.)

Further, [redacted]

2882. [redacted] (PX7094 (Nolan (Freenome) Dep. at 277-278) (*in camera*)).

Response to Finding No. 2882:

Respondents have no specific response except to note that the Open Offer [redacted] ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; Berry (Illumina) Tr. 865–66; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) As Ms. Berry testified, "the open offer obligates Illumina to provide access to a customer to not only the same [product and support] services for which the customer had before the transaction but also any [product and support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a

customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.)

2883. [redacted] (PX7094 (Nolan (Freenome) Dep. at 277-278) (*in camera*)).

Response to Finding No. 2883:

Respondents have no specific response except to note that the Open Offer [redacted] ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; Berry (Illumina) Tr. 865–66; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) As Ms. Berry testified, "the open offer obligates Illumina to provide access to a customer to not only the same [product and support] services for which the customer had before the transaction but also any [product and support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.)

Further, the Open Offer prevents Illumina from delaying technical support in a way that would affect customers' development efforts. (PFF ¶¶ 1084.1–1084.2; Berry (Illumina) Tr. 871, 878–79; RX6002 (Guerin-Calvert Trial Dep. at 65, 67).) Ms. Berry testified that "if Illumina deliberately delayed or even refused to service an instrument that belonged to a test developer who signed the open offer", "we'd be in breach of the agreement." (Berry (Illumina) Tr. 871.)

2884. [redacted] (PX7094 (Nolan (Freenome) Dep. at 156-157) (*in camera*)).

Response to Finding No. 2884:

Respondents incorporate their response to CCFF ¶ 2883 herein. Respondents further note that the Open Offer requires that to the extent that Illumina has access to customer confidential information, Illumina shall not share such information with GRAIL, any GRAIL subsidiary or any employee who works within GRAIL. (PFF ¶ 1038; [redacted]; Berry (Illumina) Tr. 916–17; PX0064 (Illumina) at 9.) The Open Offer thus "speak[s] to keeping [sensitive customer] information completely confidential from GRAIL, [and] it also restricts access from within the legacy Illumina organization to who can access such confidential information." (Berry (Illumina) Tr. 917.)

2885. [redacted] (PX7110 (Conroy (Exact) Dep. at 72) (*in camera*)).

Response to Finding No. 2885:

Respondents have no specific response except to note that the Open Offer [redacted] ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; Berry (Illumina) Tr. 865–66; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) As Ms. Berry testified, "the open offer obligates Illumina to provide access to a customer to not only the same [product and support] services for which the customer had before the transaction but also any [product and support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.)

2886. [redacted] (Conroy (Exact) Tr. 1584 (*in camera*)).

Response to Finding No. 2886:

Respondents have no specific response except to note that the Open Offer [redacted] prevents Illumina from delaying technical support in a way that would affect customers' development efforts. (PFF ¶¶ 1084.1–1084.2; Berry (Illumina) Tr. 871, 878–79; RX6002 (Guerin-Calvert Trial Dep. at 65, 67).) Ms. Berry testified that "if Illumina deliberately delayed or even refused to service an instrument that belonged to a test developer who signed the open offer", "we'd be in breach of the agreement." (Berry (Illumina) Tr. 871.)

2887. [redacted] (Lengauer (Third Rock Ventures) Tr. 231 (*in camera*)).

Response to Finding No. 2887:

The proposed finding is incomplete and misleading without additional context. In the portion of Dr. Lengauer's testimony immediately after the cited portion, Dr. Lengauer provided context for this answer: [redacted]

2888. [redacted]

Response to Finding No. 2888:

Respondents have no specific response except to note that the Open Offer [redacted] prevents Illumina from delaying support services. (PFF ¶¶ 1084.1–1084.2; Berry (Illumina) Tr. 871, 878–79; RX6002 (Guerin-Calvert Trial Dep. at 65, 67).) Ms. Berry testified that "if Illumina deliberately delayed or even refused to service an instrument that belonged to a test developer who signed the open offer", "we'd be in breach of the agreement." (Berry (Illumina) Tr. 871.)

[redacted]

2889. [redacted]

Response to Finding No. 2889:

Respondents have no specific response except to note that the Open Offer [redacted] prevents Illumina from materially delaying support services. (PFF ¶¶ 1084.1–1084.2; Berry (Illumina) Tr. 871, 878–79; RX6002

(Guerin-Calvert Trial Dep. at 65, 67).) Ms. Berry testified that "if Illumina deliberately delayed or even refused to service an instrument that belonged to a test developer who signed the open offer", "we'd be in breach of the agreement." (Berry (Illumina) Tr. 871.)

[redacted] He also agreed that, in his experience, he has never known Illumina "to delay providing services or replacement parts to FMI" or to "monkey[] with supply". (Fiedler (FMI) Tr. 4471.) [redacted]

2890. [redacted]

Response to Finding No. 2890:

Respondents have no specific response except to note that the Open Offer prevents Illumina from materially delaying support services. (PFF ¶¶ 1084.1–1084.2; Berry (Illumina) Tr. 871, 878–79; RX6002 (Guerin-Calvert Trial Dep. at 65, 67).) Ms. Berry testified that "if Illumina deliberately delayed or even refused to service an instrument that belonged to a test developer who signed the open offer", "we'd be in breach of the agreement." (Berry (Illumina) Tr. 871.)

[redacted]

[redacted]

2891. [redacted]

Response to Finding No. 2891:

Respondents have no specific response except to note that the Open Offer [redacted] ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; Berry (Illumina) Tr. 865–66; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) As Ms. Berry testified, "the open offer obligates Illumina to provide access to a customer to not only the same [product and support] services for which the customer had before the transaction but also any [product and support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.)

[redacted]

[redacted] He also agreed that, in his experience, he has never known Illumina "to delay providing services or replacement parts to FMI". (Fiedler (FMI) Tr. 4471.) [redacted]

[redacted]

(iii) MCED Test Developers Testified that the Speed and Quality of Illumina's Product Development Support Can Alter the Quality, Development, and Delivery of Developers' Products

2892. Guardant's Bill Getty explained that if Illumina were to slow down its service of Guardant's Illumina equipment, "[I]t may be so impactful that it would slow down our competitiveness in the marketplace such that we would, you know, not be a viable player in the market." (PX7105 (Getty (Guardant) Dep. at 62)).

Response to Finding No. 2892:

Respondents have no specific response except to note that the Open Offer ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; Berry (Illumina) Tr. 865–66; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) As Ms. Berry testified, "the open offer obligates Illumina to provide access to a customer to not only the same [product and support] services for which the customer had before the transaction but also any [product and support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.) Ms. Berry also testified that "if Illumina deliberately delayed or even refused to service an instrument that belonged to a test developer who signed the open offer", "we'd be in breach of the agreement." (Berry (Illumina) Tr. 871.)

[redacted]

[redacted]

2893. Mr. Getty testified that turnaround time "is one of the most important aspects and features of a test." (PX7105 (Getty (Guardant) Dep. at 63-64)). Mr. Getty stated bluntly, "cancer doesn't wait for us to, you know, get our machines fixed. The faster we can deliver that information, the more . . . valuable that information is. . . . [W]e know from many hours of market research that from a physician's standpoint, it's incredibly important." (PX7105 (Getty (Guardant) Dep. at 63-64)).

Response to Finding No. 2893:

Respondents have no specific response except to note that the Open Offer ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; Berry (Illumina) Tr. 865–66; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) As Ms. Berry testified, "the open offer obligates Illumina to provide access to a customer to not only the same [product and support] services for which the customer had before the transaction but also any [product and support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.) Ms. Berry also testified that "if Illumina deliberately delayed or even refused to service an instrument that belonged to a test developer who signed the open offer", "we'd be in breach of the agreement." (Berry (Illumina) Tr. 871.)

[redacted]

2894. [redacted] (PX7110 (Conroy (Exact) Dep. at 72) (*in camera*)).

Response to Finding No. 2894:

Respondents have no specific response except to note that the Open Offer [redacted] requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶ 1010; Berry (Illumina) Tr. 881; PX0064 (Illumina) at 6.) At trial, Mr. Conroy had not actually read the Open Offer and did not know about the Open Offer's provision on development agreements, so his testimony should be given little weight. (PFF ¶¶ 1073, 1073.2; Conroy (Exact/Thrive) Tr. 1725–27.)

2895. [redacted] (Chahine (Helio) Tr. 1074-75 (*in camera*)).

Response to Finding No. 2895:

Respondents have no specific response except to note that the Open Offer [redacted] expressly prohibits Illumina from sharing any customer confidential information with GRAIL or its subsidiaries or employees, or with Illumina employees who work with GRAIL, and requires Illumina to establish a firewall that prohibits the flow of customer confidential information between Illumina and GRAIL. (PFF ¶ 1038–39; [redacted]; Berry (Illumina) Tr. 916–17; PX0064 (Illumina) at 9–10.) Dr. Chahine agreed that implementing the firewall in the Open Offer would mitigate concerns about the potential for sharing sensitive information between Illumina and GRAIL. (PFF ¶ 1039.7; PX7077 (Chahine (Helio) Dep. at 123–24.)

2896. [redacted] (Conroy (Exact) Tr. 1583 (*in camera*)).

Response to Finding No. 2896:

Respondents have no specific response except to note that the Open Offer [redacted] ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; Berry (Illumina) Tr. 865–66; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) As Ms. Berry testified, "the open offer obligates Illumina to provide access to a customer to not only the same [product and support] services for which the customer had before the transaction but also any [product and

support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.)

2897. [redacted] (Conroy (Exact) Tr. 1584 (*in camera*)).

Response to Finding No. 2897:

The proposed finding is incomplete and misleading without additional context because the phrase "development support" is vague and ambiguous. In the portion of Mr. Conroy's testimony cited here, Mr. Conroy was asked [redacted] Illumina does not traditionally provide support in the development of customers' products. (PFF ¶¶ 1010.4–1010.7; Berry (Illumina) Tr. 844–47.) Dr. Lengauer of Exact/Thrive admitted at trial that [redacted]

Additionally, the Open Offer [redacted] ensures that customers will continue to receive access to the same technical support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; Berry (Illumina) Tr. 865–66; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) As Ms. Berry testified, "the open offer obligates Illumina to provide access to a customer to not only the same [product and support] services for which the customer had before the transaction but also any [product and support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.)

2898. [redacted]

Response to Finding No. 2898:

The proposed finding is incomplete and misleading without additional context. [redacted] Illumina does not traditionally provide support in the development of customers' products. (PFF ¶¶ 1010.4–1010.7; Berry (Illumina) Tr. 844–47.)

2899. [redacted]

Response to Finding No. 2899:

Respondents have no specific response except to note that the Open Offer [redacted]

[redacted] ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; Rabinowitz (Natera) Tr. 420–21; Berry (Illumina) Tr. 865–66; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) As Ms. Berry testified, "the open offer obligates Illumina to provide access to a customer to not only the same [product and support] services for which the customer had before the transaction but also any [product and support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.)

2900. [redacted]

Response to Finding No. 2900:

Respondents have no specific response except to note that the Open Offer [redacted] ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; [redacted]; Berry (Illumina) Tr. 865–66; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) As Ms. Berry testified, "the open offer obligates Illumina to provide access to a customer to not only the same [product and support] services for which the customer had before the transaction but also any [product and support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.)

(b) Like Rival MCED Test Developers, Grail Depends on Illumina for Pricing, Supply, Product Support, and Customer Assistance throughout the Product Lifecycle

2901. As discussed in detail in Section V.D.2., MCED test developers, including Grail, are reliant upon Illumina NGS.

Response to Finding No. 2901:

To the extent that Complaint Counsel relies on its Proposed Findings in Section V.D.2, Respondents incorporate their responses to those Proposed Findings herein.

2902. Grail relies on Illumina as a sole supplier for next-generation sequencers and associated reagents. (Bishop (Grail) Tr. 1336; PX4082 (Grail) at 015 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, et al., attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 2902:

The proposed finding relates to irrelevant subject matter because GRAIL's use of Illumina as a supplier is not probative of Illumina's alleged ability or incentive to foreclose putative GRAIL rivals. In any event, Illumina is not the only supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.) To the extent that this proposed finding suggests that putative GRAIL rivals cannot use other NGS suppliers; this is incorrect. (*See* PFF ¶¶ 776–796; 916–926.) To the contrary, other purported MCED test developers identified by Complaint Counsel are already developing their respective tests using non-Illumina NGS platforms or are capable of using non-Illumina NGS platforms. (*See* PFF ¶¶ 780–780.6.) For example, Singlera's PanSeer test may be used with Thermo Fisher's Ion Torrent S5 system. (PFF ¶ 533; RX3115 (Chen et al., 2020) at 7; RX3637 (Singlera) at 1–6; Gao (Singlera) Tr. 2875, 2894, 2928–29; PX7102 (Gao (Singlera) Dep. at 78); RX3869 (Cote Expert Report) ¶ 239; *see also* PFF ¶¶ 668, 1894.) Similarly, [redacted]

[redacted]

[redacted].

2903. [redacted] (PX4016 (Grail) at 007 (GRAIL Strategy Planning Roadmap (Workshop #2) (Sept. 2, 2020)) (*in camera*)).

Response to Finding No. 2903:

Respondents have no specific response except to note that Illumina is not the only supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.) To the extent that this proposed finding suggests that putative GRAIL rivals cannot use other NGS suppliers; this is incorrect. (*See* PFF ¶¶ 776–796; 780–780.6; 916–926.) Further, Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 34), and therefore should not be entitled to rely on it to establish anything beyond the words on the page. Respondents also incorporate their response to CCFF ¶ 2902 herein.

2904. [redacted] (Freidin (Grail) Tr. 3065 (*in camera*)).

Response to Finding No. 2904:

The proposed finding relates to irrelevant subject matter because GRAIL's use of Illumina since 2016 is not probative of Illumina's alleged ability or incentive to foreclose putative GRAIL rivals. In particular, unlike any other purported MCED test developer, GRAIL was founded within Illumina. (PFF ¶ 44; Aravanis (Illumina) Tr. 1872; PX0036 (GRAIL) at 5; PX7079 (Flatley (Illumina) Dep. at 35–37); PX7104 (Aravanis (Illumina) Dep. at 159–160).) When Illumina formed GRAIL, the goal of developing a test that could detect multiple types of cancer in asymptomatic individuals through a blood draw was a "moonshot" ambition. (PFF

¶ 45; RX3970 (Illumina) at 10.) As Illumina's then-CEO, Jay Flatley put it at the time, "GRAIL is going after a much more daunting technology, scientific and biological problem that [no other companies] to [Illumina's] knowledge . . . have even begun to address". (PFF ¶ 45; RX3970 (Illumina) at 10.) To position GRAIL for its moonshot objective, Illumina seeded GRAIL with the talent, R&D capabilities, development plans and data it would need to investigate how to use NGS technology for multi-cancer early detection through foundational, population-scale trials. (PFF ¶ 47; PX7107 (deSouza (Illumina) Dep. at 182–83).)

In any event, Illumina is not the only supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.) To the extent that this proposed finding suggests that putative GRAIL rivals cannot use other NGS suppliers; this is incorrect. (*See* PFF ¶¶ 776–796; 780–780.6; 916–926.) Respondents also incorporate their response to CCFF ¶ 2902 herein.

2905. [redacted] (PX7066 (Freidin (Grail) IHT at 212-213 (*in camera*); PX6049 (Grail) at 023 [redacted] (*in camera*)).

Response to Finding No. 2905:

The proposed finding relates to irrelevant subject matter because GRAIL's development of its products on Illumina's sequencers is not probative of Illumina's alleged ability or incentive to foreclose putative GRAIL rivals. In particular, unlike any other purported MCED test developer, GRAIL was founded within Illumina. (PFF ¶ 45; Aravanis (Illumina) Tr. 1872; PX0036 (GRAIL) at 5; PX7079 (Flatley (Illumina) Dep. at 35–37); PX7104 (Aravanis (Illumina) Dep. at 159–160).) In any event, Illumina is not the only supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.) To the extent that this proposed finding suggests that putative GRAIL rivals cannot use other NGS suppliers;

this is incorrect. (*See* PFF ¶¶ 776–796; 780–780.6; 916–926.) Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their response to CCFF ¶ 2902 herein.

2906. [redacted] (*in camera*)).

Response to Finding No. 2906:

The proposed finding relates to irrelevant subject matter because GRAIL's development of its products on Illumina's sequencers is not probative of Illumina's alleged ability or incentive to foreclose putative GRAIL rivals. In particular, unlike any other purported MCED test developer, GRAIL was founded within Illumina. (PFF ¶ 45; Aravanis (Illumina) Tr. 1872; PX0036 (GRAIL) at 5; PX7079 (Flatley (Illumina) Dep. at 35–37); PX7104 (Aravanis (Illumina) Dep. at 159–160).) From the start, Illumina viewed GRAIL as an extension of its core goal of expanding and accelerating adoption of NGS technology in new applications. (PFF ¶ 46; Aravanis (Illumina) Tr. 1870–71, 1905–1907; *cf.* [redacted] In any event, Illumina is not the only supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.) To the extent that this proposed finding suggests that putative GRAIL rivals cannot use other NGS suppliers; this is incorrect. (*See* PFF ¶¶ 776–796; 780–780.6; 916–926.)

Further, Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 55), and therefore should not be entitled to rely on it to establish anything beyond the words on the page. Respondents also incorporate their response to CCFF ¶ 2902 herein.

2907. [redacted] (Freidin (Grail) Tr. 3065-66 (*in camera*)).

Response to Finding No. 2907:

The proposed finding is not adequately supported by the cited evidence. In the portion of Mr. Freidin's testimony cited here, Mr. Freidin stated that [redacted]

Further, the proposed finding relates to irrelevant subject matter because GRAIL's agreements with Illumina prior the Transaction are not probative of Illumina's alleged ability or incentive to foreclose putative GRAIL rivals. GRAIL's supply agreements with Illumina were unique because Illumina founded GRAIL. In particular, although Illumina reduced its investment in GRAIL in 2017, Illumina remained heavily invested in GRAIL's success. (PFF ¶ 50.) In addition to its equity stake in GRAIL (around 12% of GRAIL's outstanding shares on a fully diluted basis before the transaction closed), Illumina had a long-term agreement to supply GRAIL with NGS instruments and reagents for its genomic testing needs, and also had the right to receive approximately [redacted] of future net sales of any GRAIL oncology products or services. (PFF ¶ 50; [redacted]; *see also* Aravanis (Illumina) Tr. 1876–77; RX3984 (Illumina) at 14–15.)

To the extent that this proposed finding suggests that putative GRAIL rivals are not permitted to pursue alternative NGS suppliers, this is misleading and incorrect. (*See* PFF ¶¶ 776–796; 780–780.6; 916–926.) To the contrary, the Open Offer allows customers to terminate their supply relationship with Illumina for any reason and switch to other NGS suppliers. (PFF ¶ 1001; Berry (Illumina) Tr. 862–63; PX0064 (Illumina) at 10.) In any event,

Illumina is not the only supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.) Respondents also incorporate their response to CCFF ¶ 2902 herein.

2908. Grail identified its reliance on Illumina as a risk factor in its Form S-1. (Bishop (Grail) Tr. 1335-36; PX4082 (Grail) at 015 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, et al., attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 2908:

The proposed finding relates to irrelevant subject matter because the risk factors in GRAIL's S-1 from September 2020 from its proposed IPO prior to the Transaction are not probative of Illumina's alleged ability or incentive to foreclose putative GRAIL rivals. In any event, Illumina is not the only supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.) To the extent that this proposed finding suggests that putative GRAIL rivals cannot use other NGS suppliers; this is incorrect. (*See* PFF ¶¶ 776–796; 780–780.6; 916–926.) Respondents also incorporate their responses to CCFF ¶¶ 2902, 2906–07 herein.

2909. In an internal email discussing attempts to reduce prices received from Illumina in connection with sequencing, Grail personnel described "cost per sequencing read [as] the most important." (PX4019 (Grail) (Email from M. Chung, Grail, to J. Wong, Grail, Sept. 29, 2018)).

Response to Finding No. 2909:

Respondents have no specific response except to note that, Illumina's "entire history and . . . entire ethos as a company has been to very significantly lower costs and expand the market for sequencing". (deSouza (Illumina) Tr. 2401.) Thus, over the "13 years or so since the introduction of some of the early Illumina sequencing instruments, the price of sequencing has dropped extremely dramatically, and throughout that time Illumina really has been the driver of sequencing price reductions to its present level today". (Berry (Illumina) Tr. 810–11.) This

trend is expected to continue. As economic expert Dennis Carlton testified, [redacted] (RX6000 (Carlton Trial Dep. at 31–32).) As a result, views about the importance of sequencing costs *three years* before the Illumina-GRAIL transaction closed are irrelevant and will only become more irrelevant over time.

Moreover, under the Open Offer, by 2025, Illumina has contractually committed to reducing the inflation-adjusted Volume-Based Net Price per gigabase of sequencing using the highest throughput instrument then available, with the highest throughput, best-performance flow cell and kit then available, at full capacity, by at least 43%. (PFF ¶¶ 1023–1023.1; Berry (Illumina) Tr. 712–13, 897, 903–04; PX0064 (Illumina) at 7.) By reducing the price per gigabase by 43%, Illumina will also reduce the price per sequencing read by 43% because the given number of reads in a given flow cell kit is constant. (PFF ¶ 1023.3; Berry (Illumina) Tr. 923.)

Further, Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 34), and therefore should not be entitled to rely on it to establish anything beyond the words on the page.

2910. In its SEC Form S-1, Grail identified risks that it would encounter from switching suppliers:

> Transitioning to a new supplier for this equipment or these materials would be time-consuming and expensive, could result in interruptions in or otherwise affect the performance specifications of our laboratory operations and sample processing or could require that we revalidate our products and, if we receive FDA clearance or approval for our products, could require a new submission to FDA and oilier regulatory bodies to approve or clear such changes.

(PX4082 (Grail) at 034 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, et al., attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 2910:

Respondents have no specific response except to note that the proposed finding confirms that test developers can transition to different suppliers for NGS. Additionally, contrary to the suggestion of the statement in the Form S-1, switching between Illumina's platform and alternative platforms is feasible, and is, in fact a routine part of test development. (PFF ¶¶ 645–74; RX2869 (Cote Expert Report) ¶ 336.) As Dr. Richard Cote explained, "[t]est developers routinely re-validate their tests to account for new developments in their tests, new and improved technology relating to consumables, or for any number of other reasons. These revalidations are part of a good test developer's business plan." (RX3869 (Cote Expert Report) ¶ 338.) For example, Natera's Signatera test was initially validated on Illumina's HiSeq 2500 NGS platform but now uses BGI's DNBSEQ Platform in China. (PFF ¶ 652; RX3499 (Natera) at 6; [redacted]; RX3062 (BGI) at 1.) Similarly, Singlera has stated that its PanSeer assay is compatible with both Illumina and Thermo Fisher's sequencing platforms, so switching between these two NGS suppliers would not be likely to require any significant time for Singlera. (RX3869 (Cote Expert Report) ¶ 353.) Respondents also incorporate their response to CCFF ¶ 2911 herein.

2911. At trial, Mr. Bishop described the risks to Grail of switching suppliers, as stated in Grail's Form S-1 (PX4082):

> [O]ur understanding of the risks are as written in the sentence you've highlighted for us [in Grail's Form S-1, PX4082]. Transitioning to a new supplier for the equipment or materials listed above could take time, could be expensive, could result in interruptions and, as it goes on to say, could require that we revalidate our products if we receive FDA clearance or approval for those products, so it's speculating on a number of scenarios.

(Bishop (Grail) Tr. 1341).

Response to Finding No. 2911:

Respondents have no specific response except to note that Mr. Bishop's testimony indicates that the Form S-1 is only "speculating" on possible risks and to note that the weight of the evidence shows that switching between Illumina's platform and alternative platforms is feasible. (PFF ¶¶ 645–74; RX2869 (Cote Expert Report) ¶ 336.)

2912. In its Form S-1, Grail identified "consistent source of supply" as a risk that could force Grail to alter its laboratory operations and test procedures: "[W]e purchase certain products on a purchase order basis and cannot guarantee a consistent source of supply. The use of equipment or materials provided by a replacement supplier could require us to alter our laboratory operations and sample collection and processing and related procedures." (PX4082 (Grail) at 034 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, et al., attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 2912:

The proposed finding is irrelevant and misleading because the cited portion of GRAIL's S-1 does not relate to any specific type of product or supplier. To the extent that the proposed finding suggests that a purported GRAIL rival would not have a "consistent source of supply" from Illumina, this is incorrect. To the contrary, the Open Offer requires Illumina to provide customers with a consistent source of supply of sequencing instruments and core consumables. (*See* PFF ¶¶ 1000, 1005, 1007, 1009, 1011, 1037; Berry (Illumina) Tr. 690–91, 861, 864, 874–75, 878–79, 883; PX0064 (Illumina) at 5–6, 9; RX3935 (Illumina) at 2; RX6002 (Guerin-Calvert Trial Dep. at 59–60, 77–79.) To the extent that the proposed finding suggests that a purported MCED test developer could not switch from Illumina's NGS platform to another platform, this is also incorrect. To the contrary, the weight of the evidence shows that test developers can switch between Illumina's platform and alternative platforms without any material impact to their tests or launch dates. (PFF ¶¶ 645–74; RX2869 (Cote Expert Report) ¶ 336.) Respondents also incorporate their response to CCFF ¶ 2910 herein.

2913. In its Form S-1, Grail expressed that a substitute to Illumina "may not be available at all":

> In the case of attempting to obtain an alternative supplier for Illumina, Streck, or Twist, replacement instruments and associated reagents, tubes, and panels that meet our quality control and performance requirements may not be available at all, or may not be available on reasonable terms or in a timely manner.

(PX4082 (Grail) at 034 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, et al., attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 2913:

The proposed finding relates to irrelevant subject matter because the statements in GRAIL's S-1 from September 2020 from its proposed IPO prior to the Transaction are not probative of Illumina's alleged ability or incentive to foreclose putative GRAIL rivals. In any event, Illumina is not the only supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.) To the extent that this proposed finding suggests that putative GRAIL rivals cannot use other NGS suppliers; this is incorrect. (*See* PFF ¶¶ 776–796; 780–780.6; 916–926.) Respondents also incorporate their responses to CCFF ¶¶ 2902, 2906–07 herein.

2914. 'In its Form S-1, Grail acknowledged, "Any disruption in Illumina's operations or breach of our supply-related agreements would impact our supply chain and laboratory operations as well as our ability to develop and commercialize our products, including Galleri and DAC." (PX5049 at 29 (Grail Form S-1, Sept. 9, 2020)).

Response to Finding No. 2914:

The proposed finding relates to irrelevant subject matter because the statements in GRAIL's S-1 from September 2020 from its proposed IPO prior to the Transaction are not probative of Illumina's alleged ability or incentive to foreclose putative GRAIL rivals. In addition, the Open Offer requires Illumina to provide customers with a consistent source of supply of sequencing instruments and core consumables. (*See* PFF ¶¶ 1000, 1005, 1007, 1009, 1011, 1037; Berry (Illumina) Tr. 690–91, 861, 864, 874–75, 878–79, 883; PX0064 (Illumina) at

5–6, 9; RX3935 (Illumina) at 2; RX6002 (Guerin-Calvert Trial Dep. at 59–60, 77–79.) In any event, Illumina is not the only supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.) To the extent that this proposed finding suggests that putative GRAIL rivals cannot use other NGS suppliers; this is incorrect. (*See* PFF ¶¶ 776–796; 780–780.6; 916–926.) Respondents also incorporate their responses to CCFF ¶¶ 2902, 2906–07 herein.

2915. In its Form S-1, Grail described how delays or difficulties in its supply of equipment, reagents, and other required materials would likely affect the company:

> If we encounter delays or difficulties in securing, reconfiguring, or revalidating the equipment, reagents, and other materials that we require for our laboratory operations and sample collection and processing, we would likely face significant delays in commercializing our products and our business, financial condition, results of operations, and growth prospects would be adversely affected.

(PX4082 (Grail) at 034 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, et al., attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 2915:

The proposed finding is irrelevant and misleading because the cited portion of GRAIL's S-1 does not relate to any specific type of product or supplier. To the extent that this proposed finding suggests that putative GRAIL rivals will face inconsistent supply from Illumina, Respondents note that the Open Offer requires Illumina to provide customers with access to sequencing instruments and core consumables within 5 days of GRAIL or any other For-Profit Entity receiving access. (PFF ¶¶ 1005–08; Berry (Illumina) Tr. 702, 878–79; deSouza (Illumina) Tr. 2434–35, 2437–38; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) The Open Offer's access provisions "very specifically" address the concern that Illumina could delay access to products because they "level[] the playing field" and prevent individual customers from "lagging

behind in terms of [the products] available to [them]". (PFF ¶ 1009.4; RX6002 (Guerin-Calvert Trial Dep. at 61–62).)

2916. In a presentation prepared for Grail's Board of Directors by Morgan Stanley in connection with evaluating the potential acquisition by Illumina, Morgan Stanley included a slide titled "Key Risks to Stand Alone Value Realization." On that slide, Morgan Stanley wrote that "[m]argin impact from supply agreement and royalties owed to [Illumina] may limit financial and strategic flexibility," and referenced a "heavy reliance on Illumina's products" in the "cancer genomics space." (PX4148 (Grail) at 019 (Email from M. Song, Grail, to C. Friedman, et al., attaching Morgan Stanley, Discussion Materials: Project Valor, Sept. 14, 2020)).

Response to Finding No. 2916:

The proposed finding relates to irrelevant subject matter because the statements by Morgan Stanley to GRAIL's Board of Directors prior to the Transaction are not probative of Illumina's alleged ability or incentive to foreclose putative GRAIL rivals. Respondents note that prior to the reunion of Illumina and GRAIL, GRAIL owed royalties to Illumina, which have been eliminated since the Transaction. (*See* PFF ¶¶ 1146–51.) GRAIL's supply agreements with Illumina were unique because Illumina founded GRAIL. In particular, although Illumina reduced its investment in GRAIL in 2017, Illumina remained heavily invested in GRAIL's success. (PFF ¶ 50.) In addition to its equity stake in GRAIL (around 12% of GRAIL's outstanding shares on a fully diluted basis before the transaction closed), Illumina had a long-term agreement to supply GRAIL with NGS instruments and reagents for its genomic testing needs, and also had the right to receive approximately [redacted] of future net sales of any GRAIL oncology products or services. (PFF ¶ 50; [redacted]; *see also* Aravanis (Illumina) Tr. 1876–77; RX3984 (Illumina) at 14–15.) Respondents also incorporate their responses to CCFF ¶¶ 2902, 2906–07 herein.

2917. [redacted]

(PX4618 (Grail) at 001-08 (Email from R. Huang, Grail, to Y. Hu, Grail, Apr. 29, 2021 (*in camera*)).

Response to Finding No. 2917:

Respondents have no specific response except to note that, under the Open Offer, if Illumina created a new product or an improved version of an existing product, Illumina would be required to provide putative GRAIL rivals with access to it within 5 days of GRAIL or any other For-Profit Entity receiving access. (PFF ¶¶ 1005–1005.2; deSouza (Illumina) Tr. 2448; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) When asked by Judge Chappell, "[i]f Illumina invented or created, let's say, NovaSeq-3, is there any way you provide that to GRAIL ahead of competitors?", Mr. deSouza responded: "No. We would not do that, and we're contractually committing here that we will make sure everybody, you know, gets it, certainly within five days of GRAIL getting it." (deSouza (Illumina) Tr. 2448.) Additionally, the Open Offer requires Illumina to provide customers, within 5 days, with the same information that GRAIL receives about final product specifications of any sequencing instruments or core consumables. (PFF ¶ 1006; RX3935 (Illumina) at 2.) Further, the Open Offer requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶¶ 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.) "[T]his provision [of the Open Offer] provides the opportunity for Illumina and the customer to discuss and develop potentially a separate agreement that might relate to a customer's interest in modifying a supplied product specifically for that customer and to, you know, work optimally with that customer's part of the workflow or their tests. (Berry (Illumina) Tr. 881.) The development agreement provision "not only prevents Illumina from engaging in particular activity, requires Illumina to act in a particular way to support the ability

of rivals to be furthering their own competitive products." (RX6002 (Guerin-Calvert Trial Dep. at 68).)

2918. Illumina Has the Ability to Disadvantage Grail's Rivals by Reducing the Quality of Assistance, Service, and Support Provided to MCED Customers [redacted] (Conroy (Exact) Tr. 1584 (*in camera*)).

Response to Finding No. 2918:

Respondents have no specific response except to note that the Open Offer ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; Berry (Illumina) Tr. 865–66; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) The Open Offer also prevents Illumina from delaying technical support in a way that would affect customers' development efforts. (PFF ¶¶ 1084.1–1084.2; Berry (Illumina) Tr. 871; RX6002 (Guerin-Calvert Trial Dep. at 65, 67).) For example, Ms. Berry testified that "if Illumina deliberately delayed or even refused to service an instrument that belonged to a test developer who signed the open offer", "we'd be in breach of the agreement." (Berry (Illumina) Tr. 871.)

2919. Guardant's William Getty stated, "They [Illumina] could also, you know, one day turn around and, you know, say simple things like, you know, 'We can't get a technician out to your sequencers until next Friday' or 'the Friday after,' and that could create challenges around turnaround time and disappoint customers and therefore hurt us competitively." (PX7105 (Getty (Guardant) Dep. at 69-71)).

Response to Finding No. 2919:

Respondents have no specific response except to note that the Open Offer prevents Illumina from delaying technical support in a way that would affect customers' development efforts. (PFF ¶¶ 1084.1–1084.2; Berry (Illumina) Tr. 871; RX6002 (Guerin-Calvert Trial Dep. at 65, 67).) For example, Ms. Berry testified that "if Illumina deliberately delayed or even refused

to service an instrument that belonged to a test developer who signed the open offer", "we'd be in breach of the agreement." (Berry (Illumina) Tr. 871.)

2920. [redacted] (Chudova (Guardant) Tr. 1229-30 (*in camera*)).

Response to Finding No. 2920:

Respondents have no specific response except to note that the Open Offer requires Illumina to provide customers with a consistent source of supply of sequencing instruments and core consumables. (See PFF ¶¶ 1000, 1005, 1007, 1009, 1011, 1037; Berry (Illumina) Tr. 690–91, 861, 864, 874–75, 878–79, 883; PX0064 (Illumina) at 5–6, 9; RX3935 (Illumina) at 2; RX6002 (Guerin-Calvert Trial Dep. at 59–60, 77–79.) Specifically, the Open Offer requires Illumina to allocate supply in an equitable manner among its customers in the event of a supply shortage. (PFF ¶ 1012; Berry (Illumina) Tr. 885–86; PX0064 (Illumina) at 9.) As Ms. Berry testified, "if we had a particular kit, for example, that was in short supply, we would allocate a supply that we had across customers that had outstanding orders for that kit in an equitable manner. We wouldn't disadvantage a customer under this open offer relative to their access to a short supply product relative to GRAIL." (Berry (Illumina) Tr. 886.)

2921. [redacted] (PX7110 (Conroy (Exact) Dep. at 72) (*in camera*)).

Response to Finding No. 2921:

Respondents have no specific response except to note that Mr. Conroy's testimony on this point is incorrect given the protections of the Open Offer: The Open Offer prevents Illumina from delaying support services. (PFF ¶¶ 1084.1–1084.2; Berry (Illumina) Tr. 871, 878–79; RX6002 (Guerin-Calvert Trial Dep. at 65, 67).) For example, Ms. Berry testified that "if

Illumina deliberately delayed or even refused to service an instrument that belonged to a test developer who signed the open offer", "we'd be in breach of the agreement." (Berry (Illumina) Tr. 871.) Further, Mr. Conroy testified at trial that he had not read the Open Offer and, beyond what counsel had described to him, did not know what the Open Offer actually required Illumina to do, so his testimony on this point should be given little weight. (PFF ¶ 1073; Conroy (Exact/Thrive) Tr. 1725–27.)

2922. [redacted] (*See, e.g.*, PX7051 (Lengauer (Third Rock Ventures) IHT at 93-94) (*in camera*).

Response to Finding No. 2922:

Respondents have no specific response except to note that the Open Offer requires Illumina to provide customers with the same access to purchase sequencing instruments and core consumables that GRAIL or any other For-Profit Entity has within 5 days of when GRAIL or such For-Profit Entity receives access. (PFF ¶ 1007; deSouza (Illumina) Tr. 2434–35, 2437–38; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) As Ms. Berry testified, "if Illumina deliberately delayed fulfilling a purchase order for a customer or somehow, you know, monkeyed with supply", "Illumina would be in breach of the [Open Offer] agreement". (Berry (Illumina) Tr. 878–79.) Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2923. [redacted] (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 69-71); PX7055 (Otte (Freenome) IHT at 108-109) (*in camera*)).

Response to Finding No. 2923:

The proposed finding is inaccurate, incomplete and misleading without additional context. Illumina cannot delay access to new or updated instruments or consumables or information necessary to use such products. The Open Offer requires Illumina to provide customers with the same access to purchase sequencing instruments and core consumables that GRAIL or any other For-Profit Entity has within 5 days of when GRAIL or such For-Profit Entity receives access. (PFF ¶ 1007; deSouza (Illumina) Tr. 2434–35, 2437–38; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) The Open Offer also requires Illumina to give customers access to purchase any Pre-Release Sequencing Products to which GRAIL or any For-Profit Entity is offered access within 5 days of when GRAIL or such For-Profit Entity is offered access. (PFF ¶ 1008; [redacted]; Berry (Illumina) Tr. 702; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) These access provisions explicitly address the concern that Illumina could delay access to products because they level the playing field and prevent individual customers from lagging behind in terms of the products available to them. (PFF ¶ 1009.4; RX6002 (Guerin-Calvert Trial Dep. at 61–62).) Further, to the extent the proposed finding relies on IH testimony, Respondents had no opportunity to cross examine and it should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2924. [redacted] (*See* PX7110 (Conroy (Exact) Dep. at 72) (*in camera*); PX7105 (Getty (Guardant) Dep. at 69-71)).

Response to Finding No. 2924:

Respondents have no specific response except to note that Mr. Getty's and Mr. Conroy's cited testimony on this point is incorrect given the protections of the Open Offer [redacted]: The Open Offer [redacted]

[redacted] ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; [redacted]; Berry (Illumina) Tr. 865–66; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) Further, Mr. Conroy testified at trial that he had not read the Open Offer and, beyond what counsel had described to him, did not know what the Open Offer actually required Illumina to do, so his testimony on this point should be given little weight. (PFF ¶ 1073; Conroy (Exact/Thrive) Tr. 1725–27.)

[redacted]

2925. [redacted] (*See* PX2600 (Illumina) at 002 (Email from T. Trinh, Illumina, to E. Chen, Illumina, Feb. 12, 2020) (*in camera*) ([redacted]); PX2605 (Illumina) (Email from E. Chen, Illumina, to N. Kargozaran, Illumina, et al., Sept. 21, 2020 (*in camera*) ([redacted]).

Response to Finding No. 2925:

The proposed finding is incomplete and misleading without additional context. *First*, [redacted] (*See* PFF ¶ 70; PX0122 (Illumina) at 1; RX3349 (GRAIL) at 1; RX3971 (Illumina) at 293; PX0378 (Illumina) at 3–4.) Therefore, to the extent this email record reflects any delay by Illumina, it is not specific to the Transaction. *Second*, the proposed finding is directed to irrelevant subject matter because this request was resolved before Illumina created its Open Offer. Illumina cannot delay shipments in light of the protections of the Open Offer, which is now available to all of Illumina's oncology customers. The Open Offer requires Illumina to provide customers with the same access to purchase sequencing instruments and core consumables that GRAIL or any other For-Profit Entity has within 5 days of when GRAIL or such For-Profit Entity receives access. (PFF ¶ 1007; Berry (Illumina) Tr. 878–79; deSouza (Illumina) Tr. 2434–35, 2437–38; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) The Open Offer's access provisions specifically address the concern that Illumina could delay access to products because they level the playing field and prevent individual customers from lagging behind in terms of the products available to them. (PFF ¶ 1009.4; RX6002 (Guerin-Calvert Trial Dep. at 61–62).) As Ms. Berry testified, "if Illumina deliberately delayed fulfilling a purchase order for a customer or somehow, you know, monkeyed with supply", "Illumina would be in breach of the [Open Offer] agreement". (Berry (Illumina) Tr. 878–79.)

2926. [redacted] (PX2605 (Illumina) at 008 (Email from E. Chen, Illumina, to N. Kargozaran, Illumina, et al., Sept. 21, 2020 (*in camera*)).

Response to Finding No. 2926:

The proposed finding is incomplete and misleading without additional context. *First*, Guardant's shipment request is from February 2020, long before Illumina executed the agreement to acquire GRAIL, and even before Illumina began considering the possibility of acquiring GRAIL. (*See* PFF ¶ 70; PX0122 (Illumina) at 1; RX3349 (GRAIL) at 1; RX3971 (Illumina) at 293; PX0378 (Illumina) at 3–4.) Therefore, to the extent this email record reflects any delay by Illumina, it is not specific to the Transaction. *Second*, the proposed finding is misleading because the term "improved service" is vague and ambiguous. The cited email discusses shipping products to a new warehouse; it does not discuss providing additional services, faster services or any other "improved" services. (PX2605 (Illumina) at 8.) In any event, to the extent that the proposed finding suggests that Illumina could provide disparate levels of service to different customers, the Open Offer expressly forbids this behavior: The Open Offer requires Illumina to provide customers with the same access to services that GRAIL or any other For-Profit Entity has access to, and at the same prices. (PFF ¶ 1004; [redacted]; Berry (Illumina) Tr. 865–66; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) The Open Offer also ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; [redacted]; Berry (Illumina) Tr. 865–66; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).)

2927. [redacted] (PX7110 (Conroy (Exact) Dep. at 72-73) (*in camera*)).

Response to Finding No. 2927:

The proposed finding is inaccurate, incomplete and misleading without additional context. The Open Offer prevents Illumina from delaying technical support in a way that would affect customers' development efforts. (PFF ¶¶ 1084.1–1084.2; Berry (Illumina) Tr. 871, 878–79; RX6002 (Guerin-Calvert Trial Dep. at 65, 67).) Ms. Berry testified that "if Illumina deliberately delayed or even refused to service an instrument that belonged to a test developer who signed the open offer", "we'd be in breach of the agreement." (Berry (Illumina) Tr. 871.) Additionally, MCED "tests are developed over many years", and a delay of several days would be "a very inconsequential amount of time relative to the years it takes to develop one of these products." (Aravanis (Illumina) Tr. 1930.) Further, Mr. Conroy testified at trial that he had not read the Open Offer and, beyond what counsel had described to him, did not know what the Open Offer actually required Illumina to do, so his testimony on this point should be given little weight. (PFF ¶ 1073; Conroy (Exact/Thrive) Tr. 1725–27.)

2928. [redacted]
(Fiedler (FMI) Tr. 4491-92 (*in camera*)).

Response to Finding No. 2928:

The proposed finding is incomplete and misleading without additional context including because the phrase [redacted] is vague and ambiguous. In the portion of Dr. Fiedler's testimony just before that cited here, Dr. Fiedler provided additional context for this answer: [redacted] Additionally, the [redacted] depends on several other factors including, for example, the algorithms or analyses used to analyze genetic data. (*See, e.g.*, PFF ¶ 1010.7.1; Berry (Illumina), Tr. 679.) Illumina

does not have a role in the development of customers' assays. (PFF ¶¶ 1010.4–1010.7; Berry (Illumina) Tr. 844–47; [redacted].)

2929. [redacted] (Fiedler (FMI) Tr. 4492 (*in camera*)).

Response to Finding No. 2929:

Respondents incorporate their response to CCFF ¶ 2928 herein. Respondents also note that the Open Offer prohibits Illumina from providing customers with lower quality instruments or consumables. (PFF ¶ 1092; Berry (Illumina) Tr. 878–79.)

2930. [redacted] (Fiedler (FMI) Tr. 4492-93 (*in camera*)).

Response to Finding No. 2930:

The proposed finding is incomplete and misleading to the extent that it suggests that Illumina has a role in the development of customers' assays or that Illumina would disadvantage FMI vis-à-vis GRAIL; this is incorrect. Respondents note that the Open Offer prohibits Illumina from providing customers with lower quality instruments or consumables. (PFF ¶ 1092; Berry (Illumina) Tr. 878–79.) As Ms. Berry testified, if Illumina "monkeyed with supply" or provided lower quality sequencing instruments or consumables, "Illumina would be in breach of the [Open Offer] agreement". (Berry (Illumina) Tr. 878–79.) Dr. Fielder agreed that Illumina had not ever "monkeyed with supply" and that FMI was a "satisfied customer" of Illumina. (Fiedler (FMI) Tr. 4471.) [redacted]

[redacted] Respondents also incorporate their response to CCFF ¶ 2928 herein.

2931. [redacted] (Fiedler (FMI) Tr. 4493 (*in camera*)).

Response to Finding No. 2931:

The proposed finding is incomplete and misleading to the extent that it suggests that Illumina has a role in the development of customers' assays or that Illumina would disadvantage FMI vis-à-vis GRAIL; this is incorrect. Respondents note that the Open Offer prohibits Illumina from providing customers with lower quality instruments or consumables. (PFF ¶ 1092; Berry (Illumina) Tr. 878–79.) Respondents also incorporate their responses to CCFF ¶¶ 2928 and 2830 herein.

2932. [redacted] (PX8324 (Roche) at 005 (*in camera*)).

Response to Finding No. 2932:

The proposed finding is incomplete and misleading because it does not account for Roche's statements about the Transaction after this presentation was prepared. After this presentation, Dr. Severin Schwan, the CEO of Roche stated in a letter that [redacted]

[redacted]

Respondents also note that this presentation was prepared in October 2020, before the Open Offer, and the Open Offer addresses each of the concerns identified here. *First*, the Open Offer's provisions in their totality also ensure that Illumina's incentives are to support GRAIL's rivals. (PFF ¶ 1082.2–1082.4; see [redacted], 108–09; RX6000 (Carlton Trial Dep. at 84–85).) *Second*, the most important issue with regard to the efficacy of the Open Offer is whether it sufficiently prevents Illumina from acting on any alleged incentive to foreclose GRAIL's potential rivals. (PFF ¶ 1082.1; RX6002 (Guerin-Calvert Trial

Dep. at 20–21, 109).) As relevant here, the Open Offer requires Illumina to: a) maintain equitable pricing for its sequencing products and lower pricing by 2025 by at least 43%, b) continue to provide the same services available to customers before the transaction and c) continue to provide access to products in a timely manner. (*See, e.g.*, PFF ¶¶ 1007, 1084.1–1084.2, 1009.4, 1013, 1023; [redacted]; Berry (Illumina) Tr. 712–13, 871, 878–79, 897, 903–04; Conroy (Exact/Thrive) Tr. 1731–32; deSouza (Illumina) Tr. 2402–03, 2434–35, 2437–38; PX0064 (Illumina) at 6–8; RX3935 (Illumina) at 2; RX6002 (Guerin-Calvert Trial Dep. at 61–62, 65, 67).)

d) Illumina Can Deny Access to Information, Agreements, and Licenses Necessary for FDA Approval and Commercialization of MCED Tests

2933. As discussed in Section II.E.2. (FDA Approval Process), MCED tests will need FDA approval to gain broad reimbursement status and reach the broader MCED test market.

Response to Finding No. 2933:

Respondents have no specific response. To the extent Complaint Counsel relies on its Proposed Findings in Section II.E.2, paragraphs 506–51, Respondents incorporate their responses to those Proposed Findings herein.

2934. As part of the FDA review process described in Section II.E.2. (FDA Approval Process), MCED test developers must provide substantial information and data to the FDA, including information related to the MCED test's use of Illumina's NGS platforms.

Response to Finding No. 2934:

Respondents have no specific response. To the extent Complaint Counsel relies on its Proposed Findings in Section II.E.2, paragraphs 506–51, Respondents incorporate their responses to those Proposed Findings herein.

2935. In Section II.E.2. (FDA Approval Process), executives of MCED test developers, Illumina, and Grail testified that the FDA approval process is lengthy, complicated, difficult, and requires several submissions of details information and data.

Response to Finding No. 2935:

Respondents have no specific response. To the extent Complaint Counsel relies on its Proposed Findings in Section II.E.2, paragraphs 506–51, Respondents incorporate their responses to those Proposed Findings herein.

2936. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 154-55) (*in camera*)).

Response to Finding No. 2936:

Respondents have no specific response except to note that [redacted]

Further, the proposed finding relies on impermissible lay opinion testimony. Dr. Lengauer was not called as an expert witness on the FDA review process and his opinion on that process should be disregarded. Finally, the proposed finding relies on IH testimony which

Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2937. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 154-55) (*in camera*)).

Response to Finding No. 2937:

Respondents incorporate their response to CCFF ¶ 2936 herein. Further, the proposed finding relies on impermissible lay opinion testimony. Dr. Lengauer was not called as an expert witness on the FDA review process and his opinion on that process should be disregarded. Finally, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2938. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 154-55) (*in camera*)).

Response to Finding No. 2938:

Respondents incorporate their response to CCFF ¶ 2936 herein. Additionally, Respondents note that the Open Offer requires Illumina to provide documentation to assist customers with FDA approval or marketing authorization to sell a for-profit, clinical test using Illumina's sequencing instruments and core consumables. (PFF ¶ 1027; PX0064 (Illumina) at 8; PX7093 (Young (Illumina) Dep. at 68).) Further, to the extent that Exact/Thrive intends to seek approval of its CancerSEEK test as a distributed IVD, the Open Offer includes a right of reference to any relevant Illumina regulatory documentation for Illumina's IVD partners. (PFF ¶ 1027.2; Leite (Illumina/InterVenn) Tr. 2156; PX0064 (Illumina) at 39; [redacted].) Under this right, a partner developing on Illumina systems may

reference Illumina's files in their regulatory submission. (PFF ¶ 1027.2; PX0064 (Illumina) at 39; [redacted].) [redacted] [redacted].)

Further, the proposed finding relies on impermissible lay opinion testimony. Dr. Lengauer was not called as an expert witness on the FDA review process and his opinion on that process should be disregarded. Finally, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2939. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 154-55) (*in camera*)).

Response to Finding No. 2939:

Respondents incorporate their response to CCFF ¶ 2938 herein. Further, the proposed finding relies on impermissible lay opinion testimony. Dr. Lengauer was not called as an expert witness on the FDA review process and his opinion on that process should be disregarded. Finally, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2940. [redacted] (Conroy (Exact) Tr. 1587 (*in camera*); PX7110 (Conroy (Exact) Dep. 75-76) (*in camera*)).

Response to Finding No. 2940:

Respondents have no specific response except to note that Mr. Conroy admitted that [redacted]

[redacted] Respondents also incorporate their response to CCFF ¶ 2938 herein. Further, the proposed finding relies on impermissible lay opinion testimony. Mr. Conroy was not called as an expert witness on the FDA approval process and his opinion on that process should be disregarded.

2941. [redacted]

[redacted]

(Conroy (Exact) Tr. 1588 (*in camera*)).

Response to Finding No. 2941:

Respondents have no specific response except to note that the Open Offer requires Illumina to provide to provide documentation to assist customers with FDA approval or marketing authorization to sell a for-profit, clinical test using Illumina's sequencing instruments and core consumables. (PFF ¶ 1027; PX0064 (Illumina) at 8; PX7093 (Young (Illumina) Dep. at 68).) [redacted] (PFF ¶ 1027.2; Leite (Illumina/InterVenn) Tr. 2156; PX0064 (Illumina) at 39; [redacted] Under this right, a partner developing on Illumina systems may reference Illumina's files in their regulatory submission. (PFF ¶ 1027.2; PX0064 (Illumina) at 39; [redacted].) [redacted]

[redacted].) Respondents also incorporate their response to CCFF ¶ 2938 herein.

Further, the proposed finding relies on impermissible lay opinion testimony. Mr. Conroy was not called as an expert witness on the FDA approval process and his opinion on that process should be disregarded.

2942. [redacted] (PX7110 (Conroy (Exact) Dep. 76) (*in camera*)).

Response to Finding No. 2942:

Respondents incorporate their response to CCFF ¶ 2941 herein. Further, the proposed finding relies on impermissible lay opinion testimony. Mr. Conroy was not called as an expert witness on the FDA approval process and his opinion on that process should be disregarded.

2943. [redacted] (PX7110 (Conroy (Exact) Dep. 76) (*in camera*)).

Response to Finding No. 2943:

Respondents incorporate their response to CCFF ¶ 2941 herein. Further, the proposed finding relies on impermissible lay opinion testimony. Mr. Conroy was not called as an expert witness on the FDA approval process and his opinion on that process should be disregarded.

2944. [redacted] (PX7110 (Conroy (Exact) Dep. 73-74) (*in camera*)).

Response to Finding No. 2944:

Respondents incorporate their response to CCFF ¶ 2941 herein. Further, the proposed finding relies on impermissible lay opinion testimony. Mr. Conroy was not called as an expert witness on the FDA approval process and his opinion on that process should be disregarded.

(1) MCED Test Developers Testified that a Distributed or Kitted Version of MCED Tests Are Part of Their Product Pipeline

2945. An IVD test developer may seek FDA approval for its test as a "single-site" IVD test, which can run at one approved lab, or as a "distributed" IVD test, which can run at any third-party lab. (*See* PX7063 (Berry (Illumina) IHT at 202); PX7112 (Bailey (PGDx) Dep. at 14); PX7093 (Young (Illumina) Dep. at 43-44)). A distributed or "kitted" IVD is an IVD test that has received PMA approval from the FDA permitting analysis by independent testing providers, such as hospitals or large reference labs like LabCorp or Quest. (Goswami (Illumina) Tr. 3186-87; Leite (Illumina) Tr. 2150; PX7049 (Bailey (PGDx) IHT at 68-69); PX7063 (Berry (Illumina) IHT at 202); PX7112 (Bailey (PGDx) Dep. at 14-18); PX7093 (Young (Illumina) Dep. at 44)).

Response to Finding No. 2945:

Respondents have no specific response.

2946. [redacted]

Response to Finding No. 2946:

Respondents incorporate their response to CCFF ¶ 2941 herein.

2947. [redacted]

Response to Finding No. 2947:

Respondents incorporate their response to CCFF ¶ 2941 herein. Additionally, Respondents note that the proposed finding confirms that Guardant is not pursuing a kitted version of its test at this time. Further, respondents note that the weight of the evidence shows that distributable IVDs would not be an appropriate option for MCED tests. (*See* PFF ¶¶ 675–78.) For example, [redacted] In a distributed model, a small hospital or laboratory—precisely the types of customers who purportedly benefit from distributed kitted tests—are unlikely to be able to achieve the throughput necessary to make a NovaSeq Dx platform cost-effective. (PFF ¶ 677.2; Goswami (Illumina) Tr. 3194–95.) [redacted]

A distributed test makes the most sense in circumstances where there is a small amount of DNA sample such that "labs might prefer not to ship on the sample" or there is a need for very fast turnaround time. (Goswami (Illumina) Tr. 3197–98.) This would be most useful for a Stage III or Stage IV cancer patient who is very sick: "Usually it is quite hard to get enough tumor tissue from [these patients]. . . . And you want that result to be turned around fairly quickly so that the patient can be treated with the right drug as soon as possible." (Goswami (Illumina) Tr. 3199.) However, for early detection cancer screening, these considerations would not come into play. In those circumstances, "you're either looking at blood or some other, you know, tissue that's a little bit more easily available." (Goswami (Illumina) Tr. 3200.) And, "you also don't

have time same time restrictions" because the intervention will often require a secondary test to determine how to treat the patient. (Goswami (Illumina) Tr. 3200.)

2948. [redacted]

Response to Finding No. 2948:

Respondents have no specific response except to note that the proposed finding confirms that Exact does not intend to lead with a distributed model for its CancerSEEK test.

Respondents also incorporate their response to CCFF ¶ 2947 herein.

2949. [redacted]

Response to Finding No. 2949:

Respondents have no specific response except to note that the proposed finding confirms that Freenome does not intend to release a kitted version of its MCED test at this time.

Respondents also incorporate their response to CCFF ¶ 2947 herein.

2950. Singlera wants to offer the PanSeer test as a distributed test in order to differentiate it from single-site tests. (PX7042 (Gao (Singlera) IHT at 109) ("Q. Then switching back to the PanSeer, does Singlera plan to offer this, the PanSeer test, as a distributed IVD test? A. That's our original thought. We want to differentiate from single-site licensing. We want to be a distributed mode. So our business model will be deliver the test in a distributed way so we can work with the partners.")).

Response to Finding No. 2950:

The proposed finding is incomplete and misleading without additional context. Specifically, regardless of what Singlera "wants" to do, Dr. Gao admitted that Singlera expects to launch its ColonES product first before it launches PanSeer. (PFF ¶ 1891; Gao (Singlera) Tr. 2918.) Dr. Gao also admitted that Singlera expects it will be several years' time before ColonES obtains FDA approval, that Singlera is at least one year away from even starting clinical trials in

the U.S. for ColonES, and that to obtain FDA approval, a clinical trial for ColonES could take three to four years. (PFF ¶ 1889; Gao (Singlera) Tr. 2911–12, 2920–23.) Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their response to CCFF ¶ 2947 herein.

2951. Dr. Gao testified that selling the PanSeer test as a distributed test would allow Singlera to "quickly scale up to sell." (PX7042 (Gao (Singlera) IHT at 110-11)).

Response to Finding No. 2951:

Respondents incorporate their responses to CCFF ¶¶ 2947 and 2950 herein.

2952. [redacted]

Response to Finding No. 2952:

Respondents have no specific response except to note that the proposed finding confirms that, in the shorter term, Helio is not pursuing a distributed model for its cancer screening test. Further, the Open Offer requires Illumina, on a customer's request, to enter into a separate standardized agreement with the customer to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33; [redacted]; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; PX0087 (Illumina); PX0088 (Illumina); PX0089 (Illumina); [redacted].) As Dr. Goswami testified, by making standardized IVD agreement terms public through the Open Offer, "a test developer essentially already has access to the types of terms we offer" in oncology. (Goswami (Illumina) Tr. 3205.) So, the developer "would be able to look at" the template agreements and "would then be able to make

[the] decision on, you know, which type of agreement they want to look at, what types of instruments they want to develop their test on." (Goswami (Illumina) Tr. 3205.) And as economist and President of the Center for Healthcare Economics and Policy and Senior Managing Director at FTI Consulting, Margaret Guerin-Calvert, testified, the IVD agreement provisions in the Open Offer prevent Illumina from withholding support as putative MCED test developers seek FDA approval. (PFF ¶ 1035; RX6002 (Guerin-Calvert Trial Dep. at 74).) Respondents also incorporate their response to CCFF ¶ 2947 herein.

2953. [redacted]

Response to Finding No. 2953:

The proposed finding is incomplete and misleading without additional context. Specifically, [redacted]

Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their response to CCFF ¶ 2947 herein.

2954. Distributed IVD tests allow samples to be processed locally, which improves turnaround time for test results and alleviates capacity constraints at developers' centralized labs, which will likely be critical for test developers as MCED tests become routinely used in the market. (PX7042 (Gao (Singlera) IHT at 110-11); PX7049 (Bailey (PGDx) IHT at 68-69)).

Response to Finding No. 2954:

Respondents have no specific response except to note that the Open Offer requires Illumina, on a customer's request, to enter into a separate standardized agreement with the customer to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33; [redacted]; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; PX0087 (Illumina); PX0088 (Illumina); PX0089 (Illumina); [redacted].) These requirements in the Open Offer prevent Illumina from withholding support as putative MCED test developers seek FDA approval. (PFF ¶ 1035; RX6002 (Guerin-Calvert Trial Dep. at 74).) Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their response to CCFF ¶ 2947 herein.

Respondents also note that features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (PFF ¶¶ 675–678.5 (RX3869 (Cote Expert Report) ¶¶ 359–363; Goswami (Illumina) Tr. 3189–92, 3194–95).) The test developer's decision whether to proceed with an IVD kit as opposed to a centralized model is an economic decision driven by test-specific factors. (Goswami (Illumina) Tr. 3197.) IVD kits are most suitable for tests that have precious samples, that present shipping challenges and require fast turnaround times. (Goswami (Illumina) Tr. 3196–3200; *see also* RX3869 (Cote Expert Report) § XI, ¶¶ 360–63.) Respondents also note that Illumina's NovaSeq is not yet available as Dx instrument. (Goswami (Illumina) Tr. 3194.)

(2) For the FDA to Approve a Distributed or Kitted Version of an MCED Test, the MCED Test Developer Needs an IVD Agreement with Illumina and Illumina Must Provide More Detailed Information to the FDA on Behalf of the MCED Test Developer

2955. A single-site PMA or a single-site IVD is an IVD test that has received PMA approval from the Food & Drug Administration ("FDA") requiring sample analysis at a single designated facility. (Goswami (Illumina) Tr. 3186).

Response to Finding No. 2955:

Respondents have no specific response.

2956. A distributed kit (or "kitted") in-vitro diagnostic is when the test developer generates a "kit" version of the test, which can then be distributed to other CLIA/CAP-certified labs to be processed. (Goswami (Illumina) Tr. 3186-88).

Response to Finding No. 2956:

Respondents have no specific response.

2957. A kitted IVD is an IVD test that has received PMA approval from the FDA permitting analysis by independent testing providers. (Goswami (Illumina) Tr. 3187).

Response to Finding No. 2957:

Respondents have no specific response.

2958. To develop a kitted version of an MCED test, the MCED test developer needs an IVD agreement with Illumina. (Goswami (Illumina) Tr. 3188-89; 3234-35)

Response to Finding No. 2958:

The proposed finding is incomplete and misleading. Features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (PFF ¶¶ 675–678.5 (RX3869 (Cote Expert Report) ¶¶ 359–363; Goswami (Illumina) Tr. 3189–92, 3194–95).) The test developer's decision whether to proceed with an IVD kit as opposed to a centralized model is an economic decision driven by test-specific factors. (Goswami (Illumina) Tr. 3197.) IVD kits are most suitable for tests that have precious samples, that present shipping challenges and require fast turnaround times.

(Goswami (Illumina) Tr. 3196–3200; *see also* RX3869 (Cote Expert Report) § XI, ¶¶ 360–63.)

Respondents also note that Illumina's NovaSeq is not yet available as Dx instrument. (Goswami (Illumina) Tr. 3194.)

2959. Illumina requires customers to enter into an IVD agreement to run a test on Illumina's Dx instruments. (Goswami (Illumina) Tr. 3268).

Response to Finding No. 2959:

The proposed finding is incomplete and misleading for the reasons identified in the response CCFF ¶ 2958, which Respondents incorporate herein.

2960. Illumina provides a device master file to the FDA when a kitted IVD test developer is seeking FDA approval. (Goswami (Illumina) Tr. 3224).

Response to Finding No. 2960:

The proposed finding is incomplete and misleading for the reasons identified in the response CCFF ¶ 2958, which Respondents incorporate herein.

2961. When a kitted IVD test developer choses to develop its test on Illumina's sequencers, Illumina learns the test developer's development plans, when the developer will need the local run module for its test, when the developer plans to submit to the FDA for approval, and when the developer plans to commercialize its test. (Goswami (Illumina) Tr. 3226-27).

Response to Finding No. 2961:

The proposed finding is incomplete and misleading without additional context. In the portion of Dr. Goswami's testimony immediately after the cited portion, Dr. Goswami explained that Illumina does not "see anything proprietary about how the test functions". (Goswami (Illumina) Tr. 3227.) Instead, Illumina receives "just general information" that is used "to plan for certain commitments and obligations that [Illumina] ha[s] to the test developer itself". (Goswami (Illumina) Tr. 3227.) Respondents also incorporate their response to CCFF ¶ 2958 herein.

2962. Dr. Goswami testified that customers provide Illumina with volume information so that "Illumina can provide the right level of support and inventory." (Goswami (Illumina) Tr. 3272).

Response to Finding No. 2962:

Respondents incorporate their response to CCFF ¶ 2961 herein.

2963. Guardant relies on Illumina to support interactions with the FDA. (Getty (Guardant) Tr. 2509).

Response to Finding No. 2963:

The proposed finding is incomplete and misleading without additional context. Specifically, in the portion of Mr. Getty's testimony immediately after the cited portion, Mr. Getty provided context for this answer: Mr. Getty explained that, in the regulatory process, Guardant relies on Illumina "as a manufacturer" to provide information on Illumina's products. (Getty (Guardant) Tr. 2515.) Further, Mr. Getty admitted that Illumina did not have a role in developing Guardant's LUNAR-2 assay and has not been involved in any FDA review or consideration of the LUNAR-2 assay. (Getty (Guardant) Tr. 2645.)

Additionally, the Open Offer requires Illumina to provide to provide documentation to assist customers with FDA approval or marketing authorization to sell a for-profit, clinical test using Illumina's sequencing instruments and core consumables. (PFF ¶ 1027; PX0064 (Illumina) at 8; PX0087 (Illumina) at 23; PX0088 (Illumina) at 20; PX0089 (Illumina) at 20; [redacted].) The Open Offer includes a right of reference to any relevant Illumina regulatory documentation for Illumina's IVD partners. (PFF ¶ 1027.2; Leite (Illumina/InterVenn) Tr. 2156; PX0064 (Illumina) at 39; PX0087 (Illumina) at 23; PX0088 (Illumina) at 20; PX0089 (Illumina) at 20; [redacted].) Under this right, a partner developing on Illumina systems may reference Illumina's files in their regulatory submission. (PFF ¶ 1027.2; PX0064 (Illumina) at 39; PX0087 (Illumina) at 23;

PX0088 (Illumina) at 20; PX0089 (Illumina) at 20; [redacted]).) [redacted].)

Finally, the proposed finding relies on impermissible lay opinion testimony. Mr. Getty was not called as an expert witness on the FDA approval process and his opinion on that process should be disregarded.

2964. Guardant relies on Illumina to provide documentation relating to Illumina NGS that is necessary for Guardant to pursue FDA approval. (Getty (Guardant) Tr. 2515).

Response to Finding No. 2964:

Respondents incorporate their response to CCFF ¶ 2963 herein.

2965. Mr. Getty testified at trial that Guardant "would need to work with Illumina" in order to obtain FDA approval to sell Guardant's MCED test as a distributed IVD test. (Getty (Guardant) Tr. 2689).

Response to Finding No. 2965:

Respondents have no specific response except to note that the Open Offer requires Illumina to provide to provide documentation to assist customers with FDA approval or marketing authorization to sell a for-profit, clinical test using Illumina's sequencing instruments and core consumables. (PFF ¶ 1027; PX0064 (Illumina) at 8; [redacted]).) The Open Offer includes a right of reference to any relevant Illumina regulatory documentation for Illumina's IVD partners. (PFF ¶ 1027.2; Leite (Illumina/InterVenn) Tr. 2156; PX0064 (Illumina) at 39; PX0087 (Illumina) at 23; PX0088 (Illumina) at 20; PX0089 (Illumina) at 20; [redacted] Under this right, a partner developing on Illumina systems may reference Illumina's files in their regulatory submission. (PFF ¶ 1027.2; PX0064 (Illumina) at 39; PX0087 (Illumina) at 23; PX0088 (Illumina) at 20; PX0089 (Illumina) at 20; [redacted]).) [redacted]

[redacted].) Respondents also incorporate their response to CCFF ¶ 2963 herein.

Further, Mr. Getty admitted that Guardant has not developed any kitted forms of any of its tests, including LUNAR-2, its purported MCED test in development. (Getty (Guardant) Tr. 2692.) Similarly, [redacted] Finally, Respondents note that for the reasons identified their response to CCFF ¶ 2947, a distributed kit would not be appropriate for an MCED test.

2966. [redacted] (PX7040 (Getty (Guardant) IHT at 86) (*in camera*)).

Response to Finding No. 2966:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Further, Mr. Getty admitted that Guardant has not developed any kitted forms of any of its tests, including LUNAR-2, its purported MCED test in development. (Getty (Guardant) Tr. 2692.) Similarly, [redacted] Finally, Respondents note that for the reasons identified their response to CCFF ¶ 2947, a distributed kit would not be appropriate for an MCED test.

2967. [redacted] (PX7040 (Getty (Guardant) IHT at 85-86) (*in camera*)).

Response to Finding No. 2967:

The proposed response is incorrect and misleading because Mr. Getty is not qualified to testify about the rationale for Illumina's financial decisions. Further, under the Open Offer, Illumina is required, on a customer's request, to enter into separate standardized agreements with the customer to develop IVD test kits for use on Illumina's platforms. (PFF ¶ 1026; [redacted]; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; PX0087 (Illumina); PX0088 (Illumina); PX0089 (Illumina); [redacted] The Open Offer also requires Illumina to provide customers with standard terms for IVD agreements and to provide documentation to assist the customer with FDA approval or marketing authorization. (PFF ¶ 1027; PX0064 (Illumina) at 8; PX0087 (Illumina) at 23; PX0088 (Illumina) at 20; PX0089 (Illumina) at 20; [redacted]

Additionally, the financial terms for these IVD agreements are standard in the industry. (PFF ¶ 1032.1; Goswami (Illumina) Tr. 3212; [redacted]; PX7097 (Felton (Thermo Fisher) Dep. at 127–29).) The financial terms were chosen based on what is common in the industry and securing a return on Illumina's upfront investments. (PFF ¶¶ 1032.3–1032.5; Goswami (Illumina) Tr. 3213–16.) As Dr. Goswami testified at trial, "Illumina has to develop these [Dx sequencing] platforms way in advance of them ever having content built on them by a partner. And that development often takes several tens of millions of dollars over several years and is done completely at risk, right. We have no guarantee that it will be successful, that we'll be able to get the regulatory [approval that is required], or that

customers will ever adopt that platform. So there is – as a business, we have to seek a return on that investment at risk that we make to make that Dx infrastructure broadly available". (Goswami (Illumina) Tr. 3213.)

Further, Mr. Getty admitted that Guardant has not developed any kitted forms of any of its tests, including LUNAR-2, its purported MCED test in development. (Getty (Guardant) Tr. 2692.) Similarly, [redacted] Finally, Respondents note that for the reasons identified their response to CCFF ¶ 2947, a distributed kit would not be appropriate for an MCED test.

Finally, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2968. [redacted] (PX7040 (Getty (Guardant) IHT at 88) (*in camera*)). [redacted]

(PX7040 (Getty (Guardant) IHT at 88) (*in camera*)).

Response to Finding No. 2968:

Respondents have no specific response except to note that the Open Offer requires Illumina, on a customer's request, to enter into a separate standardized agreement with the

customer to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33; [redacted]; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; PX0087 (Illumina); PX0088 (Illumina); PX0089 (Illumina); [redacted].) These requirements in the Open Offer prevent Illumina from withholding support as purported MCED test developers seek FDA approval. (RX6002 (Guerin-Calvert Trial Dep. at 74).)

Further, Mr. Getty admitted that Guardant has not developed any kitted forms of any of its tests, including LUNAR-2, its purported MCED test in development. (Getty (Guardant) Tr. 2692.) Similarly, [redacted] Finally, Respondents note that for the reasons identified their response to CCFF ¶ 2947, a distributed kit would not be appropriate for an MCED test.

Finally, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2969. [redacted] (PX7075 (Stahl (Invitae) Dep. at 63-64) (*in camera*)) [redacted].

Response to Finding No. 2969:

The proposed finding is incomplete, irrelevant and misleading without additional context.

[redacted]

Second, the Open Offer requires Illumina, on a customer's request, to enter into a separate standardized agreement with the customer to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33; [redacted]; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; PX0087 (Illumina); PX0088 (Illumina); PX0089 (Illumina); [redacted].) In any event, the proposed finding is irrelevant because Mr. Stahl's testimony relates to oncology testing efforts that are entirely unrelated to early cancer screening.

2970. [redacted]

[redacted] (PX7075 (Stahl (Invitae) Dep. at 59-60) (*in camera*).

Response to Finding No. 2970:

Respondents have no specific response except to note that the Open Offer requires Illumina, on a customer's request, to enter into a separate standardized agreement with the customer to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33; [redacted]; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; PX0087 (Illumina); PX0088 (Illumina); PX0089 (Illumina); [redacted].) Additionally, the Open Offer requires Illumina to provide to provide documentation to assist customers with FDA approval or marketing authorization to sell a for-profit, clinical test using Illumina's sequencing instruments and core consumables. (PFF ¶ 1027; PX0064 (Illumina) at 8; [redacted].) The Open Offer includes a right of reference to any relevant Illumina regulatory documentation for Illumina's IVD partners. (PFF ¶ 1027.2; Leite (Illumina/InterVenn) Tr. 2156; PX0064 (Illumina) at 39; PX0087 (Illumina) at 23; PX0088 (Illumina) at 20; PX0089 (Illumina) at 20; [redacted].) Under this right, a partner developing on Illumina systems may reference Illumina's files in their regulatory submission. (PFF ¶ 1027.2; PX0064 (Illumina) at 39; PX0087 (Illumina) at 23; PX0088 (Illumina) at 20; PX0089 (Illumina) at 20; [redacted].) These requirements in the Open Offer prevent Illumina from withholding support as putative MCED test developers seek FDA approval. (RX6002 (Guerin-Calvert Trial Dep. at 74).) Respondents also incorporate their response to CCFF ¶ 2970 herein.

The proposed finding is based on speculation. [redacted]

[redacted]

Finally, the proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

2971. [redacted]

[redacted]

(PX7049 (Bailey (PGDx) IHT at 42-43) (*in camera*)).

Response to Finding No. 2971:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2970, which Respondents incorporate herein.

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2972. [redacted]

[redacted] (PX7063 (Berry (Illumina) IHT at 95) (*in camera*)).

Response to Finding No. 2972:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2970, which Respondents incorporate herein.

2973. Illumina provides a device master file to the FDA when a kitted IVD test developer is seeking FDA approval. (Goswami (Illumina) Tr. 3224).

Response to Finding No. 2973:

Respondents have no specific response except to note that, the Open Offer includes a right of reference to any relevant Illumina regulatory documentation for Illumina's IVD partners, [redacted] (PFF ¶ 1027.2; Leite (Illumina/InterVenn) Tr. 2156; Goswami (Illumina) at 3224; PX0064 (Illumina) at 39; PX0087 (Illumina) at 23; PX0088 (Illumina) at 20; PX0089 (Illumina) at 20; [redacted].) Under this right, a partner developing on Illumina systems may reference Illumina's files in their regulatory submission. (PFF ¶ 1027.2; PX0064 (Illumina) at 39; PX0087 (Illumina) at 23; PX0088 (Illumina) at 20; PX0089 (Illumina) at 20; [redacted].)

2974. [redacted] (Conroy (Exact) Tr. 1587 (*in camera*)). [redacted] (Conroy (Exact) Tr. 1587 (*in camera*)).

Response to Finding No. 2974:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2970, which Respondents incorporate herein.

Additionally, Mr. Conroy admitted that [redacted]

[redacted]

The proposed finding is also incomplete and misleading with respect to Exact/Thrive's purported reliance on Illumina's NGS systems. [redacted]

Further, Dr. Vogelstein, the founder of Thrive stated, [redacted]

[redacted] The proposed finding is also inaccurate, incomplete, and misleading for the

reasons explained in Respondents' responses to CCFF ¶¶ 928–29 and 2833, which Respondents incorporate herein.

2975. [redacted] (PX7110 (Conroy (Exact) Dep. at 78) (*in camera*)).

Response to Finding No. 2975:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2970 and 2974, which Respondents incorporate herein.

Additionally, Mr. Conroy admitted that [redacted]

2976. [redacted] (Conroy (Exact) Tr. 1589 (*in camera*)).

Response to Finding No. 2976:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2970 and 2974, which Respondents incorporate herein.

Additionally, Mr. Conroy admitted that [redacted]

[redacted]

2977. [redacted] (Conroy (Exact) Tr. 1591 (*in camera*)).

Response to Finding No. 2977:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2970 and 2974, which Respondents incorporate herein.

Additionally, Mr. Conroy admitted that [redacted]

Respondents also note that features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (PFF ¶¶ 675–678.5 (RX3869 (Cote Expert Report) ¶¶ 359–363; Goswami (Illumina) Tr. 3189–92, 3194–95).) The test developer's decision whether to proceed with an IVD kit as opposed to a centralized model is an economic decision driven by test-specific factors. (Goswami (Illumina) Tr. 3197.) IVD kits are most suitable for tests that have precious samples, that present shipping challenges and require fast turnaround times. (Goswami (Illumina) Tr. 3196–3200; *see also* RX3869 (Cote Expert Report) § XI, ¶¶ 360–63.) Indeed, Exact's Cologuard test "started off in . . . the 2014 time frame, and [Exact has still] announced no plans to really take that test as a distributed IVD test . . . so it remains as a single-site-available test

alone." (PFF ¶ 1412; Goswami (Illumina) Tr. 3196–97.) Respondents also note that Illumina's NovaSeq is not yet available as Dx instrument. (Goswami (Illumina) Tr. 3194.)

Respondents also incorporate their responses to CCFF ¶¶ 1089, 2612, 2617, 2620, 2634 and 2636 herein.

(3) To Run an FDA-Approved Distributed MCED Test, Third-Party Labs Must Have the Corresponding Illumina Dx Instrument Enabled and Supported by Illumina

2978. A test developer needs an IVD agreement with Illumina to distribute its test to third-party labs. (Goswami (Illumina) Tr. 3261-62).

Response to Finding No. 2978:

Respondents have no specific response except to note that the Open Offer requires Illumina, on a customer's request, to enter into such an IVD agreement with the customer based on standardized terms. (PFF ¶¶ 1026–35; Rabinowitz (Natera) Tr. 423–24; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; [redacted].)

Respondents also note that features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (PFF ¶¶ 675–678.5 (RX3869 (Cote Expert Report) ¶¶ 359–363; Goswami (Illumina) Tr. 3189–92, 3194–95).) The test developer's decision whether to proceed with an IVD kit as opposed to a centralized model is an economic decision driven by test-specific factors. (Goswami (Illumina) Tr. 3197.) IVD kits are most suitable for tests that have precious samples, that present shipping challenges and require fast turnaround times. (Goswami (Illumina) Tr. 3196–3200; *see also* RX3869 (Cote Expert Report) § XI, ¶¶ 360–63.) Respondents also note that Illumina's NovaSeq is not yet available as Dx instrument. (Goswami (Illumina) Tr. 3194.)

2979. If an MCED test developer wants to offer its MCED test as an FDA-approved distributed kit, the third-party labs that run the test would need access to the NGS instrument approved

for use with the kit and license to operate the instrument in the diagnostic ("Dx") mode specified in the FDA's approval. (PX7045 (Chudova (Guardant) Dep. at 81-83)).

Response to Finding No. 2979:

Respondents have no specific response except to note that the evidence shows that the requirements in the Open Offer prevent Illumina from withholding support as putative MCED test developers seek FDA approval. (PFF ¶¶ 1026–33; RX6002 (Guerin-Calvert Trial Dep. at 74).) Respondents also note that the Open Offer requires Illumina, on a customer's request, to enter into such an IVD agreement with the customer for the test developer to offer an FDA-approved distributed kit, based on standardized terms. (PFF ¶¶ 1026–35; [redacted] deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; [redacted].)

Respondents also note that features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (PFF ¶¶ 675–678.5 (RX3869 (Cote Expert Report) ¶¶ 359–363; Goswami (Illumina) Tr. 3189–92, 3194–95).) The test developer's decision whether to proceed with an IVD kit as opposed to a centralized model is an economic decision driven by test-specific factors. (Goswami (Illumina) Tr. 3197.) IVD kits are most suitable for tests that have precious samples, that present shipping challenges and require fast turnaround times. (Goswami (Illumina) Tr. 3196–3200; *see also* RX3869 (Cote Expert Report) § XI, ¶¶ 360–63.) Indeed, Exact's Cologuard test "started off in . . . the 2014 time frame, and [Exact has still] announced no plans to really take that test as a distributed IVD test . . . so it remains as a single-site-available test alone." (PFF ¶ 1412; Goswami (Illumina) Tr. 3196–97.) Respondents also note that Illumina's NovaSeq is not yet available as Dx instrument. (Goswami (Illumina) Tr. 3194.)

2980. For kitted IVDs, Illumina makes a one-time "local run module," which provides a software module to the test developer for reading the genetic output from the Illumina platform. (Goswami (Illumina) Tr. 3189).

Response to Finding No. 2980:

The proposed finding is incomplete and misleading. Illumina's role in customers' development of IVD test kits is limited and the "test manufacturer has sole responsibility for the distributed kit" in the FDA approval process. (Goswami (Illumina) Tr. 3189.) Further, the Open Offer requires Illumina, on a customer's request, to enter into an IVD agreement with the customer based on standardized terms. (PFF ¶¶ 1026–35; [redacted]; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; [redacted].) As part of these IVD agreements, Illumina is required to "develop and verify the [Local Run Module] for each IVD Test Kit" pursuant to an approved IVD plan. (Goswami (Illumina) Tr. 3189; PX0087 (Illumina) at 11; PX0088 (Illumina) at 10; PX0089 (Illumina) at 10.)

Respondents also note that features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (PFF ¶¶ 675–678.5 (RX3869 (Cote Expert Report) ¶¶ 359–363; Goswami (Illumina) Tr. 3189–92, 3194–95).) The test developer's decision whether to proceed with an IVD kit as opposed to a centralized model is an economic decision driven by test-specific factors. (Goswami (Illumina) Tr. 3197.) IVD kits are most suitable for tests that have precious samples, that present shipping challenges and require fast turnaround times. (Goswami (Illumina) Tr. 3196–3200; *see also* RX3869 (Cote Expert Report) § XI, ¶¶ 360–63.) Indeed, Exact's Cologuard test "started off in . . . the 2014 time frame, and [Exact has still] announced no plans to really take that test as a distributed IVD test . . . so it remains as a single-site-available test

alone." (PFF ¶ 1412; Goswami (Illumina) Tr. 3196–97.) Respondents also note that Illumina's NovaSeq is not yet available as Dx instrument. (Goswami (Illumina) Tr. 3194.)

2981. The test developer incorporates the local run module and can then distribute the module as part of its kitted IVD. (Goswami (Illumina) Tr. 3189).

Response to Finding No. 2981:

Respondents have no specific response except to incorporate their response to CCFF ¶ 2980 herein.

2982. Guardant's Dr. Chudova testified that to initiate a sequencing run on an Illumina Dx instrument, Guardant needs Illumina's help:

> [I]n order for [Guardant] to initiate a sequencing run on the Dx instrument using a particular sequencing protocol, we would need that enabled by Illumina on the Dx box, so whether it exists in [Guardant's] lab or in partners' labs, [Illumina] would need to enable access to the protocol to run Guardant 360 liquid biopsy . . . [a]nd unless they do it, customer cannot turn it on their own on the diagnostic box, right. It's a locked device that has a particular configuration.
>
> (PX7045 (Chudova (Guardant) Dep. at 89)).

Response to Finding No. 2982:

The proposed finding is incomplete and misleading. *First*, the Open Offer requires Illumina, on a customer's request, to enter into a separate standardized agreement with the customer to develop IVD test kits for use on Illumina's Dx instruments. (PFF ¶¶ 1026–33; [redacted]; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; [redacted].)

The Open Offer also addresses any concern that Illumina would withhold access to the NextSeq Dx instrument or any other sequencing instruments, because it specifically provides that customers can receive a right under Illumina's core intellectual property to use Illumina's sequencing instruments and core consumables. (PFF ¶ 1036; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.)

Second, the proposed finding is misleading to the extent it suggests that only Illumina offers Dx sequencing instruments. To the contrary, Dr. Felton explained how the PGM Dx platform, a fully FDA-approved system, is used in oncology applications. (Felton (Thermo Fisher) Tr. 1983–87.) [redacted]. (PFF ¶¶ 778–778.2; 2085.)

Third, the proposed finding is irrelevant. Respondents also note that features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (PFF ¶¶ 675–678.5 (RX3869 (Cote Expert Report) ¶¶ 359–363; Goswami (Illumina) Tr. 3189–92, 3194–95).) The test developer's decision whether to proceed with an IVD kit as opposed to a centralized model is an economic decision driven by test-specific factors. (Goswami (Illumina) Tr. 3197.) IVD kits are most suitable for tests that have precious samples, that present shipping challenges and require fast turnaround times. (Goswami (Illumina) Tr. 3196–3200; *see also* RX3869 (Cote Expert Report) § XI, ¶¶ 360–63.) Indeed, Exact's Cologuard test "started off in . . . the 2014 time frame, and [Exact has still] announced no plans to really take that test as a distributed IVD test . . . so it remains as a single-site-available test alone." (PFF ¶ 1412; Goswami (Illumina) Tr. 3196–97.) Respondents also note that Illumina's NovaSeq is not yet available as Dx instrument. (Goswami (Illumina) Tr. 3194.)

2983. [redacted] (PX7045 (Chudova (Guardant) Dep. at 82-83); *see also* PX7040 (Getty (Guardant) IHT at 85-86) (*in camera*)).

Response to Finding No. 2983:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2982, which Respondents incorporate herein.

(4) Illumina Can Deny MCED Rivals' Access to IVD Agreements

2984. [redacted] (*See, e.g.*, PX2089 (Illumina) at 001-003 (Email from T. Dodge, Illumina, to D. Daly, Illumina, Aug. 31, 2018) (*in camera*); PX2095 (Illumina) at 002-003 (Email from J. Leite, Illumina, to G. Hampton, Illumina, Dec. 5, 2018) (*in camera*) ([redacted])).

Response to Finding No. 2984:

The proposed finding is incomplete and misleading. Specifically, in the present, the Open Offer requires Illumina, on a customer's request, to enter into a separate standardized agreement with the customer to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33; [redacted]; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; [redacted].) These requirements in the Open Offer prevent Illumina from withholding support as putative MCED test developers seek FDA approval. (PFF ¶ 1035; RX6002 (Guerin-Calvert Trial Dep. at 74).)

[redacted]

[redacted]

2985. In negotiating IVD agreements, Dr. Leite testified that Illumina dictates which tests gain an IVD agreement and accept customer proposals only if they made financial sense for Illumina. (Leite (Illumina) Tr. 2186).

For additional evidence on how Illumina disadvantaged its clinical test rivals through denying, delaying, or dictating unfavorable terms in IVD negotiations and agreements, see Section VII.D.2.

Response to Finding No. 2985:

The proposed finding is not supported by the cited evidence. In the portion of Mr. Leite's testimony cited, Mr. Leite discusses the value that a smaller company might place on the reputational benefit of an IVD agreement with Illumina, as well as alternative paths for developing IVD test kit without an IVD agreement with Illumina. (Leite (Illumina) Tr. 2186.)

In any event, regardless of Illumina's past IVD agreement negotiations, the Open Offer requires Illumina, on a customer's request, to enter into such an agreement with the customer based on standardized terms. (PFF ¶¶ 1026–33; [redacted]; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; [redacted].) [redacted] (PFF ¶ 1035.2; PX7138 (Scott Morton Trial Dep. at 288).)

To the extent that Complaint Counsel relies on its Proposed Findings in Section VII.D.2, Respondents incorporate their responses to those Proposed Findings herein.

e) Illumina Can Alter its NGS Products to Disadvantage Grail's MCED Rivals

2986. When Illumina first formed Grail, it noted that "Illumina understands the sequencer better than anyone since they developed it and can in partnership with [Grail] optimize i[t] for ctDNA applications (e.g., improved error profile). This means that [Grail] can get better performance than someone who has to use the off the shelf version." (PX2712 (Illumina) at 028 (Email from P. Scagnetti, Illumina, to M. Nguyen, Illumina, attaching Python: A Revolution in Early Cancer Detection, Dec. 3, 2019)).

Response to Finding No. 2986:

The proposed finding is irrelevant because any special pricing and other benefits Illumina may have provided to GRAIL in its original supply agreement when GRAIL was formed and controlled by Illumina are irrelevant to evaluating the effects of the Transaction on competition. (PFF ¶ 979.) At the time of GRAIL's formation, the objective of creating a cancer screening test was a moonshot concept, and Illumina believed that without deep discounting, it would be impossible for GRAIL to develop a cancer screening test. (PFF ¶¶ 980–980.4.)

The proposed finding is also outdated. Although the cited exhibit was drafted in 2019, the proposed finding appears to suggest that, even today, three years later, Illumina applies the same approach. The proposed finding is also misleading to the extent it suggests that GRAIL will receive access to sequencing instruments and core consumables, as well as associated services, that are unavailable to other putative MCED test developers. This is incorrect. Any customer that signs the Open Offer shall have the same access to services that GRAIL or any other For-Profit Entity has access to, at the same prices. (PFF ¶ 1004; [redacted]; Berry (Illumina) Tr. 865–66; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.)). Similarly, the Open Offer provides customers the same access to purchase sequencing instruments and core consumables to which GRAIL has access. (PFF ¶ 1005; [redacted]; Berry (Illumina) Tr. 878–79; deSouza (Illumina) Tr. 2434–35, 2437–38; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) Further, the timing of the access to these services and sequencing products shall be the same for GRAIL as it is for its

putative rivals: the Open Offer requires that "Customer shall have access to the Supplied Products for purchase that GRAIL . . . has access, within 5 days of when GRAIL . . . is offered such access (if not earlier) for purchase." (PFF ¶ 1005.1; RX3935 (Illumina) at 2.)

The Open Offer also requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶ 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.)

2987. Illumina previously collaborated with Grail on "extraction methodology to improve library yields" and on the development of library prep and sequencing kits, including kits "built specifically for Grail." (PX2541 (Illumina) at 008, 010, 017 (Interim Review: K2-Grail, Feb. 2, 2017)).

For additional information on how Illumina gave Grail preferential, exclusive, and customized treatment when it owned more than 50 percent of Grail (but not once it spun off Grail), see Sections I.A.2.–3. (Formation of Grail & Spinoff of Grail (Reducing Ownership to Less Than 50 Percent) and VII.D.1. (Illumina Identified Tools When it Launched and Spun Off Grail).

Response to Finding No. 2987:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2986, which Respondents incorporate herein. The proposed finding is also improper because it treats Complaint Counsel's inaccurate, misleading and argumentative headers as purported facts. To the extent Complaint Counsel relies on its Proposed Findings in Sections I.A.2–.3 and VII.D.1, paragraphs 19 –67 and 3669–3748, Respondents incorporate their responses to those Proposed Findings herein.

2988. [redacted] (*See, e.g.*, PX7051 (Lengauer (Third Rock Ventures) IHT at 91-92) (*in camera*)).

Response to Finding No. 2988:

The proposed finding is inaccurate, incomplete and misleading.

First, as Mr. deSouza testified at trial, Illumina is not in the business of developing reagents that only work for one customer. Contrary to Complaint Counsel's unproven contention, Illumina will continue to make general purpose reagents that work for all customers and will not be designing reagents that specifically improve GRAIL's work flow. (deSouza (Illumina) Tr. 2434 ("Q. But it could be designed to specifically improve GRAIL's work flow, correct? A. We're not a consulting firm, so we don't design products for one customer. If we are going to embark on a substantial undertaking from an engineering team perspective, we want a product that can meet the needs more broadly of a customer. So we don't do -- we are not a consulting firm, so we don't do custom development for -- like that.") Further, Illumina has never previously made or optimized reagents for one customer. (deSouza (Ilumina) Tr. 2434; Berry (Illumina) Tr. 844.) For example, [redacted]

Second, the Open Offer requires Illumina to continue to offer the same reagents that it offered before the Transaction for the entire duration of the Open Offer. Under the Open Offer, Illumina is prohibited from discontinuing products that any oncology customer has purchased in the prior year. (PFF ¶ 1011; [redacted]; Berry (Illumina) Tr. 883; PX0064 (Illumina) at 6; PX7085 (Harada (Exact/Thrive) Dep. at 94–95).) This provision adequately addresses the concern that Illumina could advantage GRAIL by simply no longer providing a product and ensures that customers as "certainly no worse off than in the current world". (PFF ¶¶ 1011.7–.8; RX6002 (Guerin-Calvert Trial Dep. at 71–73).) Therefore, to the extent that Exact/Thrive or another putative MCED test developer purchased a specific Illumina

product before the Transaction that works with its putative MCED test, Illumina *must* continue offering that product for the next twelve years.

Third, the Open Offer requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶ 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.) This not only prevents Illumina from disadvantaging potential GRAIL rivals, but also requires Illumina to act in a particular way to support customers developing competing products. (PFF ¶ 1010.10; [redacted].)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2989. [redacted] (Lengauer (Third Rock Ventures) Tr. 197-98 (*in camera*)).

Response to Finding No. 2989:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2988, which Respondents incorporate herein.

2990. [redacted] (Lengauer (Third Rock Ventures) Tr. 196-99 (*in camera*)).

Response to Finding No. 2990:

R The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2988, which Respondents incorporate herein.

2991. [redacted]
(PX7051 (Lengauer (Third Rock Ventures) IHT at 92-93, 189-91) (*in camera*)).

Response to Finding No. 2991:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2988, which Respondents incorporate herein.

2992. [redacted] (Lengauer (Third Rock Ventures) Tr. 197-98 (*in camera*)).

Response to Finding No. 2992:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2988, which Respondents incorporate herein.

2993. [redacted] (Lengauer (Third Rock Ventures) Tr. 200 (*in camera*)).

Response to Finding No. 2993:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2988, which Respondents incorporate herein.

2994. [redacted]

(Lengauer (Third Rock Ventures) Tr. 200 (*in camera*)).

Response to Finding No. 2994:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2988, which Respondents incorporate herein.

2995. [redacted] (Fiedler (FMI) Tr. 4494 (*in camera*)).

Response to Finding No. 2995:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2988, which Respondents incorporate herein.

Further, [redacted]

2996. [redacted] (Fiedler (FMI) Tr. 4493 (*in camera*)).

Response to Finding No. 2996:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2988 and 2995, which Respondents incorporate herein.

2997. [redacted]

[redacted] (PX7068 (Perettie (FMI-Roche) IHT at 97) (*in camera*)).

Response to Finding No. 2997:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2988 and 2995, which Respondents incorporate herein.

Further, [redacted]

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

f) Illumina Can Share the Competitively Sensitive Information of MCED Test Developers with Grail

(1) MCED Test Developers Share Competitively Sensitive Information with Illumina

2998. Illumina has access to a variety of sources and means to collect information about MCED test developers. (*See supra* Section VII.A.1 (Illumina Has the Ability to Identify and Discriminate Against MCED Test Developers Posing Competitive Threats to Grail's Galleri Test and the Tools to Foreclose or Reduce the Competitiveness of Grails' Rivals).

Response to Finding No. 2998:

The proposed finding is improper because it treats Complaint Counsel's inaccurate, misleading and argumentative headers as purported facts. To the extent Complaint Counsel

relies on its Proposed Findings in Section VII.A.1, paragraphs 2607–2701, Respondents incorporate their responses to those Proposed Findings herein.

2999. Illumina learns several types of information from its IVD customers. (Goswami (Illumina) Tr. 3226-27). For example, Illumina learns about its customer's development plans, when a customer will need the local run module for its test, when the customer plans to seek FDA approval, and when the customer plans to commercialize its test. (Goswami (Illumina) Tr. 3226-27).

Response to Finding No. 2999:

The proposed finding is inaccurate, incomplete and misleading, including because the phrase "several types of information" is vague and ambiguous. In the portion of Dr. Goswami's testimony cited, Dr. Goswami explained that Illumina does not "see anything proprietary about how the test functions". (Goswami (Illumina) Tr. 3227.) Instead, Illumina receives "just general information" that is used "to plan for certain commitments and obligations that [Illumina] ha[s] to the test developer itself". (Goswami (Illumina) Tr. 3227.) Similarly, as Ms. Berry explained, "we don't get into designing assays with customers." (Berry (Illumina) Tr. 845.)

Further, this information is not widely available to Illumina employees. For example. Illumina takes measures to protect any customer information that it treats as confidential—such as order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.)

In any event, Illumina takes extensive precautions to protect the confidentiality of information it receives from developers including: (1) setting up confidentiality agreements with partners, (2) training staff and requiring them to sign confidentiality agreements, (3) separating teams who might work on similar products, (4) using document control processes and (5) providing legal guidance if individuals request access to protected documents. (PFF ¶¶ 1040–1040.5; Goswami (Illumina) Tr. 3227–30.) These practices are standard in the industry and

generally accepted by companies that serve multiple clients in the same industry. (PFF ¶ 1040.8; Goswami (Illumina) Tr. 3228–29.)

The Open Offer requires that to the extent that Illumina has access to customer confidential information, Illumina shall not share such information with GRAIL, any GRAIL subsidiary or any employee who works within GRAIL. (PFF ¶ 1038; **c**; Berry (Illumina) Tr. 916–17; PX0064 (Illumina) at 9.)

Under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (PFF ¶ 1039; [redacted]; deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted].)

3000. Illumina's Dr. Goswami testified that customers provide Illumina with volume information so that "Illumina can provide the right level of support and inventory." (Goswami (Illumina) Tr. 3272).

Response to Finding No. 3000:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3000, which Respondents incorporate herein. Respondents also note that Dr. Goswami's testimony was limited to customers who have entered into agreements with Illumina to develop distributed IVD kits. (*See* Goswami (Illumina) Tr. 3271–72.)

Respondents also note that features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (PFF ¶¶ 675–678.5 (RX3869 (Cote Expert Report) ¶¶ 359–363; Goswami (Illumina) Tr. 3189–92, 3194–95).) Dr. Goswami pointed out that an IVD kit offering is rare and due to the burdens associated with IVD kits and test developers often choose to stay with an LDT model as

opposed to seeking to provide an IVD kit; for example, the longest available molecular test, the BRCA test, was introduced in the 1990s and has never been offered as an IVD kit—neither has Exact Sciences' Cologuard test. (Goswami (Illumina) Tr. 3196.)

Further, this information is not widely available to Illumina employees. As discussed in Respondents responses to CCFF ¶ 2999, incorporated herein, Illumina takes measures to protect any customer information that it treats as confidential—such as order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.)

3001. When Illumina enters into supply agreements with customers, Illumina encourages customers to provide "some insight and visibility into what their future needs are." (Berry (Illumina) Tr. 662-63).

Response to Finding No. 3001:

The proposed finding is incomplete and misleading. In the portion of Ms. Berry's testimony cited here, Mr. Berry provided context for this answer: "So we – you know, to the extent to which a customer is comfortable, we encourage them to provide us some insight and visibility into what their future needs are, and absent that, we sort of use their historical purchases to try to just do our best to anticipate what they might need and plan accordingly." (Berry (Illumina) Tr. 663 (emphasis added).)

In the ordinary course of business, Illumina does not require customers to report that information, and Illumina does not solicit detailed, technical information from its customers. As Ms. Berry explained, "we don't get into designing assays with customers." (Berry (Illumina) Tr. 845.) Respondents also incorporate their responses to CCFF ¶ 2661 herein.

Further, this information is not widely available to Illumina employees. As discussed in Respondents responses to CCFF ¶ 2999, incorporated herein, Illumina takes measures to protect

any customer information that it treats as confidential—such as order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.)

3002. The information that customers usually provide to Illumina includes the anticipated frequency and quantity of shipments and mix of product purchases. (Berry (Illumina) Tr. 663).

Response to Finding No. 3002:

The proposed finding is incomplete and misleading. In the portion of Ms. Berry's testimony cited here, Mr. Berry provided context for this answer: Ms. Berry testified that "[i]f the customer chooses to provide that level of detail, [customer forecasts] could potentially include" this information. (Berry (Illumina) Tr. 663 (emphasis added).) Respondents also incorporate their responses to CCFF ¶¶ 2661 and 3001 herein.

3003. If customers do not provide forecast information to Illumina, then Illumina uses customers' historical purchases to create customer forecasts. (Berry (Illumina) Tr. 662-63).

Response to Finding No. 3003:

Respondents have no specific response except to note that this proposed finding supports the fact that Illumina does not require its customers to provide detailed forecast information if they are not comfortable doing so. (*See also* RRFF ¶¶ 3002–03.)

3004. Some customers' sequencers connect to Illumina online allowing Illumina to monitor the instrument. (deSouza (Illumina) Tr. 2384-85).

Response to Finding No. 3004:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2673, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention, Mr. deSouza was unequivocal in testifying that customers could run their sequencers with an "airgap"—that is, they can "completely just run it on their own and don't have any connection to the Internet at all." (deSouza (Illumina) Tr.

2383–84.) The Proactive monitoring service and the cloud storage services are both voluntary, opt-in programs for customers. (*See also* PX7076 (Berry (Illumina) Dep. at 30.) Respondents also note that it is "an important bright line" for Illumina to "never access or look at or review any customer's genomic data", which customers do not provide to Illumina even if they are connected to the Proactive service. (deSouza (Illumina) Tr. 2385.) Respondents also incorporate their responses to CCFF ¶¶ 2612 and 2678 herein.

3005. Some customers' sequencers connect to Illumina via the internet to monitor the instrument or connect to Illumina's cloud-based data storage service. (deSouza (Illumina) Tr. 2383-85).

Response to Finding No. 3005:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2673 and 3004, which Respondents incorporate herein.

3006. A customer can choose to send only instrumentation metrics—how the instrument is performing—or instrumentation metrics and the underlying genomic data to Illumina's cloud-based storage service. (deSouza (Illumina) Tr. 2384-85).

Response to Finding No. 3006:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2673 and 3004, which Respondents incorporate herein.

The cited testimony also confirms that customers have the choice of how much information to send to Illumina' storage service. Further, Mr. deSouza offered additional context for this answer explaining that Illumina "will not mine [data sent to the cloud-based storage service] for drug discoveries or anything like that" and instead acts as a "steward[] of that data". (deSouza (Illumina) Tr. 2385.) Mr. deSouza agreed that "under no circumstances do[es] [Illumina] access or look at or review any customer's genomic data" because "that's an important bright line" for Illumina. (deSouza (Illumina) Tr. 2385.)

3007. [redacted]

Response to Finding No. 3007:

The proposed finding is incomplete and misleading because the given customer's volume information is not widely available to Illumina employees and is not available to GRAIL. As discussed in Respondents responses to CCFF ¶ 2999, incorporated herein, Illumina takes measures to protect any customer information that it treats as confidential—such as order history, pending purchase orders and order forecasts—including employee training and viewing restrictions on data stored in the databases (Berry (Illumina) Tr. 853–55.)

Further, the Open Offer requires that to the extent that Illumina has access to customer confidential information, Illumina shall not share such information with GRAIL, any GRAIL subsidiary or any employee who works within GRAIL. (PFF ¶ 1038; [redacted]; Berry (Illumina) Tr. 916–17; PX0064 (Illumina) at 9.) Further, under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (PFF ¶ 1039; [redacted]; deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted].)

In addition, although Illumina may have an understanding of the types of applications a customer is developing or marketing, in many cases it does not know what specific tests are in its customers' development pipeline. (Berry (Illumina) Tr. 849–53.) For example, many of the putative MCED tests Complaint Counsel claims are in development are unknown to Illumina even today—much less their specific attributes that would allow Illumina to predict with

confidence whether any test will be a close substitute to Galleri, or, instead, a market-expanding complement, foreclosure of which would cause no material diversion to Galleri but would result in substantial lost upstream sales. (RX6000 (Carlton Trial Dep. at 24, 26–27).)

Finally, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3008. [redacted]

Response to Finding No. 3008:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3007 and 3010–11, which Respondents incorporate herein.

3009. [redacted]

Response to Finding No. 3009:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3007 and 3010–11, which Respondents incorporate herein.

3010. [redacted]

Response to Finding No. 3010:

The proposed finding is incomplete and misleading without additional context. In the portion of Dr. Lengauer's testimony immediately after the cited portion, Dr. Lengauer explained

that [redacted] Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3011. [redacted]

Response to Finding No. 3011:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3007 and 3010, which Respondents incorporate herein.

Contrary to the cited testimony, [redacted]

[redacted]

3012. [redacted].

Response to Finding No. 3012:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3007 and 3010–11, which Respondents incorporate herein.

3013. [redacted]

Response to Finding No. 3013:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3007, which Respondents incorporate herein.

In the ordinary course of business, Illumina's customers may volunteer high-level information about their tests to Illumina. Illumina does not require customers to report that information, and Illumina does not solicit detailed, technical information from its customers. As Ms. Berry explained, "we don't get into designing assays with customers." (Berry (Illumina) Tr. 845.)

Further, Mr. Getty did not explain the types of purportedly confidential information that Guardant apparently shared with Illumina and accordingly, this testimony should be accorded little weight.

Additionally, Mr. Getty admitted that Illumina did not have a role in developing Guardant's LUNAR-2 assay and has not been involved in any FDA review or consideration of the LUNAR-2 assay. (Getty (Guardant) Tr. 2645.) Similarly, [redacted]

3014. [redacted]

Response to Finding No. 3014:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3007, which Respondents incorporate herein.

In the ordinary course of business, Illumina's customers may volunteer high-level information about their tests to Illumina. Illumina does not require customers to report that information, and Illumina does not solicit detailed, technical information from its customers. As Ms. Berry explained, "we don't get into designing assays with customers." (Berry (Illumina) Tr. 845.)

Further, in the portion of Dr. Rabinowitz's testimony cited here, Dr. Rabinowitz admitted that [redacted]

[redacted]

3015. [redacted]

Response to Finding No. 3015:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3007, which Respondents incorporate herein.

In the ordinary course of business, Illumina's customers may volunteer high-level information about their tests to Illumina. Illumina does not require customers to report that information, and Illumina does not solicit detailed, technical information from its customers. As Ms. Berry explained, "we don't get into designing assays with customers." (Berry (Illumina) Tr. 845.)

Further, in the portion of Dr. Rabinowitz's testimony cited here, Dr. Rabinowitz admitted that [redacted]

3016. [redacted]

Response to Finding No. 3016:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3007, which Respondents incorporate herein.

In the ordinary course of business, Illumina's customers may volunteer high-level information about their tests to Illumina. Illumina does not require customers to report that information, and Illumina does not solicit detailed, technical information from its customers. As

Ms. Berry explained, "we don't get into designing assays with customers." (Berry (Illumina) Tr. 845.)

Further, in the portion of Dr. Rabinowitz's testimony cited here, Dr. Rabinowitz admitted that [redacted] 3017. [redacted]

Response to Finding No. 3017:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3007, which Respondents incorporate herein.

In the ordinary course of business, Illumina's customers may volunteer high-level information about their tests to Illumina. Illumina does not require customers to report that information, and Illumina does not solicit detailed, technical information from its customers. As Ms. Berry explained, "we don't get into designing assays with customers." (Berry (Illumina) Tr. 845.)

Additionally, Dr. Fiedler of FMI [redacted]

[redacted]

Finally, the proposed finding is directed to irrelevant subject matter because currently, FMI/Roche markets the following types of oncology tests: FoundationOne® CDx, an FDA-approved solid tumor therapy selection test; FoundationOne® Liquid CDx, an FDA-approved liquid biopsy therapy selection test; FoundationOne® Heme, a solid tumor therapy selection test; and Roche's AVENIO line of comprehensive genomic profiling solid tumor kits for therapy selection. (PFF ¶ 454; RX3232 (Roche/FMI); RX3234 (Roche/FMI); RX3233 (Roche/FMI); RX3615 (Roche/FMI); RX2565 (Roche/FMI); [redacted]

3018. [redacted]

Response to Finding No. 3018:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3007, which Respondents incorporate herein.

Additionally, [redacted]

[redacted]

3019. [redacted]

Response to Finding No. 3019:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3007, which Respondents incorporate herein.

Additionally, Dr. Fiedler of FMI [redacted]

[redacted]

3020. [redacted]

Response to Finding No. 3020:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3007, which Respondents incorporate herein.

Additionally, Dr. Fiedler of FMI [redacted]

[redacted]

3021. [redacted]

Response to Finding No. 3021:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3007, which Respondents incorporate herein.

Additionally, Dr. Fiedler of FMI [redacted]

[redacted]

3022. [redacted]

Response to Finding No. 3022:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3007, which Respondents incorporate herein.

On March 4, 2021, after Roche submitted this set of objections to the FTC, Dr. Severin Schwan, the CEO of Roche stated in a letter that [redacted]

[redacted]

The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2673 and 3004, which Respondents incorporate herein. Contrary to Complaint Counsel's unproven contention, Mr. deSouza was unequivocal in testifying that customers could run their sequencers with an "airgap"—that is, they can "completely just run it on their own and don't have any connection to the Internet at all." (deSouza (Illumina) Tr. 2383–84.) The Proactive monitoring service and the cloud storage services are both voluntary, opt-in programs for customers. (*See also* PX7076 (Berry (Illumina) Dep. at 30.) Respondents also note that it is "an important bright line" for Illumina to "never access or look at or review any customer's genomic data", which customers do not provide to Illumina even if they are connected to the Proactive service. (deSouza (Illumina) Tr. 2385.) Respondents also incorporate their responses to CCFF ¶¶ 2612 and 2678 herein.

Additionally, Dr. Fiedler of FMI [redacted]

[redacted]

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 59), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

(2) No Firewall Can Prevent Disclosure of Competitively Sensitive Material

3023. Section 10(b) of the Open Offer provides for the establishment of a firewall to prevent Grail from accessing any "confidential information" that other Illumina customers provide to Illumina. (Berry (Illumina) Tr. 716).

Response to Finding No. 3023:

Respondents have no specific response.

3024. Illumina's Nicole Berry testified that the Open Offer does not define what constitutes confidential information. (Berry (Illumina) Tr. 716-18).

Response to Finding No. 3024:

The proposed finding is incomplete and misleading. In the portion of Ms. Berry's testimony cited, Ms. Berry provided context for this answer: She testified that the customers contemplating executing the Open Offer "have a good understanding of what confidential information is, specifically related to their experience executing supply agreements with Illumina" and that the definition is "pretty standardized and well understood". (Berry (Illumina) Tr. 717–18.) Similarly, Dr. Goswami testified, "in the [required] training [for Illumina employees] on confidential information we clearly outline what is confidential and what the employee's obligations are under that confidentiality agreement". (Goswami (Illumina) Tr.

3232.) This is a "very standard process in the industry and [Illumina] know[s] how to do this." (Goswami (Illumina) Tr. 3232.)

3025. As described in detail in Section VIII.A.3.j. (Illumina's Commitments to Confidentiality Are Flawed), MCED test developers testified that Illumina's Open Offer firewall provision is insufficient to prevent the sharing of their competitively sensitive information between Illumina and Grail.

Response to Finding No. 3025:

The proposed finding is improper because it treats Complaint Counsel's inaccurate, misleading and argumentative headers as purported facts. To the extent Complaint Counsel relies on its Proposed Findings in Section VIII.A.3.j, paragraphs 4724–4803, Respondents incorporate their responses to those Proposed Findings herein.

3026. [redacted] (PX7109 (Daly (Singular Genomics) Dep. at 54-59) (*in camera*)).

Response to Finding No. 3026:

The proposed finding is incomplete and misleading. The cited portion of Mr. Daly's testimony indicates that [redacted]

[redacted] (PFF ¶ 1039; [redacted]; deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted].) The Open Offer thus "speak[s] to keeping [sensitive customer] information completely confidential from GRAIL, [and] it also restricts access from within the legacy Illumina organization to who can access such confidential information." (Berry (Illumina) Tr. 917.)

Additionally, as noted in CCFF ¶ 2667, which Respondents incorporate herein, even if Illumina could access sufficiently detailed information about GRAIL's putative rivals (it cannot without the consent of the putative rival's consent), Illumina is prohibited from disclosing that information to GRAIL.

Contrary to Mr. Daly's unsubstantiated testimony, Respondents also note that it is "an important bright line" for Illumina to "never access or look at or review any customer's genomic data", which customers do not provide to Illumina even if they are connected to the Proactive service. (deSouza (Illumina) Tr. 2385.) As stated, the data to which Illumina has access is only instrument physical state data—things like the temperature of the instrument or the laser power, which is not competitively sensitive. Respondents also incorporate their responses to CCFF ¶¶ 2612 and 2678 herein.

3027. [redacted] (PX7110 (Conroy (Exact) Dep. 248-49) (*in camera*)).

Response to Finding No. 3027:

The proposed finding is incomplete and misleading. Contrary to Mr. Conroy's testimony, [redacted]

[redacted]

(PFF ¶ 1041; RX6002 (Guerin-Calvert Trial Dep. at 80–85); PX7138 (Scott Morton Trial Dep. at 294).) The Open Offer's firewall provision will have the characteristics of an effective firewall, specifically: monitoring and auditing, methods to report violations and consequences for violations. (PFF ¶¶ 1041.5, 1100; RX6002 (Guerin-Calvert Trial Dep. at 84–85).)

Further, Illumina is very familiar with how to set up and operate these types of confidentiality provisions because it already shields confidential information in other contexts. (PFF ¶ 1041.3; Goswami (Illumina) Tr. 3231.) Illumina takes extensive precautions to protect the confidentiality of information it receives from developers including: (1) setting up confidentiality agreements with partners, (2) training staff and requiring them to sign confidentiality agreements, (3) separating teams who might work on similar products, (4) using document control processes and (5) providing legal guidance if individuals request access to protected documents. (PFF ¶¶ 1040–1040.5; Goswami (Illumina) Tr. 3227–30.) These practices are standard in the industry and generally accepted by companies that serve multiple clients in the same industry. (PFF ¶ 1040.8; Goswami (Illumina) Tr. 3228–29.)

The Open Offer's provisions in their totality also ensure that Illumina's incentives are to support GRAIL's rivals. (PFF ¶ 1082.2–1082.4; see RX6002 (Guerin-Calvert Trial Dep. at 20–22, 108–09; RX6000 (Carlton Trial Dep. at 84–85).)

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. Mr. Conroy, as an Exact executive, has no basis to know what Illumina's incentives are or will be in the future and therefore his cited testimony should be discounted.

3028. [redacted] (Getty (Guardant) Tr. 2557 (*in camera*)).

Response to Finding No. 3028:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3027, which Respondents incorporate herein.

3029. [redacted] (Getty (Guardant) Tr. 2559 (*in camera*)).

Response to Finding No. 3029:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3027, which Respondents incorporate herein. Further, the Open Offer [redacted] allows Guardant to monitor Illumina and GRAIL's compliance with the firewall provision. Specifically, this provision, like the entirety of the Open Offer, is subject to bi-annual audits of Illumina's compliance. (PFF ¶ 1047; deSouza (Illumina) Tr. 2405, 2438; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.) Specifically, an independent auditor can successfully audit the confidentiality provisions by obtaining a list of Illumina employees working with GRAIL and ensuring the list is complete and accurate, obtaining a list of all Illumina and GRAIL employees who are authorized to receive confidential information, executing employee compliance certifications regularly, examining reports of violations, performing keyword email searches, creating and testing electronic barriers, testing for noncompliance with respect to hard-copy information and interviewing select personnel. (RX6003 (Rock Trial Dep. at 67–71).) Moreover, in addition to the bi-annual audits, "if [Illumina] become[s] aware of a breach of confidentiality of any kind, we are obligated to promptly notify the other party of such breach". (Goswami (Illumina) Tr. 3233.)

3030. [redacted] (Getty (Guardant) Tr. 2559 (*in camera*)).

Response to Finding No. 3030:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3027, which Respondents incorporate herein. Mr. Getty, as a Guardant executive, has no basis to know what Illumina's or GRAIL's incentives are or will be in the future and therefore his cited testimony should be discounted.

3031. [redacted] (Rabinowitz (Natera) Tr. 373 (*in camera*)).

Response to Finding No. 3031:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3027, which Respondents incorporate herein. Further, neither Complaint Counsel nor Dr. Rabinowitz provided any examples of instances where Illumina did not comply with its firewall obligations in connection with NIPT, and therefore, Dr. Rabinowitz's unsubstantiated testimony should be disregarded.

3032. [redacted] (deSouza (Illumina) Tr. 2280-81 (*in camera*)).

Response to Finding No. 3032:

Respondents have no specific response.

3033. [redacted] (deSouza (Illumina) Tr. 2281 (*in camera*)).

Response to Finding No. 3033:

Respondents have no specific response.

3034. [redacted] (deSouza (Illumina) Tr. 2281 (*in camera*)). [redacted] (deSouza (Illumina) Tr. 2281 (*in camera*)).

Response to Finding No. 3034:

Respondents have no specific response.

3035. [redacted] (deSouza (Illumina) Tr. 228182 (*in camera*)).

Response to Finding No. 3035:

Respondents have no specific response.

3036. Grail's new CEO is Illumina veteran Bob Ragusa, who served as Illumina COO prior to this appointment and worked at Illumina since 2013. (PX0405 (Press Release, Illumina Appoints Bob Ragusa as Chief Executive Officer (CEO) of GRAIL, Oct. 14, 2021)). As of September 2020, Ragusa holds about $1 million in Illumina stock. (PX4619 (Grail) at 187, 197 (Email from V. Korobkin, Morgan Stanley, to M. Podoll, Morgan Stanley, et al., attaching "Public Information Book: Watson," Sept. 12, 2020)).

Response to Finding No. 3036:

The proposed finding is incomplete and misleading. The evidence cited to show that Mr. Ragusa holds $1 million in Illumina stock is from almost a year prior to his appointment as GRAIL's CEO. This evidence is out of date, particularly because Mr. Ragusa has now sold his Illumina stock. Thus, it should be given no weight.

3037. [redacted] (PX6056 (Illumina) at 038-043 (Illumina, Narrative Responses of Illumina, Inc. to the Second Request for Additional Information and Documentary Material Issued by the Federal Trade Commission on November 9, 2020, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 3037:

The proposed finding is incomplete and misleading. To the extent that Complaint Counsel attempts to suggest that Mr. Ragusa's membership on the Pricing Committee will lead to more favorable discounts for GRAIL, this is mistaken. Under the Open Offer, GRAIL

receives pricing under a universal pricing grid. (PFF ¶ 1016.5; Berry (Illumina) Tr. 894.) All customers have access to pricing on the same universal pricing grid that GRAIL receives. (PFF ¶¶ 1014, 1016; Berry (Illumina) Tr. 892–94.)

3038. [redacted] (deSouza (Illumina) Tr. 2282 (*in camera*)).

Response to Finding No. 3038:

Respondents have no specific response.

3039. [redacted] (deSouza (Illumina) Tr. 2282 (*in camera*)).

Response to Finding No. 3039:

The proposed finding is incomplete and misleading. In the portion of Mr. deSouza's testimony cited here, Mr. deSouza provided context for this answer: [redacted]

3040. [redacted] (deSouza (Illumina) Tr. 2282 (*in camera*)).

Response to Finding No. 3040:

Respondents have no specific response except to note that the merger agreement (signed in September 2020) contemplated that GRAIL's board would dissolve immediately upon closing. (RX0699 (GRAIL) at 96.)

3041. [redacted] (deSouza (Illumina) Tr. 2282 (*in camera*)).

Response to Finding No. 3041:

Respondents have no specific response.

3042. [redacted] (deSouza (Illumina) Tr. 2282 (*in camera*)).

Response to Finding No. 3042:

The proposed finding is incomplete and misleading. In the cited portion of Mr. deSouza's testimony, Mr. deSouza explained that [redacted]

3043. [redacted] (deSouza (Illumina) Tr. 2284 (*in camera*)).

Response to Finding No. 3043:

Respondents have no specific response.

3044. [redacted] (deSouza (Illumina) Tr. 2283-84 (*in camera*)).

Response to Finding No. 3044:

Respondents have no specific response.

3045. [redacted] (deSouza (Illumina) Tr. 2284-85 (*in camera*)).

Response to Finding No. 3045:

The proposed finding is incomplete and misleading. In the cited portion of Mr. deSouza's testimony, Mr. deSouza offered context for this answer: [redacted]

[redacted]

3046. [redacted] (deSouza (Illumina) Tr. 2285 (*in camera*)).

Response to Finding No. 3046:

Respondents incorporate their response to CCFF ¶ 3045 herein.

3047. [redacted] (deSouza (Illumina) Tr. 2285-86 (*in camera*)).

Response to Finding No. 3047:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3045, which Respondents incorporate herein.

3048. [redacted] (deSouza (Illumina) Tr. 2286 (*in camera*)).

Response to Finding No. 3048:

Respondents have no specific response.

3049. [redacted] (deSouza (Illumina) Tr. 2286 (*in camera*)).

Response to Finding No. 3049:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3045, which Respondents incorporate herein.

3050. [redacted] (deSouza (Illumina) Tr. 2286 (*in camera*)).

Response to Finding No. 3050:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3045, which Respondents incorporate herein.

3051. [redacted] (deSouza (Illumina) Tr. 2286 (*in camera*)).

Response to Finding No. 3051:

Respondents have no specific response.

3052. [redacted] (deSouza (Illumina) Tr. 2286 (*in camera*)).

Response to Finding No. 3052:

Respondents have no specific response.

3053. [redacted] (deSouza (Illumina) Tr. 2286 (*in camera*)).

Response to Finding No. 3053:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3045, which Respondents incorporate herein.

3054. [redacted] (deSouza (Illumina) Tr. 2286-87 (*in camera*)).

Response to Finding No. 3054:

Respondents have no specific response.

3055. [redacted] (deSouza (Illumina) Tr. 2287 (*in camera*)).

Response to Finding No. 3055:

The proposed finding is incomplete and misleading. In the cited portion of Mr. deSouza's testimony, Mr. deSouza provided context for this answer: [redacted]

[redacted]

[redacted]

3056. [redacted] (deSouza (Illumina) Tr. 2287 (*in camera*)).

Response to Finding No. 3056:

Respondents have no specific response.

3057. [redacted] (deSouza (Illumina) Tr. 2287 (*in camera*)).

Response to Finding No. 3057:

The proposed finding is incomplete and misleading. In the cited portion of Mr. deSouza's testimony, Mr. deSouza provided context for this answer: [redacted]

[redacted]

[redacted]

[redacted]

3058. [redacted] (deSouza (Illumina) Tr. 2287 (*in camera*)).

Response to Finding No. 3058:

Respondents have no specific response.

3059. [redacted] (deSouza (Illumina) Tr. 2287-2288 (*in camera*)).

Response to Finding No. 3059:

The proposed finding is incomplete and misleading. In the cited portion of Mr. deSouza's testimony, Mr. deSouza provided context for this answer: [redacted]

[redacted]

[redacted]

3060. [redacted] (deSouza (Illumina) Tr. 2288 (*in camera*)).

Response to Finding No. 3060:

Respondents have no specific response.

3061. [redacted] (deSouza (Illumina) Tr. 2287 (*in camera*)). [redacted] (deSouza (Illumina) Tr. 2288 (*in camera*)).

Response to Finding No. 3061:

The proposed finding is incomplete and misleading. In the cited portion of Mr. deSouza's testimony, Mr. deSouza provided context for this answer: [redacted]

3062. [redacted] (deSouza (Illumina) Tr. 2288 (*in camera*)).

Response to Finding No. 3062:

Respondents have no specific response.

3063. [redacted] (deSouza (Illumina) Tr. 2288 (*in camera*)).

Response to Finding No. 3063:

Respondents have no specific response.

3064. [redacted] (deSouza (Illumina) Tr. 2288-2289 (*in camera*)).

Response to Finding No. 3064:

Respondents have no specific response.

3065. [redacted] (deSouza (Illumina) Tr. 2289 (*in camera*)).

Response to Finding No. 3065:

Respondents have no specific response.

3066. [redacted] (deSouza (Illumina) Tr. 2289 (*in camera*)).

Response to Finding No. 3066:

Respondents have no specific response.

g) Illumina Can Control IP Access and Sue for Application-Specific IP Infringement

3067. When analyzing potential acquisitions, Illumina internally favored markets where it could use IP as a "blocking mechanism to protect the profitability of the diagnostic market." (PX2056 (Illumina) at 001 (Email from R. Chambers, Illumina, to N. Naclerio, Illumina, Nov. 17, 2015)).

Response to Finding No. 3067:

The proposed finding, including the term "favored", is vague and ambiguous, as well as misleading to the extent it suggests that Illumina used IP to block competition in a diagnostic market. Further, the evidence shows that Illumina does not wield intellectual property in a anti-competitive manner and, in fact, has helped to resolve intellectual property disputes that previously held back markets before Illumina's involvement. (PFF ¶ 1099; see deSouza (Illumina) Tr. 2470–71.)

For example, in the nascent NIPT market that existed before Illumina acquired Verinata, several companies, such as Verinata, Sequenom and Ariosa, were engaged in ongoing intellectual property litigation. (PFF ¶ 1099.4; PX7089 (Naclerio (Illumina) Dep. at 49).) These disputes led to exceedingly high prices for NIPT tests for patients. (PFF ¶ 1099.4; PX7089 (Naclerio (Illumina) Dep. at 49–50).) Illumina recognized that these disputes held back the NIPT market. (PFF ¶ 1099.4; PX7089 (Naclerio (Illumina) Dep. at 49–50).) Illumina chose to acquire Verinata in part to accelerate adoption of NIPT by settling this intellectual property

litigation. (PFF ¶ 1099.5; PX7089 (Naclerio (Illumina) Dep. at 57–58).) Illumina recognized that it could accomplish this because Illumina could help bring the companies in disputes to the negotiating table. (PFF ¶ 1099.5; PX7089 (Naclerio (Illumina) Dep. at 57–59).) Illumina's strategy in this acquisition was to settle the intellectual property litigation promptly and then make NIPT technology available to other labs around the world to grow the market and lower prices. (PFF ¶ 1099.6; PX7089 (Naclerio (Illumina) Dep. at 58–59).) As a result of this acquisition, the market for NIPT has grown significantly. (*See* PFF ¶¶ 956–63.) For example, since the acquisition, the number of NIPT tests conducted by Verinata's rivals on Illumina's platforms in the U.S. has increased in each year for which there is available data. (PFF ¶ 956; RX3864 (Carlton Expert Report) ¶ 165.) Furthermore, there has been a steady stream of new entry and substantial investment into NIPT testing in the U.S. since the Verinata acquisition, indicating that downstream competitors to Verinata are not concerned that Illumina will act anticompetitively, and that Illumina has not in fact acted anticompetitively, in the NIPT space. (PFF ¶ 962; RX3589 (Illumina); RX3864 (Carlton Expert Report) ¶ 162.)

3068. Michael Nolan, CEO of Freenome, testified that [redacted] (Nolan (Freenome) Tr. 2783-84 (*in camera*)).

Response to Finding No. 3068:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

[redacted]

Further, under the Open Offer [redacted] Illumina commits to give customers a right under Illumina's core intellectual property to use its sequencing instruments and core consumables. (PFF ¶ 1036; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.) Illumina also commits that it will not have the right to cease shipments of the products solely on the basis of a claim of infringement of Illumina's intellectual property rights. (PFF ¶ 1037; Berry (Illumina) Tr. 864; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.)

3069. [redacted] (Nolan (Freenome) Tr. 2783-84 (*in camera*)).

Response to Finding No. 3069:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3068, which Respondents incorporate herein.

3070. [redacted] (Nolan (Freenome) Tr. 2781 (*in camera*)).

Response to Finding No. 3070:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3068, which Respondents incorporate herein.

3071. [redacted] (Nolan (Freenome) Tr. 2781 (*in camera*)).

Response to Finding No. 3071:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3068, which Respondents incorporate herein.

3072. [redacted] (Nolan (Freenome) Tr. 2781 (*in camera*)).

Response to Finding No. 3072:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3068, which Respondents incorporate herein.

3073. Mr. Nolan explained that Freenome wants to have [redacted] (Nolan (Freenome) Tr. 2784 (*in camera*)).

Response to Finding No. 3073:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3068, which Respondents incorporate herein.

3074. Mr. Nolan testified that Freenome wants [redacted] (Nolan (Freenome) Tr. 2784 (*in camera*)).

Response to Finding No. 3074:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3068, which Respondents incorporate herein.

3075. [redacted] (PX8324 (Roche) at 003 (*in camera*)).

Response to Finding No. 3075:

The proposed finding is incomplete and misleading. Contrary to Complaint Counsel's unproven contention, Illumina's efforts in creating this patent pool actually helped prevent the non-competitive use of intellectual property rights in the market for non-invasive prenatal tests (NIPT). (PFF ¶ 1099.3; *See* PX7089 (Naclerio (Illumina) Dep. at 49–50, 57–58, 150).) In the nascent NIPT market that existed before Illumina acquired Verinata, several companies, such as Verinata, Sequenom and Ariosa, were engaged in ongoing intellectual property litigation. (PFF ¶ 1099.4; PX7089 (Naclerio (Illumina) Dep. at 49).) These disputes led to exceedingly high prices for NIPT tests for patients. (PFF ¶ 1099.4; PX7089 (Naclerio (Illumina) Dep. at 49–50).)

Illumina recognized that these disputes held back the NIPT market. (PFF ¶ 1099.4; PX7089 (Naclerio (Illumina) Dep. at 49–50).) Illumina chose to acquire Verinata in part to accelerate adoption of NIPT by settling this intellectual property litigation. (PFF ¶ 1099.5; PX7089 (Naclerio (Illumina) Dep. at 57–58).) Illumina recognized that it could accomplish this because Illumina could help bring the companies in disputes to the negotiating table. (PFF ¶ 1099.5; PX7089 (Naclerio (Illumina) Dep. at 57–59).) Illumina's strategy in this acquisition

was to settle the intellectual property litigation promptly and then make NIPT technology available to other labs around the world to grow the market and lower prices. (PFF ¶ 1099.6; PX7089 (Naclerio (Illumina) Dep. at 58–59).)

Illumina ultimately succeeded in this strategy when, after acquiring Verinata, it negotiated a set of cross-licensing agreements to create a patent pool among six different entities. (PFF ¶ 1099.7; [redacted], 150).) The entities in the pool have the right to use each other's intellectual property and to split revenue from the patents in the pool. (PFF ¶ 1099.7; [redacted], 150).)

In addition, on March 4, 2021, after Roche submitted this set of objections to the FTC, Dr. Severin Schwan, the CEO of Roche stated in a letter that [redacted]

[redacted]

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 59), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3076. [redacted] (PX8324 (Roche) at 007 (*in camera*)).

Response to Finding No. 3076:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3075, which Respondents incorporate herein.

3077. [redacted]

(PX8324 (Roche) at 007 [redacted] (emphasis in original).

Response to Finding No. 3077:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3075, which Respondents incorporate herein.

3078. [redacted] (PX8324 (Roche) at 007 [redacted] (*in camera*)).

For additional evidence on how Illumina has used intellectual property to inhibit its clinical competitors, see Section VII.D.3. (Illumina Identified and Used Similar Tools in the NIPT Market).

Response to Finding No. 3078:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3075, which Respondents incorporate herein. The proposed finding is also improper because it treats Complaint Counsel's inaccurate, misleading and argumentative headers as purported facts.

To the extent that Complaint Counsel relies on its Proposed Findings in Section VII.D.3, Respondents incorporate their responses to those Proposed Findings herein.

B. ILLUMINA HAS THE INCENTIVE TO LESSEN COMPETITION IN THE U.S. MCED TEST MARKET BY DISADVANTAGING GRAIL'S RIVALS

3079. Vicky Demas, Grail's Platform Product Manager and New Products Program Lead, informed Grail CEO Hans Bishop and Grail's Executive Leadership Team that "GRAIL's acquisition by Illumina was a question to many of our competitors and to Illumina itself" at a September 2020 industry conference, and that "the focus was on [I]llumina as a platform provider and how those relationships might change." (PX4005 (Grail) at 001 (Email from V. Demas, Grail, to Grail's Executive Leadership Team, et al., September 28, 2020)).

Response to Finding No. 3079:

The proposed finding is irrelevant. It is of no moment to the issues before the Court that questions reportedly were raised at a conference immediately after Illumina's announcement of the Grail merger agreement regarding whether the acquisition might impact any Illumina customer relationships. Illumina anticipated such questions, and that is precisely why Illumina conducted outreach its top oncology customers assuring them that there would be no such change. (E.g., PFF ¶¶ 987–99.) Illumina then crafted the Open Offer to provide contractually-based assurances, consistent with Illumina's incentives to encourage third parties to develop tests for Illumina's systems to expand demand for its NGS products. (PFF ¶¶ 987–99.) Respondents

further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and should not be entitled to rely on it to establish anything beyond the words on the page.

3080. In 2015, Illumina's CEO at the time, Jay Flatley, sent Francis deSouza "Final Notes" from a Board Strategic Offsite that describe the vision for Illumina's "Org and Culture" as follows:

> "May God have mercy on my enemies, because I will not!"
>
> (PX2358 (Illumina) at 005 (Email from J. Flatley, Illumina, to F. deSouza, Illumina, attaching "Final Notes – 2015 Board Strategic Offsite," Nov. 9, 2015) (further advocating for "violent[] execut[ion]" of corporate plans)).

Response to Finding No. 3080:

The proposed finding is irrelevant and misleading. The document, and the quote that Complaint Counsel misleading excerpts from it, has nothing to do with the issues before the Court. The language was included along with other generalized, high level bullets under the category "Evolving our Org and Culture", in a 2015 internal presentation, before GRAIL was even formed by Illumina. If the quoted language shows anything, it is that Illumina strives to be an effective competitor. And, contrary to Complaint Counsel's attempted insinuation in taking this quote out of context, it is because Illumina strives to compete effectively that Illumina has every incentive to support all customers, including any putative Grail rival, in order to encourage development on its own systems rather than competing platforms that are available today and more so that will be available to test developers in the near future, and to maintain the reputation for innovation and low cost sequencing that will drive future development of sales of clinical tests on its systems. (E.g., PFF ¶¶ 847-864.)

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 17), or in any deposition, and should not be entitled to rely on it to establish anything beyond the words on the page.

1. A Combined ILMN-Grail Has the Incentive to Maximize Firmwide Profits

a) Pre-Merger, ILMN Had the Incentive to Promote Innovation and Multiple MCED Tests

3081. Dr. Fiona Scott Morton explained:

[redacted]

(PX6090 (Scott Morton Report) ¶ 165 (*in camera*)).

Response to Finding No. 3081:

The proposed finding is nothing more than a conclusory assertion by an economist who by her own admission has no expertise in MCED test development or NGS technology, asserting her non-expert interpretation of a cherry-picked set of documents. It is therefore irrelevant and misleading. To the extent this proposed finding is meant to assert that Illumina benefits from having its customers invest in the development of clinical tests on its platform, and that it does not know which of its customers' assays-in-development will increase demand for sequencing and to what extent, that is true. However, it is also true (and Complaint Counsel has not shown otherwise) that, *after* the Transaction, Illumina continues to benefit from having customers choose its platform for their development efforts. Illumina does not know which tests in development on its platform will accelerate and expand demand for its sequencing products, and so it has an incentive to encourage all such development. That is why Illumina, post-Transaction, has continued, and will continue, to support and encourage development of clinical tests on its platform—i.e., Illumina's desire to accelerate and expand demand for its NGS systems bolsters its incentives to support all customers. (*E.g.*, PFF ¶¶ 847-872.)

To the extent the proposed finding is asserting that there is an innovation race between Galleri and other test developers to develop a test with attributes comparable to, and therefore substitutable with, Galleri, the proposed finding is contradicted by the weight of the record evidence, as detailed extensively in Respondents' Proposed Findings of Fact. (*E.g.*, PFF ¶¶ 701–706.) Further, as noted below, Complaint Counsel, and here Dr. Scott-Morton, mischaracterize and draw invalid inferences from Illumina's spin-off of Grail in 2017. (*See* Respondents' responses to CCFF ¶¶ 3669-3748.)

3082. [redacted] *see also* PX4291 (Grail) [redacted] (*in camera*) [redacted].

Response to Finding No. 3082:

Respondents have no specific response.

3083. Illumina stated in internal Q&A bullets that that divesting Grail would "accelerate the liquid biopsy market for all." (PX2406 (Illumina) at 005 (Email from J. Flatley, Illumina, to E. Endicott et al., Illumina, attaching Illumina/Grail Q&A, Jan. 2, 2017).

Response to Finding No. 3083:

The proposed finding is incomplete and misleading without additional context. As cited document shows, the quote is in response to the hypothetical question: "By creating and unleashing GRAIL have you created a competitor for your customers." (PX2406 (Illumina) at 005.) In the document, the response to that question does not say, as Complaint Counsel suggests, that MCED test development would be accelerated just by virtue of the fact that Illumina was spinning off GRAIL. That is an incoherent suggestion that finds no support in the document, which talks about accelerating "liquid biopsy" more broadly as a result of Illumina both "creating and unleashing" Grail. Mr. Flatley, who drafted the language quoted by

Complaint Counsel, directly refuted the inference Complaint Counsel hopes to draw from the document when he was asked about it at his deposition (which Complaint Counsel conveniently fails to cite). Mr. Flatley explained that what he meant with this language is that "if GRAIL has the constraints taken off it in terms of field of use, the could now compete against customers where in the earlier format [before the spin-off] they could not have because the field was constrained." (PX7079 (Flatley (Illumina) Dep. at 174).) Mr. Flatley went on to explain that, prior to the spin-off, the question regarding the creation an entity that would compete with customers more broadly in liquid biopsy was not a consideration because GRAIL was constrained to developing only an MCED test, "there were no customers in the screening market" and "there was a market that didn't exist and still doesn't, so there are no customers in the screening market." (PX7079 (Flatley (Illumina) Dep. at 175).)

3084. Following Illumina's spinoff of Grail in 2017, Francis deSouza stated publicly:

> There are 70-plus players now in the liquid biopsy space. We want to encourage them to look at all different avenues because this is important and the outcome's terrific for mankind. There are different points of view. There are companies that believe it's going to be a combination of ultra-deep screening of the blood samples plus tissue, whole transcriptome analysis to identify tissue of origin. And to be honest, I think people are approaching it slightly differently and the market will sort of determine where the biology is and what the right answer is. In every case though, we're talking about a lot of sequencing.

(PX0376 at 007 (Illumina Inc. at Goldman Sachs Global Healthcare Conference Call Transcript, June 13, 2017).

Response to Finding No. 3084:

Respondents note that Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 3), and therefore should not be entitled to rely on it to establish anything beyond the words on the page.

Further, to the extent that this proposed finding is meant to imply that today—five years after Mr. DeSouza's quoted statement—the amount of sequencing required for an MCED test is the same as what was thought might be required in 2017, that implication is misleading and contrary to the evidence. As Dr. Aravanis testified, Illumina determined that the amount of sequencing that an MCED test will require "will decrease over time", which will further "compound the overall reduction in sequencing costs as a fraction of the test." (Aravanis Tr. 1924:20-1925:11.) Relatedly, Dr. Aravanis explained that the "cost of sequencing as a percentage of the development cost of Galleri" is "about 10 percent" and so too is the "cost of sequencing as a percentage of the revenue of Galleri", which is anticipated to decline to "5 percent and then even less over time". (Aravanis Tr. 1923:14-1924:22.; *see also* Respondents' PFOF at ¶¶ 909-915.) [redacted]

3085. At the same conference, deSouza stated of the liquid biopsy market: "[W]e want to encourage that market because that market, I think, is very promising from a patient perspective, but it uses a lot of sequencing." (PX0376 at 007 (Illumina Inc. at Goldman Sachs Global Healthcare Conference, FD (Fair Disclosure) Wire, Conference Call Transcript, June 13, 2017).

Response to Finding No. 3085:

Respondents have no specific response but note that Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 3), and therefore should not be entitled to rely on it to establish anything beyond the words on the page. Respondents further note that Mr. deSouza (as the quote made clear) was talking about liquid biopsy generally, not MCED tests specifically.

3086. In a 2017 presentation to Sands Capital Management, Illumina told investors "We spun out Grail to encourage investment into many different NGS-based companies focused on early

cancer detection to have as many shots on goal as possible." (PX2561 (Illumina) at 017 (Email from J. Cunningham, Illumina, to F. deSouza, Illumina, attaching "DRAFT Sands Investor Talking Points," Oct. 30, 2020); deSouza (Illumina) Tr. 2204-5).

Response to Finding No. 3086:

The proposed finding is incomplete and misleading without additional context. Mr. deSouza testified that early cancer detection screening companies would have "shots on goal" independent of whether Illumina spun GRAIL out or not. (deSouza (Illumina) Tr. 2204). He further noted that this language referred to the fact that, at this time, there were many uncertainties regarding the right scientific and technical approach to early cancer screening. (deSouza (Illumina) Tr. 2204.)

3087. Dr. Scott Morton explained that [redacted] (PX6090 (Scott Morton Report) ¶ 165 (*in camera*)). Dr. Scott Morton concluded: [redacted] (PX6090 (Scott Morton Report) ¶ 165 (*in camera*)).

Response to Finding No. 3087:

The proposed finding is nothing more than a conclusory assertion by an economist who by her own admission has no expertise in MCED test development or NGS technology, asserting her non-expert interpretation of a cherry-picked set of documents. It is therefore irrelevant and misleading.

To the extent this proposed finding is meant to assert that Illumina benefits from having its customers invest in the development of clinical tests on its platform, and that it does not know which of its customers' assays-in-development will increase demand for sequencing and to what extent, that is true. However, it is also true (and Complaint Counsel has not shown otherwise) that, *after* the Transaction, Illumina continues to benefit from having customers choose its

platform for their development efforts. [redacted] (*E.g.*, PFF ¶ 857.8). That is why Illumina, post-Transaction, has continued, and will continue, to support and encourage development of clinical tests on its platform—i.e., Illumina's desire to accelerate and expand demand for its NGS systems bolsters its incentives to support all customers. (*E.g.*, PFF ¶ 857.)

3088. With respect to the pricing of Illumina's products, Dr. Scott Morton concluded that: [redacted] (PX6090 (Scott Morton Report) ¶ 166 (*in camera*)).

Response to Finding No. 3088:

The proposed finding is misleading to the extent it is intended to imply that Dr. Scott Morton conducted any reliable analysis of Illumina's pre-merger and post-merger incentives. She did not. (E.g., PFF ¶¶ 138, 808-814, 913-915, 972, 1077.) Respondents further note that while there is no evidence that there is any MCED tests comparable to GRAIL in development and that would launch in the foreseeable future, Illumina's post-merger incentives remain the same as they were pre-merger. (E.g., PFF ¶ 857.)

3089. [redacted] (PX7138 (Scott Morton, Trial Dep. at 54-55) (*in camera*)).

Response to Finding No. 3089:

The proposed finding is misleading to the extent it is intended to imply that Dr. Scott Morton conducted any reliable analysis of Illumina's pre-merger and post-merger incentives. She did not. (E.g., PFF ¶¶ 138, 808-814, 913-915, 972, 1077.) Respondents further note that

while there is no evidence that there is any MCED tests comparable to GRAIL in development and that would launch in the foreseeable future, Illumina's post-merger incentives remain the same as they were pre-merger. (E.g., PFF ¶ 857.)

3090. [redacted] (PX7138 (Scott Morton, Trial Dep. at 57) (*in camera*)).

Response to Finding No. 3090:

The proposed finding is inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3087. It is nothing more than a conclusory assertion by Complaint Counsel's economic expert, who did no work to model the effects of the Transaction or Illumina's post-merger incentives or to evaluate the real world post-Transaction constraints on Illumina's supposed ability and incentive to foreclose putative downstream rivals. (*E.g.*, PFF ¶¶ 138, 808-814, 913-915, 972, 1077.)

3091. [redacted] (PX6090 (Scott Morton Report) ¶ 171 (*in camera*)).

Response to Finding No. 3091:

The proposed finding is misleading and incomplete. It is true, as the proposed finding asserts, [redacted] However, it is also true that that incentive remains post-merger. Further, Dr. Scott Morton simply ignores the fact that the pre-merger NGS input prices that Illumina charges today and that it projected to charge GRAIL in the future are now guaranteed by the terms of the Open Offer, and she conducted no reliable analysis of Illumina's pre-merger and post-merger incentives. (E.g., PFF ¶¶ 138, 808-814, 913-915, 972, 1077.)

3092. [redacted] (PX6090 (Scott Morton Report) ¶ 166 (*in camera*)).

Response to Finding No. 3092:

The proposed finding is incorrect and misleading. It is a conclusory assertion by Complaint Counsel's economic expert, apparently meant to imply that Illumina and GRAIL (or any other Illumina customer) can eliminate double marginalization ("EDM") by contract. In that regard, the proposed finding is directly contradicted by the fact that Illumina and GRAIL have not achieved EDM by contract, nor has Illumina eliminated double margins with any other customer. (E.g., PFF ¶ 1155.5.)

3093. [redacted]

(PX6090 (Scott Morton Report) ¶ 167-68 (*in camera*)).

Response to Finding No. 3093:

The proposed finding is a conclusory assertion by Complaint Counsel's economic expert, apparently meant to attempt to explain why [redacted]

[redacted] (E.g. PFF ¶¶ 909-10.)

3094. When acquiring Grail, deSouza told Illumina's investors that the Acquisition will create more value to Illumina's shareholders than simply selling instruments and reagents to Grail. (deSouza (Illumina) Tr. 2220).

Response to Finding No. 3094:

Respondents have no specific response, as it is truism that Illumina acquired GRAIL because it believed that the acquisition would create more shareholder value than not acquiring GRAIL.

3095. [redacted] (PX6090 (Scott Morton Report) ¶ 168 (*in camera*)).

Response to Finding No. 3095:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3093, which Respondents incorporate herein.

b) Post-Merger, ILMN Has the Financial Incentive to Maximize the Combined Profits of ILMN and Grail

3096. [redacted] (PX5030 (Illumina) at 009 ; PX7059 (Scagnetti (Illumina) IHT at 67-68) (*in camera*)).

Response to Finding No. 3096:

The proposed finding is misleading and inaccurate. Dr. Aravanis was questioned about this specific language and testified that the [redacted] (Aravanis (Illumina) Tr. 1805-06.)

3097. [redacted] (PX2150 (Illumina) at 001 [redacted] (*in camera*)).

Response to Finding No. 3097:

The proposed finding is incorrect and misleading, as the words on the page of the cited document do not support the meaning that Complaint Counsel attempts to import on it. Nowhere does it say anything about competition from MCED competitors, nor is there any indication as to the reliability of the data or the assumptions underlying it. As the document states on its face, [redacted], with no indication as to what is included in the assumptions (*e.g.*, it does not say whether it includes MCED tests and single cancer tests), and, indeed, the recipient of the table noted that the numbers do not [redacted] Further, Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 9), or in any deposition, and should not be entitled to rely on it to establish anything beyond the words on the page.

3098. Dr. Carlton stated that the amount of downstream diversion is an important factor in determining the likely effects of the transaction. (PX7134 (Carlton Dep. at 152-53).

Response to Finding No. 3098:

Respondents have no specific response, except to note that the proposed finding is correct that downstream diversion is an important factor, and neither Dr. Scott Morton (as she acknowledges) nor Complaint Counsel have offered any reliable estimates of diversion ratios of sales from GRAIL and any putative GRAIL rival. (*E.g.* PFF ¶¶ 1938-42.)

3099. [redacted] (*See* PX7138 (Scott Morton Trial Dep. at 248-49) (*in camera*)). [redacted]

(PX6090 (Scott Morton Report) ¶ 268) (*in camera*)).

Response to Finding No. 3099:

The proposed finding is nothing more than a conclusory assertion by Complaint Counsel's economic expert, not backed by any empirical analysis and based solely on implausible assumptions and mischaracterizations about Galleri and the tests of putative GRAIL rivals. (E.g., PFF ¶¶ 138, 808-814, 913-915, 972, 1077.) It is therefore irrelevant and misleading. Further, neither Dr. Scott Morton (as she acknowledges) nor Complaint Counsel have offered any reliable estimates of diversion ratios of sales from GRAIL and any putative GRAIL rival. (E.g., PFF ¶¶ 1938-42.)

3100. [redacted] (PX6090 (Scott Morton Report) ¶ 171 (*in camera*)).

Response to Finding No. 3100:

The proposed finding is nothing more than a conclusory assertion by Complaint Counsel's economic expert, not backed by any empirical analysis and based solely on implausible assumptions and mischaracterizations about Galleri and the tests of putative GRAIL rivals. (E.g., PFF ¶¶ 138, 808-814, 913-915, 972, 1077.) It is therefore irrelevant and misleading, and also inaccurate. First, there is no [redacted] between Galleri and any other test in development. (E.g., PFF ¶¶ 837, 839-841.) Second, Illumina will continue post-merger to have strong incentives to support any putative GRAIL rival (E.g., PFF ¶¶ 849, 857), and is bound by the Open Offer to do so (E.g., PFF ¶¶ 1000-1057).

3101. [redacted] (PX6090 (Scott Morton Report) ¶ 171 (*in camera*)).

Response to Finding No. 3101:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3100, which Respondents incorporate herein.

3102. [redacted]

(PX6090 (Scott Morton Report) ¶ 171 (*in camera*)).

Response to Finding No. 3102:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3100, which Respondents incorporate herein.

3103. [redacted] (PX8324 (Roche) at 003 [redacted] (*in camera*)).

Response to Finding No. 3103:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 59), or in any deposition, and should not be entitled to rely on it to establish anything beyond the words on the page. Furthermore, Dr. Fiedler testified that in [redacted] (Fiedler (FMI) Tr. 4481.)

3104. [redacted]

[redacted] (PX6090 (Scott Morton Report) ¶ 171 (*in camera*)).

Response to Finding No. 3104:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3100, which Respondents incorporate herein. Respondents further note that the alleged harms Dr. Scott Morton hypothesizes have not materialized; and in fact, contrary to her prediction, there has been a surge of investment in liquid biopsy test development since Illumina announced the GRAIL acquisition. (*See* PFF ¶¶ 928-929.)

3105. When deciding whether to approve Illumina's acquisition of Grail, Illumina's Board of Directors considered [redacted]. (PX2549 (Illumina) at 032 (Board of Directors Meeting (Virtual), Apr. 28, 2020) (*in camera*)).

Response to Finding No. 3105:

Respondents have no specific response.

3106. When Illumina considered whether to acquire Grail, Illumina understood that [redacted]. (PX2549 (Illumina) at 032 (Board of Directors Meeting (Virtual), Apr. 28, 2020) (*in camera*)).

Response to Finding No. 3106:

The proposed finding is misleading and incomplete. There is no possibility of current diversion because Galleri is the only NGS-based MCED test on the market. (RX6000 (Carlton Trial Dep. at 46).) There is also no basis to predict future diversion given differentiation of Galleri and other tests in development, and the lack of evidence that any test comparable to GRAIL will be launched in the foreseeable future. (See PFF ¶¶ 832-846.3.) Further, the document makes clear that the [redacted] (PX2549 at 031)—it was not based on any reliable predictions about the likely future of MCED testing. Indeed, not even Dr. Scott Morton believes

that the oncology screening market will be characterized by "limited differentiation." (PFOF ¶ 2013.)

2. Potential Profits of MCED Tests Far Outweigh Profits from NGS Sales

3107. As discussed below, internal Illumina documents from fall 2020 reflect a growing realization that [redacted] (PX2169 (Illumina) at 045 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*)); PX2488 (Illumina) at 008 [redacted] (*in camera*)).

Response to Finding No. 3107:

The proposed finding is misleading and incomplete . Those same documents show that the downstream profit pool shifts and estimated revenue projected from clinical testing services will not reach the levels described in the proposed finding until 2035, and the evidence uniformly shows that Illumina's NGS business will remain its core business and will account for most of its profits for "many, many years". (PFF ¶¶ 869-872.) Further, Complaint Counsel overlooks the significance of these projections; as Dr. Carlton explained, [redacted] (PFF at ¶ 910.)

3108. Illumina's internal projections forecast revenues from its NGS instruments and core consumables to grow from [redacted] (PX2488 (Illumina) at 008 [redacted] (*in camera*)).

Response to Finding No. 3108:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein.

3109. Illumina's internal analysis presented to the Board of Directors stated that [redacted]. (PX2488 (Illumina) at 008 (*in camera*)); PX2465 (Illumina) at 007 [redacted] (*in camera*); PX2169 (Illumina) at 042 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*)).

Response to Finding No. 3109:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein.

3110. Illumina's CEO, Francis deSouza, testified at trial that he expects a decline in the profit pools associated with sequencers. (deSouza (Illumina) Tr. 2385).

Response to Finding No. 3110:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein.

3111. Mr. deSouza testified at trial that Illumina's "core business is to sell sequencers and consumables. That's how we make the vast majority of our revenue." (deSouza (Illumina) Tr. 2378).

Response to Finding No. 3111:

Respondents have no specific response except to note that the proposed finding is accurate and that it will remain true for "many, many years" after the Transaction. (PFF ¶¶ 869–871.)

a) Illumina's Documents and Market Participants Project Massive Revenue and Profit from the MCED Testing Market

3112. In its internal documents, Illumina recognizes that [redacted] (PX2151 (Illumina) at 005 (Email from J. Cunningham, Illumina, to S. Samad, Illumina, attaching "Sands Capital Management Call," Oct. 11, 2020)). *See* (PX2035 (Illumina) at 002 (Illumina, Oncology Testing 5-Year Strategy Refresh) (*in camera*) (explaining that [redacted]); PX2316 (Illumina) at 023 (Email from J. Goswami, Illumina, to A. Qadan et al., Illumina, attaching "Board of Directors M&A Landscape," Apr. 29, 2020) (*in camera*) (estimating that [redacted])).

Response to Finding No. 3112:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein.

3113. In a board presentation, Illumina's SVP of Corporate Development & Strategic Planning, Joydeep Goswami, [redacted] (PX2316 (Illumina) at 008 (Email from J. Goswami, Illumina, to A. Qadan et al., Illumina, attaching "Board of Directors M&A Landscape," Apr. 29, 2020) (*in camera*)); PX7087 (Goswami (Illumina) Dep. at 94-96) (discussing PX2316)(*in camera*)).

Response to Finding No. 3113:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein. Furthermore, as to this document, Dr. Goswami testified that the [redacted] PX7087 (Goswami (Illumina) Dep. at 148-49.)

3114. Illumina's 2021-2025 Strategic Plan [redacted] (PX2169 (Illumina) at 038 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*)).

Response to Finding No. 3114:

Respondents have no specific response.

3115. Illumina's 2021-2025 Strategic Plan stated that [redacted] (PX2169 (Illumina) at 041 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*) [redacted]).

Response to Finding No. 3115:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein.

3116. Illumina's 2021-2025 Strategic Plan concluded, [redacted] (PX2169 (Illumina) at 042 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*)).

Response to Finding No. 3116:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein.

3117. Illumina's 2021-2025 Strategic Plan noted, [redacted] (PX2169 (Illumina) at 042 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*)).

Response to Finding No. 3117:

Respondents have no specific response.

3118. A presentation to Illumina's Audit Committee stated that [redacted] (PX2465 (Illumina) at 006 [redacted] (*in camera*)).

Response to Finding No. 3118:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein.

3119. A presentation to Illumina's Board of Directors [redacted] (PX2488 (Illumina) at 003 [redacted] (*in camera*)).

Response to Finding No. 3119:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein.

3120. Illumina sought to [redacted] (PX2169 (Illumina) at 045 (Illumina Strategic Plan 2021-2025, Board Discussion Document," Oct. 23, 2020) (*in camera*)).

Response to Finding No. 3120:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein.

3121. [redacted] (PX2465 (Illumina) at 006-008 [redacted]

Response to Finding No. 3121:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein.

3122. [redacted] (PX2488 (Illumina) at 008 [redacted]

Response to Finding No. 3122:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein.

3123. In Illumina's presentation to the Board of Directors [redacted] (PX2488 (Illumina) at 007 (Email from S. Muppaneni, Illumina, to K. Reeves, Illumina, attaching "Project Valor," Sept. 29, 2020) (*in camera*)).

Response to Finding No. 3123:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein.

3124. [redacted] (PX2488 (Illumina) at 008 [redacted]

Response to Finding No. 3124:

Respondents have no specific response.

3125. [redacted] (*in camera*)) [redacted].

Response to Finding No. 3125:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein.

3126. [redacted] (PX2488 (Illumina) at 008 [redacted] (*in camera*)).

[redacted]

Response to Finding No. 3126:

Respondents have no specific response.

3127. Illumina's internal analysis recognized that [redacted] (PX2488 (Illumina) at 009 (*in camera*)). But the analysis warned that [redacted] (PX2488 (Illumina) at 009 (*in camera*)).

Response to Finding No. 3127:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein.

3128. In a presentation to Illumina's Board of Directors, Illumina [redacted]

[redacted] (PX2488 (Illumina) at 012 [redacted] (*in camera*)).

Response to Finding No. 3128:

The proposed finding is incomplete and misleading to the extent it is meant to imply that Illumina lacks the resources that GRAIL needs to accelerate the scaled adoption of Galleri, as there is substantial evidence that, while Illumina will need to invest in developing certain capabilities such as a global physician salesforce, it has the expertise, experience and resources that make it optimally positioned to bring Galleri to consumers sooner and at lower cost than GRAIL could achieve on its own. (E.g., PFF ¶¶ 1121-1173.)

3129. Therefore, Illumina predicted that [redacted] (PX2488 (Illumina) at 009 [redacted] (*in camera*) (*see* image inset below); PX2465 (Illumina) at 008 [redacted] (*in camera*); PX2169 (Illumina) at 043 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*)).

[redacted]

Response to Finding No. 3129:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein.

3130. In a presentation to Illumina's Board of Directors, Illumina estimated that [redacted] (PX2488 (Illumina) at 003 [redacted] (*in camera*)).

Response to Finding No. 3130:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein.

3131. In this presentation to Illumina's Board of Directors [redacted] (PX2488 (Illumina) at 003 [redacted] (*in camera*)); *see also* (PX2465 (Illumina) at 003 [redacted]

[redacted] (*in camera*)).

Response to Finding No. 3131:

The proposed finding is misleading, incomplete and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3128, which Respondents incorporate herein.

3132. Further, in this presentation to Illumina's Board of Directors, a [redacted] (PX2488 (Illumina) at 011 [redacted] (*in camera*)).

Response to Finding No. 3132:

The proposed finding is misleading, incomplete and inaccurate for the reasons explained in Respondents' responses to CCFF ¶¶ 3107 and 3128, which Respondents incorporate herein.

3133. [redacted] (PX2488 (Illumina) at 011 [redacted] (*in camera*)); *see also* (PX2465 (Illumina) at 009 [redacted] (*in camera*)).

Response to Finding No. 3133:

Respondents have no specific response.

3134. [redacted] (*in camera*)).

Response to Finding No. 3134:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein.

3135. Illumina's former CEO and Board Chairman, Jay Flatley, testified that Illumina forecasted that, in the long run, its revenue and profits would be greater through the acquisition of Grail compared to a smaller ownership stake. (Flatley (Illumina) Tr. 4096-97; PX2575 (Illumina) at 003 (Illumina, GRAIL Announcement Q&A, Sept. 20, 2020)).

Response to Finding No. 3135:

Respondents have no specific response except to incorporate by reference their responses to CCFF ¶ 3094.

3136. Illumina's CEO, Francis de Souza, publicly stated in an investor call in September 2020 that the MCED market represents up to a $60 billion incremental opportunity: "[s]pecifically, the acquisition positions Illumina to participate in what we expect will be a $75 billion market for NGS-based oncology tests by 2035, $60 billion higher than our oncology TAM [total addressable market] excluding GRAIL." (PX2575 (Illumina) at 069 (Illumina, Investor Call Transcript, Sept. 21, 2020); *see also* (PX2031 (Illumina) at 003 (Illumina, Cowen Liquid Biopsy Summit with Francis deSouza, Sept. 24, 2020) (stating that Illumina has "been moving into select clinical applications, and this acquisition adds the largest genomics application to our portfolio – and with it, an incremental $60B TAM")).

Response to Finding No. 3136:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein.

3137. Mr. deSouza told investors that the "early detection of cancer segment is the largest segment in the clinical market we can see for the next decade." (PX2575 (Illumina) at 060 (Illumina, Illumina Inc at Cowen Liquid Biopsy Summit (Virtual), Sept. 24, 2020)); PX2151 (Illumina) at 005 (Illumina, Sands Capital Management Call, Oct. 11, 2020) (stating that "[e]arly cancer detection is the largest opportunity in clinical genomics in our lifetime representing an incremental $60B market opportunity by 2035.")).

Response to Finding No. 3137:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein. Further, it omits the context that numerous Illumina witnesses testified that there are many clinical applications that have yet to be conceived and that could turn out to be substantial revenue and demand drivers for NGS. (E.g., PFF ¶ 857.1 (Dr. Aravanis explaining that NGS is still in the

"early days" as a "tool for clinical diagnostics", and Mr. deSouza explaining that "we have so much undiscovered in front of us" and that there is "no doubt we will see a lot more clinical applications emerge in the future.").)

3138. Mr. deSouza told investors, "Direct participation ensures that our revenue share of these high value clinical applications will be higher than it would be if we are limited to supplying the hardware and consumables only. In short, Illumina's revenue reflects clinical value, not simply the underlying sequencing output." (PX2575 (Illumina) at 016 (Illumina, Cowen Liquid Biopsy Summit with Francis deSouza, Sept. 23, 2020)). At trial, Mr. deSouza acknowledged that "by participating directly in that segment with our own solution, it allows Illumina to get a larger percentage of the value created in that solution rather than just being the platform provider." (deSouza (Illumina) Tr. 2219) (referring to PX2575 (Illumina) at 060)).

Response to Finding No. 3138:

Respondents have no specific response except to incorporate by reference their responses to CCFF ¶ 3094.

3139. In a discussion at the Cowen Liquid Biospy Summit, Francis deSouza stated that "the Grail acquisition gives [Illumina] a leading position in this very large market opportunity. And the early detection cancer market dwarfs the clinical markets we see today, NIPT and therapy selection for oncology combined." (deSouza (Illumina) Tr. 2218-19 (referring to PX2575 (Illumina) at 060); *see* PX2564 (Illumina) at 005 (Email from J. Ross, Illumina, to F. deSouza, Illumina, Sept. 5, 2020 attaching Draft Project Valor Script) ("[W]e believe that the screening opportunity dwarfs therapy selection and monitoring.")). Mr. deSouza acknowledged at trial that he was talking about the market opportunity that the Grail acquisition provided. (deSouza (Illumina) Tr. 2219).

Response to Finding No. 3139:

Respondents have no specific response except to incorporate by reference their responses to CCFF ¶ 3094, and further note that the proposed finding omits the context that numerous Illumina witnesses testified that there are many clinical applications that have yet to be conceived and that could turn out to be substantial revenue and demand drivers for NGS. (E.g., PFF ¶ 857.1 (Dr. Aravanis explaining that NGS is still in the "early days" as a "tool for clinical

diagnostics", and Mr. deSouza explaining that "we have so much undiscovered in front of us" and that there is "no doubt we will see a lot more clinical applications emerge in the future.").)

3140. In representations to investors, Illumina's CEO Mr. deSouza has acknowledged that MCED customers account for "roughly 2% of [Illumina's] total revenue" and are aware of "maybe 20 out of [its] 6,600 customers who are targeting a commercial screening test." (deSouza (Illumina) Tr. 2221-22) (referring to PX2575 (Illumina) at 018 (Cowen Liquid Biopsy Summit with Francis deSouza, Sept. 23, 2020); PX2031 (Illumina) at 002 (Cowen Liquid Biopsy Summit with Francis deSouza, Sept. 24, 2020). Illumina included Guardant, Thrive, Freenome, Singlera, Exact, and Grail as early cancer screening companies. (deSouza (Illumina) Tr. 2221-2222).

Response to Finding No. 3140:

Respondents have no specific response, except to note that the "roughly 2%" estimate is a reflection of Illumina's historical business with those test developers, which says nothing about the future significance of these customers to Illumina's upstream business, or the magnitude of future lost profits that Illumina would incur if it attempted to foreclose them. The evidence shows that the future profits Illumina expects from its clinical customers is substantial. (E.g., PFOF at ¶ 857.1 (Dr. Aravanis explaining that NGS is still in the "early days" as a "tool for clinical diagnostics", and Mr. deSouza explaining that "we have so much undiscovered in front of us" and that there is "no doubt we will see a lot more clinical applications emerge in the future.").)

3141. [redacted] (deSouza (Illumina) Tr. 2291 (*in camera*), 2382-83).

Response to Finding No. 3141:

Respondents have no specific response.

3142. In her expert report, Dr. Fiona Scott Morton concluded:

[redacted]

[redacted]

(PX6090 (Scott Morton Report) ¶ 201 (*in camera*)).

Response to Finding No. 3142:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3107, which Respondents incorporate herein.

b) Market Participants Estimate That the MCED Market Will Grow to Be Significant

3143. At trial, Mr. Getty of Guardant estimated the potential size of the MCED market in terms of revenue as over $50 billion. (Getty (Guardant) Tr. 2503).

Response to Finding No. 3143:

Respondents have no specific response.

3144. Guardant's MCED test will target 100 to 120 million average-risk individuals in the United States. (Getty (Guardant) Tr. 2501-02).

Response to Finding No. 3144:

The proposed finding is misleading and incomplete. Mr. Getty testified to this effect,

[redacted] (Getty (Guardant) Tr. 2606–08, 2611–13; Cote Tr. 3830–31; RX3869 (Cote Expert Report) ¶ 202.)

3145. Mr. Getty of Guardant projected that, on the low end, the MCED test market will reach $50 billion: this is based on his estimation that the "market of a hundred million people and you look at the current cancer-screening modalities in the marketplace, take Cologuard as the exemplar, which has an average selling price of $500, you quickly come to a conclusion of probably close to 50 billion dollars on the low end of things. If you're providing more value through multi-cancer, ostensibly you would have a higher price." (PX7105 (Getty (Guardant) Dep. at 50-51)).

Response to Finding No. 3145:

Respondents have no specific response.

3146. [redacted]
(PX8324 (Roche) at 012 [redacted] (*in camera*)).

Response to Finding No. 3146:

Respondents have no specific response.

3147. Singlera estimated that the global market for early-stage cancer screening is "expected to exceed" $100 billion. (PX8515 (Singlera) at 004 (Singlera, Singlera Genomics)).

Response to Finding No. 3147:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 64), or in any deposition, and should not be entitled to rely on it to establish anything beyond the words on the page.

c) Third Parties Foresee Illumina's Changed Incentive as a Result of the Acquisition of Grail

3148. Several of Illumina's MCED test developer customers have expressed concerns about Illumina's incentives to favor Grail over its competitors post-merger. For example, Bill Getty, Guardant's Senior Vice President of Commercial, testified that Illumina's incentives will change as a result of acquiring Grail, "without question." (PX7040 (Getty (Guardant) IHT at 173)).

Response to Finding No. 3148:

The proposed finding is irrelevant, incomplete and misleading. First, third parties are not reliable sources of Illumina's own incentives. Indeed, it is telling and a reflection of Complaint Counsel's double standard approach that it argues the speculation of a small number of third party executives regarding Illumina's supposed post-Transaction incentives is proof of those incentives, whereas the testimony of Illumina's own executive leaders as to Illumina's incentives

are given no weight. Second, the Open Offer comprehensively addresses any alleged concern with the Transaction. (PFF ¶¶ 1000-1057.)

3149. On September 16, 2020, Rodger Currie, Grail's Senior VP of External Affairs, alerted Grail executives, including its CEO, Hans Bishop: "Thrive['s] SVP is now freaking out on me and wanting info [about the acquisition]. Obviously they feel this is not good for them. Which is entertaining." Currie added that it was "surely not a surprise to you to hear [Thrive is] freaking." (PX4021 (Grail) at 001 (Email from R. Currie, Grail, to H. Bishop, Grail, et al., Sept. 16, 2020)).

Response to Finding No. 3149:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and should not be entitled to rely on it to establish anything beyond the words on the page.

3150. Mr. Getty of Guardant explained: "there's a much bigger market opportunity for Illumina as a screening company than there is as a sequencing company. . . . [T]herefore, you know, getting into [the cancer screening] business and controlling it through vertical integration of the technology underlying it, yeah, I mean, you would want to put us out of business, because ultimately they don't compete with us in the sequencing business . . . .[b]ut we are certainly in the screening business, so, you know, by default, they want to push us out of that." (PX7040 (Getty (Guardant) IHT at 173)).

Response to Finding No. 3150:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3148, which Respondents incorporate herein.

3151. Guardant's Mr. Getty testified, "the merger makes [Illumina] a player in this much bigger screening market, so they don't need the customer of Guardant really anymore." (PX7040 (Getty (Guardant) IHT at 173-74)).

Response to Finding No. 3151:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3148, which Respondents incorporate herein.

3152. Mr. Getty explained that [redacted] (PX7040 (Getty (Guardant) IHT at 173-74) (*in camera*)).

Response to Finding No. 3152:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3148, which Respondents incorporate herein.

3153. But Mr. Getty warned,

> [I]n the future, if they have access to this massive market, and that market is now, let's say, a $50 billion opportunity, and Grail can become a $25-billion-a-year company based on that other screening market, well, guess what, [redacted] so why would you want to keep us happy at the same time and also have a competitor that splits that $50 billion by another, you know, third or half. It just, you know, it -- it is completely in their best interest that we are not around.

(PX7040 (Getty (Guardant) IHT at 174-75) (*in camera*)).

Response to Finding No. 3153:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3148, which Respondents incorporate herein.

3154. Mr. Getty of Guardant also explained that the "[t]he sequencing business is a much, much smaller slice . . . relative to that 60-billion-dollar opportunity. So as an organization, [Illumina's] acquisition of Grail is ostensibly geared to moving into this much bigger opportunity and maximizing that opportunity." (PX7105 (Getty (Guardant) Dep. at 68-69)).

Response to Finding No. 3154:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3148, which Respondents incorporate herein.

3155. [redacted]

Response to Finding No. 3155:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3148, which Respondents incorporate herein.

3156. [redacted]

Response to Finding No. 3156:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3148, which Respondents incorporate herein.

3157. [redacted]

Response to Finding No. 3157:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3148, which Respondents incorporate herein.

3158. [redacted]

Response to Finding No. 3158:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3148, which Respondents incorporate herein.

3159. [redacted]

[redacted]

Response to Finding No. 3159:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3148, which Respondents incorporate herein. Moreover, Mr. Conroy admitted that [redacted] (Conroy (Exact/Thrive) Tr. 1677–79), has not read Illumina's full open offer, and does not know the details of the open offer (Conroy (Exact/Thrive) Tr. 1725–26). Thus, Mr. Conroy cannot opine on the adequacy of the firewall provisions in the Open Offer.

3160. [redacted]

Response to Finding No. 3160:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3148 and 3159, which Respondents incorporate herein.

3161. [redacted]

Response to Finding No. 3161:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3148 and 3159, which Respondents incorporate herein

3162. [redacted]

Response to Finding No. 3162:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3163. [redacted]

Response to Finding No. 3163:

The proposed finding is inaccurate. The Open Offer expressly prevents Illumina from raising prices and, in fact, Commits Illumina to lower prices for its highest throughput instrument, using pricing that was assumed and modelled for GRAIL in connection with Illumina's valuation of the Transaction. (PFF ¶¶ 1013-1025.) Moreover, Mr. Conroy admitted [redacted] (Conroy (Exact/Thrive) Tr. 1677–79), has not read Illumina's full open offer, and does not know the details of the open offer (Conroy (Exact/Thrive) Tr. 1725–26).

3164. [redacted]

Response to Finding No. 3164:

The proposed finding is inaccurate and irrelevant. First, the unrefuted evidence shows that it would not be practical for Illumina to optimize its NGS platforms in the ways Mr. Conroy speculates. (E.g., PFF ¶ 1319.) Second, the Open Offer requires Illumina to enter into development agreements, on customers' requests, to design or modify Illumina's products to optimize interoperability with customers' tests—something Illumina has not done historically, meaning test developers with an interest in such optimization are better off under the Open Offer

than the pre-Transaction status quo. (E.g., PFF ¶ 1010.) Third, there is nothing anticompetitive with Illumina optimizing products for GRAIL—if it can do so, that would be a benefit of vertical integration that benefits competition and consumers, not a harm. Moreover, Mr. Conroy admitted that he never even read Illumina's offering email (Conroy (Exact/Thrive) Tr. 1677–79), has not read Illumina's full open offer, and does not know the details of the open offer (Conroy (Exact/Thrive) Tr. 1725–26).

3165. [redacted]

Response to Finding No. 3165:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3148, which Respondents incorporate herein.

3166. [redacted]

Response to Finding No. 3166:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3148, which Respondents incorporate herein.

3167. [redacted]

Response to Finding No. 3167:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3148, which Respondents incorporate herein.

3168. [redacted]

Response to Finding No. 3168:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3148, which Respondents incorporate herein.

3169. [redacted]

Response to Finding No. 3169:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3148 and 3163, which Respondents incorporate herein.

3170. [redacted]

Response to Finding No. 3170:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3148, which Respondents incorporate herein. The proposed finding is also irrelevant because the Open Offer directly addresses this supposed concern, by providing that if Illumina experiences a supply shortage, it must allocate the existing supply in an equitable manner among its customers, including GRAIL and other affiliates. (PF ¶ 1012.)

3171. [redacted]

Response to Finding No. 3171:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3148, which Respondents incorporate herein. The proposed finding is also irrelevant because the Open Offer directly addresses this supposed concern, by providing for a robust firewall that would prevent such information sharing. (PFF ¶¶ 1038-1039.)

3172. [redacted]

Response to Finding No. 3172:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3148, which Respondents incorporate herein.

3173. [redacted]

Response to Finding No. 3173:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3148, which Respondents incorporate herein

d) Dr. Scott Morton's Analysis of Illumina's Pre- and Post-Merger Profits Demonstrates Quantitatively Illumina's Incentive to Foreclose and Raise Costs to GRAIL's Rivals

3174. [redacted] (PX6090 (Scott Morton Report) ¶¶ 194-97 (*in camera*)).

Response to Finding No. 3174:

The proposed finding is incorrect. Dr. Scott Morton did not conduct any meaningful analysis of Illumina's incentives, neither quantitative nor qualitative. She merely speculates based on unsupported and implausible assumptions (such as the assumption, which has no basis

in reality, that foreclosure of any of the putative MCED tests in development would result in 100% diversion) and mischaracterizations of the record (such as mischaracterizations as to Illumina's actions in prior vertical integrations), while ignoring real world facts such as the Open Offer that undoubtedly influence Illumina's incentives in ways that Dr. Scott Morton has not accounted for. (E.g., PFF ¶¶ 138, 808-814, 913-915, 972, 1077.)

3175. Dr. Scott Morton's analysis of Illumina's incentives employed [redacted] (PX6090 (Scott Morton Report) ¶¶ 194-97, Table 2, n. 1-6 (*in camera*)).

Response to Finding No. 3175:

The proposed finding is incorrect for the reasons explained in Respondents' response to CCFF ¶ 3174, which Respondents' incorporate herein.

3176. Table 2 below reflects the results of Dr. Scott Morton's analysis of Illumina's incentives before and after acquiring Grail:

(PX6090 (Scott Morton Report) ¶ 194 (*in camera*)).

Response to Finding No. 3176:

The proposed finding is incorrect for the reasons explained in Respondents' response to CCFF ¶ 3174, which Respondents' incorporate herein. Further, the proposed finding is irrelevant because the analysis it cites is unreliable and invalid. Specifically, Dr. Scott Morton's purported (E.g., PFF ¶¶ 820-821.) When Dr. Carlton replicated Dr. Scott Morton's

analysis and corrected just the erroneous assumptions therein concerning future royalties, the results showed that there is no material change in Illumina's incentives even assuming as true Dr. Scott Morton's other assumptions as to Illumina's post-merger ability and incentives to foreclose downstream rivals. (PFF ¶ 822.)

3177. [redacted] (PX6090 (Scott Morton Report) ¶¶ 194-97 (*in camera*)). [redacted] (PX6090 (Scott Morton Report) ¶¶ 194-97 (*in camera*)). [redacted] (PX6090 (Scott Morton Report) ¶¶ 194-97 (*in camera*)).

Response to Finding No. 3177:

The proposed finding is incorrect and irrelevant for the reasons explained in Respondents' response to CCFF ¶ 3174 and 3176, which Respondents' incorporate herein.

3178. [redacted] (PX6090 (Scott Morton Report) ¶¶ 194, 196 (*in camera*)). [redacted] (PX6090 (Scott Morton Report) ¶¶ 194, 196 (*in camera*)). [redacted] (PX6090 (Scott Morton Report) ¶¶ 194, 197 (*in camera*)).

Response to Finding No. 3178:

The proposed finding is incorrect and irrelevant for the reasons explained in Respondents' response to CCFF ¶ 3174 and 3176, which Respondents' incorporate herein.

3179. [redacted] (PX6090 (Scott Morton Report) ¶¶ 194-97 (*in camera*)).

Response to Finding No. 3179:

The proposed finding is incorrect and irrelevant for the reasons explained in Respondents' response to CCFF ¶ 3174 and 3176, which Respondents' incorporate herein.

3180. [redacted] (PX6090 (Scott Morton Report) ¶¶ 194-97 (*in camera*)).

Response to Finding No. 3180:

The proposed finding is incorrect and irrelevant for the reasons explained in Respondents' response to CCFF ¶ 3174 and 3176, which Respondents' incorporate herein.

3181. [redacted] (PX6090 (Scott Morton Report) ¶¶ 194-97 (*in camera*)).

Response to Finding No. 3181:

The proposed finding is incorrect and irrelevant for the reasons explained in Respondents' response to CCFF ¶ 3174 and 3176, which Respondents' incorporate herein.

3182. Based on her comparisons of Illumina's pre-merger and post-merger gross profit calculations, Dr. Scott Morton concluded,

[redacted]

(PX6090 (Scott Morton Report) ¶ 194 (*in camera*)).

Response to Finding No. 3182:

The proposed finding is incorrect and irrelevant for the reasons explained in Respondents' response to CCFF ¶ 3174 and 3176, which Respondents' incorporate herein.

3183. [redacted] (PX7138 (Scott Morton Trial Dep. at 31-32) (*in camera*)).

Response to Finding No. 3183:

The proposed finding is incorrect and irrelevant for the reasons explained in Respondents' response to CCFF ¶ 3174 and 3176, which Respondents' incorporate herein.

3184. [redacted] (PX7138 (Scott Morton Trial Dep. at 85) (*in camera*)).

Response to Finding No. 3184:

The proposed finding is incorrect and irrelevant for the reasons explained in Respondents' response to CCFF ¶ 3174 and 3176, which Respondents' incorporate herein.

3185. [redacted] (PX7138 (Scott Morton Trial Dep. at 57) (*in camera*)).

Response to Finding No. 3185:

The proposed finding is incorrect and irrelevant for the reasons explained in Respondents' response to CCFF ¶ 3174 and 3176, which Respondents' incorporate herein.

3186. [redacted] (PX7138 (Scott Morton Trial Dep. at 65-66) (*in camera*)).

Response to Finding No. 3186:

The proposed finding is irrelevant, incomplete and misleading. Dr. Scott Morton did not actually examine the therapy selection market or the impact of Illumina's vertical integration in it. Her supposed analysis is wholly superficial and ignores the record evidence. As Dr. Carlton

explained, if one were to do an actual economic analysis of the impact of Illumina's vertical integration into therapy selection, "the relevant question" would have to be "what's the but-for world", meaning, "was there a benefit from Illumina being vertically integrated into therapy selection and selling to Roche compared to not having Illumina in therapy selection". (PFF ¶ 972.1.) [redacted] (PFF ¶ 972.6.) And in fact, contrary to Dr. Scott Morton's suggestion that Illumina raised rivals' costs with IVD fees, by charging fees for IVD rights, Illumina was actually following market practice, as other platform suppliers [redacted] also charge for such rights. (PFF ¶ 973.) IVD rights have value, and there is nothing anticompetitive about charging fees for things of value.

If Dr. Scott Morton had actually examined the competitive effects of Illumina's vertical integration in therapy selection, she would have discovered that the parade of horribles and innovation harms she and Complaint Counsel speculate will occur in the alleged MCED market as a result of the Transaction never materialized. (PFF ¶¶ 966–973.) Today, Illumina has collaboration agreements in place with Roche, PGDx and numerous other test developers in therapy selection pursuant to which these formidable competitors are developing IVD tests that

will compete with Illumina's own therapy selection test. (PFF ¶ 966.) Illumina provides customer support to its therapy selection rivals, and investment and innovation has increased in in recent years. (PFF ¶ 967.) In fact, the therapy selection market is thriving. (PFF ¶ 967.1) Despite all of Complaint Counsel's allegations about Roche, no Roche witness testified about any foreclosure concern in therapy selection.

Thus, it is of no moment that, in the early days of its IVD technology and its therapy selection strategy, Illumina evaluated the impact of IVD partnerships on its profits. Illumina had invested substantial amounts in its IVD technology, there were few IVD kitted tests even commercially available, and Illumina had not yet even received FDA authority to market a higher-throughput IVD system. The evaluation Illumina undertook of different potential approaches to this new technology and mode of distribution is what any profit maximizing firm would do when considering a major strategic decision such as the one Illumina faced when it first considered how and to what extent to enable third party kits on its new IVD systems.

What matters to understanding Illumina's incentives are the choices Illumina made, not the strategies some within Illumina evaluated along the way. Ultimately, Illumina determined that having more players in the field would be better than going at it alone because it would help accelerate and expand demand for Illumina's NGS products in a nascent clinical use case. (PFF ¶ 971.3.) Therefore, the evidence from Illumina's vertical integration in therapy selection shows the opposite of what Dr. Scott Morton and Complaint Counsel claim: Illumina determined that having others in the space who would be willing to invest resources and effort toward developing NGS-based IVD tests, and growing demand for them, was the best outcome for Illumina's reputation and bottom line. (E.g., PFF ¶ 968.)

3187. [redacted]

[redacted] (PX7138 (Scott Morton Trial Dep. at 66-67) (*in camera*)).

Response to Finding No. 3187:

The proposed finding is incorrect and irrelevant for the reasons explained in Respondents' response to CCFF ¶ 3174 and 3176, which Respondents' incorporate herein. There are other viable NGS platforms on the market and soon to be on the market that can support MCED tests in development; switching is feasible and unlikely to affect the timelines for MCED test development. (E.g., PFF ¶¶ 645-674; 776-796.)

3188. [redacted] (PX6090 (Scott Morton Report) ¶¶ 199-203 (*in camera*)).

Response to Finding No. 3188:

The proposed finding is incorrect and irrelevant for the reasons explained in Respondents' response to CCFF ¶¶ 3148, 3174 and 3176, which Respondents' incorporate herein. Further, the proposed finding is misleading and incomplete in that the referenced Illumina documents show that the downstream profit pool shifts and estimated revenue projected from clinical testing services will not reach the levels suggested in the proposed finding until 2035, and the evidence uniformly shows that Illumina's NGS business will remain its core business and will account for most of its profits for "many, many years". (PFF ¶¶ 869-872.) Further, Complaint Counsel and Dr. Scott Morton overlook the significance of these projections; as Dr. Carlton explained, projections of Illumina's dramatically shrinking prices and relative future margins signify that there are powerful and growing constraints on Illumina—including intensifying upstream competition and reputational constraints—that will drive Illumina to

continue supplying all customers willing to invest in developing applications for its platform with low cost, innovative NGS systems. (PFF at ¶ 910.)

3. Other MCED Tests Are Likely to Compete Closely with Galleri

a) Other MCED Developers Are Targeting the Same MCED Space

3189. [redacted] (*See supra* Section VI (Competitors Are Racing to Develop MCED Tests); *see also* PX7058 (Conroy (Exact) IHT at 114-115) (*in camera*)); PX7053 (Fesko (Natera) IHT at 86-87) (*in camera*); PX7105 (Getty (Guardant) Dep. at 41-42)).

Response to Finding No. 3189:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1902–2606.

The proposed finding is misleading to the extent that [redacted]

Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted], Helio, and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test

capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3190. [redacted] (*See e.g.*, Ofman (Grail) Tr. 3303-05; Nolan (Freenome) Tr. 2756-59 (*in camera*); Getty (Guardant) Tr. 2537-39; Conroy (Exact) Tr. 1615 (*in camera*); PX7121 (Otte (Freenome) Dep. at 29-31) (*in camera*)).

Response to Finding No. 3190:

Respondents have no specific response except to note that the proposed finding confirms that test developers are adopting different approaches to the development of their putative MCED tests, suggesting that if these putative tests come to market, each such test may be a complement to GRAIL's Galleri test, rather than a substitute. Further, Respondents incorporate their responses to CCFF ¶¶ 426, 2286, 3290 herein.

3191. [redacted] (PX7087 (Goswami (Illumina) Dep. at 1223 (*in camera*)))

Response to Finding No. 3191:

The proposed finding is misleading and irrelevant. The proposed finding is misleading to the extent it suggests that Dr. Goswami testified that [redacted]

[redacted] As discussed in Respondents' responses to CCFF ¶¶ 605–830, there is no evidence to suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

3192. [redacted] (Strom (Morgan Stanley) Tr. 3556-58 (*in camera*) (discussing PX8458 (Morgan Stanley) at 001, 003 (Email from M. Strom, Morgan Stanley, to M. Moeen, Morgan Stanley, attaching "Early Detection Data Disclosure: Morgan Stanley Benchmarking, May 4, 2020 ([redacted]) (*in camera*)).

Response to Finding No. 3192:

The proposed finding is misleading and incomplete. [redacted] Respondents address each putative MCED test developer in turn.

[redacted]

[redacted]

Respondents also incorporate their responses to CCFF ¶¶ 427, 927 and 2273 herein

Exact/Thrive. The proposed finding is also incomplete and misleading including insofar as it suggests that Exact/Thrive is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. Respondents note that CancerSEEK is still under development (PFF ¶ 417 (Lengauer (Exact/Thrive) Tr. 158)), that [redacted] (Conroy (Exact) Tr. 1717), and that CancerSEEK is combined with a whole-body

PET-CT, which [redacted]. (*See*, *e.g.*, Lengauer (Exact/Thrive) Tr. 248; RX3419 (Lennon et al., 2020) at 3; [redacted]; PFF ¶¶ 419, [redacted], 425, [redacted], 739, 760, [redacted], 841.3, [redacted], 1723–24.) Respondents also note that [redacted] (Conroy (Exact) Tr. 1621.) Respondents incorporate PFF ¶¶ 414–43, 709.3, 717.1.1, 721.1–21.2, 726–26.8, 735, 738–40.1 and their responses to CCFF ¶¶ 389, 413–14, 418–19, 696–97, 703, 715, 736, 738-39, 773–76, 785, 929, and 1912 herein.

Freenome. The proposed finding is also incomplete and misleading without additional context including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. Mr. Nolan testified that [redacted] (PX7094 (Nolan (Freenome) Dep. at 307).) [redacted] (PFF ¶¶ 459-70.) [redacted]

Mr. Otte, Freenome's former CEO, also testified that [redacted]

[redacted] Respondents incorporate their responses to CCFF ¶¶ 945 and 2355 herein.

Finally, Complaint Counsel has never even mentioned the putative MCED test developer, Adaptive. Complaint Counsel did not subpoena or notice any witnesses from Adaptive. Nor has Adaptive reached out to the Commission to address this Transaction.

3193. Respondents' expert, Dr. Katz agreed that "MCED test developers are undertaking development efforts in the hope that they will succeed in the marketplace for multicancer early detection tests[.]" (RX6004 (Katz Trial Dep. at 99)).

Response to Finding No. 3193:

The proposed finding is misleading. In response to this question from Complaint Counsel, Dr. Katz testified, "[a]s long as we're using 'marketplace' [] not to refer to [] the specific relevant market, yes, I agree with that." (RX6004 (Katz Trial Dep. at 99).)

3194. Respondents' expert, Dr. Katz, testified that racing to be the first to launch a product to market is a dimension of competition. (RX6004 (Katz Trial Dep. at 100)).

Response to Finding No. 3194:

The proposed finding is misleading. Dr. Katz said that "[a]s a general matter, that can happen in some industries." (RX6004 (Katz Trial Dep. at 100).)

3195. Respondents' expert, Dr. Katz, testified that firms competing as part of R&D competition may assess their competitors' products. (RX6004 (Katz Trial Dep. at 102)).

Response to Finding No. 3195:

The proposed finding is incomplete and misleading to the extent that it suggests that Dr. Katz testified that other putative MCED tests would compete closely with Galleri. As Dr. Katz testified, [redacted]

(RX6004 (Katz Trial Dep. at 105) (emphasis added).)

Respondents incorporate their responses to CCFF ¶¶ 773–76 herein.

3196. Respondents' expert, Dr. Katz, testified that monitoring rivals can drive competition. (RX6004 (Katz Trial Dep. at 103)).

Response to Finding No. 3196:

The proposed finding is incomplete and misleading to the extent that it suggests that Dr. Katz testified that other putative MCED tests would compete closely with Galleri. Dr. Katz testified that monitoring rivals can drive competition "[i]f you are assuming that the firms . . . have knowledge of the characteristics of these products". (RX6004 (Katz Trial Dep. at 103).) Dr. Katz clearly testified that such an assumption cannot be made here: [redacted] (RX6004 (Katz Trial Dep. at 21-22).)

Respondents further incorporate their responses to CCFF ¶¶ 773–76 herein.

3197. Respondents' expert, Dr. Katz, testified that monitoring rivals can also be an "input[] into the decision-making process of how much to invest or in what ways to invest[.]" (RX6004 (Katz Trial Dep. at 103)).

Response to Finding No. 3197:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3195–96, which Respondents incorporate herein.

Respondents further incorporate their responses to CCFF ¶¶ 773–76 herein.

3198. Respondents' expert, Dr. Katz, testified that firms that are developing MCED tests have identified other MCED developers as competitors. (RX6004 (Katz Trial Dep. at 104)).

Response to Finding No. 3198:

The proposed finding is incomplete and misleading to the extent that it suggests that Dr. Katz testified that other putative MCED tests would compete closely with Galleri. Dr. Katz expressly testified that this fact was unavailing. [redacted] (RX6004 (Katz Trial Dep. at 21-22).) Therefore, statements by competitors "are not going to answer these questions about the trade-offs or . . . the degree of differentiation or how consumers are going to really behave." (RX6004 (Katz Trial Dep. at 21.)

Respondents further incorporate their responses to CCFF ¶¶ 773–76 herein

3199. Respondents' expert, Dr. Katz, testified that firms developing MCED tests have assessed their rivals' product features for their MCED tests. (RX6004 (Katz Trial Dep. at 104)).

Response to Finding No. 3199:

The proposed finding is incomplete and misleading to the extent that it suggests that Dr. Katz testified that other putative MCED tests would compete closely with Galleri. Dr. Katz testified that [redacted] (RX6004 (Katz Trial Dep. at 105).)

Respondents incorporate their responses to CCFF ¶¶ 773–76 herein.

3200. Mr. Bishop testified that he was aware that companies including Exact, Thrive, Guardant, Singlera, and Burning Rock had indicated an intent to develop a multicancer test. (PX7069 (Bishop (Grail) IHT at 127-28)).

Response to Finding No. 3200:

The proposed finding is incomplete and misleading. Regardless of any "intent" of companies to develop a MCED test, the evidence shows that any tests in development are in their early stages and would not compete with Galleri. Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted], Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–06) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698).

Specifically, [redacted] Respondents also incorporate their responses to CCFF ¶¶ 929 and 1912.

There is also no indication based on Guardant's work to date that [redacted] (PFF ¶ 458 ([redacted]; RX3869 (Cote Expert Report) ¶ 193).) Respondents also incorporate their responses to CCFF ¶¶ 927 and 2273.

[redacted]

[redacted] (PFF ¶ 530 (RX3869 (Cote Expert Report) at ¶ 238; Cote Tr. at 3869).) Respondents also incorporate their responses to CCFF ¶¶ 982 and 2421.

The proposed finding is irrelevant because it relates to a putative Chinese cancer test developer that Complaint Counsel has not shown will enter the U.S. market in the foreseeable future. Indeed, Complaint Counsel has never even mentioned the putative MCED test developer, Burning Rock. Complaint Counsel did not subpoena or notice any witnesses from Burning Rock. Nor has Burning Rock reached out to the Commission to address this Transaction.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3201. Mr. Bishop identified "many and varied" types of information for learning about these cancer screening companies, including "press reports, different presentations from companies in the field, medical conferences and symposia, [and] journal publications." (PX7069 (Bishop (Grail) IHT at 125-127)).

Response to Finding No. 3201:

The proposed finding is incomplete and misleading for the reasons identified in Respondents' responses to CCFF ¶ 3200, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3202. In an email discussing Grail's investor relations, dated July 7, 2020, Grail CEO Hans Bishop stated that [redacted] (PX4241 (Grail) at 002 (Email from H. Bishop, Grail, to A. Jasmshidi, Grail, et al., July 7, 2020) (*in camera*)).

Response to Finding No. 3202:

The proposed finding is incomplete and misleading for the reasons identified in Respondents' responses to CCFF ¶ 3200, which Respondents incorporate herein.

3203. In the same July 7, 2020 email, Mr. Bishop noted that [redacted] (PX4241 (Grail) at 002 (Email from H. Bishop, Grail, to A. Jasmshidi, Grail, et al., July 7, 2020) (*in camera*)).

Response to Finding No. 3203:

The proposed finding is incomplete and misleading for the reasons identified in Respondents' responses to CCFF ¶ 3200, which Respondents incorporate herein.

(1) Exact and Thrive

(a) Exact/Thrive is Developing an MCED Test

3204. [redacted] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 13-14) (*in camera*)).

Response to Finding No. 3204:

Respondents have no specific response.

3205. [redacted] (Conroy (Exact) Tr. 1650 (*in camera*)).

Response to Finding No. 3205:

The proposed finding is inaccurate, incomplete and misleading. The only case-controlled study Thrive has published was its first clinical study of a different version of CancerSEEK that focused on only eight types of cancer. (*See* RX3142 (Cohen 2018) at 1; PFF ¶¶ 426.1, 427.) There is no evidence in the record that [redacted] The proposed finding is also misleading to the extent it suggests that [redacted]

[redacted] Further, Respondents note that the latest version of CancerSEEK with published data identified only ten cancer types and failed to detect six cancers in the DETECT-A study. (*See* Conroy (Exact/Thrive) Tr. 1706–07; PFF ¶¶ 430.1, 1699.) Respondents incorporate their responses to CCFF ¶¶ 1939, 2015–16 herein.

3206. [redacted] (Conroy (Exact) Tr. 1650 (*in camera*)).

Response to Finding No. 3206:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938 and 3205, which Respondents incorporate herein.

Respondents incorporate their responses to CCFF ¶ 1939 herein.

3207. [redacted] (Lengauer (Third Rock Ventures) Tr. 194 (*in camera*)).

Response to Finding No. 3207:

The proposed finding is inaccurate, incomplete and misleading. In the DETECT-A trial, which is the most recent clinical trial conducted for the Exact/Thrive CancerSEEK test, [redacted] (*See* (Lengauer (Exact/Thrive) Tr. 243; Conroy (Exact/Thrive) Tr. 1706–07; PFF ¶¶ [redacted], 721.1 1699.) CancerSEEK is also unable to detect several cancers that Galleri has detected. (PFF ¶ 430.1; *compare* RX3419 (Lennon et al., 2020) at 1, 6–7, 9 *with* (RX3409 (Klein et al., 2021) at 1, 5; Cote Tr. 3818–19.)

[redacted] Further, CancerSEEK's design does not support the proposition that it was "intended to detect all types of cancers"; to the contrary, its biomarkers shows that it focuses on epithelial cancers. (PFF ¶ 428-29.1 (RX3419 (Lennon et al., 2020) at 9, Fig. 3; RX3869 (Cote Expert Report) ¶ 177; PFF ¶ 169.1 (Cote Tr. 3810-11)).

Respondents also incorporate PFF ¶¶ 414–43, 709.3, 717.1.1, 721.1–21.2, 726–26.8, 735, 738–40.1 and their responses to CCFF ¶¶ 389, 413–14, 418–19, 696–97, 703, 715, 736, 738-39, 773–76, 785, 929, 1912, 2027, 2042 herein.

3208. [redacted] (Lengauer (Third Rock Ventures) Tr. 194 (*in camera*)).

Response to Finding No. 3208:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938–39 and 3206–07, which Respondents incorporate herein.

3209. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 53-55, 57-58) (*in camera*)).

Response to Finding No. 3209:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938–39 and 3206–08, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3210. [redacted] (Conroy (Exact) Tr. 1571 (*in camera*)).

Response to Finding No. 3210:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938–39 and 3206–08, which Respondents incorporate herein.

(b) Exact/Thrive Considers Grail a Competitor

3211. [redacted] (PX8530 (Exact/Thrive) at 003 (Thrive, All Hands Meeting Talk Track, Sept. 21, 2020)); *see also* (PX7085 (Harada (Exact) Dep. at 227) (*in camera*)).

Response to Finding No. 3211:

The proposed finding is incomplete and misleading. *First*, the proposed finding is incomplete and misleading insofar as it suggests that Exact/Thrive is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. Respondents note that CancerSEEK is still under development (PFF ¶ 417 (Lengauer (Exact/Thrive) Tr. 158)), that [redacted] (Conroy (Exact) Tr. 1717), and that CancerSEEK is combined with a whole-body PET-CT, which [redacted]. (*See*, *e.g.*, Lengauer (Exact/Thrive) Tr. 248; RX3419 (Lennon et al., 2020) at 3; [redacted]; PFF ¶¶ 419, [redacted], 425, [redacted] 739, 760, [redacted],

841.3, [redacted], 1723–24.) Respondents also note that [redacted] (Conroy (Exact) Tr. 1621.)

Second, the the proposed finding is incomplete and misleading insofar as it suggests Galleri and CancerSEEK are reasonably interchangeable. They are not. Galleri detects more than 50 cancer types (PFF ¶ 61), [redacted] (Lengauer (Exact/Thrive) Tr. 245; RX3869 (Cote Expert Report) ¶ 177; PFF ¶¶ 429–430.1). In the DETECT-A trial, which is the most recent clinical trial conducted for the Exact/Thrive CancerSEEK test, [redacted] (*See* (Lengauer (Exact/Thrive) Tr. 243; Conroy (Exact/Thrive) Tr. 1706–07; PFF ¶¶ [redacted], 721.1 1699.) CancerSEEK is also unable to detect several cancers that Galleri has detected. (PFF ¶ 430.1; *compare* RX3419 (Lennon et al., 2020) at 1, 6–7, 9 *with* (RX3409 (Klein et al., 2021) at 1, 5; Cote Tr. 3818–19.) [redacted] By contrast, [redacted] (PFF ¶¶ 419 (RX3869 (Cote Expert Report) ¶ 174), 684.2 (Lengauer (Exact/Thrive) Tr. 246–48).) Dr. Lengauer also observes that the [redacted] (PFF ¶ 429 (Lengauer (Exact/Thrive) Tr. 245; RX3869 (Cote Expert Report) ¶ 177).) Dr. Lengauer also testified that [redacted] (PFF ¶¶ 725 (RX3409 (Klein et al., 2021) at 5; RX3419 (Lennon et al., 2020) at 7; RX3115 (Chen et al., 2020) at 4).) Thus, [redacted]

[redacted] (PFF ¶ 421.)

Respondents incorporate PFF ¶¶ 414–43 and their responses to CCFF ¶¶ 414, 785, 929 and 1912 herein.

3212. [redacted] (Conroy (Exact) Tr. 1614 (*in camera*)).

Response to Finding No. 3212:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 785, 1912 and 3211, which Respondents incorporate herein.

3213. [redacted] (PX7051 (Lenguaer IHT at 176-77) (*in camera*)).

Response to Finding No. 3213:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 785, 1911 and 3211, which Respondents incorporate herein.

3214. [redacted] (Conroy (Exact) Tr. 1614 (*in camera*)).

Response to Finding No. 3214:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 785, 1911 and 3211, which Respondents incorporate herein.

3215. [redacted] (Conroy (Exact) Tr. 1662 (*in camera*)).

Response to Finding No. 3215:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 785, 1911 and 3211, which Respondents incorporate herein.

3216. [redacted] (Conroy (Exact) Tr. 1614 (*in camera*)).

Response to Finding No. 3216:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 785, 1911 and 3211, which Respondents incorporate herein.

3217. [redacted] (Conroy (Exact) Tr. 1614 (*in camera*)).

Response to Finding No. 3217:

The proposed finding is irrelevant. [redacted] Further, Complaint Counsel has made no allegation that the Transaction will cause monopsony harm in any labor market.

The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 785, 1911 and 3211, which Respondents incorporate herein.

3218. [redacted] (Conroy (Exact) Tr. 1614-15 (*in camera*)).

Response to Finding No. 3218:

The proposed finding is irrelevant for the reasons explained in Respondents' responses to CCFF ¶ 3216, which Respondents incorporate herein.

The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 785, 1911 and 3211, which Respondents also incorporate herein.

3219. [redacted] (Conroy (Exact) Tr. 1558-59 (*in camera*)); PX7058 (Conroy (Exact) IHT at 143 (*in camera*)) ([redacted]).

Response to Finding No. 3219:

The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 785, 1911 and 3211, which Respondents also incorporate herein

3220. [redacted] (Lengauer (Third Rock Ventures) Tr. 196 (*in camera*); *see also* Conroy (Exact) Tr. 1617-18 (*in camera*) [redacted].

Response to Finding No. 3220:

The proposed finding is incomplete and misleading. [redacted]

The proposed finding is also deserving of no weight, because any assertion [redacted] As Bill Getty of Guardant testified, "[i]n the context of the blood-based screening market, which is yet to evolve to its maturity, it would be very difficult to speculate about the relevancy of price." (PX7105 (Getty (Guardant) Dep. at 106–07).)

The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 785, 1911 and 3211, which Respondents also incorporate herein.

3221. [redacted] (Conroy (Exact) Tr. 1615 (*in camera*)).

Response to Finding No. 3221:

The proposed finding is incomplete and misleading to the extent it suggests this is evidence that CancerSEEK and Galleri are in the same relevant product market. As Dr. Katz testified that [redacted] (RX6004 (Katz Trial Dep. at 105.)

The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 785, 1911, 1971, 1983 and 3211, which Respondents also incorporate herein.

3222. [redacted] (Conroy (Exact) Tr. 1615 (*in camera*)).

Response to Finding No. 3222:

The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 785, 1911, 1971, 1983 and 3211, which Respondents also incorporate herein.

3223. [redacted] (Conroy (Exact) Tr. 1616-17 (*in camera*)).

Response to Finding No. 3223:

The proposed finding is incomplete and misleading. *First*, the proposed finding is incomplete and misleading insofar as it suggests that Exact/Thrive is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. Respondents note that CancerSEEK is still under development (PFF ¶ 417 (Lengauer (Exact/Thrive) Tr. 158)), that [redacted] (Conroy (Exact) Tr. 1717), and that CancerSEEK is combined with a whole-body PET-CT, which [redacted]. (*See*, *e.g.*, Lengauer (Exact/Thrive) Tr. 248; RX3419 (Lennon et al., 2020) at 3; [redacted]; PFF ¶¶ 419, [redacted], 425, [redacted], 739, 760, [redacted], 841.3, [redacted], 1723–24.) Respondents also note that [redacted] (Conroy (Exact) Tr. 1621.)

Second, the proposed finding is incomplete and misleading insofar as it suggests Galleri and CancerSEEK are reasonably interchangeable. They are not. Galleri detects more than 50 cancer types (PFF ¶ 61), [redacted] (Lengauer (Exact/Thrive) Tr. 245; RX3869 (Cote Expert Report) ¶ 177; PFF ¶¶ 429–430.1). [redacted] By contrast, [redacted] (PFF ¶¶ 419 (RX3869 (Cote Expert Report) ¶ 174), 684.2 (Lengauer (Exact/Thrive) Tr. 246–48).) Dr. Lengauer also observes that the [redacted]

[redacted] (PFF ¶ 429 (Lengauer (Exact/Thrive) Tr. 245; RX3869 (Cote Expert Report) ¶ 177).) Dr. Lengauer also testified that [redacted] (PFF ¶¶ 725 (RX3409 (Klein et al., 2021) at 5; RX3419 (Lennon et al., 2020) at 7; RX3115 (Chen et al., 2020) at 4).) Thus, [redacted] and little evidence to indicate that [redacted] (PFF ¶ 421.)

Respondents incorporate PFF ¶¶ 414–43 and their responses to CCFF ¶¶ 414, 785, 929 and 1912 herein.

3224. [redacted] (PX7110 (Conroy (Exact) Dep. at 58 (*in camera*))); PX7051 (Lengauer (Third Rock Ventures) IHT at 142-43 (*in camera*))).

Response to Finding No. 3224:

The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 785, 1911, 3211 and 3223, which Respondents also incorporate herein.

3225. [redacted] (PX7110 (Conroy (Exact) Dep. at 247-48) (*in camera*); *see also* PX7058 (Conroy (Exact) IHT at 111-13 (*in camera*)).

Response to Finding No. 3225:

The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 785, 1911, 3211 and 3223, which Respondents also incorporate herein.

3226. [redacted]

[redacted] (PX7085 (Harada (Exact) Dep. at 229-30 (*in camera*))).

Response to Finding No. 3226:

The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 785, 1911, 3211 and 3223, which Respondents also incorporate herein.

3227. [redacted] (PX7085 (Harada (Exact) Dep. at 233 (*in camera*))).

Response to Finding No. 3227:

The proposed finding is incomplete, misleading and inherently speculative. [redacted]

The proposed finding is also deserving of no weight, because any assertion [redacted] As Bill Getty of Guardant testified, "[i]n the context of the blood-based screening market, which is yet to evolve to its maturity, it would be very difficult to speculate about the relevancy of price." (PX7105 (Getty (Guardant) Dep. at 106–07).)

The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 785, 1911, 3211 and 3220, which Respondents also incorporate herein.

3228. [redacted] (Conroy (Exact) Tr. 1617 (*in camera*)).

Response to Finding No. 3228:

The proposed finding is irrelevant. [redacted]

The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 785, 1911 and 3211, which Respondents also incorporate herein.

3229. [redacted] (PX7058 (Conroy (Exact) IHT at 114-15) (*in camera*)).

Response to Finding No. 3229:

The proposed finding is incomplete, speculative and irrelevant. *First*, Complaint Counsel undertook no analysis to define an innovation or research and development product market. (PFF ¶ 772.) As Dr. Katz explained, in analyzing an innovation market, the relevant questions are: (i) "[D]id a hypothetical monopolist that controlled some set of assets to innovation . . . find it profitable to cut back on innovation?"; and (ii) to find the boundaries of the market, what are the firm's "capabilities to do innovation?" (PFF ¶ 772.) Dr. Scott Morton did no such analysis. (PFF ¶ 772 (RX6004 (Katz Trial Dep. at 26)

Second, Complaint Counsel has not established that Illumina has any incentive to harm innovation. (*See* Resps.' Post-Trial Br. 117–20; PFF ¶¶ 868–78.) The unrefuted evidence shows that Illumina benefits from any vibrant innovation that may catalyze development and expansion of sequencing into new applications, increasing demand for sequencing and growing Illumina's opportunity to sell more of its sequencing products. (*See* PFF ¶¶ 847–67; deSouza (Illumina) Tr. 2378.) Further, the overwhelming weight of the evidence shows that Illumina is incentivized,

and is now contractually bound, to support any development and commercialization on its platform by any downstream rivals. (*See* PFF ¶¶ 847–67, 1010; Berry (Illumina) Tr. 881–82; deSouza (Illumina) Tr. 2378; PX0064 (Illumina) at 6.)

The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 785, 1911 and 3211, which Respondents also incorporate herein.

3230. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 142-43 (*in camera*))).

Response to Finding No. 3230:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 785, 1911 and 3211, which Respondents incorporate herein. Further, contrary to the cited testimony, immediately after Illumina announced its plan to acquire GRAIL, Thrive executive Josephine Harada sent John Leite, an Illumina executive, an email stating, "Congratulations on the recent GRAIL announcement! It's certainly an exciting time for the screening field and a great validation of the opportunity to improve outcomes through early detection/intervention. It's great to see Illumina leading the way and on the vanguard of oncology care." (RX1646 (Thrive/Illumina) at 1.)

The cited testimony is also further evidence [redacted] (Lengauer (Third Rock) Tr. 205–206.)

(c) Grail Considers Exact/Thrive a Competitor

3231. A May 2021 Grail AACR Conference Report identifies Exact/Thrive as Grail's "most significant competitor in [the] MCED space." (PX4616 (Grail) at 030 (AACR Conference Report, May 5, 2021)).

Response to Finding No. 3231:

The proposed finding is incomplete and misleading. The document notes [redacted] (PX4190 (GRAIL) at 016.)

Respondents incorporate their responses to CCFF ¶¶ 757 and 768 herein

3232. [redacted] (PX4048 (Grail) at 002, 004 (Email from M. Chin, Grail, to C. Della Porta, Grail, attaching "CI Update, Potential Competitors to Galleri, DAC and MRD" Report, Sept. 28, 2020) (*in camera*)).

Response to Finding No. 3232:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

In addition, Hans Bishop, GRAIL's CEO at the time of trial, was shown another document created in 2020 describing Thrive's purported test (PX4456) and testified, [redacted] (Bishop (GRAIL) Tr. 1496.)

[redacted]

Accordingly, this cited document is entitled to little to no weight and Complaint Counsels should not be permitted to rely on inferences from this document.

Respondents further incorporate their responses to CCFF ¶¶ 696, 766 and 771 herein.

3233. [redacted] (PX4075 (Grail) at 009, 027 (Email from A. Aravanis, Grail, to M. Young, Grail, attaching, "Competitive Intelligence: An Overview," Aug. 14, 2019) (*in camera*)).

Response to Finding No. 3233:

The proposed finding is inaccurate, incomplete, and misleading. [redacted]

Respondents also incorporate their responses to CCFF ¶¶ 755–56, 759 herein.

3234. [redacted] (PX4075 (Grail) at 032 (Email from A. Aravanis, Grail, to M. Young, Grail, attaching, "Competitive Intelligence: An Overview," Aug. 14, 2019 (*in camera*))).

Response to Finding No. 3234:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, which Respondents incorporate herein.

3235. [redacted] (PX4288 (Grail) at 001 (Email exchange between H. Bishop, Grail, and R. Currie et al., Grail, July 8, 2020 (*in camera*))).

Response to Finding No. 3235:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, which Respondents incorporate

herein. In addition, to the extent the cited email indicates "concern[]", such concern is based on information that is now out of date, as any analysis of CancerSEEK's characteristics is premature, as Exact is going back to the drawing board with the test and apparently "combining the Exact Sciences and Thrive approaches in one test." (PFF ¶ 726.6; RX4007 (Exact/Thrive) at 7.)

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 43), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3236. [redacted] (PX4048 (Grail) at 007 (Email from M. Chin, Grail, to C. Della Porta, Grail, attaching, "CI Update, Potential Competitors to Galleri, DAC and MRD," Sept. 28, 2020) (*in camera*) (further noting that [redacted]).

Response to Finding No. 3236:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, which Respondents incorporate herein.

3237. [redacted] (PX4048 (Grail) at 006 (Email from M. Chin, Grail, to C. Della Porta, Grail, attaching "CI Update, Potential Competitors to Galleri, DAC and MRD," Sept. 28, 2020) (*in camera*)).

Response to Finding No. 3237:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, which Respondents incorporate

herein. Further, Exact's experience was limited to Cologuard, which is a single cancer screening test for colon cancer; Exact does not have experience bringing an MCED test from biomarker identification to the patient. (Conroy (Exact) Tr. 1533.)

Respondents also note that [redacted] (*See* PPF ¶ 442 (Lengauer (Exact/Thrive) Tr. 212–13.) Exact acquired Thrive, which had started biomarker identification for its CancerSEEK test as part of PapGene. Respondents note that CancerSEEK is still under development (PFF ¶ 417 (Lengauer (Exact/Thrive) Tr. 158)), and that [redacted] (Conroy (Exact) Tr. 1717). Respondents also note that Exact has not commercialized any MCED test. (Conroy (Exact) Tr. 1621.)

3238. [redacted] (PX4207 (Grail) at 052 (Competitive Intelligence Updates: Deep Dive, June 9, 2020) (*in camera*)).

Response to Finding No. 3238:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, which Respondents incorporate herein.

3239. [redacted] (Della Porta (Grail) Tr. 482-83 (*in camera*); PX4145 (Grail) at 009 (Competitive Intelligence, Aug. 14, 2019 (*in camera*)).

Response to Finding No. 3239:

The proposed finding is incomplete and misleading. *First*, as Mr. Della Porta testified, [redacted] (Della Porta (GRAIL) Tr. 547–50.)

Second, as Dr. Katz testified, [redacted] (RRFF ¶ 773 (RX6004 (Katz Trial Dep. at 105) (emphasis added).)

The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 413–14, 418, 697, 755–56, 759, 773–76, 785, 1911, 3211 and 3231–33, which Respondents incorporate herein.

3240. [redacted]
(PX4142 (Grail) at 067 (Email from B. Rapp, Grail, to N. Hanafy et al., Grail, attaching "McKinsey & Company, Grail Commercial Offsite: Gallery Walk and Wall Posters," Aug. 25, 2018 (*in camera*))).

Response to Finding No. 3240:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, which Respondents incorporate herein. Respondents also note that this document from 2018 lists [redacted] that is not within Complaint Counsel's proposed product market.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 38), or in any deposition, and therefore, the document should be

accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3241. Grail described Exact and Thrive as "competitors" in its SEC S-1 filing. (PX4082 (Grail) at 036 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 3241:

The proposed finding is incomplete and misleading. The S-1 is evidence that GRAIL refers to competitors more broadly, rather than as those who have products which belong in the relevant product market. GRAIL defined "competitors" in its S-1 as companies "that have stated that they are developing tests designed to detect cancer".

The proposed finding is also incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3242, which Respondents incorporate herein.

3242. [redacted] (PX6049 (Grail) at 035 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 3242:

The proposed finding is incomplete and misleading. [redacted] (PX6049 (GRAIL) at 36, 39–40).)

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 55), or in any deposition, and therefore, the document should be

accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3243. [redacted] (PX4145 (Grail) at 021 (*in camera*)).

Response to Finding No. 3243:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, which Respondents incorporate herein.

Respondents further did not elicit any testimony regarding the specific language or slide it relies upon with Mr. Della Porta (*see* PX7106 (Della Porta (GRAIL) Dep. at 254–93, 304–25), and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3244. [redacted] (PX4145 (Grail) at 033 (Competitive Intelligence, Aug. 14, 2019) (*in camera*); *see also* Della Porta (Grail) Tr. 492-93 (*in camera*)).

Response to Finding No. 3244:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, which Respondents incorporate herein.

3245. Hans Bishop, Grail's CEO, asked [redacted] (PX4443 (Grail) at 002-03 (Email from J. Ofman, Grail, to A. Chen et al., Grail, June 13, 2020) (*in camera*)). Josh Ofman, its Chief Medical Officer and External Affairs, described [redacted] (PX4443 (Grail) at 002-03 (Email from J. Ofman, Grail, to A. Chen et al., Grail, June 14, 2020) (*in camera*)).

Response to Finding No. 3245:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, which Respondents incorporate herein.

[redacted] Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 48), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3246. [redacted] (PX4443 (Grail) at 002 (Email from J. Ofman, Grail, to A. Chen et al., Grail, June 14, 2020) (*in camera*)).

Response to Finding No. 3246:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33 and 3245, which Respondents incorporate herein.

[redacted]

[redacted]

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 48), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3247. [redacted] (PX4023 (Grail) at 001 (Email from A. Chen, Grail, to J. Ofman et al., Grail, Jun. 15, 2020 (*in camera*))).

Response to Finding No. 3247:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33 and 3245, which Respondents incorporate herein.

[redacted]

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3248. In July 2020, Grail's CEO [redacted] (PX4007 (Grail) at 002 (Email from A. Chen, Grail, to Grail's Executive Leadership Team, et al., July 15, 2020) (*in camera*) (further stating that [redacted])).

Response to Finding No. 3248:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33 and 3245, which Respondents incorporate herein.

[redacted]

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3249. In an internal email discussing [redacted] (PX4318 (Grail) at 001 (Email from R. Currie, Grail, to J. Ofman, et al., Grail, July 30, 2020) (*in camera*)).

Response to Finding No. 3249:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33 and 3245, which Respondents incorporate herein.

[redacted]

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 44), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

(d) Grail Created a Thrive "Red Team" to Analyze Risks Thrive Posed to Galleri

3250. [redacted] (Bishop (Grail) Tr. 1487 (*in camera*); PX4442 (Grail) at 001-02 (Email from A. Chen, Grail, to H. Bishop et al., Grail, July 7, 2020) (*in camera*)).

Response to Finding No. 3250:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33 and 3245, which Respondents incorporate herein. As Hans Bishop, GRAIL's CEO at the time, testified about a similar document (PX4456), [redacted]

[redacted] **(Bishop (GRAIL) Tr. 1496.)**

Accordingly, the cited document is entitled to little weight.

3251. [redacted] (PX4443 (Grail) at 003 (Email from A. Chen, Grail, to J. Ofman, Grail, Jun. 13, 2020 (*in camera*))).

Response to Finding No. 3251:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245 and 3250, which Respondents incorporate herein.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 48), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3252. [redacted] (PX4456 (Grail) at 002 (Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*); *see also* (Bishop (Grail) Tr. 1491 (*in camera*)).

Response to Finding No. 3252:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245 and 3250, which Respondents incorporate herein.

3253. [redacted] (PX4006 (Grail) at 001 (Email from A. Chen, Grail, to Executive Leadership Team et al., Grail, July 7, 2020) (*in camera*)).

Response to Finding No. 3253:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245 and 3250, which Respondents incorporate herein.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3254. [redacted] (Bishop (Grail) Tr. 1486-88 (*in camera*); PX4442 (Grail) at 001-02 (Email from A. Chen, Grail, to H. Bishop et al., Grail, July 8, 2020) (*in camera*)).

Response to Finding No. 3254:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245 and 3250, which Respondents incorporate herein.

3255. [redacted] (Bishop (Grail) Tr. 1485-86, 1497 (*in camera*)).

Response to Finding No. 3255:

Respondents have no specific response.

3256. [redacted] (PX4441 (Grail) at 002, 004 (Assessment of Impact of THRIVE to Regulatory and Reimbursement Strategy, July 2020) (*in camera*)).

Response to Finding No. 3256:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245 and 3250, which Respondents incorporate herein.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 48), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3257. [redacted]

(PX4456 (Grail) at 002 (Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)).

Response to Finding No. 3257:

The proposed finding is incomplete and misleading. Hans Bishop, GRAIL's CEO at the time, testified at trial that PX4456 [redacted] **(Bishop (GRAIL) Tr. 1496).** Accordingly, this proposed finding is entitled to little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245 and 3250, which Respondents incorporate herein.

3258. [redacted]
(PX4456 (Grail) at 002 (Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)).

Response to Finding No. 3258:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250 and 3257, which Respondents incorporate herein.

3259. [redacted]

(PX4456 (Grail) at 012 (Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)).

Response to Finding No. 3259:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250 and 3257, which Respondents incorporate herein.

3260. In an internal presentation labeled [redacted] (PX4554 (Grail) at 003-04 (Grail, "Thrive Red Team Questions") (*in camera*)).

Response to Finding No. 3260:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250 and 3257, which Respondents incorporate herein.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 52), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3261. In an internal presentation labeled [redacted] (PX4554 (Grail) at 008 (Grail, "Thrive Red Team Questions") (*in camera*)). [redacted] (PX4554 (Grail) at 008 (Thrive Red Team Questions) (*in camera*)).

Response to Finding No. 3261:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250 and 3257, which Respondents incorporate herein.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 52), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3262. [redacted]

[redacted]

(PX4456 (Grail) at 012-13 (Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)).

Response to Finding No. 3262:

The proposed finding is inaccurate, incomplete, and misleading. Hans Bishop, GRAIL's CEO at the time, testified that PX4456 [redacted]

(Bishop (GRAIL) Tr. 1496.) Accordingly, the cited document is entitled to little weight.

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250 and 3257, which Respondents incorporate herein

3263. [redacted] (PX4441 (Grail) (Assessment of Impact of THRIVE to Regulatory and Reimbursement Strategy, July 2020) (*in camera*)). [redacted] (PX4441 (Grail) at 003 (Assessment of Impact of THRIVE to Regulatory and Reimbursement Strategy, July 2020) (*in camera*)).

Response to Finding No. 3263:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250 and 3257, which Respondents incorporate herein.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 48), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

(i) [redacted]

3264. [redacted] (PX4456 (Grail) at 013 (Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)). [redacted] (PX4456 (Grail) at 013 (Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)).

Response to Finding No. 3264:

The proposed finding is incomplete and misleading without additional context. Hans Bishop, GRAIL's CEO at the time, testified that PX4456 [redacted]

[redacted] (Bishop (GRAIL) Tr. 1496.) Accordingly, the cited document is entitled to little weight.

Furthermore, the evidence shows that NGS costs will be a very small part of any commercialized MCED test's revenues. (PFF ¶ 884 (RX6000 (Carlton Trial Dep.) at 30–31).) The only evidence presented at trial regarding projected future NGS costs came from Illumina's [redacted]

[redacted] Respondents incorporate their responses to CCFF ¶ 696 herein.

(ii) [redacted]

3265. [redacted] (PX4456 (Grail) at 005 (Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)).

Response to Finding No. 3265:

The proposed finding is incomplete and misleading without additional context. Hans Bishop, GRAIL's CEO at the time, testified that PX4456 [redacted] (Bishop (GRAIL) Tr. 1496.) Accordingly, the cited document is entitled to little weight.

3266. In an email sent on July 5, 2020, Hans Bishop, Grail's CEO, remarked that [redacted] (PX4241 (Grail) at 005 (Email from H. Bishop, Grail, to A. Freidin, Grail, July 5, 2020) (*in camera*)).

Response to Finding No. 3266:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257 and 3265, which Respondents incorporate herein.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 41), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3267. Dr. Ofman explained that, in an interventional study, patients' test results are returned to the health care provider, who then apply those results to aid their patients. (PX7092 (Ofman (Grail) Dep. at 253)).

Response to Finding No. 3267:

Respondents have no specific response.

3268. In an email discussing a "Round Table" meeting sent to Grail's Executive Team on May 5, 2020, Nichole D'Arco, Grail's Associate Director of Internal Communications, identified a list of questions to discuss at the meeting—including "[h]ow does Thrive's DETECT-A compare to our test? Are there any competitive advantages?" and "how [does] their DETECT-A study design compare[ ] to PATHFINDER." (PX4315 (Grail) at 001 (Email from N. D'Arco, Grail, to Grail's Executive Team et al., Grail, May 5, 2020)).

Response to Finding No. 3268:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257 and 3265, which Respondents incorporate herein.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 43), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3269. [redacted] (PX4207 (Grail) at 033 (Competitive Intelligence Updates: Deep Dive, June 9, 2020) (*in camera*)). [redacted] (PX4207 (Grail) at 033 (Competitive Intelligence Updates: Deep Dive, June 9, 2020) (*in camera*)).

Response to Finding No. 3269:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257 and 3265, which Respondents incorporate herein.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 40), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3270. [redacted] (PX4456 (Grail) at 012 (Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)). [redacted] (PX4456 (Grail) at 012 (Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)).

Response to Finding No. 3270:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257 and 3265, which Respondents incorporate herein.

3271. [redacted]

[redacted] (PX4456 (Grail) at 012 (Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)). [redacted] (PX4456 (Grail) at 012 (Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)).

Response to Finding No. 3271:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257 and 3265, which Respondents incorporate herein.

3272. In July 2020, Josh Ofman, Chief Medical Officer, and Alice Chen, Grail VP of Product and Head of Program Management Organization, emailed with other Grail executives regarding [redacted] (PX4027 (Grail) at 001-004 (Email from J. Ofman, Grail, to A. Chen, et al., Grail, July 29, 2020) (*in camera*)).

Response to Finding No. 3272:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257 and 3265, which Respondents incorporate herein.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3273. [redacted] (PX4456 (Grail) at 012 (Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)). [redacted]

(PX4456 (Grail) at 012 (Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)).

Response to Finding No. 3273:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257 and 3265, which Respondents incorporate herein.

(iii) [redacted]

3274. [redacted]

(PX4456 (Grail) at 013 (Grail, Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)).

Response to Finding No. 3274:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257 and 3265, which Respondents incorporate herein.

3275. Hans Bishop, Grail's CEO, emailed Alice Chen and other Grail executives on July 8, 2020, with [redacted] Bishop wrote: [redacted] (PX4442 (Grail) at 001 (Email from Hans Bishop, Grail, to Alice Chen, et. al, Grail, July 8, 2020) (*in camera*)).

Response to Finding No. 3275:

The proposed finding is misleading. Mr. Bishop explained at trial that [redacted] (Bishop (GRAIL) Tr. 1489–90).)

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257 and 3265, which Respondents incorporate herein.

3276. In an email dated July 15, 2020, Josh Ofman, Grail's Chief Medical Officer and External Affairs, wrote [redacted] (PX4007 (Grail) at 001 (Email from J. Ofman, Grail, to A. Chen, Grail, et al., July 15, 2020) (*in camera*)). Dr. Ofman also asked [redacted] (PX4007 (Grail) at 001 (Email from J. Ofman, Grail, to A. Chen, Grail, et al., July 15, 2020) (*in camera*)).

Response to Finding No. 3276:

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3277. [redacted] (Della Porta (Grail) Tr. 487 (*in camera*)); PX4145 (Grail) at 024 (Grail, "Competitive Intelligence," Aug. 14, 2019) (*in camera*)). [redacted] (Della Porta (Grail) Tr. 487 (*in camera*)). [redacted] (Della Porta (Grail) Tr. 487 (*in camera*)). [redacted] (Della Porta (Grail) Tr. 488 (*in camera*)).

Response to Finding No. 3277:

The proposed finding is irrelevant. *First*, Exact's ability to launch a single indication screening test is irrelevant because as Complaint Counsel acknowledges, single-cancer tests are not in its proposed product market. [redacted]

[redacted]

Exact's experience was limited to Cologuard, which is a single cancer screening test for colon cancer; Exact does not have experience bringing an MCED test from biomarker identification to the patient. (Conroy (Exact) Tr. 1533.) Respondents also note that Exact's CancerSEEK test is still under development (PFF ¶ 417 (Lengauer (Exact/Thrive) Tr. 158)), and that [redacted] (Conroy (Exact) Tr. 1717). Respondents also note that Exact has not commercialized any MCED test. (Conroy (Exact) Tr. 1621.)

(iv) [redacted]

3278. On May 3, 2020, Alex Aravanis, Grail's Chief Scientific Officer and Head of R&D, circulated [redacted] (PX4074 (Grail) at 001 (Email from A. Aravanis, Grail, to Grail's Executive Leadership Team, et al., May 3, 2020) (*in camera*)). Dr. Aravanis highlighted [redacted] (PX4074 (Grail) at 001 (Email from A. Aravanis, Grail, to Grail's Executive Leadership Team, et al., May 3, 2020) (*in camera*)). [redacted] (PX4074 (Grail) at 099 (Grail, "Science, Medicine, and Technology Board Subcommittee Meeting," May 2, 2020) (*in camera*)).

Response to Finding No. 3278:

The proposed finding is incomplete and misleading to the extent that it suggests that Exact/Thrive's PET-CT based approach in CancerSEEK is superior to Galleri's molecular approach for identifying the cancer signal of origin.

To the contrary, full-body PET-CT is a fairly poor tool for cancer signal of origin determination. This is reflected in Exact/Thrive's own study. Of the 53 patients identified by PET-CT as having imaging concerning for cancer in Exact/Thrive's DETECT-A study, only 15 was determined to have cancer, with only a 28.3% detection rate, compared with the 88.7% accuracy of cancer signal of origin prediction achieved by GRAIL's Galleri v1 in the CCGA3 study. (*See* PFF ¶¶ 426.3–426.4.) [redacted]; and the Cohen study found the PET-CT approach is not well suited to be a primary screening modality for the general population also because it is financially and operationally impractical (Conroy (Exact/Thrive) Tr. 1707–08). (*See* PFF ¶ 1700.)

Dr. Lengauer of Exact/Thrive admitted that a diagnostic full-body PET-CT confers a higher radiation exposure than a standard CT; the radiation exposure from diagnostic PET-CT and follow-up imaging tests in the participants without cancer is a recognized source of potential harm associated with the DETECT-A CancerSEEK protocol; investigators of the DETECT-A trial recognized that the diagnostic PET-CT scans are not well suited to be the primary screening modality for the general population, in part because of a low disease prevalence and a relatively high rate of incidental findings; and even after the full-body PET-CT scan, there may be a need to do additional biopsies to further characterize the cancer. (*See* Lengauer (Exact/Thrive) Tr. 248–50; PFF ¶ 1724.)

Respondents also note that [redacted] RX3419 (Lennon et al., 2020); Cote Tr. 3811–14.)

Respondents incorporate their responses to CCFF ¶¶ 1938–39 and 1963 herein.

3279. [redacted] (PX4198 (Grail) at 005 (Email from A. Chen, Grail, to Grail "Thrive Red Team," June 24, 2020) (*in camera*)).

Response to Finding No. 3279:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3265 and 3275, which Respondents incorporate herein.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 40), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3280. Hans Bishop, Grail's CEO, emailed Alice Chen and other Grail executives on July 8, 2020, with [redacted] Bishop wrote: [redacted] (PX4442 (Grail) at 001 (Email from Hans Bishop, Grail, to Alice Chen, et. al, Grail, July 8, 2020) (*in camera*)).

Response to Finding No. 3280:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3265, 3275, and 3278 which Respondents incorporate herein.

Mr. Bishop explained that [redacted] (Bishop (GRAIL) Tr. 1489–90).)

The data shows that patients taking the Galleri test do not experience a "diagnostic odyssey". To the contrary, Galleri v1 demonstrated a cancer signal of origin prediction accuracy of 93%. (PFF ¶ 389 (RX3430 (Liu et al., 2020) at 1, 9; RX0744 (GRAIL) at 68; RX3869 (Cote Expert Report) ¶ 143).) CCGA3, the third CCGA sub-study, reported that Galleri v2 demonstrated a cancer signal of origin prediction accuracy of 88.7%. (PFF ¶ 393 (RX3408 (Klein et al., 2021) at 10; RX3869 (Cote Expert Report) ¶ 144).) GRAIL demonstrated this performance in a prospective clinical trial environment as well, with PATHFINDER. In the PATHFINDER trial, Galleri returned an overall CSO accuracy (for both first and second CSO) of 96.3%. (RX3053 (Beer et al., 2021).)

As Dr. Ofman testified, the CSO accuracy (together with Galleri's extremely high specificity of more than 99.5%) are critical in avoiding the "diagnostic odyssey", and allow GRAIL's innovative Galleri test to avoid it: "So the test, if it's a multicancer early detection test, has to have a very low false positive rate because you're looking for so many different kinds of cancer. And that will contribute to what we call a high positive predictive value. Positive predictive value is the most important clinical measure that a doctor needs to know about when using this test. And PPV really refers to, of those with a positive result, how many actually have cancer. And so these are really important that these numbers, the very low false positive rate and a much higher PPV than what is typically seen with single-cancer screening tests. Finally, for any multicancer screening test, it has to be able to predict the tissue of origin in order to direct an efficient and focused workup. Otherwise, doctors really won't know what to do with the result." (Ofman (GRAIL) Tr. 3289.)

3281. [redacted] (PX4456 (Grail) at 005 (Grail, Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)). [redacted] (PX4456 (Grail) at 005 (Grail, Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)).

Response to Finding No. 3281:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3265, 3275, 3278, and 3280, which Respondents incorporate herein.

3282. [redacted] (PX4456 (Grail) at 005 (Grail, Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)).

Response to Finding No. 3282:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 1963, 3231–33, 3245, 3250, 3257 and 3265, which Respondents incorporate herein.

Respondents note that full-body PET-CT is a fairly poor tool for cancer signal of origin determination. This is reflected in Exact/Thrive's own study. Of the 53 patients identified by PET-CT as having imaging concerning for cancer in the DETECT-A study, only 15 was determined to have cancer, with only a 28.3% detection rate, compared with the 88.7% accuracy of cancer signal of origin prediction achieved by GRAIL's Galleri v1 in the CCGA3 study. (*See* PFF ¶¶ 426.3–426.4.) [redacted] (*See* PFF ¶ 439.) [redacted]; and the Cohen study found the PET-CT approach is not well suited to be a primary screening modality for the general population also because it is financially and operationally impractical (Conroy (Exact/Thrive) Tr. 1707–08). (*See* PFF ¶ 1700.)

Dr. Lengauer admitted that a diagnostic full-body PET-CT confers a higher radiation exposure than a standard CT; the radiation exposure from diagnostic PET-CT and follow-up imaging tests in the participants without cancer is a recognized source of potential harm associated with the DETECT-A CancerSEEK protocol; investigators of the DETECT-A trial recognized that the diagnostic PET-CT scans are not well suited to be the primary screening

modality for the general population, in part because of a low disease prevalence and a relatively high rate of incidental findings; and even after the full-body PET-CT scan, there may be a need to do additional biopsies to further characterize the cancer. (*See* Lengauer (Exact/Thrive) Tr. 248–50; PFF ¶ 1724.)

Respondents also note that [redacted] RX3419 (Lennon et al., 2020); Cote Tr. 3811–14.)

Respondents incorporate their responses to CCFF ¶¶ 1938–39 and 1963 herein.

3283. [redacted] (PX4456 (Grail) at 012 (Grail, Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)). [redacted]

(PX4456 (Grail) at 012 (Grail, Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)).

Response to Finding No. 3283:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3265, 3275, 3278 and 3280 which Respondents incorporate herein.

3284. [redacted]

(PX4456 (Grail) at 013 (Grail, Thrive Red Team Update: ELT Discussion, July 9, 2020)

(*in camera*)). [redacted] (PX4456 (Grail) at 013 (Grail, Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)). [redacted] (PX4456 (Grail) at 013 (Grail, Thrive Red Team Update: ELT Discussion, July 9, 2020) (*in camera*)).

Response to Finding No. 3284:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3265, 3275, 3278 and 3280, which Respondents incorporate herein.

(2) Guardant

(a) Guardant Is Developing an MCED Test

3285. Guardant is currently developing an MCED test and plans to initiate MCED test trials in the near future. (Getty (Guardant) Tr. 2497).

Response to Finding No. 3285:

The proposed finding is incomplete and misleading. [redacted] Respondents also refer to RFFF ¶¶ 2269, 2272, 2274, 2278, 2285, and incorporate their responses to CCFF ¶¶ 2273 and 2340 herein.

3286. In an email dated September 10, 2020, Mark Morgan, Grail's SVP of Market Access & Health System Partnerships, wrote to Scott Osler, Grail's Senior Director of Employer Partnerships, stating that "Guardant is [ ] working on a pan cancer assay (Lunar) but instead of going for all cancers, they are starting with colorectal given there is a reimbursement pathway (similar to [C]ologuard)." (PX4194 (Grail) at 001 (Email from M. Morgan, Grail, to S. Osler, Grail, Sept. 10, 2020)).

Response to Finding No. 3286:

The proposed finding is incomplete and misleading. In the portion of the cited email just after this, Mr. Morgan stated "[t]hese are my layperson descriptions". (PX4194 (GRAIL) at 001.) There is no indication based on Guardant's work to date that [redacted] (PFF ¶ 458 ([redacted]; RX3869 (Cote Expert Report) ¶ 193).)

3287. [redacted] (Getty (Guardant) Tr. 2533, 2537 (*in camera*)).

Response to Finding No. 3287:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74, 2277–78 and 2310, which Respondents incorporate herein. Respondents also note that the proposed finding is evidence of differentiation between Guardant's proposed MCED test and GRAIL's Galleri test, suggesting that if Guardant's test comes to market, it will be a complement to GRAIL's Galleri test, rather than a substitute.

[redacted]

3288. [redacted] (Getty (Guardant) Tr. 2537-38 (*in camera*)).

Response to Finding No. 3288:

The proposed finding is incomplete and misleading including insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74 and 2277–78, which Respondents incorporate herein. Further, [redacted] (PFF ¶¶ 476–92.). Respondents incorporate their responses to CCFF ¶¶ 2325 and 2273 herein.

(b) Guardant Considers Grail a Competitor

3289. Guardant views Grail, Natera, Exact, and Freenome as competitors in MCED test development. (Getty (Guardant) Tr. 2687-88).

Response to Finding No. 3289:

The proposed finding is not supported by the cited testimony. The full exchange is as follows: "Q. So is it accurate that GRAIL, Natera, Exact Sciences and Freenome, among others are competitors to Guardant in minimal residual disease testing and early cancer screening? A. Yes." From the full testimony, it is evident that Mr. Getty was referring to Natera as a competitor in minimal residual disease testing, as Natera has publicly said that it is not pursuing early cancer screening. (PFF ¶ 526.3; RX3492 (Natera) at 6.) It is also clear that Mr. Getty was referring to Freenome and Exact as competitors in colorectal cancer screening, as Exact has its Cologuard test, and Freenome is publicly known to be pursuing colorectal cancer screening. Nowhere did Mr. Getty mention the word "MCED competitor."

The proposed finding is also inaccurate and misleading. There is no indication based on Guardant's work to date that [redacted]; RX3869 (Cote Expert Report) ¶ 193); *see also* RRFF ¶ 2273.)

3290. Guardant anticipates that its LUNAR-2 test will compete with Galleri; Guardant is "really focused" on Grail as a competitor. (Getty (Guardant) Tr. 2505-07).

Response to Finding No. 3290:

The proposed finding is incomplete and misleading insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. [redacted]

[redacted]

Accordingly, while Guardant may claim to be "really focused" on GRAIL as its competition, there is no evidence that Guardant will launch in the foreseeable future a cancer screening test that is a close substitute to the Galleri test. (PFF ¶¶ 476–92.) Respondents incorporate their responses to CCFF ¶¶ 426, 927 and 2273 herein.

3291. [redacted] (Getty (Guardant) Tr. 2566 (*in camera*)). [redacted] (Getty (Guardant) Tr. 2566 (*in camera*)).

Response to Finding No. 3291:

Respondents have no specific response except to note that the cited testimony confirms that Guardant and GRAIL are adopting different approaches to the development of an MCED test, suggesting that if Guardant's test comes to market, it will be a complement to GRAIL's Galleri test, rather than a substitute.

Respondents also note that there is typically a tradeoff between specificity and sensitivity. (PFF ¶ 180 (RX3869 (Cote Expert Report) ¶ 95).) [redacted] Given the same conditions, a test applying cutoff thresholds that minimizes false positives, *i.e.*, higher specificity, may often have a lower sensitivity than a test that results in a higher false positive rate. (PFF ¶ 180 (RX3869 (Cote Expert Report) ¶ 95).)

[redacted]

Despite Guardant's purported focus on sensitivity, however, Respondents also note that, [redacted]

[redacted] In contrast, Galleri's current sensitivity rate for version 2 of its test (which is the version that is available as an LDT) is 51.5% for all cancer types across stages. (PFF ¶ 335.)

Respondents also note that Guardant's prioritization of sensitivity shows that it is not pursuing an MCED test option that will be a competitor to Galleri. [redacted] By contrast, the standard of care screening methods such as mammography have very low specificities and correspondingly high false positive rates.

Further, Respondents incorporate their responses to CCFF ¶¶ 386, 426, 2286, 3290 herein.

3292. [redacted] (PX7105 (Getty (Guardant) Dep. at 37) (*in camera*); *see also* PX7040 (Getty (Guardant) IHT at 157) (describing Grail as "a competitor and a formidable one at that.")).

Response to Finding No. 3292:

Respondents incorporate their responses to CCFF ¶¶ 386, 426 and 3290–91 herein.

3293. [redacted] (PX8503 (Guardant) at 066 (Guardant, 2021-2025 LRP Product Roadmap, Aug. 13, 2020) (*in camera*)).

Response to Finding No. 3293:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 2285, which Respondents incorporate herein.

Respondents also note that there is typically a tradeoff between specificity and sensitivity. (PFF ¶ 180 (RX3869 (Cote Expert Report) ¶ 95).) Given the same conditions, a test applying cutoff thresholds that minimizes false positives, i.e., higher specificity, may often have a lower sensitivity than a test that results in a higher false positive rate. (PFF ¶ 180 (RX3869 (Cote Expert Report) ¶ 95).)

Despite Guardant's purported focus on sensitivity, however, Respondents also note that, In contrast, Galleri's current sensitivity rate for version 2 of its test (which is the version that is available as an LDT) is 51.5% for all cancer types across stages. (PFF ¶ 335.)

Further,

[redacted]

Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 64), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also incorporate their responses to CCFF ¶ 2309 herein.

(c) Grail Considers Guardant a Competitor

3294. [redacted] (Della Porta (Grail) Tr. 484-85 (*in camera*)); PX4145 (Grail) at 017 (Grail, "Competitive Intelligence," Aug. 14, 2019) (*in camera*)).

Response to Finding No. 3294:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

3295. [redacted] (PX4018 (Grail) at 005 (Grail, presentation labeled "CIA function @ GRAIL," last modified Nov. 19, 2020) (*in camera*)).

Response to Finding No. 3295:

The proposed finding is incomplete and misleading. [redacted] Thus, GRAIL uses the terms "competitor" and "market" broadly, and those and similar terms do not reflect GRAIL's views of companies it would consider to be in the same relevant antitrust product market.

Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market. (PFF ¶ 698.) There is no indication based on Guardant's work to date that [redacted]

[redacted] (PFF ¶ 458 ([redacted]; RX3869 (Cote Expert Report) ¶ 193); RRFF ¶¶ 927, 2273.)

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3296. [redacted] (PX4018 (Grail) at 006 (Grail, presentation labeled "CIA function @ GRAIL," last modified Nov. 19, 2020) (*in camera*); PX4052 (Grail) at 044 (Grail, "Grail Strategy Workshop #1," Aug. 17, 2020) (*in camera*)).

Response to Finding No. 3296:

The proposed finding is incomplete and misleading. [redacted] Thus, GRAIL uses the terms "competitor" and "market" broadly, and those and similar terms do not reflect GRAIL's views of companies it would consider to be in the same relevant antitrust product market.

Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market. (PFF ¶ 698.) There is no indication based on Guardant's work to date that [redacted] (PFF ¶ 458 ([redacted]; RX3869 (Cote Expert Report) ¶ 193).)

Respondents further note that Complaint Counsel chose not to discuss these documents at trial, (CC Exhibit Index at 34; 35), or in any deposition, and therefore, the document should be

accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3297. [redacted] (Della Porta (Grail) Tr. 482 (*in camera*)); PX4145 (Grail) at 009 (Grail, "Competitive Intelligence," Aug. 14, 2019 (*in camera*)).

Response to Finding No. 3297:

The proposed finding is incomplete and misleading insofar as it suggests that Guardant is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. The proposed finding is incomplete and misleading without additional context insofar as it suggests that Guardant is developing a product that is reasonably interchangeable with Galleri. (See Resps.' Post-Trial Br. at 18.).

First, [redacted]

Second, like Mr. Della Porta, Complaint Counsel's own witness, Dr. Lengauer of Thrive, testified at trial that [redacted] (Lengauer (Exact/Thrive) Tr. 205–06.)

Third, as Dr. Katz testified, [redacted] (RRFF ¶ 773 (RX6004 (Katz Trial Dep. at 105) (emphasis added).)

Respondents further incorporate their responses to CCFF ¶¶ 433–434, 436, 771, 773–76 herein.

3298. Grail described Guardant as a "competitor" in its SEC S-1 filing. (PX4082 (Grail) at 036 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 3298:

The proposed finding is incomplete and misleading to the extent that it suggests that Guardant is anywhere close to launching an MCED test in the foreseeable future. There is no indication based on Guardant's work to date that [redacted] (PFF ¶ 458 [redacted]; RX3869 (Cote Expert Report) ¶ 193).)

The S-1 is evidence that GRAIL refers to competitors more broadly, rather than as those who have products which belong in the relevant product market. GRAIL defined "competitors" in its S-1 as companies "that have stated that they are developing tests designed to detect cancer".

3299. An internal Grail Excel spreadsheet, which [redacted] (PX4011 (Grail) at 003-005 (Grail, Overview of Liquid Biopsy Players) (*in camera*)).

Response to Finding No. 3299:

The proposed finding is incomplete and misleading. [redacted] Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit

Index at 34), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3300. In an internal presentation labeled [redacted] (PX4267 (Grail) at 032 (Grail, "Deep Dive: Competitive Strategy," May 2, 2019) (*in camera*)). Grail further mentioned [redacted] (PX4267 (Grail) at 036 (Grail, "Deep Dive: Competitive Strategy," May 2, 2019) (*in camera*)).

Response to Finding No. 3300:

The proposed finding is incomplete and misleading. [redacted]

In fact, there is no indication based on Guardant's work to date that [redacted] (PFF ¶ 458 [redacted]; RX3869 (Cote Expert Report) ¶ 193).)

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 42), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3301. [redacted] (Della Porta (Grail) Tr. 486 (*in camera*)); PX4145 (Grail) at 017 (Grail, "Competitive Intelligence," Aug. 14, 2019) (*in camera*)). [redacted] (Della Porta (Grail) Tr. 486 (*in camera*)). [redacted] (Della Porta (Grail) Tr. 486 (*in camera*)).

Response to Finding No. 3301:

The proposed finding is incomplete and misleading to the extent it suggests that Guardant is a competitor of GRAIL. There is no indication based on Guardant's work to date that [redacted] (PFF ¶ 458 ([redacted]; RX3869 (Cote Expert Report) ¶ 193).)

3302. [redacted] (PX4075 (Grail) at 010, 017 (Grail, Competitive Intelligence: An Overview, Aug. 14, 2019) (*in camera*)).

Response to Finding No. 3302:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

There is no indication based on Guardant's work to date that [redacted]; RX3869 (Cote Expert Report) ¶ 193).)

Respondents also incorporate their responses to CCFF ¶¶ 405, 426–427, 433, 436 and 437 herein.

3303. [redacted] (PX4075 (Grail) at 017 (Grail, Competitive Intelligence: An Overview, Aug. 14, 2019) (*in camera*)).

Response to Finding No. 3303:

The proposed finding is incomplete and misleading. [redacted]

There is no indication based on Guardant's work to date that [redacted] (PFF ¶ 458 ([redacted]; RX3869 (Cote Expert Report) ¶ 193).)

3304. [redacted] (PX4075 (Grail) at 017 (Grail, Competitive Intelligence: An Overview, Aug. 14, 2019) (*in camera*)).

Response to Finding No. 3304:

The proposed finding is incomplete and misleading for the reasons identified in the responses to CCFF ¶ 3303, which Respondents incorporate herein.

3305. [redacted] (Della Porta (Grail) Tr. 506 (*in camera*); PX4266 (Grail) at 045-046 (Grail, "Competitive Intelligence Updates: Deep Dive," June 9, 2020) (*in camera*)).

Response to Finding No. 3305:

[redacted]

[redacted]

In fact, there is no indication based on Guardant's work to date that [redacted] (PFF ¶ 458 ([redacted]; RX3869 (Cote Expert Report) ¶ 193).)

3306. In an internal memo dated September 28, 2020, Grail noted that [redacted] (PX4444 (Grail) at 009 (Grail, "Potential Competitors to Galleri, DAC and MRD," Sept. 28, 2020) (*in camera*); *see also* PX4054 (Grail) at 008 (Grail, "Highlights, Key Competitive Messaging & Initial Thoughts") (*in camera*)).

Response to Finding No. 3306:

The proposed finding is incomplete and misleading. [redacted] There is no indication based on Guardant's work to date that [redacted] (PFF ¶ 458 ([redacted]; RX3869 (Cote Expert Report) ¶ 193).)

Further, Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 35, 48), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3307. [redacted] (PX6049 (Grail) at 038 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 3307:

The proposed finding is inaccurate, incomplete and misleading. [redacted] Indeed, there is no indication based on Guardant's work to date that [redacted] (PFF ¶ 458 ([redacted]; RX3869 (Cote Expert Report) ¶ 193).) Respondents incorporate their responses to CCFF ¶¶ 378, 382, 398 and 709 herein.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 55), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

(3) Freenome

(a) Freenome Is Developing an MCED Test

3308. [redacted] (PX7121 (Otte (Freenome) Dep. at 17-18) (*in camera*); *see also* Nolan (Freenome) Tr. 2709 (stating that Freenome's multiomics platform is "built for the purpose of having application across a range of cancer types").

Response to Finding No. 3308:

The proposed finding is inaccurate, incomplete and misleading. [redacted] Respondents refer to RRFF ¶¶ 945 and 2355–58, and incorporate their responses to CCFF ¶ 2373 herein.

3309. [redacted] (Nolan (Freenome) Tr. 2748-50 (*in camera*)). [redacted] (Nolan (Freenome) Tr. 2749-50 (*in camera*)).

Response to Finding No. 3309:

The proposed finding is incomplete, inaccurate and misleading without additional cancers. [redacted]

[redacted] Respondents refer to RRFF ¶¶ 2355–58, and incorporate their responses to CCFF ¶¶ 2379-80 herein.

3310. [redacted] (Nolan (Freenome) Tr. 2748-49 (*in camera*)).

Response to Finding No. 3310:

The proposed finding is inaccurate, incomplete and misleading.

[redacted]

[redacted] Therefore, this cited testimony should be accorded little weight.

3311. Mr. Nolan explained at trial that "starting with colorectal cancer early detection on [Freenome's] multiomics platform . . . activates [the algorithm's] learning engine and gives [Freenome] the opportunity to move to those next cancer types more efficiently[.]" (Nolan (Freenome) Tr. 2709); *see* Nolan (Freenome) Tr. 2748 (*in camera*) ([redacted]).

Response to Finding No. 3311:

The proposed finding is incomplete and misleading including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2355–58, 2373 and 2379, which Respondents incorporate herein. Respondents also note that [redacted]

[redacted] Accordingly, there is no indication based on Freenome's work to date that [redacted] (PFF ¶ 458 ([redacted]; RX3869 (Cote Expert Report) ¶ 193).)

The proposed finding is also misleading to the extent it suggests that it is a viable option to convert from a single cancer screening test to a multi-cancer screening test. To the contrary, even once a company has developed a cancer screening test for a single cancer type, it does not become easier to add additional cancer types, because "[t]he development of biomarkers for a particular cancer will not be adequate for other cancers" and "[w]hile there may be overlap, one still needs to go through all of the [development] steps," including "go[ing] through the case-control verification to determine whether or not the assay has the performance characteristics needed . . . for the new target cancer," and "go[ing] through a prospective trial depending on which cancer is being targeted." . (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123; PFF ¶¶ 328–328.1.) Dr. Aravanis testified that GRAIL considered developing a single cancer screening test as a route to multicancer screening test but abandoned it because it would take far too long; building a multicancer test by developing single cancer tests seriatim could take four or five years for each cancer; to develop a 50-cancer test one cancer at a time a developer would need to do a research study, discovery study and collect relevant samples, determine the right technology, go into a new test development phase and clinical trials for each new cancer; GRAIL was able to develop a test capable of detecting 50 cancer types simultaneously directly by undergoing a much more intensive process to develop a test for 50 cancer types at the same time.

(Aravanis (Illumina) Tr. 1895–97.) Respondents also incorporate their responses to CCFF ¶ 405 herein.

3312. [redacted] (Nolan (Freenome) Tr. 2750 (*in camera*)).

Response to Finding No. 3312:

The proposed finding is incomplete and misleading without additional context. [redacted]

To the contrary, even once a company has developed a cancer screening test for a single cancer type, it does not become easier to add additional cancer types, because "[t]he development of biomarkers for a particular cancer will not be adequate for other cancers" and "[w]hile there may be overlap, one still needs to go through all of the [development] steps," including "go[ing] through the case-control verification to determine whether or not the assay has the performance characteristics needed . . . for the new target cancer," and "go[ing] through a

prospective trial depending on which cancer is being targeted." (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123; PFF ¶¶ 328–328.1.) Dr. Aravanis testified that GRAIL considered developing a single cancer screening test as a route to multicancer screening test but abandoned it because it would take far too long; building a multicancer test by developing single cancer tests seriatim could take four or five years for each cancer; to develop a 50-cancer test one cancer at a time a developer would need to do a research study, discovery study and collect relevant samples, determine the right technology, go into a new test development phase and clinical trials for each new cancer; GRAIL was able to develop a test capable of detecting 50 cancer types simultaneously directly by undergoing a much more intensive process to develop a test for 50 cancer types at the same time. (Aravanis (Illumina) Tr. 1895–97.)

[redacted] Respondents incorporate their responses to CCFF ¶ 2370 herein.

(b) Freenome Considers Grail a Competitor

3313. [redacted] (Nolan (Freenome) Tr. 2772-73 (*in camera*)).

Response to Finding No. 3313:

The proposed finding is incomplete and misleading without additional context insofar as it suggests that [redacted]

Respondents also note that [redacted]

[redacted] Respondents further incorporate their responses to CCFF ¶¶ 439–446, 801–03 and 2353–2400 herein.

3314. Mr. Nolan testified that Freenome considers Grail to be an MCED competitor. (Nolan (Freenome) Tr. 2727; *see also* Nolan (Freenome) Tr. 2777 (*in camera*) ([redacted]; PX7094 (Nolan (Freenome) Dep. at 260-62) (*in camera*) ([redacted]).

Response to Finding No. 3314:

The proposed finding is incomplete and misleading without additional context insofar as it suggests that [redacted]

Respondents also note that the proposed finding is incomplete and misleading to the extent it implies that Mr. Nolan's testimony is representative of Freenome's views writ large. In fact, [redacted] Respondents further incorporate their responses to CCFF ¶¶ 439–446, 804 and 2353–2400 herein.

3315. [redacted] (Nolan (Freenome) Tr. 2774 (*in camera*)).

Response to Finding No. 3315:

Respondents have no specific response.

3316. [redacted] (Nolan (Freenome) Tr. 2774-75 (*in camera*)).

Response to Finding No. 3316:

The proposed finding is incomplete and misleading insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future.

First, Mr. Nolan's characterization notwithstanding, Freenome's expectations are entirely speculative, and do not support any meaningful forecasts about the theoretical, future MCED test market. [redacted] Respondents incorporate their responses to CCFF ¶ 698 herein.

3317. [redacted] (PX7094 (Nolan (Freenome) Dep. at 262-63) (*in camera*)).

Response to Finding No. 3317:

The proposed finding is incomplete and misleading. There is no indication based on Freenome's work to date that [redacted] (PFF ¶ 458 ([redacted]; RX3869 (Cote Expert Report) ¶ 193).) Respondents also note that [redacted]

With respect to Mr. Nolan's statement about [redacted] (PX7094, Nolan (Freenome) Dep. Tr. 262–63.)

3318. [redacted] (PX8368 (Freenome) at 079 (Crossover Round Company Overview, 2020) (*in camera*) ([redacted]); PX7055 (Otte (Freenome) IHT at 83) (*in camera*) ([redacted]; *see* PX7050 (Nolan (Freenome) IHT at 85) (*in camera*); *see also* PX7121 (Otte (Freenome) Dep. at 148 (*in camera*))).

Response to Finding No. 3318:

The proposed finding is incomplete and misleading. Mr. Otte, Freenome's former CEO, testified that [redacted]

Further while Freenome may aspire to develop a multiomics platform that could support both an MCED and single cancer test, Freenome has not published any clinical data showing that it is remotely close to achieving this objective. [redacted] Respondents also incorporate their responses to CCFF ¶¶ 405, 439–440, 444, 666, 698, 801, 806, 945 and 1140 herein.

Accordingly, there is no indication based on Freenome's work to date that [redacted]

[redacted] (PFF ¶ 458 ([redacted]; RX3869 (Cote Expert Report) ¶ 193); RRFF ¶¶ 945 and 2355.)

(c) Grail Considers Freenome a Competitor

3319. [redacted] (PX4075 (Grail) at 009, 033-37 (Email from A. Aravanis, Grail to M. Young and H. Bishop, Grail, attaching Competitive Intelligence: An Overview, Sept. 7, 2019) (*in camera*)).

Response to Finding No. 3319:

The proposed finding is incomplete and misleading. [redacted] The proposed finding is also incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including [redacted] (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Respondents also incorporate their responses to CCFF ¶¶ 439–40, 444–45 herein.

3320. [redacted] (PX4018 (Grail) at 005 (CIA function @ GRAIL) (*in camera*)).

Response to Finding No. 3320:

[redacted] Thus, GRAIL uses the terms like

"market" and "competitor" broadly, and those terms do not reflect GRAIL's views of companies it would consider to be in the same relevant antitrust product market.

Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market. (PFF ¶ 698.) There is no indication based on Freenome's work to date that [redacted] (PFF ¶ 458 ([redacted]; RX3869 (Cote Expert Report) ¶ 193).)

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3321. [redacted] (PX4018 (Grail) at 006 (CIA function @ GRAIL) (*in camera*); PX4052 (Grail) at 044 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)).

Response to Finding No. 3321:

The proposed finding is incomplete and misleading for the reasons identified in Respondents' responses to CCFF ¶ 3320, which Respondents incorporate herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34; 35), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3322. [redacted] (Della Porta (Grail) Tr. 483 (*in camera*)); PX4145 (Grail) at 009 (Competitive Intelligence: An Overview, Aug. 14, 2019 (*in camera*)).

Response to Finding No. 3322:

The proposed finding is incomplete and misleading insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. The proposed finding is also incomplete and misleading insofar as it suggests that Freenome is developing a product that is reasonably interchangeable with Galleri. (See Resps.' Post-Trial Br. at 18.)

First, [redacted]

Second, and similar to Mr. Della Porta, Complaint Counsel's own witness, Dr. Lengauer of Thrive, testified at trial that [redacted] (Lengauer (Exact/Thrive) Tr. 206.)

Third, as Dr. Katz testified, [redacted] (RRFF ¶ 773 (RX6004 (Katz Trial Dep. at 105) (emphasis added).).

Respondents further incorporate their responses to CCFF ¶¶ 439, 444, 771, 773–76 herein.

3323. [redacted] (PX4444 (Grail) at 013 (Email from M. Morgan, Grail to Market Access & Health Systems Partnerships et al, Grail, attaching Potential Competitors to Galleri, DAC and MRD, Oct. 23, 2020) (*in camera*); *see also* PX4054 (Grail) at 012 (CI Summary Top Competitors, Sept. 28, 2020) (*in camera*)).

Response to Finding No. 3323:

The proposed finding is incomplete and misleading. [redacted]

(PFF ¶ 458 [redacted]; RX3869 (Cote Expert Report) ¶ 193).)

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 35; 48), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3324. [redacted]
(PX6049 (Grail) at 035 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 3324:

The proposed finding is incomplete and misleading. [redacted]

Additionally, Mr. Otte, Freenome's former CEO, testified that [redacted]

Further while Freenome may aspire to develop a multiomics platform that could support both an MCED and single cancer test, Freenome has not published any clinical data showing that it is remotely close to achieving this objective. [redacted] **Respondents also incorporate their responses to CCFF ¶¶ 405, 439–440, 444, 666, 698, 801, 806, 945 and 1140 herein.**

Accordingly, there is no indication based on Freenome's work to date that [redacted] (PFF ¶ 458 [redacted]; RX3869 (Cote Expert Report) ¶ 193).)

Moreover, proteomics-based tests do not rely on NGS technology (*see* PFF ¶¶ 155 –56; Cance (ACS) Tr. 606; Cote Tr. 3730, 3736–37; RX3869 (Cote Expert Report) ¶ 74), which undermines Complaint Counsel's position that any future MCED tests will inevitably rely on NGS.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 55), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3325. [redacted] (PX6049 (Grail) at 036 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 3325:

The proposed finding is inaccurate, incomplete and misleading. [redacted]

There is no indication based on Freenome's work to date that [redacted]. (PFF ¶ 458 ([redacted]; RX3869 (Cote Expert Report) ¶ 193).)

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 55), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

(4) Singlera

(a) Singlera Is Developing an MCED Test

3326. Singlera is currently developing an MCED test referred to as the PanSeer test. (PX7102 (Gao (Singlera) Dep. at 23-24)).

Response to Finding No. 3326:

Respondents have no specific response except to note that the finding is ambiguous as to the meaning of "MCED". No analytical or clinical data that Singlera has collected provides support for the proposition that PanSeer can detect more than 5 cancer types. (Gao (Singlera) Tr. 2917–18; RX3869 (Cote Expert Report) ¶ 241; Cote Tr. 3869.) Singlera does not currently have any clinical trials relating to screening for multiple cancers listed on clinicaltrials.gov. (RX3869 (Cote Expert Report) ¶ 242.); Gao (Singlera) Tr. 2926; Cote Tr. 3869.) Respondents incorporate their responses to CCFF ¶ 2417 herein.

3327. Singlera conducted a clinical study of PanSeer, called the Taizhou Longitudinal Study. (Gao (Singlera) Tr. 2877-78). The Taizhou Longitudinal Study involved the collection of blood plasma samples from over 120,000 healthy (asymptomatic) subjects who were subsequently monitored for cancer occurrence. (RX1699 (Illumina) (Email from M. Nguyen, Illumina, to J. Godsey et al., Illumina attaching Chen X. et al., Non-invasive Early Detection of Cancer Four Years before Conventional Diagnosis Using a Blood Test," *Nature Communications* 11:3475 (2020), July 21, 2020)).

Response to Finding No. 3327:

The proposed finding is incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF

¶¶ 2406, 2416–17 and 2421, which Respondents incorporate herein. The proposed finding is also inaccurate because it states that PanSeer was studied in over 120,000 people (RX3115 (Chen et al., 2020) at 4, Table 1). PanSeer was only studied in a retrospective, observational study of 418 participants. (PFF ¶ 534; RX3637 (Singlera) at 1–6; Gao (Singlera) Tr. 2877–79.)

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (RC Exhibit Index at 78), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3328. Singlera published a paper in Nature in 2020 based on data from the Taizhou Longitudinal Study, which reported on Panseer's sensitivity and specificity at detecting five different cancers. (Gao (Singlera) Tr. 2879-80; RX1699 (Illumina) (Email from M. Nguyen, Illumina, to J. Godsey et al., Illumina attaching Chen X. et al., Non-invasive Early Detection of Cancer Four Years before Conventional Diagnosis Using a Blood Test," *Nature Communications* 11:3475 (2020), July 21, 2020)).

Response to Finding No. 3328:

The proposed finding is inaccurate, incomplete, and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2406, 2416–17 and 2421, which Respondents incorporate herein.

The reported characteristics of the PanSeer test in development are also far from being suitable for being used in a multi-cancer screening test. In a retrospective, observational study (the only study performed on PanSeer) of 418 participants from part of the Taizhou Longitudinal Study with samples from 113 post-diagnosis cancer patients, 98 prediagnostic cancer patients, and 207 healthy individuals, PanSeer achieved a 96% specificity. (PFF ¶ 532; RX3637 (Singlera) at 1–6; Gao (Singlera) Tr. 2877–79.) [redacted]

[redacted]

Respondents also note that Complaint Counsel chose not to discuss this document at trial, (RC Exhibit Index at 78), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3329. Singlera plans to demonstrate the PanSeer test's ability to detect more cancers than the five demonstrated in the TLS study. (Gao (Singlera) Tr. 2881-82 (further explaining that the PanSeer test is designed to detect "all kinds of cancer," and not just the five cancers used in the TLS study)).

Response to Finding No. 3329:

The proposed finding is incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2406, 2416–17, 2421, 2467, 3328, 3330–32, which Respondents incorporate herein. While Dr. Gao may testify that Singlera's goal is "all kinds of cancer" or "pan-cancer", there is no such thing as a universal or pan-cancer marker. (*See* RRFF ¶ 2416; PFF ¶¶ 308–309 (Cote Tr. 3787; Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106).)

3330. Dr. Gao testified that Singlera's "goal is pan-cancer" for the PanSeer test. (Gao (Singlera) Tr. 2881).

Response to Finding No. 3330:

The proposed finding is incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2406 and 2416–17, which Respondents incorporate herein. While Dr. Gao may testify that

Singlera's goal is "pan-cancer", there is no such thing as a universal or pan-cancer marker. (*See* RRFF ¶ 2416; PFF ¶¶ 308–309 (Cote Tr. 3787; Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106).)

(b) Singlera Considers Grail a Competitor

3331. Singlera views Grail's Galleri test as a competitor to PanSeer. (PX7042 (Gao (Singlera) IHT at 96-97)).

Response to Finding No. 3331:

By Dr. Gao's own calculation, PanSeer is at least eight to ten years away from potential launch in the United States, and Singlera does not currently have any clinical trials relating to screening for multiple cancers listed on clinicaltrials.gov. (PFF ¶¶ 536.1-36.2.) Accordingly,

[redacted]

Respondents also incorporate their responses to CCFF ¶¶ 447, 451, 982 and 2421 herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3332. Dr. Gao testified that Singlera is "ahead of [Grail]" based on its publication of results from Singlera's Taizhou Longitudinal Study. (Gao (Singlera) Tr. 2950).

Response to Finding No. 3332:

The proposed finding is incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2406 and 2416–17, which Respondents incorporate herein.

The characteristics of the PanSeer test in development are also far from being suitable for being used in a multi-cancer screening test. In a retrospective, observational study of 418 participants from part of the Taizhou Longitudinal Study with samples from 113 post-diagnosis cancer patients, 98 prediagnostic cancer patients, and 207 healthy individuals, PanSeer achieved a 96% specificity. (PFF ¶ 532; RX3637 (Singlera) at 1–6; Gao (Singlera) Tr. 2877–79.)

[redacted]

Consistent with their very early stage of development, Singlera testified that it is "far away" from starting clinical trials for PanSeer in the United States, and that it is "still not in the really starting clinical trial state." (PFF ¶ 536.1; Gao (Singlera) Tr. 2926; PX7102 (Gao (Singlera) Dep. at 113–14, 81–82.) By Dr. Gao's own calculation, PanSeer is at least eight to ten years away from potential launch in the United States. (PFF ¶ 536.2; Gao (Singlera) Tr. 2925–26; RX3869 (Cote Expert Report) ¶ 242.)

3333. Singlera expects its PanSeer test to compete directly with Grail's Galleri test once on the market. (PX7042 (Gao (Singlera) IHT at 98-99)).

Response to Finding No. 3333:

The proposed finding is incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2406, 2416–17, 2421, 2467, 3328, 3330–32, which Respondents incorporate herein.

Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3334. Singlera expects to compete with Grail on price, efficacy, and innovation of its MCED test. (PX7042 (Gao (Singlera) IHT at 98-100)). Further, Gary Gao, Singlera's Co-Founder and current Scientific Advisor, testified that he expects that the company's MCED test will compete on "accuracy, sensitivity, [and] specificity" of the tests. (PX7042 (Gao (Singlera) IHT at 99-100)).

Response to Finding No. 3334:

The proposed finding is incomplete and misleading including insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2406, 2416–17, 2421, 2467, 3328, 3330–32, which Respondents incorporate herein.

Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(c) Grail Considers Singlera a Competitor

3335. [redacted] (PX4075 (Grail) at 009, 038-43 (Email from A. Aravanis, Grail to M. Young and H. Bishop, Grail, attaching Competitive Intelligence: An Overview, Sept. 7, 2019) (*in camera*)).

Response to Finding No. 3335:

The proposed finding is incomplete and misleading. [redacted] The proposed finding is also incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are

anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including Singlera, do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 447, 451 and 452 herein.

3336. [redacted] (PX4018 (Grail) at 005 (CIA function @ GRAIL) (*in camera*)).

Response to Finding No. 3336:

The proposed finding is incomplete and misleading. [redacted] Thus, GRAIL uses terms like "competitor" and "market" broadly, and those terms do not reflect GRAIL's views of companies it would consider to be in the same relevant antitrust product market.

Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market. (PFF ¶ 698.) [redacted] (PFF ¶ 530 (RX3869 (Cote Expert Report) at ¶ 238; Cote Tr. at 3869).)

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3337. [redacted] (PX4018 (Grail) at 006 (CIA function @ GRAIL) (*in camera*); PX4052 (Grail) at 044 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)).

Response to Finding No. 3337:

The proposed finding is incomplete and misleading. [redacted] Thus, GRAIL uses terms like "competitor" and "market" broadly, and those terms do not reflect GRAIL's views of companies it would consider to be in the same relevant antitrust product market.

Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market. (PFF ¶ 698.) [redacted] (PFF ¶ 530 (RX3869 (Cote Expert Report) at ¶ 238; Cote Tr. at 3869).)

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34; 35), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3338. [redacted] (Della Porta (Grail) Tr. 483 (*in camera*)); PX4145 (Grail) at 009 (Grail, Competitive Intelligence: An Overview, Aug. 14, 2019 (*in camera*)).

Response to Finding No. 3338:

The proposed finding is incomplete and misleading insofar as it suggests that Singlera is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. The proposed finding is also incomplete and misleading to the extent it suggests Singlera is developing a product that is reasonably interchangeable with Galleri. (See Resps.' Post-Trial Br. at 18.)

First, Galleri does not compete with Singlera's PanSeer test, which is very different from Galleri. Singlera's data from a 418-sample case control study shows only that Singlera's PanSeer assay detected five types of cancer and achieved only 96.1% specificity. (RX3115 (Chen et al 2020) at 3; Cote Tr. 3867-69; Abrams Tr. 3628-29**.)** [redacted] Indeed, Singlera is "far, far away" from launching its PanSeer test" (PX7102 (Gao (Singlera) Dep. at 118-19) and does not currently have a price for the product. (Gao (Singlera) Tr. 2893.) Respondents also incorporate their responses to CCFF ¶ 447 herein.

Second, the proposed finding also relates to irrelevant subject matter. Whether GRAIL's competitive intelligence team monitored other test developers has no bearing on whether there is industry or public recognition of a separate "economic entity" comprising any NGS-based MCED test and thus on whether such test developers may comprise the same market under federal antitrust law. Respondents also incorporate their responses to CCFF ¶¶ 451, 773–76 herein.

3339. Grail described Singlera as a "competitor" in its SEC S-1 filing. (PX4082 (Grail) at 036 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 3339:

The proposed finding is incomplete and misleading. [redacted]

(PFF ¶ 530 (RX3869 (Cote Expert Report) at ¶ 238; Cote Tr. at 3869).) The S-1 is evidence that GRAIL refers to competitors more broadly, rather than as those who have products which belong in the relevant product market. GRAIL defined "competitors" in its S-1 as companies "that have stated that they are developing tests designed to detect cancer".

3340. In a November 2018 Grail Board Meeting, Mr. Alex Aravanis, Grail's then head of research and development, discussed Singlera being "a competitor who is developing something overlapping with GRAIL" because of Singlera's "interesting methylation technology." (PX4340 (Grail) at 004 (Email from F. Yu, Ally Bridge, to A. Aravanis, Grail, Nov. 12, 2018)).

Response to Finding No. 3340:

The proposed finding is incomplete and misleading. The cited document is from 2018, over two years before GRAIL launched its Galleri test. [redacted]

[redacted]

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 45), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3341. [redacted] (PX4267 (Grail) at 048 (Deep Dive: Competitive Strategy, May 2, 2019) (*in camera*)).

Response to Finding No. 3341:

[redacted]

[redacted]

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 42), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3342. [redacted] (PX4145 (Grail) at 044 (Competitive Intelligence: An Overview, Aug. 14, 2019) (*in camera*)).

Response to Finding No. 3342:

The proposed finding is incomplete and misleading. [redacted]

[redacted] (PFF ¶ 530 (RX3869 (Cote Expert Report) at ¶ 238; Cote Tr. at 3869).)

3343. [redacted] (PX4145 (Grail) at 044 (Competitive Intelligence: An Overview, Aug. 14, 2019) (*in camera*); *see also* Della Porta (Grail) Tr. 495 (*in camera*) ([redacted])).

Response to Finding No. 3343:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶ 3342, which Respondents incorporate herein.

3344. [redacted] (PX4025 (Grail) at 001 (Email from M. Sturm, Grail, to R. Licata et al., Grail, Sept. 3, 2020) (*in camera*)).

Response to Finding No. 3344:

The proposed finding is incomplete and misleading. In the same email chain, [redacted]

[redacted]

(PFF ¶ 530 (RX3869 (Cote Expert Report) at ¶ 238; Cote Tr. at 3869).)

Additionally, [redacted]

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3345. [redacted] (Della Porta (Grail) Tr. 495 (*in camera*)). [redacted] (Della Porta (Grail) Tr. 495-96 (*in camera*)). [redacted] (Della Porta (Grail) Tr. 496 (*in camera*)).

Response to Finding No. 3345:

Respondents have no specific response.

3346. [redacted] (PX4048 (Grail) at 015 (Email from M. Chin, Grail, to C. Della Porta, Grail, attaching Potential Competitors to Galleri, DAC and MRD, Sep. 28, 2020) (*in camera*)).

Response to Finding No. 3346:

The proposed finding is incomplete and misleading. [redacted] (PFF ¶ 530 (RX3869 (Cote Expert Report) at ¶ 238; Cote Tr. at 3869).)

3347. [redacted] (PX4011 (Grail) (Overview of Liquid Biopsy Players) (*in camera*)).

Response to Finding No. 3347:

The proposed finding is incomplete and misleading. [redacted] (PFF ¶ 530 (RX3869 (Cote Expert Report) at ¶ 238; Cote Tr. at 3869).)

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and therefore, the document should be

accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3348. [redacted] (Della Porta (Grail) Tr. 496-97 (*in camera*)).

Response to Finding No. 3348:

The proposed finding is incomplete and misleading. [redacted]

3349. [redacted] (PX4049 (Grail) at 002 (Email from A. Chen, Grail, to M. Young et al., Grail, Jul. 27, 2020) (*in camera*)).

Response to Finding No. 3349:

The proposed finding is incomplete and misleading. Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 35), or in any deposition. It also chose not to call Alice Chen or Gautam Kollu as a witness at trial. As a result, neither Ms. Chen, Mr. Kollu, nor anyone else could provide any context for the meaning of certain terms like [redacted]

[redacted]. Therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

In any event, [redacted] (PFF ¶ 530 (RX3869 (Cote Expert Report) at ¶ 238; Cote Tr. at 3869).)

3350. [redacted] (PX6049 (Grail) at 037 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 3350:

The proposed finding is incomplete and misleading. [redacted] (PFF ¶ 530 (RX3869 (Cote Expert Report) at ¶ 238; Cote Tr. at 3869).)

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 55), or in any deposition, and therefore, the document should be

accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

(5) [redacted]

(a) [redacted]

3351. [redacted]

Response to Finding No. 3351:

The proposed finding is incomplete and misleading insofar as it suggests [redacted] (PFF ¶¶ 508–09.) The evidence suggests that [redacted] (PFF ¶¶ 509–10.) There is no evidence based on [redacted]. (PFF ¶ 511 (RX3869 (Cote Expert Report) ¶ 227; [redacted]).) [redacted] Respondents incorporate their responses to CCFF ¶¶ 420, 928 and 2216 herein.

3352. [redacted]

Response to Finding No. 3352:

The proposed finding is inaccurate, incomplete and misleading. [redacted] "***We are not focused on asymptomatic cancer screening or early detection***." (PFF ¶ 526.3.) Further, [redacted] Accordingly, there is no evidence based on [redacted]. (PFF ¶ 511 (RX3869 (Cote Expert Report) ¶ 227; [redacted]).) Respondents incorporate their responses to CCFF ¶¶ 422, 928 and 2216 herein.

(b) [redacted]

3353. [redacted]

Response to Finding No. 3353:

The proposed finding is incomplete and misleading including insofar as it suggests that [redacted]. (PFF ¶ 511; RX3869 (Cote Expert Report) ¶ 227; [redacted].) Respondents also incorporate their responses to CCFF ¶ 3352 herein.

The proposed finding is also not supported by the cited evidence because [redacted] 3354. [redacted]

Response to Finding No. 3354:

The proposed finding is incomplete and misleading . Respondents incorporate their responses to CCFF ¶¶ 420, 422, 3352–53 herein. Respondents also note that even other purported MCED test developers recognize that [redacted] Dr. Lengauer of Exact/Thrive testified at trial that [redacted] (Lengauer (Exact/Thrive) Tr. 206.) Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents incorporate their responses to CCFF ¶ 424 herein.

3355. [redacted]

Response to Finding No. 3355:

The proposed finding is incomplete and misleading. There is no evidence based on [redacted]. (PFF ¶ 511; RX3869 (Cote Expert Report) ¶ 227; [redacted].) Respondents also incorporate their responses to CCFF ¶¶ 928, 2216, 3352–53 herein.

Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3356. [redacted]

[redacted]

Response to Finding No. 3356:

The proposed finding is incomplete and misleading. There is no evidence based on [redacted] (PFF ¶ 511; RX3869 (Cote Expert Report) ¶ 227; [redacted].) Respondents also incorporate their responses to CCFF ¶¶ 928, 2216, 3352–53 herein.

Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3357. [redacted]

Response to Finding No. 3357:

The proposed finding is incomplete and misleading. There is no evidence based on [redacted] (PFF ¶ 511; RX3869 (Cote Expert Report) ¶ 227; [redacted].) Respondents also incorporate their responses to CCFF ¶¶ 928, 2216, 3352–53 herein.

Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(c) [redacted]

3358. [redacted] (PX4037 (Grail) at 008 (Email from C. Della Porta, Grail, to H. Fitzpatrick, Health Advances, et. al, attaching Molecular Screening Industry Report, Nov. 9, 2018) (*in camera*)).

Response to Finding No. 3358:

The proposed finding is inaccurate, incomplete, and misleading. [redacted]

Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 35), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3359. [redacted] (PX4018 (Grail) at 007 (CIA function @ GRAIL) (*in camera*)).

Response to Finding No. 3359:

The proposed finding is incomplete and misleading. [redacted]

[redacted] Thus, GRAIL uses terms like "competitor" and "market" broadly, and those terms do not reflect GRAIL's views of companies it would consider to be in the same relevant product market.

Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market. (PFF ¶ 698.) There is no evidence based on [redacted] (PFF ¶ 511; RX3869 (Cote Expert Report) ¶ 227; [redacted].)

Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3360. Grail competitive intelligence [redacted] (PX4267 (Grail) at 009 (Deep Dive: Competitive Strategy, May 2, 2019) (*in camera*).

Response to Finding No. 3360:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

There is no evidence based on [redacted].)

Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 42), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3361. [redacted] (PX6049 (Grail) at 039 (Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 3361:

The proposed finding is incomplete and misleading. [redacted]

There is no evidence based on [redacted].)

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 55), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

(6) Helio (LAM)

(a) Helio Is Developing an MCED Test

3362. Helio is developing an early detection test for liver cancer and colon cancer. (Chahine (Helio) Tr. 1000, 1033).

Response to Finding No. 3362:

The proposed finding is incomplete and misleading. [redacted]

3363. Dr. Kenneth Chahine, Board Advisor to Helio and former CEO of Helio, testified that Helio's test will eventually evolve into a MCED test: "[W]here GRAIL has chosen to do

multiple cancers at one time, Helio and a few others have taken a strategic approach to say let's get one cancer done right and then add a second and a third and a fourth." (Chahine (Helio) Tr. 1031-32) (further explaining that "it would be hard to find anyone in this industry that would say that all of these tests aren't eventually going to become a multicancer screening test").

Response to Finding No. 3363:

The proposed finding is incomplete and misleading. [redacted]

(b) Helio Considers Grail a Competitor

3364. Dr. Chahine testified: [redacted] (PX7077 (Chahine (Helio) Dep. at 83) (*in camera*)).

Response to Finding No. 3364:

The proposed finding is incomplete and misleading. [redacted]

3365. [redacted] (RX0894 (Helio) at 24 (Helio Health, May 31, 2021) (*in camera*); *see also id.* at 19 [redacted].

Response to Finding No. 3365:

The proposed finding is incomplete and misleading. [redacted]

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (RC Exhibit Index at 49), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3366. [redacted] (PX8655 (Helio) at 031 (Email attaching LAM Company and Technology Overview, Mar. 7, 2019) (*in camera*) ([redacted]).

Response to Finding No. 3366:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 68), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3367. [redacted] (Chahine (Helio) Tr. 1067 (*in camera*); *see also* PX7077 (Chahine (Helio) Dep. at 64, 82-83 (*in camera*)); PX8652 (Helio) at 001 (Helio, Early Cancer Detection Technology & Commercialization Chart, May 20, 2021 (*in camera*)).

Response to Finding No. 3367:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 68), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3368. [redacted] (PX7077 (Chahine (Helio) Dep. at 82-84) (*in camera*)).

Response to Finding No. 3368:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶¶ 3366–67, which Respondents incorporate herein.

3369. [redacted] (Chahine (Helio) Tr. 1112-13 (*in camera*)).

Response to Finding No. 3369:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶¶ 3366–67, which Respondents incorporate herein.

(c) Grail Considers Helio a Competitor

3370. [redacted] (PX4075 (Grail) at 009, 038-43 (Email from A. Aravanis, Grail, to M. Young attaching Competitive Intelligence: An Overview, Aug. 14, 2019) (*in camera*)).

Response to Finding No. 3370:

The proposed finding is incomplete and misleading. [redacted] The proposed finding is also incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including Helio, do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Respondents also incorporate their responses to CCFF ¶ 454–59 herein.

3371. [redacted] (Della Porta (Grail) Tr. 483 (*in camera*)); PX4145 (Grail) at 009 (Grail, "Competitive Intelligence," Aug. 14, 2019 (*in camera*)). [redacted] (Della Porta (Grail) Tr. 483 (*in camera*)). [redacted] (Della Porta (Grail) Tr. 483 (*in camera*)).

Response to Finding No. 3371:

The proposed finding is incomplete and misleading insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. The proposed finding is also incomplete and misleading to the extent it suggests Helio is

developing a product that is reasonably interchangeable with Galleri. (*See* Resps.' Post-Trial Br. at 18.)

First, [redacted]

Second, Respondents also note that Complaint Counsel's own witness, Dr. Lengauer of Thrive, confirmed at trial that [redacted] (Lengauer (Exact/Thrive) Tr. 206.)

Third, as Dr. Katz testified, [redacted] (RRFF ¶ 773 (RX6004 (Katz Trial Dep. at 105) (emphasis added).) Respondents further incorporate their responses to CCFF ¶¶ 454–58 and 773–76 herein.

3372. Grail described "Laboratory for Advanced Medicine" (Helio) as a "competitor" in its SEC S-1 filing. (PX4082 (Grail) at 036 (Email attaching Grail 2020 S-1/Amended, Sept. 2020).

Response to Finding No. 3372:

The proposed finding is incomplete and misleading. [redacted] The S-1 is evidence that

GRAIL refers to competitors more broadly, rather than as those who have products which belong in the relevant product market. GRAIL defined "competitors" in its S-1 as companies "that have stated that they are developing tests designed to detect cancer".

3373. [redacted]
(PX4018 (Grail) at 007 (CIA function @ GRAIL, Nov. 19, 2020) (*in camera*)).

Response to Finding No. 3373:

The proposed finding is incomplete and misleading. [redacted] Thus, GRAIL uses terms like "competitor" and "market" broadly, and those terms do not reflect GRAIL's views of companies it would consider to be in the same relevant product market.

Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market. (PFF ¶ 698.) [redacted]

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and therefore, the document should be

accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3374. [redacted] (PX4250 (Grail) at 011 (Grail, [redacted] (*in camera*)).

Response to Finding No. 3374:

The proposed finding is incomplete and misleading. [redacted]

3375. Grail identified Helio as a company it had been tracking in its "CIA Monthly Newsletter" for December 2020. (PX4129 (Grail) at 001 (Grail, "Grail CIA Monthly Newsletter: December 2020")). Its newsletter noted that Helio "over the last few months has been building a strong leadership team (Ancestry, Amazon)." (PX4129 (Grail) at 001 (Grail, "Grail CIA Monthly Newsletter: December 2020")).

Response to Finding No. 3375:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶ 3374, which Respondents incorporate herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 37), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

(7) [redacted]

(a) [redacted]

3376. [redacted]

Response to Finding No. 3376:

The proposed finding is incomplete and misleading insofar as it suggests that [redacted] to GRAIL today or will be a competitor to GRAIL in the foreseeable future. [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 462–65, 807 and 1190 herein.

(b) [redacted]

3377. [redacted]

Response to Finding No. 3377:

The proposed finding is incomplete and misleading including insofar as it suggests that [redacted].

[redacted]

Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3378. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 50) (*in camera*)).

Response to Finding No. 3378:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶¶ 3377–78, which Respondents incorporate herein.

[redacted]

[redacted]

Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3379. [redacted]

Response to Finding No. 3379:

The proposed finding is incomplete and misleading. [redacted]

[redacted] Further, the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (See Resps.' Post-Trial Br. at 275–76.) Respondents incorporate their responses to CCFF ¶ 464 herein.

3380. [redacted] (PX7074 (Perettie (FMI-Roche) Dep. at 174-76 (*in camera*))).

Response to Finding No. 3380:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶¶ 3377–78, which Respondents incorporate herein.

In particular, the cited testimony supports the proposition that [redacted]

(c) [redacted]

3381. As of August 17, 2020, Grail identified [redacted] (PX4052 (Grail) at 045 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)).

Response to Finding No. 3381:

The proposed finding is incomplete and misleading. [redacted] Respondents also incorporate their responses to CCFF ¶¶ 3377–38 herein.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 35), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3382. [redacted] (PX4018 (Grail) at 007 (CIA function @ GRAIL, Nov. 19, 2020) (*in camera*)).

Response to Finding No. 3382:

The proposed finding is incomplete and misleading. [redacted] Thus, GRAIL uses terms like "competitor" and "market" broadly, and those terms do not reflect GRAIL's views of companies it would consider to be in the same relevant product market. [redacted] Respondents also incorporate their responses to CCFF ¶¶ 3377–38 herein.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3383. In an internal memo discussing [redacted] (PX4053 (Grail) at 005 (Highlights from the Cowen 2020 Liquid Biopsy Summit by Cowen) (*in camera*)). [redacted] (PX4053 (Grail) at 005 (Highlights from the 2020 Liquid Biopsy Summit by Cowen) (*in camera*)).

Response to Finding No. 3383:

The proposed finding is incomplete and misleading. [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 3377–38 herein.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 35), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3384. [redacted] (PX6049 (Grail) at 040 (Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 3384:

The proposed finding is incomplete and misleading. [redacted] Respondents also incorporate their responses to CCFF ¶¶ 3377–38 and 2562 herein.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 55), or in any deposition, and therefore, the document should be

accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

(8) Grail Tracked Other Companies as Competitors in the Cancer Screening Space

3385. Grail identified Burning Rock as a competitor in the early cancer detection space in its IPO prospectus. (PX4082 (Grail) at 036, 127 (Email attaching Grail S-1/Amended, Sept. 2020)).

Response to Finding No. 3385:

The proposed finding is irrelevant because it relates to a putative Chinese cancer test developer that Complaint Counsel has not shown will enter the U.S. market in the foreseeable future. Indeed, Complaint Counsel has never even mentioned the putative MCED test developer, Burning Rock. Complaint Counsel did not subpoena or notice any witnesses from Burning Rock. Nor has Burning Rock reached out to the Commission to address this Transaction.

Respondents also note that the S-1 is evidence that GRAIL refers to competitors more broadly, rather than as those who have products which belong in the relevant product market. GRAIL defined "competitors" in its S-1 as companies "that have stated that they are developing tests designed to detect cancer".

3386. Mr. Bishop, Grail's previous CEO, testified that Burning Rock is currently developing a cancer screening test and has declared its intent to develop a multicancer test. (PX7069 (Bishop (Grail) IHT at 124-27)).

Response to Finding No. 3386:

The proposed finding is irrelevant because it relates to a putative Chinese cancer test developer that Complaint Counsel has not shown will enter the U.S. market in the foreseeable future. Indeed, Complaint Counsel has never even mentioned the putative MCED test developer, Burning Rock. Complaint Counsel did not subpoena or notice any witnesses from Burning Rock. Nor has Burning Rock reached out to the Commission to address this Transaction.

Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3387. As of December 2020, Grail CIA Monthly Newsletter identifies Delfi as a competitor. (PX4129 (Grail) at 001 (Grail CIA Monthly Newsletter, Dec. 2020)).

Response to Finding No. 3387:

The proposed finding is irrelevant because Complaint Counsel has never even mentioned the putative MCED test developer, Delfi. Complaint Counsel did not subpoena or notice any witnesses from Delfi. Nor has Delfi reached out to the Commission to address this Transaction.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 37), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3388. [redacted] (PX6049 (Grail) at 037, 041 (Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 3388:

The proposed finding is irrelevant because it relates to a [redacted]

Similarly, the proposed finding is irrelevant because Complaint Counsel has never even mentioned [redacted]

[redacted]

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 55), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

b) [redacted]

3389. [redacted] (*See, e.g.*, (PX4066 (Grail) at 003 (Email from Hans Bishop, Grail, to C. Della Porta, Grail, et al., July 14, 2019); PX4005 (Grail) at 001 (Email from V. Demas, Grail, to Grail's Executive Leadership Team, et al., Sept. 28, 2020); PX4053 (Grail) at 001 (Highlights from the 2020 Liquid Biopsy Summit by Cowen) (*in camera*)); PX4021 (Grail) at 001 (Email from R. Currie, Grail, to H. Bishop, et al., Sept. 16, 2020); PX4519 (Grail) at 001 (Email from J. Owens, Grail, to C. Arnold, July 9, 2019); PX4046 (Grail) at 094 (Board of Directors Meeting, Feb. 14, 2019) (*in camera*); PX4111 (Grail) at 001 (Email from H. Bishop, Grail, to A. Freidin, Grail, et al., Oct. 27, 2020); PX4241 (Grail) at 002 (Email from H. Bishop, Grail, to A. Jamshidi, Grail, et al., July 7, 2020) (*in camera*).

Response to Finding No. 3389:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

[redacted] Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted], Singlera, Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–06), and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698).

Respondents further note that Complaint Counsel chose not to discuss PX4005, PX4053, PX4021, PX4519, PX4046, PX4111 or PX4241 at trial, (CC Exhibit Index at 34; 35; 37; 41; 51), or in any deposition, and therefore, the documents should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from them.

3390. Grail's Form S-1, which was filed with the SEC in September 2020, states that the "testing and diagnostics products industry is intensely competitive." (PX4082 (Grail) at 036 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 3390:

The proposed finding is incomplete and misleading. The S-1 is evidence that GRAIL refers to competitors more broadly, rather than as those who have products which belong in the relevant product market. GRAIL defined "competitors" in its S-1 as companies "that have stated that they are developing tests designed to detect cancer".

3391. In August 2020, Grail identified [redacted] (PX4052 (Grail) at 012 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)).

Response to Finding No. 3391:

The proposed finding is incomplete and misleading. [redacted] Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted] Singlera, Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–06), and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698).

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 35), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3392. In a document labeled [redacted] (PX4150 (Grail) at 008 (Market Access & Evidence Subteam Charters) (*in camera*)).

Response to Finding No. 3392:

The proposed finding is incomplete and misleading. [redacted] Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted] Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–06), and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698).

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 38), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3393. In a document labeled [redacted] (PX4150 (Grail) at 032 (Market Access & Evidence Subteam Charters) (*in camera*)).

Response to Finding No. 3393:

The proposed finding is incomplete and misleading. [redacted] Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted] Singlera, Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–06), and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698).

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 38), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

(1) Background on Grail Competitive Intelligence Team ("CIA Team")

3394. [redacted] (PX7069 (Bishop (Grail) IHT at 35-36) (*in camera*)).

Response to Finding No. 3394:

The proposed finding is vague and misleading without further context. [redacted] The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted] Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–06) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

[redacted]

[redacted]

Furthermore, the proposed finding relies in part on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.).

3395. Grail's CIA team was founded in 2018. (Della Porta (Grail) Tr. 465).

Response to Finding No. 3395:

Respondents have no specific response.

3396. Grail's CIA team doubled in size from 2018 to 2021. (Della Porta (Grail) Tr. 465-67).

Response to Finding No. 3396:

Respondents have no specific response except to note that this "doubling" resulted in a team size of only ten people. (Della Porta (GRAIL) Tr. 465-67.)

3397. Grail's Senior Director of Growth Strategy, Mr. Della Porta, was the co-lead of Grail's CIA team until January 2021. (Della Porta (Grail) Tr. 465-67).

Response to Finding No. 3397:

Respondents have no specific response.

3398. In Mr. Della Porta's role as co-lead of the competitive intelligence team, he responded to specific requests for information from Grail leadership. (Della Porta (Grail) Tr. 466).

Response to Finding No. 3398:

Respondents have no specific response.

3399. [redacted] (PX4075 (Grail) at 001 (Email from A. Aravanis, Grail, to M. Young, attaching Competitive Intelligence: An Overview, Aug. 14, 2019) (*in camera*); *see* PX7083 (Bishop (Grail) Dep. at 48)).

Response to Finding No. 3399:

The proposed finding is misleading without further context. [redacted]

[redacted]

3400. [redacted] (Bishop (Grail) Tr. 1473 (*in camera*); Della Porta (Grail) Tr. 465). The CIA Team's role is to monitor industry developments that were relevant to Grail. (Della Porta (Grail) Tr. 467). [redacted] (Bishop (Grail) Tr. 1473 (*in camera*); *see also* PX7083 (Bishop (Grail) Dep. at 55-56); PX7069 (Bishop (Grail) IHT at 35-36, 38) (*in camera*)).

Response to Finding No. 3400:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394 and 3399 herein. Furthermore, the proposed finding relies in part on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.).

The proposed finding is misleading to the extent it [redacted]

[redacted]

3401. Grail's competitive intelligence team ("CIA Team") surveyed the scientific and commercial landscape in the context of cancer screening and related technologies. (Della Porta (Grail) Tr. 467-68).

Response to Finding No. 3401:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394 and 3399 herein.

3402. Grail's competitive intelligence team ("CIA Team") created competitive updates from conferences, profiles of technologies of interest, slide shows, and reports. (Della Porta (Grail) Tr. 468-69).

Response to Finding No. 3402:

Respondents have no specific response.

3403. Grail's Competitive Intelligence Team ("CIA team") would "meet every 4-6 weeks or at leadership's request to analyze significant events in [Grail's] space (e.g., conferences, earnings, publications)." (PX4263 (Grail) at 001 (Email from C. Della Porta, Grail, to C. Arnold, Grail, Apr. 12, 2019)).

Response to Finding No. 3403:

Respondents have no specific response

(a) Grail's "CIA Team" Was Designed to Address a Number of Grail Commercial Objectives

3404. The [redacted] (PX4018 (Grail) at 002 (CIA function @ GRAIL, last modified Nov. 19, 2020) (*in camera*); PX4444 (Grail) at 002 (Potential Competitors to Galleri, DAC and MRD, Sept. 28, 2020) (*in camera*)).

Response to Finding No. 3404:

The proposed finding is misleading. Respondents incorporate their responses to CCFF ¶¶ 3394 and 3399 herein.

The proposed finding is also misleading to the extent it [redacted]

Respondents note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34; 48), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3405. Chris Della Porta, Grail's Senior Director of Group Strategy, described the primary objective of Grail's CIA team as to "ensure GRAIL's commercial and product development strategies incorporate a rapidly evolving market landscape," which includes efforts to "ensure [Grail's] leadership is armed with knowledge of competitive strategies and tactics." (PX4263 (Grail) at 001 (Email from C. Della Porta, Grail, to C. Arnold, Grail, April 12, 2019)).

Response to Finding No. 3405:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394 and 3399 herein.

The proposed finding is also misleading to the extent it [redacted]

[redacted]

3406. In July 2020, Vicky Demas, Grail's Platform Product Manager and New Products Program Lead, wrote [redacted]

- [redacted]
- [redacted]
- [redacted]

(PX4321 (Grail) at 001, Email from V. Demas, Grail, to Grail's Executive Leadership Team, July 16, 2020) (*in* camera); *see* PX4207 (Grail) at 005 (Competitive Intelligence Updates: Deep Dive, June 9, 2020) (*in camera*) ([redacted]).

Response to Finding No. 3406:

The proposed finding is misleading. Respondents incorporate their responses to CCFF ¶¶ 3394 and 3399 herein.

Respondents note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 44), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3407. [redacted] (Della Porta (Grail) Tr. 497 (*in camera*)).

Response to Finding No. 3407:

The proposed finding is misleading to the extent it [redacted]

3408. [redacted] (Della Porta (Grail) Tr. 478-79 (*in camera*); PX4145 (Grail) at 006 (Competitive Intelligence, Aug. 14, 2019) (*in camera*) ([redacted]).

Response to Finding No. 3408:

Respondents have no specific response except to note that [redacted]

[redacted]

3409. [redacted] (Della Porta (Grail) Tr. 478 (*in camera*)). [redacted] (Della Porta (Grail) Tr. 478, 583 (*in camera*); *see also* Della Porta (Grail) Tr. 478, 583 (*in camera*) (stating that [redacted]).

Response to Finding No. 3409:

The proposed finding is misleading. Respondents incorporate their responses to CCFF ¶¶ 3407 and 3408 herein.

3410. Grail's clinical development team analyzes the clinical trials of other companies that are developing MCED tests. (Della Porta (Grail) Tr. 582-83).

Response to Finding No. 3410:

The proposed finding is misleading. Respondents incorporate their response to CCFF ¶ 3407 herein.

The proposed finding is misleading to the extent it [redacted]

3411. [redacted] (Della Porta (Grail) Tr. 476 (*in camera*)). [redacted] Della Porta (Grail) Tr. 476 (*in camera*)). [redacted] (Della Porta (Grail) Tr. 476 (*in camera*)).

Response to Finding No. 3411:

The proposed finding is misleading without further context. Respondents incorporate their response to CCFF ¶ 3407 herein.

3412. [redacted] (Della Porta (Grail) Tr. 477, 480-81 (*in camera*) ([redacted]).

Response to Finding No. 3412:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394 and 3399 herein.

3413. [redacted]

[redacted] (PX4075 (Grail) at 008 (Email from A. Aravanis, Grail, to M. Young, attaching Competitive Intelligence: An Overview, Aug. 14, 2019) (*in camera*)). [redacted] (Bishop (Grail) Tr. 1477 (*in camera*)).

Response to Finding No. 3413:

The proposed finding is misleading without further context. [redacted]

Respondents also incorporate their responses to CCFF ¶¶ 3394 and 3399 herein.

3414. Grail's CIA team began circulating a "Grail CIA Monthly Newsletter" that highlights news about relevant competitors in December 2020. (*See, e.g.*, PX4129 (Grail) (Grail CIA Monthly Newsletter, Dec. 2020); PX4059 (Grail) (Grail CIA Monthly Newsletter, Jan. 2021)). Grail circulated its "CIA Monthly Newsletter" to its Executive Leadership Team and others within the company. (*See, e.g.*, PX4131 (Grail) at 001-02 (Email from V. Demas, Grail, to Grail Executive Leadership Team, et al., Jan. 31, 2021)). To describe the newsletter, Grail's CIA team explained—"the team keeps top competitor summaries updated but also coordinates and consumes inputs from functional teams which we will be sharing in a monthly newsletter: Field Intelligence (work with sales – scope broader), Conference intelligence (MSL + Medical comms), MSL Intelligence (2nd degree information), Stakeholder events (what companies work with which KOLs), Investor conferences, Pub reviews (Medical comms), [and] Literature reviews and company assessments (R&D/New Products)." (PX4129 (Grail) at 001 (Grail CIA Monthly Newsletter, Dec. 2020)).

Response to Finding No. 3414:

The proposed finding is misleading. Respondents incorporate their responses to CCFF ¶¶ 3394 and 3399 herein. Respondents further note that Complaint Counsel chose not to discuss any

of the three cited documents at trial, (CC Exhibit Index at 35; 37), or in any deposition, and therefore, the documents should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from them..

(b) "CIA Team" Work Product Is Used Widely Across a Variety of Grail Business Functions

3415. Chris Della Porta, Grail's Director of Growth Marketing, testified that accuracy was one of the competitive intelligence team's ("CIA Team") goals because of the various uses of the CIA Team's work. (Della Porta (Grail) Tr. 469-70). He further elaborated that the CIA Team tried to present information that was up to date. (Della Porta (Grail) Tr. 470).

Response to Finding No. 3415:

Respondents have no specific response except to note that [redacted]

3416. [redacted] (PX4075 (Grail) at 008 (Email from A. Aravanis, Grail, to M. Young, Grail, et al., attaching "Competitive Intelligence: An Overview," Sept. 7, 2019) (*in camera*)).

Response to Finding No. 3416:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394 and 3399 herein.

3417. Gautam Kollu, Grail's Chief Commercial Officer, shared competitive intelligence team slides with Grail's Board of Directors. (Della Porta (Grail) Tr. 469).

Response to Finding No. 3417:

Respondents have no specific response.

3418. In February 2019, Alex Aravanis, Grail's then-Chief Scientific Officer and Head of R&D, and Onaiza Cadoret-Manier, Grail's then-Chief Commercial Officer, presented a [redacted]

[redacted] (PX4046 (Grail) at 094 (Competitive Overview, Feb. 14, 2019) (*in camera*)).

Response to Finding No. 3418:

The proposed finding is misleading without further context.

[redacted] Similarly, in the DETECT-A study of Exact/Thrive's CancerSEEK test, the researchers noted that "we cannot be certain that the DETECT-A blood test used in our study helped any participant." (RX3419 (Exact/Thrive) at 11.)

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 35), or in any deposition, and therefore, the document should be

accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3419. Reports from Grail's CIA team were shared with Grail's Board of Directors, finance teams, and investor relations teams. (Della Porta (Grail) Tr. 469).

Response to Finding No. 3419:

Respondents have no specific response other than to note that Mr. Della Porta also testified that he did not have "personal experience" regarding how Dr. Kollu would share CIA slides with the Board of Directors. (Della Porta (Grail) Tr. 469). He also did not "have experience with . . . how [the finance team] used" the CIA materials. (Della Porta (Grail) Tr. 469). Complaint Counsel never sought to obtain any testimony from a witness familiar with these reports and the cited testimony should be accorded little weight.

3420. [redacted] (PX7069 (Bishop (Grail) IHT at 36) (*in camera*); *see, e.g.*, PX4129 (Grail) (Grail CIA Monthly Newsletter, Dec. 2020)).

Response to Finding No. 3420:

The proposed finding is inaccurate. [redacted]

The proposed finding also relies in part on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.). Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 37), or in any deposition, and therefore, the

document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3421. [redacted]

[redacted]

(PX4145 (Grail) at 008 (Competitive Intelligence, Aug. 14, 2019) (*in camera*) [redacted]).

Response to Finding No. 3421:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394, 3399, and 3407 herein. [redacted]

3422. [redacted]

[redacted]

(PX4145 (Grail) at 047 (Competitive Intelligence, Aug. 14, 2019) (*in camera*); PX4075 (Grail) at 046 (Email from A. Aravanis, Grail, to M. Young, Grail, et al., attaching "Competitive Intelligence," Sept. 7, 2019) (*in camera*)).

Response to Finding No. 3422:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394, 3399, 3407, and 3421 herein.

3423. Mike Vicari, Grail's SVP of Sales, noted in an email that Grail's "legal team" uses the "type of information" provided by its CIA team to "[begin] looking at the side of patent infringement with all early stage companies in [Grail's] space." (PX4131 (Grail) at 001 (Email from M. Vicari, Grail, to Grail employees, Feb. 1, 2021)).

Response to Finding No. 3423:

The proposed finding is irrelevant. Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 37), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

(2) Grail "CIA Team" Work Product Identifies Numerous Competitors to Grail and Galleri

3424. [redacted] (Della Porta (Grail) Tr. 503-04 (*in camera*)).

Response to Finding No. 3424:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394 and 3399 herein. [redacted]

[redacted]

3425. [redacted] (PX4037 (Grail) at 008 (Email from C. Della Porta, Grail, to H. Fitzpatrick, Health Advances, et. al, attaching "Molecular Screening Industry Report," Nov. 9, 2018) (*in camera*); PX4267 (Grail) at 012 (Deep Dive Competitive Strategy, May 2, 2019) (*in camera*); PX4145 (Grail) at 006 (Competitive Intelligence, Aug. 14, 2019) (*in camera*); PX4048 (Grail) at 004 (Email from M. Chin, Grail, to C. Della Porta, Grail, attaching "Potential Competitors to Galleri, DAC and MRD," Nov. 19, 2020) (*in camera*); PX4350 (Grail) at 009 (Email from D. Lockhead, Grail, to S. Lemons, L.E.K. Consulting, et al., attaching "RFP: Grail Competitive Landscape 2021," Mar. 16, 2021) (*in camera*)).

Response to Finding No. 3425:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394 and 3399 herein. Respondents also note that Complaint Counsel chose not to discuss these documents at trial, (CC Exhibit Index at 35; 42; 45), or in any deposition, and therefore, the documents should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from them.

3426. [redacted] (Della Porta (Grail) Tr. 473 (*in camera*)).

Response to Finding No. 3426:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394 and 3399 herein.

3427. In a chart labeled [redacted] (PX4018 (Grail) at 006-07 (CIA function @ GRAIL) (*in camera*)). Grail's assessments [redacted] (PX4018 (Grail) at 006-07 (CIA function @ GRAIL) (*in camera*) ([redacted])).

Response to Finding No. 3427:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394 and 3399 herein. Respondents also note that [redacted]

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3428. Grail identified [redacted] (PX4018 (Grail) at 005 (CIA function @ GRAIL) (*in camera*)).

Response to Finding No. 3428:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394, 3399, 3427 and 3462 herein. Respondents particularly note that [redacted]

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and therefore, the document should be

accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3429. [redacted] (PX4259 (Grail) at 001 (Email from C. Della Porta, Grail, to J. Ofman, Grail, et al., Jul. 22, 2019) (*in camera*)).

Response to Finding No. 3429:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394 and 3399 herein.

3430. [redacted] (PX4259 (Grail) at 001 (Email from C. Della Porta, Grail, to J. Ofman, Grail, et al., Jul. 22, 2019) (*in camera*)). [redacted] (PX4259 (Grail) at 001 (Email from C. Della Porta, Grail, to J. Ofman, Grail, et al., Jul. 22, 2019) (*in camera*)).

Response to Finding No. 3430:

The proposed finding is incomplete and misleading without additional context. As explained in the immediately preceding sentence in the cited source, [redacted]

[redacted]

3431. [redacted] (Della Porta (Grail) Tr. 475 (*in camera*)).

Response to Finding No. 3431:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394, 3399, and 3430 herein.

3432. [redacted] (PX4259 (Grail) at 001 (Email from C. Della Porta, Grail, to J. Ofman, Grail, et al., Jul. 22, 2019) (*in camera*)).

Response to Finding No. 3432:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394, 3399, and 3430 herein.

3433. [redacted] (PX4037 (Grail) at 008 (Email from C. Della Porta, Grail, to H. Fitzpatrick,

Health Advances, et al., attaching "Molecular Screening Industry Report," Nov. 9, 2018) (*in camera*)).

Response to Finding No. 3433:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394, 3399, and 3430 herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 35), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted] Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

3434. [redacted] (PX4145 (Grail) at 009 (Competitive Intelligence, Aug. 14, 2019) (*in camera*)).

Response to Finding No. 3434:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394, 3399, and 3430 herein.

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, Helio and , do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

3435. In a May 2019 internal presentation labeled (PX4267 (Grail) at 009 (Deep Dive: Competitive Strategy, May 2, 2019) (*in camera*)). Grail specifically (PX4267 (Grail) at 009 (Deep Dive: Competitive Strategy, May 2, 2019) (*in camera*); *see also* PX4267 (Grail) at 009 (Grail, "Deep Dive: Competitive Strategy," May 2, 2019) (*in camera*) (chart tracking).

Response to Finding No. 3435:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394, 3399, 3430 and 3462 herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 42), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel,

including Guardant, Freenome, [redacted] Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

3436. [redacted] (PX4075 (Grail) at 008 (Email from A. Aravanis, Grail, to M. Young, Grail, et al., attaching "Competitive Intelligence," Sept. 7, 2019) (*in camera*)). [redacted] (Bishop (Grail) Tr. 1478-79 (*in camera*)).

Response to Finding No. 3436:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394, 3399, and 3430 herein.

3437. [redacted] (PX4075 (Grail) at 046 (Email from A. Aravanis, Grail, to M. Young, Grail, et al., attaching "Competitive Intelligence," Sept. 7, 2019) (*in camera*)).

Response to Finding No. 3437:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394, 3399, and 3430 herein.

3438. In March 2020, Grail identified [redacted] (PX4450 (Grail) at 241-42 (Email from M. Morgan, Grail, to L. Mansolillo, Grail, attaching "Commercial Competitive Strategy") (*in camera*)).

Response to Finding No. 3438:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394, 3399, 3430 and 3462 herein. [redacted]

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 49), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3439. In an internal presentation about [redacted] (PX4387 (Grail) at 043 (Galleri Commercial Approach, Q1 2020) (*in camera*)).

Response to Finding No. 3439:

Respondents incorporate their responses to CCFF ¶¶ 3394 and 3399 herein. [redacted] Respondents note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at

46), or in any deposition, so no witnesses could explain the meaning of this term or provide any other context for its use in this slide. Therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

[redacted] However, these challenges will be alleviated with Illumina's assistance and expertise. *See* Freidin (GRAIL) Tr. 2974 (discussing demonstrative RDX0010-2 outlining efficiencies of transaction).) Illumina would be able to accelerate GRAIL's centralized laboratory efforts due to Illumina's extensive experience "run[ning] labs, process[ing] lots of tests, more so than we [GRAIL] have." (Freidin (GRAIL) Tr. 3007-08.) In fact, Illumina's facilities are capable of running millions of tests per year, including Galleri, and have done so for years. (deSouza (Illumina) Tr. 2370–72.)

3440. [redacted] (PX4093 (Grail) at 020 (Overview – ILMN) (*in camera*)).

Response to Finding No. 3440:

The proposed finding is inherently speculative and misleading without further context.

[redacted]

[redacted]

3441. [redacted] (PX4093 (Grail) at 020 (Overview – ILMN) (*in camera*)).

Response to Finding No. 3441:

Respondents incorporate their response to CCFF ¶ 3440 herein. Respondents additionally note that [redacted]

3442. [redacted] (PX4093 (Grail) at 020 (Overview – ILMN) (*in camera*) (brackets in original)).

Response to Finding No. 3442:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3440 and 3441 herein.

3443. [redacted] (PX4093 (Grail) at 020 (Overview – ILMN) (*in camera*) (brackets in original)).

Response to Finding No. 3443:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3440 and 3441 herein. Respondents also note that the cited document states that LUNAR-2 is intended for high-risk individuals, which is different from the intended use for Galleri, which is not intended exclusively for high-risk individuals. (PFF ¶ 727; PX0043 (GRAIL) at 5.) Respondents further note that Mr. Getty of Guardant testified that "[i]n the context of the blood-based screening market, which is yet to evolve to its maturity, it would be very difficult to speculate about the relevancy of price." (PFF ¶ 748; PX7105 (Getty (Guardant) Dep. at 106–07).)

3444. [redacted] (PX4284 (Grail) at 012 (Email from J. Ayers, W2O, to M. Burns, Grail, attaching "2020 Corporate Communications Plan," May 20, 2020) (*in camera*)).

Response to Finding No. 3444:

The proposed finding is irrelevant and misleading without further context. [redacted]

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted] Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 43), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3445. In June 2020, [redacted] (PX4207 (Grail) at 013 (Competitive Intelligence Updates: Deep Dive, Jun. 9, 2020) (*in camera*)). [redacted] (PX4207 (Grail) at 013 (Competitive Intelligence Updates: Deep Dive, Jun. 9, 2020) (*in camera*)). Grail's presentation included [redacted] (PX4207 (Grail) at 013 (Competitive Intelligence Updates: Deep Dive, Jun. 9, 2020) (*in camera*)).

Response to Finding No. 3445:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394, 3399 and 3462 herein.

[redacted]

[redacted]

Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 40), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3446. [redacted] (PX4554 (Grail) at 003 (Thrive Red Team Questions) (*in camera*)).

Response to Finding No. 3446:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394 and 3399 herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 52), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3447. In an internal presentation dated August 17, 2020, Grail discussed [redacted] (PX4052 (Grail) at 039 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)). [redacted] (PX4052 (Grail) at 039 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)).

Response to Finding No. 3447:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394, 3399 and 3462

herein. Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 35), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted] Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

3448. In an internal presentation dated August 17, 2020, Grail identified [redacted] (PX4052 (Grail) at 040 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)). [redacted] (PX4052 (Grail) at 040 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)).

Response to Finding No. 3448:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394 and 3399 herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 35), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

The proposed finding is incomplete and misleading to the extent that it suggests that Exact/Thrive's PET-CT based approach in CancerSEEK is superior to Galleri's molecular approach for identifying the cancer signal of origin.

To the contrary, full-body PET-CT is a fairly poor tool for cancer signal of origin determination. This is reflected in Exact/Thrive's own study. Of the 53 patients identified by PET-CT as having imaging concerning for cancer in Exact/Thrive's DETECT-A study, only 15 was determined to have cancer, with only a 28.3% detection rate, compared with the 88.7% accuracy of cancer signal of origin prediction achieved by GRAIL's Galleri v1 in the CCGA3 study. (*See* PFF ¶¶ 426.3–426.4.) [redacted]; and the Cohen study found the PET-CT approach is not well suited to be a primary screening modality for the general population also because it is financially and operationally impractical (Conroy (Exact/Thrive) Tr. 1707–08). (*See* PFF ¶ 1700.)

Dr. Lengauer of Exact/Thrive admitted that a diagnostic full-body PET-CT confers a higher radiation exposure than a standard CT; the radiation exposure from diagnostic PET-CT and follow-up imaging tests in the participants without cancer is a recognized source of potential harm associated with the DETECT-A CancerSEEK protocol; investigators of the DETECT-A trial recognized that the diagnostic PET-CT scans are not well suited to be the primary screening modality for the general population, in part because of a low disease prevalence and a relatively

high rate of incidental findings; and even after the full-body PET-CT scan, there may be a need to do additional biopsies to further characterize the cancer. (*See* Lengauer (Exact/Thrive) Tr. 248–50; PFF ¶ 1724.)

3449. As of August 2020, Grail identified [redacted] (PX4052 (Grail) at 044 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)). [redacted] (PX4052 (Grail) at 039 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)).

Response to Finding No. 3449:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394, 3399 and 3462 herein. Respondents emphasize that [redacted]

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel,

including Guardant, Freenome, [redacted] Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

3450. As of August 17, 2020, Grail identified [redacted] (PX4052 (Grail) at 045 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)). [redacted] (PX4052 (Grail) at 039 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)).

Response to Finding No. 3450:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394, 3399 and 3462 herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 35), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted] Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶

698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

3451. An internal Grail presentation recognized [redacted] (PX4016 (Grail) at 007 (Grail Strategy Planning Roadmap (Workshop #2), Sept. 2, 2020) (*in camera*)).

Response to Finding No. 3451:

The proposed finding is misleading. Respondents further incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394 and 3399 herein.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3452. [redacted] (PX4048 (Grail) at 005 (Email from M. Chin, Grail, to C. Della Porta, Grail, attaching "Potential Competitors to Galleri, DAC and MRD," Nov. 19, 2020) (*in camera*)). [redacted] PX4048 (Grail) at 005 (Email from M. Chin, Grail, to C. Della Porta, Grail, attaching "Potential Competitors to Galleri, DAC and MRD," Nov. 19, 2020) (*in camera*)).

Response to Finding No. 3452:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394, 3399, 3453 and 3462 herein. [redacted]

[redacted] Thus, the document does not support the inference that Galleri faces any competition in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted] Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–06) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698).

3453. [redacted] (PX4048 (Grail) at 005 (Email from M. Chin, Grail, to C. Della Porta, Grail, attaching "Potential Competitors to Galleri, DAC and MRD," Nov. 19, 2020) (*in camera*)).

Response to Finding No. 3453:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394 and 3399 herein. Respondents also note that [redacted]

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that GRAIL is planning to incorporate [redacted] into its Galleri test.

To the contrary, GRAIL has locked version 2 of Galleri, which is the version currently on the market, and is working on an updated version of Galleri that meets current performance standards while sequencing fewer regions of the genome, thereby reducing the cost of the test. (PFF ¶ 1607 (Ofman (GRAIL) Tr. 3301–03.) GRAIL does not plan to incorporate cfRNA as an analyte into the Galleri test. (Ofman (GRAIL) Tr. 3304 (testifying that GRAIL does not have any plans at this time to modify its Galleri test to include other biomarkers apart from ctDNA).) Respondents also incorporate their responses to CCFF ¶¶ 306, 308 and 312 herein.

3454. [redacted] (PX4016 (Grail) at 006 (Grail Strategy Planning Roadmap (Workshop #2), Sep. 2, 2020) (*in camera*)).

Response to Finding No. 3454:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394 and 3399 herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3455. [redacted] (Della Porta (Grail) Tr. 510-12 (*in camera*); PX4444 (Grail) at 002 (Email from M. Morgan, Grail, to M. Chin, et al., attaching "Potential Competitors to Galleri, DAC and MRD," Oct. 23, 2020) (*in camera*)).

Response to Finding No. 3455:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394, 3399 and 3462 herein. [redacted]

[redacted] Thus, the document does not support the inference that Galleri faces any competition in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted] Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–06) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698).

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 48), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3456. As a "Field Intelligence Update" from its "CIA Monthly Newsletter" for December 2020, Grail noted that it "anticipate[s] as Thrive (and future other competitors) get closer to launch, they will use tactics to sell against Grail." (PX4129 (Grail) at 002 (Grail CIA Monthly Newsletter, Dec. 2020)).

Response to Finding No. 3456:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394, 3399 and 3462 herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 37), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3457. Grail sent an [redacted] (PX4337 (Grail) at 005-08 (Email from D. Lockhead, Grail, to Brigitte Ganter, Englightenbio, et al., attaching "RFP: Grail Competitive Landscape 2021," Mar. 16, 2021) (*in camera*); PX4350 (Grail) at 001 (Email from D. Lockhead, Grail, to S. Lemons, L.E.K. Consulting, et al., attaching "RFP: Grail Competitive Landscape 2021," Mar. 16, 2021) (*in camera*)). Grail requested [redacted] (PX4337 (Grail) at 006-07 (Email from D. Lockhead, Grail, to Brigitte Ganter, Englightenbio, et al., attaching "RFP: Grail Competitive Landscape 2021," Mar. 16, 2021) (*in camera*)). [redacted] (PX4337 (Grail) at 005 (Email from D. Lockhead, Grail, to Brigitte Ganter, Englightenbio, et al., attaching "RFP: Grail Competitive Landscape 2021," Mar. 16, 2021) (*in camera*)).

Response to Finding No. 3457:

The proposed finding is compound and misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394, 3399 and 3462 herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 44), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted] Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer

early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

3458. In May 2021, Grail prepared a report on the 2021 AACR Conference. Twenty-seven Grail employees of Grail's Medical Affairs, Research & Development, and Bioinformatics groups are credited with contributing to the report. (PX4616 (Grail) at 007-09 (AACR 2021 Conference Report, May 5, 2021); Ofman (Grail) Tr. 3421-22 (*in camera*) [redacted].

Response to Finding No. 3458:

Respondents have no specific response.

3459. Grail's "Executive Summary: MCED" for its internal report on the 2021 AACR Conference states: "MCED evolving into highly competitive landscape, though many seem to be starting with one cancer type, with intent to add more." (PX4616 (Grail) at 017 (AACR 2021 Conference Report, May 5, 2021)).

Response to Finding No. 3459:

Respondents have no specific response except to note that [redacted]

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted] Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer

simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

3460. Grail hired a company, Crayon, to "supplement and enhance [its] ongoing tracking of top competitors and key market trends such as sales related / launches, hiring and web page content changes, and executive/leadership changes, and to assist with report/summary generation." (PX4129 (Grail) at 001 (Grail CIA Monthly Newsletter, Dec. 2020); PX4059 (Grail) at 004 (Grail CIA Monthly Newsletter, Jan. 2021)). Grail's "CIA Monthly Newsletter" for January 2021 noted that Grail had started to work with Crayon to "create reports and battle cards." (PX4059 (Grail) at 004 (Grail CIA Monthly Newsletter, Jan. 2021)). Vicky Demas, Grail's Platform Product Manager and New Products Program Lead, provided [redacted] (PX4353 (Grail) at 003-04 (Email from V. Demas, Grail, to W. Cameron, Crayon, Dec. 23, 2020) (*in camera*)). Dr. Demas later explained in an email dated April 1, 2021: [redacted] (PX4359 (Grail) at 001-02 (Email from V. Demas, Grail, to D. Lockhead, Grail, et al., Apr. 1, 2021) (*in camera*)).

Response to Finding No. 3460:

The proposed finding is compound and misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 3394, 3399 and 3462 herein. Respondents further note that Complaint Counsel chose not to discuss these documents at trial, (CC Exhibit Index at 35; 37; 45), or in any deposition, and therefore, the documents should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from them.

The proposed finding is incomplete and misleading to the extent that it suggests that any test developers other than GRAIL are anywhere close to launching an MCED test in the foreseeable future. Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted] Helio and [redacted], do not expect (and none can

reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents further note that the proposed finding does not suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable.

(3) [redacted]

3461. [redacted] (PX4250 (Grail) at 003 ([redacted] (*in camera*)).

Response to Finding No. 3461:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394, 3399 and 3462 herein. Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 41) and Arash Jamshidi, the sole witness who was shown this document in any deposition or IH (*see* PX7103 (Jamshidi (GRAIL) Dep. at 149–68), "wasn't really involved" in creating the document and did not recall what, if anything, came of it (PX7103 (Jamshidi (GRAIL) Dep. at 152)). Therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it

3462. [redacted] (PX4250 (Grail) at 003, 009 ([redacted] (*in camera*)).

Response to Finding No. 3462:

The proposed finding is misleading without further context. [redacted]

[redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394 and 3399 herein.

3463. [redacted] (PX4250 (Grail) at 009 ([redacted] (*in camera*)).

Response to Finding No. 3463:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3461–62, which Respondents incorporate herein. Further, Dr. Jamshidi testified that the publications listed on the slide [redacted] (PX7103 (Jamshidi (GRAIL) Dep. at 161).) "In addition, Dr. Jamshidi testified, "I don't believe

I made the slide, so I don't know exactly what was the intention when this slide was made." (PX7103 (Jamshidi (GRAIL) Dep. at 156).) Respondents further incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394 and 3399 herein.

3464. [redacted] (PX4250 (Grail) at 012 ([redacted] (*in camera*)).

Response to Finding No. 3464:

Respondents have no specific response except to note that broader strategy, but, you know, technically, for the publications I've seen here, they haven't affected at least my approach in the way that we approach the technical work that we're doing for this.

(4) [redacted]

3465. [redacted] (PX4049 (Grail) at 003 (Email from G. Kollu, Grail, to A. Chen, Grail, et al., July 24, 2020) (*in camera*)).

Response to Finding No. 3465:

The proposed finding is misleading without further context. [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394, 3399, and 3462 herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 35), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3466. In July 2020, Guatam Kollu wrote an email to other Grail executives [redacted] (PX4049 (Grail) at 003 (Email from G. Kollu, Grail, to A. Chen, Grail, et al., July 24, 2020) (*in camera*)).

Response to Finding No. 3466:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394, 3399, 3462 and 3465 herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 35), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3467. [redacted]

[redacted] (PX4049 (Grail) at 003 (Email from G. Kollu, Grail, to A. Chen, Grail, et al., July 24, 2020) (*in camera*)).

Response to Finding No. 3467:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394, 3399, 3462 and 3465 herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 35), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3468. [redacted] (PX4049 (Grail) at 001 (Email from S. Alag, Grail, to A. Chen, Grail, et al., July 28, 2020) (*in camera*)).

Response to Finding No. 3468:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394, 3399, 3462 and 3465 herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 35), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

c) [redacted]

3469. Satnam Alag, Grail's Senior VP of Software Engineering and Chief Security Officer, wrote in a July 2020 email that [redacted] (PX4049 (Grail) at 002 (Email from S. Alag, Grail, to A. Chen, Grail, et al., July 24, 2020) (*in camera*)). [redacted] (PX4049

(Grail) at 002 (Email from A. Chen, Grail, to S. Alag, Grail, et al., July 28, 2020) (*in camera*)).

Response to Finding No. 3469:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394, 3399, 3462 and 3465 herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 3), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3470. [redacted] (PX4027 (Grail) at 002-03 (Email from M. Burns, Grail, to R. Currie, Grail, et al., July 30, 2020) (*in camera*)). [redacted] (PX4027 (Grail) at 001-02 (Email from D. Bhandari, Grail, to J. Ofman, Grail, et al., July 30, 2020) (*in camera*)).

Response to Finding No. 3470:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 755–56, 759, 3231–33, 3245, 3250, 3257, 3394, 3399, 3462 and 3465 herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

d) [redacted]

(1) Illumina Recognizes That Grail Competes with Illumina's Other NGS Customers

3471. At the Cowen Liquid Biopsy Summit on September 21, 2020, Cowen analyst Doug Schenkel asked Francis deSouza, Illumina's CEO, how Illumina's customers are reacting to the Grail deal. (deSouza (Illumina) Tr. 2221-22; PX2575 (Illumina) at 064 (Email from T. Friedman, Illumina, to J. Cunningham, Illumina, attaching Illumina Inc at Cown Liquid Biopsy Summit Transcript, Sept. 29, 2020)). Mr. deSouza responded that, "in a few segments we will provide a vertical solution that could compete with some of our customers." (deSouza (Illumina) Tr. 2221-22; PX2575 (Illumina) at 065 (Email from T. Friedman, Illumina, to J. Cunningham, Illumina, attaching Illumina Inc at Cowen Liquid Biopsy Summit Transcript, Sept. 29, 2020)).

Response to Finding No. 3471:

The proposed finding is incomplete and misleading. The proposed finding does not support the proposition that Illumina recognizes that GRAIL competes with Illumina's other NGS customers. Mr. deSouza only said that in some segments Illumina will provide a vertical solution that *could* compete with its customers.

3472. Mr. deSouza's comments at the Cowen Liquid Biopsy Summit on September 24, 2020 revealed that Illumina analyzed which of its customers a combined Illumina/Grail would compete with: "[A]bout 20 [Illumina] customers out of about 6,600 have said that they have an interest in exploring [the early detection of cancer] space. Those 20 customers represent roughly about 2% of our revenue." (PX2575 (Illumina) at 065 (Email from T. Friedman, Illumina, to J. Cunningham, Illumina, attaching Edited Transcript, ILMN.OQ – Illumina Inc at Cowen Liquid Biopsy Summit (Virtual), Sept. 29, 2020); *see also* deSouza (Illumina) Tr. 2220-22). Mr. deSouza confirmed that those 20 customers include Guardant, Roche, Freenome, Singlera, Exact/Thrive, and Grail. (deSouza (Illumina) Tr. 2220-23; PX2575 (Illumina) at 065 (Email from T. Friedman, Illumina, to J. Cunningham, Illumina, attaching Edited Transcript, ILMN.OQ – Illumina Inc at Cowen Liquid Biopsy Summit (Virtual), Sept. 29, 2020); PX2031 (Illumina) at 005 n.2 (Illumina, Cowen Liquid Biopsy Summit with Francis deSouza, Sept. 24, 2020) (listing Guardant, Thrive, Freenome, Singlera, Exact, and Grail)).

Response to Finding No. 3472:

Respondents have no specific response, except to note that the "roughly 2%" estimate is a reflection of Illumina's *historical* business with those test developers, which says nothing about the future significance of these customers to Illumina's upstream business, or the magnitude of future lost profits that Illumina would incur if it attempted to foreclose them. The evidence

shows that the *future* profits Illumina expects from its clinical customers is substantial. (*E.g.*, PFF ¶ 857.1 (Dr. Aravanis explaining that NGS is still in the "early days" as a "tool for clinical diagnostics", and Mr. deSouza explaining that "we have so much undiscovered in front of us" and that there is "no doubt we will see a lot more clinical applications emerge in the future.").)

The proposed finding is also misleading to the extent it describes [redacted] (RX3869 (Cote Expert Report ¶¶ 174 (Exact/Thrive), 184 (FMI/Roche), 193 (Freenome), 202 (Guardant), 217 (Helio), 227 (Natera), 238 (Singlera)).) [redacted] (PFF ¶¶ 722–740.1), and most of the putative MCED developers identified by Complaint Counsel do not expect (and none can reasonably be expected) to launch a screening test for more than one cancer for many years (PFF ¶¶ 701–706). Respondents also incorporate their responses to CCFF ¶¶ 2612, 2649–2660, 2694 and 2700.

3473. [redacted] (deSouza (Illumina) Tr. 2251-2253 (*in camera*); PX2569 (Illumina) at 008 (Executive Session, Apr. 28, 2020) (*in camera*)).

Response to Finding No. 3473:

The proposed finding is incomplete and misleading. For example, at trial, Mr. deSouza [redacted]

[redacted] Moreover, to the extent that customers have any concerns about the relationship between Illumina and its customers post-acquisition, the Open Offer was created to allay those concerns and ensure that Illumina treats its customers fairly relative to GRAIL and to each other. (*See* PFF ¶¶ 997–1057.)

Further, Mr. deSouza testified that after Illumina "did an exhaustive study of the market . . . and we still don't see anybody in the market that has an offering that's like GRAIL's in terms of looking at 50 cancers, identifying the tissue of origin, and so there really isn't anybody else that we felt, you know, was like GRAIL." (deSouza (Illumina) Tr. 2335.)

Respondents further incorporate their responses to CCFF ¶ 4220 herein.

3474. [redacted] (Berry (Illumina) Tr. 938 (*in camera*)). [redacted] (Berry (Illumina) Tr. 938 (*in camera*)).

Response to Finding No. 3474:

The proposed finding is inaccurate, incomplete and misleading. Later in her testimony, Ms. Berry provided context for this response. [redacted]

3475. Illumina identified "Guardant, Freenome, and Foundation Medicine" as "companies [that] were interested in early detection" of cancer and proactively reached out to them post-merger to discuss a proposed supply agreement. (deSouza (Illumina) Tr. 2429).

Response to Finding No. 3475:

The proposed finding is not supported by the cited testimony and accordingly entirely inaccurate, incomplete and misleading. The quotations cited by Complaint Counsel here are entirely from Complaint Counsel's questions—*not* from Mr. deSouza's testimony. Mr. deSouza testified that Illumina reached out to companies that Illumina believed "*might be interested* in early detection . . . or in that [cancer detection] space *in general*". (deSouza (Illumina) Tr. 2429–30 (emphases added).) [redacted]

3476. [redacted] (deSouza (Illumina) Tr. 2250-51 (*in camera*); PX2549 (Illumina) at 021 (Board of Directors Meeting, Apr. 28, 2020) (*in camera*)).

Response to Finding No. 3476:

The proposed finding is incomplete and misleading as well as contradicted by the weight of the evidence. [redacted] (PX7087 (Goswami (Illumina) IHT at 167.)

Further, Illumina did not consider purchasing any other "MCED test" developers, as Complaint Counsel defines the term. (deSouza (Illumina) Tr. 2335.) Illumina "did an exhaustive study of the market, and we had been keeping up with the market since we were the ones who . . . came up with GRAIL, and we still don't see anybody in the market that has an offering that's like GRAIL's in terms of looking at 50 cancers, identifying the tissue of origin, and so there really isn't anybody else that we felt, you know, was like GRAIL." (deSouza (Illumina) Tr. 2335.)

3477. [redacted] (PX2009 (Illumina) at 019 (Email from J. Goswami, Illumina, to M. Nguyen, Illumina, et al., attaching April BoD M&A Strategy Presentation, Apr. 14, 2020) (*in camera*)).

Response to Finding No. 3477:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3476, which Respondents incorporate herein. In addition, there is no such thing as a "pan-cancer test" because there is no such thing as a universal cancer biomarker. (PFF ¶ 308; Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106.)

3478. [redacted] (PX2009 (Illumina) at 019 (Email from J. Goswami, Illumina, to M. Nguyen, Illumina, et al., attaching April BoD M&A Strategy Presentation, Apr. 14, 2020) (*in camera*)).

Response to Finding No. 3478:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3476, which Respondents incorporate herein.

3479. [redacted] (PX2013 (Illumina) at 010 (Science & Technology Committee Cancer Screening, Apr. 28, 2020) (*in camera*)).

Response to Finding No. 3479:

The proposed finding is incomplete and misleading insofar as it suggests that Exact/Thrive, Guardant, Freenome and Natera are actual competitors to GRAIL today or will be competitors to GRAIL in the foreseeable future. Respondents also incorporate their responses to CCFF ¶¶ 927 (Guardant), 2273 (Guardant), 945 (Freenome), 2355 (Freenome), 929 (Exact/Thrive), 1912 (Exact/Thrive), 928 (Natera) and 2216 (Natera) herein.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 5), or in any deposition, and therefore, the document should be

accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3480. Illumina noted in a Thrive company overview presentation that Thrive's CancerSeek test is a "multi-cancer competitor to project Valor." (PX2054 (Illumina) at 003 (MCED Company Overview Presentation) (Valor is the project name Illumina assigned to Grail.)).

Response to Finding No. 3480:

The proposed finding is incomplete and misleading to the extent it suggests that Thrive's CancerSEEK test is a competitor to GRAIL's Galleri test because [redacted] Respondents also incorporate their responses to CCFF ¶¶ 660–61, 666, 671, 682, 929, 1912 and 3476 herein.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 6), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3481. Illumina noted in a Guardant Health company overview slide that Guardant is a "[c]ompetitor to project Valor [and a] [k]ey [c]ustomer." (PX2054 (Illumina) at 001 (MCED Company Overview Presentation) (Valor is the project name Illumina assigned to Grail)).

Response to Finding No. 3481:

The proposed finding is misleading and incomplete. The cited document notes that Guardant is "developing Lunar 1 MRD and Lunar 2 CRC screening tests" (PX2054 (Illumina) at 1)—evidence that Illumina refers to competitors more broadly than those with a product in the relevant antitrust product market.

[redacted]

[redacted]

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 6), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

Respondents incorporate their responses to CCFF ¶¶ 611, 927, 2273 and 3476 herein.

3482. Illumina noted on a Freenome overview slide that Freenome is a "[c]ompetitor to project Valor." **(**PX2054 (Illumina) at 005 (MCED company overview presentation) (Valor is the project name Illumina assigned to Grail.))

Response to Finding No. 3482:

The proposed finding is misleading and incomplete. The cited document notes that Freenome is "focused solely on developing a cancer screening test for CRC" (PX2054 (Illumina) at 5)—evidence that Illumina refers to competitors more broadly than those with a product in the relevant antitrust product market.

Further, there is no indication based on Freenome's work to date that [redacted]; RX3869 (Cote Expert Report) ¶ 193).)

Mr. Nolan testified that Freenome is [redacted] (PX7094 (Nolan (Freenome) Dep. at 307).) Freenome's multiomics platform also has not demonstrated the ability to screen for multiple cancers simultaneously. (PFF ¶¶ 459-70.) Mr. Otte, Freenome's former CEO, also testified that

[redacted]

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 6), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

Respondents incorporate their responses to CCFF ¶¶ 801, 945 and 1346 herein.

(2) [redacted]

3483. [redacted] (*See* Bishop (Grail) Tr. 1500-01 (*in camera*); PX4476 (Grail) at 002 [redacted] (*in camera*)).

Response to Finding No. 3483:

The proposed finding is incomplete and misleading. [redacted] Given that the transaction will have significant merger-specific benefits, including saving thousands of lives and billions of dollars (*see* Resps.' Post-Trial Br. at 181–231), [redacted]

In order to preserve the merger-specific efficiencies of the transaction while also addressing any concerns identified by Complaint Counsel, Respondents tried repeatedly to engage with Complaint Counsel to arrive at an ideal remedy, but Complaint Counsel declined

any meaningful engagement, even when the Court directed the parties to discuss the prospect of settlement. (PFF ¶ 1072; RX4002 (Illumina); Resps.' Post-Trial Br. at 178–79.)

3484. [redacted] (PX4476 (Grail) at 004 [redacted] (*in camera*); Bishop (Grail) Tr. 1507-08) (*in camera*)).

Response to Finding No. 3484:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶ 3483, which Respondents incorporate herein. Additionally, the proposed finding is irrelevant because the financial consideration for this consulting agreement has no bearing on Illumina's ability or incentive to foreclose putative GRAIL rivals after the acquisition.

3485. [redacted] (PX4473 (Grail) at 003 (Core Team, Apr. 15, 2021) (*in camera*) (*see* inset image).

Response to Finding No. 3485:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶¶ 3483 and 3487, which Respondents incorporate herein.

3486. [redacted] (PX4473 (Grail) at 012 (Core Team, Apr. 15, 2021) (*in camera*)). [redacted] (PX4473 (Grail) at 012 (Core Team, Apr. 15, 2021) (*in camera*)).

Response to Finding No. 3486:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶¶ 3483 and 3487, which Respondents incorporate herein.

3487. [redacted] (PX4476 (Grail) at 002 [redacted] (*in camera*)).

Response to Finding No. 3487:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶ 3483, which Respondents incorporate herein. Additionally, the cited source is evidence that Illumina customers made unreasonable demands of Illumina during supply agreement negotiations because of the pressure placed on Illumina by the FTC investigation.

For example, [redacted]

[redacted]

[redacted]

[redacted]

3488. [redacted] (PX4476 (Grail) at 004 [redacted] (*in camera*)).

Response to Finding No. 3488:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶¶ 3483 and 3487, which Respondents incorporate herein.

3489. [redacted] (PX4476 (Grail) at 004 [redacted] (*in camera*)).

Response to Finding No. 3489:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶¶ 3483 and 3487, which Respondents incorporate herein.

3490. [redacted] (PX4473 (Grail) at 005 (Core Team, Apr. 15, 2021) (*in camera*)).

Response to Finding No. 3490:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶¶ 3483 and 3487, which Respondents incorporate herein.

3491. [redacted] (PX4473 (Grail) at 005 (Core Team, Apr. 15, 2021) (*in camera*)).

Response to Finding No. 3491:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶¶ 3483 and 3487, which Respondents incorporate herein.

3492. [redacted] (*in camera*)).

Response to Finding No. 3492:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶¶ 3483 and 3487, which Respondents incorporate herein.

e) [redacted]

3493. [redacted] (*See* PX7077 (Chahine (Helio) Dep. at 30-32) (*in camera*)).

[redacted]

Response to Finding No. 3493:

The proposed finding is misleading to the extent it suggests that it is a viable option to convert from a single cancer screening test to a multi-cancer screening test. To the contrary, even once a company has developed a cancer screening test for a single cancer type, it does not

become easier to add additional cancer types, because "[t]he development of biomarkers for a particular cancer will not be adequate for other cancers" and "[w]hile there may be overlap, one still needs to go through all of the [development] steps," including "go[ing] through the case-control verification to determine whether or not the assay has the performance characteristics needed . . . for the new target cancer," and "go[ing] through a prospective trial depending on which cancer is being targeted." (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123; PFF ¶¶ 328–328.1.)

Dr. Aravanis testified that GRAIL considered developing a single cancer screening test as a route to multicancer screening test but abandoned it because it would take far too long; building a multicancer test by developing single cancer tests seriatim could take four or five years for each cancer; to develop a 50-cancer test one cancer at a time a developer would need to do a research study, discovery study and collect relevant samples, determine the right technology, go into a new test development phase and clinical trials for each new cancer; GRAIL was able to develop a test capable of detecting 50 cancer types simultaneously directly by undergoing a much more intensive process to develop a test for 50 cancer types at the same time. (Aravanis (Illumina) Tr. 1895–97.)

To the extent that Complaint Counsel relies on their proposed findings in ¶¶ 2503–09, 434–35, 2279, 2370–72, 2416, 2212 and 2571, Respondents incorporate their responses to those proposed findings herein.

3494. [redacted]

Response to Finding No. 3494:

The proposed finding is incomplete and misleading. In the portion of Dr. Cote's testimony cited here, Dr. Cote explained that [redacted]

The proposed finding is further misleading the extent it suggests that it is a viable option to convert from a single cancer screening test to a multi-cancer screening test. To the contrary, even once a company has developed a cancer screening test for a single cancer type, it does not become easier to add additional cancer types, because "[t]he development of biomarkers for a particular cancer will not be adequate for other cancers" and "[w]hile there may be overlap, one still needs to go through all of the [development] steps," including "go[ing] through the case-control verification to determine whether or not the assay has the performance characteristics needed . . . for the new target cancer," and "go[ing] through a prospective trial depending on which cancer is being targeted." (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123; PFF ¶¶ 328–328.1.)

Dr. Aravanis testified that GRAIL considered developing a single cancer screening test as a route to multicancer screening test but abandoned it because it would take far too long; building a multicancer test by developing single cancer tests seriatim could take four or five years for each cancer; to develop a 50-cancer test one cancer at a time a developer would need to do a research study, discovery study and collect relevant samples, determine the right technology, go into a new test development phase and clinical trials for each new cancer; GRAIL was able to develop a test capable of detecting 50 cancer types simultaneously directly by undergoing a much more intensive process to develop a test for 50 cancer types at the same time.

(Aravanis (Illumina) Tr. 1895–97.) Respondents also incorporate their responses to CCFF ¶ 3493 herein.

3495. [redacted]

Response to Finding No. 3495:

The proposed finding is incomplete and misleading. In the portion of Dr. Cote's testimony cited here, Dr. Cote explained that [redacted]

The proposed finding is further misleading the extent it suggests that it is a viable option to convert from a single cancer screening test to a multi-cancer screening test. To the contrary, even once a company has developed a cancer screening test for a single cancer type, it does not become easier to add additional cancer types, because "[t]he development of biomarkers for a particular cancer will not be adequate for other cancers" and "[w]hile there may be overlap, one still needs to go through all of the [development] steps," including "go[ing] through the case-control verification to determine whether or not the assay has the performance characteristics needed . . . for the new target cancer," and "go[ing] through a prospective trial depending on which cancer is being targeted." (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123; PFF ¶¶ 328–328.1.)

Dr. Aravanis testified that GRAIL considered developing a single cancer screening test as a route to multicancer screening test but abandoned it because it would take far too long; building a multicancer test by developing single cancer tests seriatim could take four or five

years for each cancer; to develop a 50-cancer test one cancer at a time a developer would need to do a research study, discovery study and collect relevant samples, determine the right technology, go into a new test development phase and clinical trials for each new cancer; GRAIL was able to develop a test capable of detecting 50 cancer types simultaneously directly by undergoing a much more intensive process to develop a test for 50 cancer types at the same time. (Aravanis (Illumina) Tr. 1895–97.) Respondents also incorporate their responses to CCFF ¶ 3493 herein.

3496. [redacted]

Response to Finding No. 3496:

The proposed finding is incomplete and misleading. [redacted] Indeed, most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted] Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–06) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698).

3497. [redacted]

Response to Finding No. 3497:

The proposed finding is incomplete and misleading. [redacted]

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 35), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

f) Expert Analysis Confirms That the Acquisition Gives Illumina the Incentive and Ability to Disadvantage MCED Test Developers That Compete with Grail

3498. [redacted] (*See* PX6090 (Scott Morton Report) ¶ 177 (*in camera*)).

Response to Finding No. 3498:

The proposed finding is incomplete and misleading. Illumina is not the sole supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.) Dr. Scott Morton's assertions to the contrary are merely unsupported claims of an economic expert who is not qualified to opine on MCED development. The weight of the evidence shows that switching between Illumina's platform and alternative platforms is feasible, and is, in fact a routine part of test development. (PFF ¶¶ 645–74; RX2869 (Cote Expert Report) ¶ 336.) As Dr. Richard Cote explained, "[t]est developers routinely re-validate their tests to account for new developments in their tests, new and improved technology relating to consumables, or for any number of other reasons. These revalidations are part of a good test developer's business plan." (RX3869 (Cote Expert Report) ¶ 338.) For example, Natera's Signatera test was initially validated on Illumina's HiSeq 2500 NGS platform but now uses BGI's DNBSEQ Platform in China. (PFF ¶ 652; RX3499 (Natera) at 6; [redacted]; RX3062 (BGI) at 1.) Similarly, Singlera has stated that its PanSeer assay is compatible with both Illumina and Thermo Fisher's sequencing platforms, so switching between these two NGS suppliers would not be likely to require any significant time for Singlera. (RX3869 (Cote Expert Report) ¶ 353.)

Moreover, Dr. Scott Morton failed to take account of the protections of the Open Offer, which ensure that Illumina cannot anticompetitively disadvantage putative GRAIL rivals,

including by raising prices, providing lower quality products, or lower service or cooperation to putative GRAIL rivals. The Open Offer provides the economically necessary terms to prevent the alleged anticompetitive harms in both the short term and the long term. (RX6002 (Guerin-Calvert Trial Dep. at 21–22).) The Open Offer also represents an improvement for customers over the premerger status quo. (RX6002 (Guerin-Calvert Trial Dep. at 37, 52–53, 57).)

Among other things, the Open Offer "prevents Illumina from being able to raise prices over the term of the agreement of any of the existing products" and further protects customers "from being charged higher prices for new version of sequencing products or instruments or consumables". (Berry (Illumina) Tr. at 901–02; *see also* PFF ¶ 1021–22.) Specifically, as Ms. Berry, the Senior Vice President and General Manager of the Americas commercial team at Illumina, testified, "there's a provision in the open offer that prevents Illumina from raising prices over the term of the agreement beyond those that would be allowable relative to inflation adjustments or cost of goods sold". (Berry (Illumina) Tr. 899; *see also* PFF ¶ 1021; [redacted]; Conroy (Exact/Thrive) Tr. 1731; PX0064 (Illumina) at 7; [redacted].) "[T]he impact [of this provision] would be that customers are essentially protected against price increases over the term" of the Open Offer. (Berry (Illumina) Tr. 900.)

The Open Offer also prohibits Illumina from providing customers with lower quality instruments or consumables. (PFF ¶ 1092; Berry (Illumina) Tr. 878–79.) As Ms. Berry testified, "we are not permitted to [supply lower-quality reagents to customers] under the open offer." (Berry (Illumina) Tr. 878.)

And, the Open Offer prevents Illumina from providing lower quality service or refusing to cooperate with putative GRAIL rivals. Indeed, the Open Offer ensures that customers will

continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; [redacted]; Berry (Illumina) Tr. 865–66; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) The Open Offer also requires Illumina to provide customers with the same access to services that GRAIL or any other For-Profit Entity has access to, and at the same prices. (PFF ¶ 1004; [redacted]; Berry (Illumina) Tr. 865–66; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) As Ms. Berry testified, "the open offer obligates Illumina to provide access to a customer to not only the same [product and support] services for which the customer had before the transaction but also any [product and support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.)

Respondents also incorporate their response to CCFF ¶¶ 3499, 3500, 3502 and 3505 herein.

3499. Dr. Scott Morton concluded that the combination of Illumina and Grail gives Illumina the incentive and ability to anoint Grail the winner in the MCED test innovation race. (PX7138 (Scott Morton Trial Dep. at 19-20)).

Response to Finding No. 3499:

The proposed finding is irrelevant, incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶¶ 3498, 3500, 3502 and 3505, which Respondents incorporate herein. The proposed finding is also inaccurate and misleading to the extent it is intended to imply that Dr. Scott Morton conducted any reliable analysis of Illumina's pre-merger and post-merger incentives, taking into account real world constraints on Illumina's conduct and incentives such as reputational constraints, competitive constraints the Open Offer.

She did not. (*E.g.*, PFF ¶¶ 138, 808-814, 913-915, 972, 1077.) Respondents further note that while there is no evidence that there is any MCED tests comparable to GRAIL in development and that would launch in the foreseeable future, Illumina's post-merger incentives remain the same as they were pre-merger. (*E.g.*, PFF ¶ 857.)

Additionally, the Open Offer's provisions in their totality reinforce Illumina's incentives to support GRAIL's putative rivals. (PFF ¶ 1082.2–1082.4; *see* RX6002 (Guerin-Calvert Trial Dep. at 20–22, 108–09; RX6000 (Carlton Trial Dep. at 84–85).) The Open Offer, as a private contract, creates an incentive for Illumina customers to take advantage of it and enforce it. (PFF ¶ 1082.4; RX6000 (Carlton Trial Dep. at 84).) Further, as Dr. Scott Morton acknowledged,

[redacted] The weight of the evidence shows that the Open Offer's provisions are extremely robust and they ensure that Illumina's incentives are to support GRAIL's rivals while disabling Illumina from using any of the purported "foreclosure tools" alleged by Complaint Counsel. (PFF ¶ 1082.2–1082.4; *see* RX6002 (Guerin-Calvert Trial Dep. at 20–22, 108–09; RX6000 (Carlton Trial Dep. at 84–85).)

3500. [redacted] (PX7138 (Scott Morton Trial Dep. at 85) (*in camera*)).

Response to Finding No. 3500:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶¶ 3498–99, 3502 and 3505, which Respondents incorporate herein. The proposed finding is inaccurate and misleading to the extent it is intended to imply

that Dr. Scott Morton conducted any reliable analysis of Illumina's pre-merger and post-merger incentives, taking into account real world constraints on Illumina's conduct and incentives such as reputational constraints, competitive constraints the Open Offer. She did not. (*E.g.*, PFF ¶¶ 138, 808-814, 913-915, 972, 1077.) Respondents further note that while there is no evidence that there is any MCED tests comparable to GRAIL in development and that would launch in the foreseeable future, Illumina's post-merger incentives remain the same as they were pre-merger. (*E.g.*, PFF ¶ 857.) The proposed finding also appears to be an attempt by Dr. Scott Morton to reconcile Complaint Counsel's theory that Illumina is a long-term monopolist with the fact that Illumina's prices have come down and are expected to continue declining dramatically, and will be a fraction of MCED test revenues and margins, however, the attempt falls flat. In reality, those projections show that test developers will have more than just "some rents", but rather a significant percentage of the total profit pool, making clear that there are and will continue to be growing, powerful constraints on Illumina's prices and conduct, contrary to Complaint Counsel's unfounded claims. (*E.g.*, PFF ¶ 938-940.)

3501. [redacted] (PX7138 (Scott Morton Trial Dep. at 57) (*in camera*)).

Response to Finding No. 3501:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶¶ 3498–3500, 3502 and 3505, which Respondents incorporate herein. Additionally, Complaint Counsel's expert improperly assumes that Illumina's incentives after the Transaction have changed from the but-for world. (PFF ¶ 1082.5; RX6002 (Guerin-Calvert Trial Dep. at 20–21, 109).) However, in the world absent the merger, Illumina would still have owned roughly 12% of GRAIL. (PFF ¶ 1082.5; RX6000 (Carlton Trial Dep. at 45–

46).) Complaint Counsel has not proven why Illumina's incentives are different after the Transaction than in the but-for world. (PFF ¶ 1082.5; RX6000 (Carlton Trial Dep. at 45–46).)

3502. [redacted] (PX7138 (Scott Morton Trial Dep. at 61-62, 656) (*in camera*)).

Response to Finding No. 3502:

The proposed finding is misleading, including to the extent that it suggests that Illumina receiving compensation for granting IVD rights is improper. To the contrary, the financial terms for these IVD agreements are standard in the industry. (PFF ¶ 1032.1; Goswami (Illumina) Tr. 3212; [redacted]; PX7097 (Felton (Thermo Fisher) Dep. at 127–29).) The financial terms for IVD rights were chosen based on what is common in the industry and securing a return on Illumina's upfront investments. (PFF ¶¶ 1032.3–1032.5; Goswami (Illumina) Tr. 3213–16.) As Dr. Goswami testified at trial, "Illumina has to develop these [Dx sequencing] platforms way in advance of them ever having content built on them by a partner. And that development often takes several tens of millions of dollars over several years and is done completely at risk, right. We have no guarantee that it will be successful, that we'll be able to get the regulatory [approval that is required], or that customers will ever adopt that platform. So there is – as a business, we have to seek a return on that investment at risk that we make to make that Dx infrastructure broadly available". (Goswami (Illumina) Tr. 3213.)

The proposed finding is also irrelevant. It is of no moment to the issues before the Court that in the early days of its IVD technology and its therapy selection strategy, Illumina "evaluated" the impact of IVD partnerships on its profits. Illumina had invested substantial amounts in its IVD technology, there were few IVD kitted tests even commercially available,

and Illumina had not yet even received FDA authority to market a higher-throughput IVD system. The evaluation Illumina undertook of different potential approaches to this new technology and mode of distribution is what any profit maximizing firm would do when considering a major strategic decision such as the one Illumina faced when it first considered how and to what extent to enable third party kits on its new IVD systems.

What matters to understanding Illumina's incentives are the choices Illumina made, not the strategies some within Illumina evaluated along the way. [redacted] (PFF ¶ 971.3.) Today, Illumina has collaboration agreements in place with Roche, PGDx and numerous other test developers in therapy selection pursuant to which these formidable competitors are developing IVD tests that will compete with Illumina's own therapy selection test. (PFF ¶ 966.) Illumina provides customer support to its therapy selection rivals, and investment and innovation has increased in in recent years. (PFF ¶ 967.) In fact, the therapy selection market is thriving.

The proposed finding is also misleading to the extent it is intended to imply that Dr. Scott Morton conducted any reliable analysis of Illumina's vertical integration in therapy selection. She did not. As Dr. Carlton explained, if one were to do an actual economic analysis of the impact of Illumina's vertical integration into therapy selection, "the relevant question" would have to be "what's the but-for world", meaning, "was there a benefit from Illumina being vertically integrated into therapy selection and selling to Roche compared to not having Illumina in therapy selection". (RX6000 (Carlton Trial Dep. at 201.)) Yet that is not what Dr. Scott

Morton did by a long shot—"she pays no attention to the benefit of vertical integration of Illumina into therapy selection." (RX6000 (Carlton Trial Dep. at 201).)

Respondents also incorporate their responses to CCFF ¶¶ 3498–3500, 3505 and 3750 herein.

3503. [redacted] (PX7138 (Scott Morton Trial Dep. at 31-32) (*in camera*); *see also* PX6090 (Scott Morton Report) ¶ 172 (*in camera*) ([redacted])).

Response to Finding No. 3503:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶¶ 3498–3500, 3502 and 3505, which Respondents incorporate herein.

3504. [redacted] PX7138 (Scott Morton Trial Dep. at 48) (*in camera*)).

Response to Finding No. 3504:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶¶ 3498–3500, 3502 and 3505, which Respondents incorporate herein.

3505. [redacted] (PX7138 (Scott Morton Trial Dep. at 54-55) (*in camera*)).

Response to Finding No. 3505:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶¶ 3498–3500 and 3502, which Respondents incorporate herein. Additionally, Illumina's NGS business is expected to be the dominant driver of Illumina's profits well into the future, and currently accounts for more than 90% of its revenues and profits. (PFF ¶ 22.) As Mr. deSouza explained, [redacted] (deSouza (Illumina) Tr. 2291.) It is only "after 2026" that Illumina gets "its first dollar of profit" from GRAIL, but "it's not until 2030 where we've recouped the losses we've made in GRAIL", and therefore, "about the next decade even, we really need and are really fueled by the profit pools associated with our sequencers." (deSouza (Illumina) Tr. 2383.) Because Illumina's "core business is to sell sequencers and consumables", its "strong incentive is to continue to be successful selling sequencers and consumables into the market segments that we serve." (deSouza (Illumina) Tr. 2378.)

3506. [redacted]
PX7138 (Scott Morton Trial Dep. at 57) (*in camera*)).

Response to Finding No. 3506:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶¶ 3498–3500, 3502 and 3505, which Respondents incorporate herein.

3507. [redacted]

[redacted] (PX7138 (Scott Morton Trial Dep. at 358) (*in camera*)).

Response to Finding No. 3507:

The proposed finding is incomplete and misleading including for the reasons identified in Respondents' responses to CCFF ¶¶ 3498–3500, 3502 and 3505, which Respondents incorporate herein.

4. Patients Will Use a Single MCED Test for Screening

3508. At trial, Bill Getty, Guardant's SVP of Commercial, Cancer Screening Core, testified that he expects primary care physicians choosing between Galleri or LUNAR-2 tests would order one for their patients, not both. (Getty (Guardant) Tr. 2675).

Response to Finding No. 3508:

The proposed finding is inaccurate, incomplete and misleading. Contrary to Mr. Getty's testimony, Dr. Richard Abrams, the founder of Colorado Preventative Medicine and the only expert primary care physician to testify in the case, [redacted]

The proposed finding is also entirely speculative and relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

3509. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 177-178) (*in camera*)).

Response to Finding No. 3509:

The proposed finding is also entirely speculative and relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Moreover, Dr. Cote opined that CancerSEEK and Galleri are not substitutes:

[redacted]

(PFF ¶ 709.5 (Cote Tr. 3814–15).) Additionally, the proposed finding is inaccurate, incomplete and misleading for the reasons identified in Respondents' responses to CCFF ¶ 3508, which Respondents incorporate herein.

The proposed finding also relies on IH testimony, which Respondents had no opportunity to cross examine, and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3510. Mr. Nolan, Freenome's CEO, testified at trial that he does not expect primary care providers to use more than one MCED test simultaneously: "I think when there's a multicancer option I think [primary care providers will] choose one and not, you know, go back and forth between one and the other. Once they actually implement one multicancer

test, I believe they'll stick with that for standardization of process and test results interpretation." (Nolan (Freenome) Tr. 2727-28).

Response to Finding No. 3510:

The proposed finding is also entirely speculative and relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

Additionally, the proposed finding is inaccurate, incomplete and misleading for the reasons identified in Respondents' responses to CCFF ¶ 3508, which Respondents incorporate herein.

3511. Respondents' expert, Dr. Abrams, testified at trial that he expects to order no more than one MCED test per patient at a time. (Abrams Tr. 3643). More specifically, Dr. Abrams explained that he does not expect to order both Grail's Galleri and Exact's CancerSEEK simultaneously for patients. (PX7137 (Abrams, Dep. at 82-83)).

Response to Finding No. 3511:

The proposed finding is incomplete and misleading. Dr. Abrams also testified that "[i]f one multicancer test had a significant number of tests that weren't covered in a second multicancer test, perhaps there might be some complementary nature of the two". (Abrams Tr. 3643.) At his deposition, Dr. Abrams testified that "[i]f there are 50 cancers discoverable through GRAIL and 30 cancers discoverable through Thrive and they don't overlap, so now there are 80 cancers, yeah, I might consider it. It's possible." (PX7137 (Abrams Dep. at 83).) Whether a primary care physician would prescribe two complementary tests *simultaneously* is irrelevant to assessing whether two tests could be used as complements. Respondents also incorporate their response to CCFF ¶ 3508 herein.

3512. [redacted] (PX6097 (Abrams Rebuttal Report) ¶ 33 (*in camera*)).

Response to Finding No. 3512:

The proposed finding is incomplete to the extent it suggests that patients will use a single MCED test. The proposed finding is also incomplete and misleading to the extent that it suggests that there is another MCED test besides Galleri that is available or that any of the putative MCED tests in development would be suitable substitutes for Galleri. The proposed finding is also incomplete and misleading for the reasons identified in Respondents' responses to CCFF ¶ 3508, which Respondents incorporate herein.

3513. [redacted] (PX6097 (Abrams Rebuttal Report) ¶ 33 (*in camera*)).

Response to Finding No. 3513:

The proposed finding does not support the proposition that patients will use a single MCED test, as Complaint Counsel suggests. The proposed finding is also incomplete and misleading to the extent that it suggests that there is another MCED test besides Galleri that is available or that any of the putative MCED tests in development would be suitable substitutes for Galleri. To the contrary, [redacted]

3514. Dr. Abrams testified that the best MCED test for a given patient may depend on a patient's risk factors. (PX7137 (Abrams Dep. at 84)).

Response to Finding No. 3514:

The proposed finding is incomplete and misleading to the extent it suggests that patients will use a single MCED test for screening. Respondents also incorporate their responses to CCFF ¶¶ 3513.

3515. Dr. Abrams admits that he is "not the least bit reticent to make a change if a new test is superior to the existing." (PX7137 (Abrams Dep. at 85-86)).

Response to Finding No. 3515:

The proposed finding is incomplete and misleading for the reasons identified in Respondents' responses to CCFF ¶¶ 3513–14, which Respondents incorporate herein.

5. MCEDs Will Compete on Various Product Features

3516. Grail's CEO, Hans Bishop, testified that, whereas Grail has chosen to focus on cfDNA methylation, other companies have chosen to focus on protein analysis and others on multiomics that "combin[e] those different modalities." (PX7069 (Bishop (Grail) IHT at 154-56)).

Response to Finding No. 3516:

The proposed finding is incomplete and misleading including insofar as it suggests that other companies have tests that do or will compete with GRAIL's Galleri test. Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted] Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698).

Respondents also note that the cited testimony confirms that test developers are adopting different approaches to the development of their putative MCED tests, suggesting that if these putative tests come to market, each such test may be a complement to GRAIL's Galleri test,

rather than a substitute. Further, Respondents incorporate their responses to CCFF ¶¶ 426, 2286, 3290 herein.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3517. Mr. Bishop explained that there are a "number of different approaches different companies are taking," including multiomics as a way to try "to get to the highest-performing technology." (PX7069 (Bishop (Grail) IHT at 154-56)).

Response to Finding No. 3517:

The proposed finding is incomplete and misleading for the reasons identified in Respondents' responses to CCFF ¶ 3516, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3518. Mr. Bishop testified that patients benefit from having multiple MCED tests in development. (*See* PX7069 (Bishop (Grail) IHT at 154-56)).

Response to Finding No. 3518:

The proposed finding is incomplete and misleading for the reasons identified in Respondents' responses to CCFF ¶ 3516, which Respondents incorporate herein.

To the extent this proposed finding is meant to assert that Illumina benefits from having its customers invest in the development of clinical tests on its platform, and that it does not know which of its customers' assays-in-development will increase demand for sequencing and to what extent, that is true. However, it is also true (and Complaint Counsel has not shown otherwise) that, after the Transaction, Illumina continues to benefit from having customers choose its platform for their development efforts. Illumina does not know which tests in development on

its platform will accelerate and expand demand for its sequencing products, and so it has an incentive to encourage all such development. That is why Illumina, post-Transaction, has continued, and will continue, to support and encourage development of clinical tests on its platform—i.e., Illumina's desire to accelerate and expand demand for its NGS systems bolsters its incentives to support all customers. (*E.g.*, PFF ¶¶ 847-872.)

To the extent the proposed finding is asserting that there is an innovation race between Galleri and other test developers to develop a test with attributes comparable to, and therefore substitutable with, Galleri, the proposed finding is contradicted by the weight of the record evidence, as detailed extensively in Respondents' Proposed Findings of Fact. (*E.g.*, PFF ¶¶ 701–706.)

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3519. Mr. Bishop testified that "one of the exciting things about the horizon scanning [Grail] do[es] and the field in general is the number of different approaches different companies are taking." (PX7069 (Bishop (Grail) IHT at 154-56)).

Response to Finding No. 3519:

The proposed finding is incomplete and misleading for the reasons identified in Respondents' responses to CCFF ¶ 3516, which Respondents incorporate herein.

The proposed finding is also misleading to the extent it [redacted]

[redacted]

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3520. Mr. Bishop testified that "difficult problems are, by definition, hard to solve, and having a multitude of different approaches is a good thing." (PX7069 (Bishop (Grail) IHT at 154-56)).

Response to Finding No. 3520:

The proposed finding is incomplete and misleading for the reasons identified in Respondents' responses to CCFF ¶ 3516, which Respondents incorporate herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3521. [redacted] (Della Porta (Grail) Tr. 478-79 (*in camera*)).

Response to Finding No. 3521:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

[redacted]

3522. [redacted] (PX7087 (Goswami (Illumina) Dep. at 122-123) (*in camera*)).

Response to Finding No. 3522:

The proposed finding is misleading and irrelevant. The proposed finding is misleading to the extent it suggests that Dr. Goswami testified that [redacted] As discussed in Respondents' responses to CCFF ¶¶ 605–830, there is no evidence to suggest that all "MCED tests" as Complaint Counsel defines it are reasonably interchangeable

The proposed finding is also incomplete and misleading insofar as it suggests that other companies have tests that do or will compete with GRAIL's Galleri test. Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted] Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698).

3523. With respect to technologies used for cancer detection, Dr. Bert Vogelstein, the Clayton Professor of Oncology and Co-Director of the Ludwig Center for Cancer, Genetics and Therapeutics at the Sidney Kimmel Comprehensive Cancer Center of Johns Hopkins University School of Medicine, testified that "[t]here are many different analytes that can be detected in blood, many different characteristics of DNA, and I don't know which will

be superior because no one, including Thrive or us that I know of, has yet done the kinds of studies that will indicate which tests will be superior in actual practice in a prospective trial." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 48-49)).

Response to Finding No. 3523:

The proposed finding is incomplete and misleading for the reasons identified in Respondents' responses to CCFF ¶¶ 3516 and 3523, which Respondents incorporate herein. Respondents further note that the proposed finding is evidence that Exact/Thrive's CancerSEEK test is still in development. Respondents note that [redacted] (Conroy (Exact) Tr. 1717.) Respondents also note that Exact has not commercialized any MCED test. (Conroy (Exact) Tr. 1621.) Respondents further incorporate PFF ¶¶ 414–43, 709.3, 717.1.1, 721.1–21.2, 726–26.8, 735, 738–40.1 and their responses to CCFF ¶¶ 413–14, 697, 703, 736, 773–76, and 929 herein.

3524. [redacted]

Response to Finding No. 3524:

The proposed finding is incomplete and misleading without additional context. [redacted]

[redacted]

Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted] Helio and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–06) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698).

3525. [redacted]

Response to Finding No. 3525:

The proposed finding is inaccurate, incomplete and misleading insofar as it suggests Galleri's ability to detect 50 cancer types is a "marketing ploy". Galleri's data has been reviewed by multiple regulatory health authorities. In particular, New York State Department of Health has reviewed the validation data supporting Galleri and has approved Galleri as an LDT to be offered to New York state residents; Galleri is the only MCED test with approval from New York State Department of Health, which is considered the highest state regulatory bar for a laboratory developed test. In addition, Galleri was reviewed by the FDA as part of two investigational device exemption applications for the conduct of PATHFINDER and PATHFINDER 2, and in both cases, FDA allowed GRAIL to report out all cancer type information generated by Galleri. Further, Galleri is analytically validated under CLIA, and

clinically validated under CAP. (RRFF ¶ 6272.) CLIA-certified laboratories undergo routine audits in which the clinical data supporting their tests and the claims that they put on their reports are reviewed; laboratories put their CLIA license at risk if they don't have sufficient data supporting their tests. (PFF ¶ 1375.)

The proposed finding is also inaccurate, incomplete and misleading insofar as it suggests CancerSEEK is [redacted] In the DETECT-A trial, which is the most recent clinical trial conducted for the Exact/Thrive CancerSEEK test (*see* Lengauer (Exact/Thrive) Tr. 169–70, 212), [redacted] (*See* Lengauer (Exact/Thrive) Tr. 243; Conroy (Exact/Thrive) Tr. 1706–07; PFF ¶¶ [redacted], 721.1 1699[redacted] Further, CancerSEEK's design does not support the proposition that it was "intended to detect all types of cancers"; to the contrary, its biomarkers shows that it focuses on epithelial cancers. (PFF ¶ 428-29.1 (RX3419 (Lennon et al., 2020) at 9, Fig. 3; RX3869 (Cote Expert Report) ¶ 177; PFF ¶ 169.1 (Cote Tr. 3810-11)).

Respondents also incorporate PFF ¶¶ 414–43, 709.3, 717.1.1, 721.1–21.2, 726–26.8, 735, 738–40.1 and their responses to CCFF ¶¶ 389, 413–14, 418–19, 696–97, 703, 715, 736, 738-39, 773–76, 785, 929 and 1912 herein.

3526. [redacted]

[redacted]

Response to Finding No. 3526:

The proposed finding is incomplete and misleading insofar as it suggests that Galleri is reasonably interchangeable with any putative MCED test. [redacted]

3527. [redacted]

Response to Finding No. 3527:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3526, which Respondents incorporate herein. Indeed, the cited testimony supports the proposition that because GRAIL is using a different approach, including targeted methylation, from the other putative MCED test developers that those tests, if they ever launch, are likely to be complements to Galleri, rather than substitutes.

3528. [redacted]

Response to Finding No. 3528:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3526, which Respondents incorporate herein.

3529. Respondents' economic expert, Dr. Carlton, conceded that differentiated products can be substitutes:

> Q. And you agree, as a general matter, that differentiated products can be substitutes depending on the cross elasticity of demand by consumers, right?
>
> A. I think I put it a little differently, that products that are differentiated can have – it can be substitutes, in part, but they won't be as substitutable as if they were identical. But just because you're not identical doesn't mean there's no substitution. That, I agree with.

(PX7134 (Carlton Dep. at 134-35)).

Response to Finding No. 3529:

The proposed finding is misleading. Dr. Carlton explained that "if products are very different from one another, it suggests that they're unlikely to be close substitutes, and if they're not close substitutes, then the diversion of sales from the rival -- to in this case GRAIL . . . [is] likely to be low or nonexistent", and "if it's low or nonexistent, then the incentive -- the profit incentive to engage in the raising rivals' cost strategy . . . will also be low or nonexistent". (PFF ¶ 826 (RX6000 (Carlton Trial Dep. at 40–41); RX3864 (Carlton Expert Report) ¶ 50)).)

3530. Respondents' economic expert, Dr. Katz, admitted that a properly defined relevant product market can include differentiated products. (PX7145 (Katz Dep. at 47)).

Response to Finding No. 3530:

The proposed finding is incomplete and misleading. Dr. Katz testified that a relevant product market could include differentiated products "[d]epending on the degree of differentiation". (PX7145 (Katz Dep. at 47).) Dr. Katz testified that in this case, Complaint Counsel failed to properly account for differentiation in defining its "MCED tests" product market. "[B]ecause we'll have to see how R&D and other issues, you know, play out by the

companies, but also there's, you know, some uncertainty about, given what dimensions of differentiation among tests are going to really matter, which characteristics are going to most drive substitution." (RX6004 (Katz Trial Dep. at 20).)

3531. Respondents' expert, Dr. Katz, testified that part of R&D competition was differentiating a firm's product to compete on different product features or functions. (RX6004 (Katz Trial Dep. at 106)).

Response to Finding No. 3531:

The proposed finding is incomplete and misleading. Dr. Katz testified that he agreed "as a general matter that's possible". (RX6004 (Katz Trial Dep. at 106).) Further, as Dr. Katz testified, Complaint Counsel failed to properly define an R&D product market. Dr. Scott Morton failed to consider: (i) "[D]id a hypothetical monopolist that controlled some set of assets to innovation . . . find it profitable to cut back on innovation?"; and (ii) to find the boundaries of the market, what are the firm's "capabilities to do innovation?" (PFF ¶ 772 RX6004 (Katz Trial Dep. at 26).) Dr. Scott Morton did no such analysis. (PFF ¶ 772 (RX6004 (Katz Trial Dep. at 26) ("I think it's clear that Professor Scott Morton when she applies her hypothetical monopolist test is applying it to defining a product market, not an innovation market.").)

3532. Respondents' expert, Dr. Katz, testified that he understood that different MCED test developers have taken different approaches to developing their MCED tests. (RX6004 (Katz Trial Dep. at 106-107)). For example, different MCED test developers are developing tests that analyze different types of biomarkers. (RX6004 (Katz Trial Dep. at 107)).

Response to Finding No. 3532:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3530–31, which Respondents incorporate herein. In addition, the mere fact that different MCED test developers have taken different approaches "doesn't answer the question of . . . how [] consumers weigh the different characteristics against

each other" or "what do they do if maybe one test looks better than the other in certain technical respects, but it also is more expensive. And just looking at the peculiar characteristics in isolation can't answer that question if . . . you have this other gap which you haven't really been able to collect information on the preferences of [clinicians, patients and payors]." (RX6004 (Katz Trial Dep. at 20-21).)

3533. Grail's 2021 AACR Conference Report states: "Methylation is not the only methodology, and several [other companies] combine this approach with others." (PX4616 (Grail) at 017 (AACR 2021 Conference Report, May 5, 2021)).

Response to Finding No. 3533:

The proposed finding is incomplete and misleading for the reasons identified in Respondents' responses to CCFF ¶¶ 3516 and 3527, which Respondents incorporate herein.

a) The Number of Cancers an MCED Test Screens for is One of Many Factors on which Tests Will Compete

(1) No Test Has Been Clinically Shown to Screen for More than Ten Cancers in an Asymptomatic Population

For evidence that no test has been clinically shown to screen for more than ten cancers in an asymptomatic population, see Section X, Appendix B (Galleri Has Not Been Clinically Shown to Provide Early Detection of More Than 50 Cancers in an Asymptomatic Population).

(2) Other MCED Developers Are Planning to Add Cancers Over Time

For additional evidence of how some MCED test developers plan to add cancers to their existing MCED test technological platform, see Section VII.B.3.e. (NGS-Based Single Cancer Tests Are an Initial Step Towards Development of MCED Tests).

3534. [redacted]

Response to Finding No. 3534:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74, 2277–78 and 2296, which Respondents

incorporate herein. [redacted]

Further, Guardant has not performed any prospective, interventional trial for more than one cancer type. (*See* RX3869 (Cote Expert Report) Appendix D, 302).)

3535. [redacted]

Response to Finding No. 3535:

The proposed finding is inaccurate, incomplete and misleading as well as contradicted by the weight of the evidence. [redacted] The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74, 2277–78, 2307 and 3534, which Respondents incorporate herein.

3536. [redacted]

Response to Finding No. 3536:

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 2273–74, 2277–78 and 2302, which Respondents incorporate herein. Further, [redacted]

[redacted]

Respondents note, however, that there is no such thing as a "pan-cancer test" because there is no such thing as a universal cancer biomarker. (PFF ¶ 308; Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106.)

3537. [redacted]

Response to Finding No. 3537:

The proposed finding is incomplete and misleading without additional context including insofar as it suggests that Freenome is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future. As noted, even once a company has developed a cancer screening test for a single cancer type (which Freenome has not yet completed), it does not become easier to add additional cancer types.

Mr. Nolan testified that "Freenome is [redacted] (PX7094 (Nolan (Freenome) Dep. at 307).) Freenome's putative multiomics platform also has not demonstrated the ability to screen for multiple cancers simultaneously. (PFF ¶¶ 459-70.) [redacted]

Mr. Otte, Freenome's former CEO, also testified that [redacted]

[redacted]

Further while Freenome may aspire to develop a multiomics platform that could support both an MCED and single cancer test, Freenome has not published any clinical data showing that it is remotely close to achieving this objective. [redacted] Respondents also incorporate their responses to CCFF ¶¶ 405, 439–440, 444, 666, 698, 801, 806, 945, 1140 and 2355 herein.

The proposed finding is misleading the extent it suggests that it is a viable option to convert from a single cancer screening test to a multi-cancer screening test. To the contrary, even once a company has developed a cancer screening test for a single cancer type, it does not become easier to add additional cancer types, because "[t]he development of biomarkers for a particular cancer will not be adequate for other cancers" and "[w]hile there may be overlap, one still needs to go through all of the [development] steps," including "go[ing] through the case-control verification to determine whether or not the assay has the performance characteristics

needed . . . for the new target cancer," and "go[ing] through a prospective trial depending on which cancer is being targeted." (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123; PFF ¶¶ 328–328.1.) Dr. Aravanis testified that GRAIL considered developing a single cancer screening test as a route to multicancer screening test but abandoned it because it would take far too long; building a multicancer test by developing single cancer tests seriatim could take four or five years for each cancer; to develop a 50-cancer test one cancer at a time a developer would need to do a research study, discovery study and collect relevant samples, determine the right technology, go into a new test development phase and clinical trials for each new cancer; GRAIL was able to develop a test capable of detecting 50 cancer types simultaneously directly by undergoing a much more intensive process to develop a test for 50 cancer types at the same time. (Aravanis (Illumina) Tr. 1895–97.)

Accordingly, there is no indication based on Freenome's work to date that [redacted] (PFF ¶ 458 [redacted]; RX3869 (Cote Expert Report) ¶ 193).

Further, Freenome has not performed any prospective, interventional trial for more than one cancer type. (*See* RX3869 (Cote Expert Report) Appendix D, 302).)

3538. [redacted]

Response to Finding No. 3538:

The proposed finding is inaccurate, incomplete and misleading. On direct examination, Mr. Nolan explained that [redacted] (Nolan (Freenome) Tr. 2767 (in camera).)

Finally, on cross examination, Mr. Nolan testified that [redacted] (Nolan (Freenome) Tr. 2815–16 (in camera).)

[redacted] Respondents also incorporate their responses to CCFF ¶ 2355 herein.

[redacted] even though Freenome was served with a subpoena by both Complaint Counsel and Respondents. RX5012-RX5013 (Freenome). Nor has Complaint Counsel identified such a document. Therefore, this cited testimony should be accorded little weight.

The proposed finding is misleading the extent it suggests that it is a viable option to convert from a single cancer screening test to a multi-cancer screening test. To the contrary, even once a company has developed a cancer screening test for a single cancer type, it does not

become easier to add additional cancer types, because "[t]he development of biomarkers for a particular cancer will not be adequate for other cancers" and "[w]hile there may be overlap, one still needs to go through all of the [development] steps," including "go[ing] through the case-control verification to determine whether or not the assay has the performance characteristics needed . . . for the new target cancer," and "go[ing] through a prospective trial depending on which cancer is being targeted." (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123; PFF ¶¶ 328–328.1.) Dr. Aravanis testified that GRAIL considered developing a single cancer screening test as a route to multicancer screening test but abandoned it because it would take far too long; building a multicancer test by developing single cancer tests seriatim could take four or five years for each cancer; to develop a 50-cancer test one cancer at a time a developer would need to do a research study, discovery study and collect relevant samples, determine the right technology, go into a new test development phase and clinical trials for each new cancer; GRAIL was able to develop a test capable of detecting 50 cancer types simultaneously directly by undergoing a much more intensive process to develop a test for 50 cancer types at the same time. (Aravanis (Illumina) Tr. 1895–97.) Further, Singlera has not performed any prospective, interventional trial for more than one cancer type. (*See* RX3869 (Cote Expert Report) Appendix D, 302).)

3539. Singlera's PanSeer test is currently focused on screening for colorectal, lung, gastric, esophageal, and liver cancers, but it is designed to detect any kind of cancer. (*See* PX7042 (Gao (Singlera) IHT at 28-30)).

Response to Finding No. 3539:

The proposed finding is incomplete and misleading. Although Singlera's "goal" may be to detect all kinds of cancer, Dr. Gao has also testified that Singlera is "far away" from starting clinical trials for PanSeer in the United States, and that it is "still not in the really starting clinical

trial state." (Gao (Singlera) Tr. 2926; PX7102 (Gao (Singlera) Dep. at 113–14, 81–82; PFF ¶ 536.1.) By Dr. Gao's own calculation, PanSeer is at least eight to ten years away from potential launch in the United States, and Singlera does not currently have any clinical trials relating to screening for multiple cancers listed on clinicaltrials.gov. (PFF ¶¶ 536.1-36.2.) Accordingly, [redacted]. Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (See Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶¶ 447, 451, 982 and 2421 herein.

Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3540. [redacted]

Response to Finding No. 3540:

The proposed finding is incomplete and misleading. While [redacted]

[redacted] (PFF ¶ 511 (RX3869 (Cote Expert Report) ¶ 227; [redacted]).) [redacted] Respondents also incorporate their responses to CCFF ¶¶ 341, 420, 422, 613, 774–75, 792, 794, 928, 965, 2216–17 and 2222 herein.

The proposed finding is misleading the extent it suggests that it is a viable option to convert from a single cancer screening test to a multi-cancer screening test. To the contrary, even once a company has developed a cancer screening test for a single cancer type, it does not become easier to add additional cancer types, because "[t]he development of biomarkers for a

particular cancer will not be adequate for other cancers" and "[w]hile there may be overlap, one still needs to go through all of the [development] steps," including "go[ing] through the case-control verification to determine whether or not the assay has the performance characteristics needed . . . for the new target cancer," and "go[ing] through a prospective trial depending on which cancer is being targeted." (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123; PFF ¶¶ 328–328.1.) Dr. Aravanis testified that GRAIL considered developing a single cancer screening test as a route to multicancer screening test but abandoned it because it would take far too long; building a multicancer test by developing single cancer tests seriatim could take four or five years for each cancer; to develop a 50-cancer test one cancer at a time a developer would need to do a research study, discovery study and collect relevant samples, determine the right technology, go into a new test development phase and clinical trials for each new cancer; GRAIL was able to develop a test capable of detecting 50 cancer types simultaneously directly by undergoing a much more intensive process to develop a test for 50 cancer types at the same time. (Aravanis (Illumina) Tr. 1895–97.) Further, Natera has not performed any prospective, interventional trial for more than one cancer type. (*See* RX3869 (Cote Expert Report) Appendix D, 303).)

3541. [redacted]

Response to Finding No. 3541:

The proposed finding is also inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3540, which Respondents incorporate herein.

Further, [redacted], Natera's CEO has stated publicly to Natera's investors that "Signatera technology is not something that can be used for early detection." (PFF ¶ 516.2; *see also* Cote Tr. 3852–53.) [redacted]. (PX8532 (Natera) at 001 (*in camera*).) [redacted] (PX8532 (Natera) at 007 (*in camera*).) [redacted] As Complaint Counsel has contended in multiple of its proposed findings and in its post-trial brief, MRD tests are not the same as MCED tests. (*See* CCFF ¶¶ 155, 624–628, 731, 2216; CC Post-Trial Br. at 51–52, 54–55.)

3542. Dr. Chahine testified that Helio plans to add additional cancers to its test for early detection of liver cancer and to later launch the test as an MCED test. (Chahine (Helio) Tr. 1000-01).

Response to Finding No. 3542:

The proposed finding is incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2481 and 2502, which Respondents incorporate herein. The proposed finding is also not supported by the cited evidence. In the cited trial testimony Dr. Chahine mentions Helio's [redacted] but does not state [redacted], and the cited portion of PX8655 [redacted]

[redacted]. (Chahine (Helio) Tr. 1000-01; PX8655 (Helio) at 019) (*in camera*).) Further, as Dr. Chahine testified, Helio abandoned those earlier multi-cancer efforts by LAM on the IvyGene test. (PFF ¶ 501.1; PX7077 (Chahine (Helio) Dep. at 218); RX3417 (Helio); RX3263 (GenomeWeb) at 1; RX3869 (Cote Expert Report) n. 334.)

The proposed finding is also misleading to the extent it implies that Helio has any plans to launch a broad MCED test that would compete with Galleri. In fact, Dr. Chahine testified that Helio's intent is to proceed by [redacted]. (PX7077 (Chahine (Helio) Dep. at 30–31) (*in camera*); Chahine (Helio) Tr. 1084 (*in camera*).) [redacted]

Dr. Chahine also testified that [redacted] Further, Helio has not performed any prospective, interventional trial for more than one cancer type. (*See* RX3869 (Cote Expert Report) Appendix D, 302).) Respondents further incorporate their responses to CCFF ¶ 2503 herein.

3543. [redacted]

Response to Finding No. 3543:

The proposed finding is incomplete and misleading including insofar as it suggests that Helio is an actual competitor to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶¶ 2481, 2502–03, 2526 and 3542, which Respondents incorporate herein.

[redacted]

Respondents further incorporate their responses to CCFF ¶ 2530 herein.

3544. Helio has told its investors that it intends to develop an MCED test by adding additional cancers to its single-cancer liver test. (Chahine (Helio) Tr. 1037-38).

Response to Finding No. 3544:

The proposed finding is not supported by the cited evidence. The cited portion of Dr. Chahine's trial testimony does not discuss Helio "adding additional cancers to its single-cancer HelioLiver test." Instead, when asked at trial, "has Helio told investors that it's developing an MCED test?" Dr. Chahine testified, "It has" but clarified that "the strategy as I've communicated it to investors . . . is . . . that, you know, ultimately the category is going in this direction ***but that we're choosing to, for the reasons I've mentioned, doing a single test first***." (Chahine (Helio) Tr. 1037 (emphasis added).) Respondents further incorporate their responses to CCFF ¶¶ 2514 and 3542 herein.

3545. [redacted]

Response to Finding No. 3545:

The proposed finding is incomplete and misleading including insofar as it suggests that [redacted] to GRAIL today or will be a competitor to GRAIL in the foreseeable future, including for the reasons explained in Respondents' responses to CCFF ¶ 2562, which Respondents incorporate herein.

Further, [redacted] (PX7074 (Perettie (FMI) Dep. at 73, 74, 77–78); Fiedler (FMI) Tr. 4476–77) [redacted] (PX7074 (Perettie (FMI) Dep. at 79–80); PX8447 (Roche) at 5.) Further, FMI has not performed any prospective, interventional trial for more than one cancer type. (*See* RX3869 (Cote Expert Report) Appendix D, 302).)

The proposed finding is also misleading the extent it suggests that it is a viable option to convert from a single cancer screening test to a multi-cancer screening test. To the contrary, even once a company has developed a cancer screening test for a single cancer type, it does not become easier to add additional cancer types, because "[t]he development of biomarkers for a particular cancer will not be adequate for other cancers" and "[w]hile there may be overlap, one still needs to go through all of the [development] steps," including "go[ing] through the case-control verification to determine whether or not the assay has the performance characteristics needed . . . for the new target cancer," and "go[ing] through a prospective trial depending on

which cancer is being targeted." (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123; PFF ¶¶ 328–328.1.)

Dr. Aravanis testified that GRAIL considered developing a single cancer screening test as a route to multicancer screening test but abandoned it because it would take far too long; building a multicancer test by developing single cancer tests seriatim could take four or five years for each cancer; to develop a 50-cancer test one cancer at a time a developer would need to do a research study, discovery study and collect relevant samples, determine the right technology, go into a new test development phase and clinical trials for each new cancer; GRAIL was able to develop a test capable of detecting 50 cancer types simultaneously directly by undergoing a much more intensive process to develop a test for 50 cancer types at the same time. (Aravanis (Illumina) Tr. 1895–97.)

b) The Ability to Identify Tissue of Origin is One of Many Factors on Which Tests Will Compete

3546. [redacted]

Response to Finding No. 3546:

The proposed finding is incomplete and misleading, as well as contradicted by the weight of the evidence. Dr. Rabinowitz's testimony is contradicted [redacted]

Dr. Rabinowitz said [redacted]

[redacted]

(PFF ¶ 733; Rabinowitz (Natera) Tr. 389.)

[redacted]

3547. As Respondents' own expert Dr. Richard Abrams testified, the exact number of cancers is just one factor that might cause him to switch between MCED tests, with accuracy being "first and foremost" the most important factor, along with other factors like price and tissue of origin capabilities. (Abrams Tr. 3632-33).

Response to Finding No. 3547:

Respondents have no specific response except to note that Dr. Abrams opined that a test that detected two or three cancer types would not be a substitute for test that could detect 50 cancer types. [redacted]

(1) [redacted]

3548. [redacted]

Response to Finding No. 3548:

[redacted]

Respondents also incorporate their responses to CCFF ¶¶ 2216–17, 2222, 2236 and 3546 herein.

3549. [redacted]

Response to Finding No. 3549:

The proposed finding is incomplete and misleading. [redacted] Respondents also incorporate their responses to CCFF ¶¶ 429, 2273–74, 2277–78 and 2315 herein.

3550. [redacted]

Response to Finding No. 3550:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3549, which Respondents incorporate herein.

Further, [redacted]

3551. [redacted]

Response to Finding No. 3551:

The proposed finding is irrelevant, incomplete and misleading**.** [redacted] Respondents also incorporate their responses to CCFF ¶¶ 1938–39, 1963 and 3278 herein.

3552. [redacted]

Response to Finding No. 3552:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3278 and 3551, which Respondents incorporate herein.

3553. [redacted]

Response to Finding No. 3553:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3278 and 3551, which Respondents incorporate herein.

3554. [redacted]

Response to Finding No. 3554:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3551, which Respondents incorporate herein.

3555. [redacted]

Response to Finding No. 3555:

The proposed finding is inaccurate, incomplete and misleading. [redacted]

[redacted]

Respondents also incorporate their responses to CCFF ¶¶ 2355–58, 2379, 2385 herein.

3556. Singlera's PanSeer test is designed to detect tissue of origin. (Gao (Singlera) Tr. 2874).

Response to Finding No. 3556:

The proposed finding is inaccurate, incomplete and misleading. Singlera has not published any ability to identify a molecular cancer signal of origin. (RX3115 (Chen et al., 2020) at 6.) Singlera has stated that any patient testing positive on PanSeer would then undergo additional blood test and/or follow-up imaging to allow tissue of origin mapping. (RX3869 (Cote Expert Report) ¶ 239; RX3115 (Chen et al., 2020) at 6.) However, Singlera has not developed such a blood test. (RX3115 (Chen et al., 2020) at 6.)

Respondents also incorporate their responses to CCFF ¶ 2426 herein.

(2) Tests Have Taken Alternative Approaches to TOO

3557. [redacted]

Response to Finding No. 3557:

The proposed response is inaccurate, incomplete and misleading. Respondents note that full-body PET-CT is a fairly poor tool for localizing cancer. This is reflected in Exact/Thrive's own study. Of the 53 patients identified by PET-CT as having imaging concerning for cancer in the DETECT-A study, only 15 were determined to have cancer, with only a 28.3% detection rate, compared with the 88.7% accuracy of cancer signal of origin prediction achieved by GRAIL's Galleri v1 in the CCGA3 study. (*See* PFF ¶¶ 426.3–426.4.) GRAIL demonstrated this performance in a prospective clinical trial environment as well, with PATHFINDER. In the

PATHFINDER trial, Galleri returned an overall CSO accuracy (for both first and second CSO) of 96.3%. (RX3053 (Beer et al., 2021).)

[redacted] (*See* PFF ¶ 439.) [redacted]; and the Cohen study found the PET-CT approach is not well suited to be a primary screening modality for the general population also because it is financially and operationally impractical (Conroy (Exact/Thrive) Tr. 1707–08). (*See* PFF ¶ 1700.)

Dr. Lengauer admitted that a diagnostic full-body PET-CT confers a higher radiation exposure than a standard CT; the radiation exposure from diagnostic PET-CT and follow-up imaging tests in the participants without cancer is a recognized source of potential harm associated with the DETECT-A CancerSEEK protocol; investigators of the DETECT-A trial recognized that the diagnostic PET-CT scans are not well suited to be the primary screening modality for the general population, in part because of a low disease prevalence and a relatively high rate of incidental findings; and even after the full-body PET-CT scan, there may be a need to do additional biopsies to further characterize the cancer. (*See* Lengauer (Exact/Thrive) Tr. 248–50; PFF ¶ 1724; *see also* PFF ¶¶ 152–152.2.)

Respondents also note that [redacted]

[redacted] RX3419 (Lennon et al., 2020); Cote Tr. 3811–14.)

Respondents also note that as Mr. Bishop, GRAIL's CEO, testified at trial: [redacted] (Bishop (GRAIL) Tr. 1489.) This appears to be precisely the posture that Mr. Conroy is taking in the cited testimony.

Respondents incorporate their responses to CCFF ¶¶ 1938–39, 1963, 3278 and 3280 herein.

3558. [redacted]

Response to Finding No. 3558:

The proposed response is inaccurate, incomplete and misleading. Full-body PET-CT is a fairly poor tool for attempting to localize cancer. This is reflected in Exact/Thrive's own study. Of the 53 patients identified by PET-CT as having imaging concerning for cancer in the DETECT-A study, only 15 were determined to have cancer, with only a 28.3% detection rate, compared with the 88.7% accuracy of cancer signal of origin prediction achieved by GRAIL's Galleri v1 in the CCGA3 study. (*See* PFF ¶¶ 426.3–426.4.) GRAIL demonstrated this performance in a prospective clinical trial environment as well, with PATHFINDER. In the PATHFINDER trial, Galleri returned an overall CSO accuracy (for both first and second CSO) of 96.3%. (RX3053 (Beer et al., 2021).)

[redacted]

[redacted]; and the Cohen study found the PET-CT approach is not well suited to be a primary screening modality for the general population also because it is financially and operationally impractical (Conroy (Exact/Thrive) Tr. 1707–08). (*See* PFF ¶ 1700.)

Dr. Lengauer admitted that a diagnostic full-body PET-CT confers a higher radiation exposure than a standard CT; the radiation exposure from diagnostic PET-CT and follow-up imaging tests in the participants without cancer is a recognized source of potential harm associated with the DETECT-A CancerSEEK protocol; investigators of the DETECT-A trial recognized that the diagnostic PET-CT scans are not well suited to be the primary screening modality for the general population, in part because of a low disease prevalence and a relatively high rate of incidental findings; and even after the full-body PET-CT scan, there may be a need to do additional biopsies to further characterize the cancer. (*See* Lengauer (Exact/Thrive) Tr. 248–50; PFF ¶ 1724; *see also* PFF ¶¶ 152–152.2.)

Respondents also note that [redacted] RX3419 (Lennon et al., 2020); Cote Tr. 3811–14.)

Respondents incorporate their responses to CCFF ¶¶ 1938–39, 1963, 3278 and 3280 herein.

3559. [redacted]

Response to Finding No. 3559:

The proposed response is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3357–58, which Respondents incorporate herein.

3560. [redacted]

Response to Finding No. 3560:

The proposed response is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3357–58, which Respondents incorporate herein.

3561. [redacted]

[redacted]

Response to Finding No. 3561:

The proposed finding is incomplete and misleading.

To the contrary, full-body PET-CT is a fairly poor tool for attempting to localize cancer. This is reflected in Exact/Thrive's own study. Of the 53 patients identified by PET-CT as having

imaging concerning for cancer in Exact/Thrive's DETECT-A study, only 15 were determined to have cancer, with only a 28.3% detection rate, compared with the 88.7% accuracy of cancer signal of origin prediction achieved by GRAIL's Galleri v1 in the CCGA3 study. (See PFF ¶¶ 426.3–426.4.) GRAIL also demonstrated this performance in a prospective clinical trial environment as well, with PATHFINDER. In the PATHFINDER trial, Galleri returned an overall CSO accuracy (for both first and second CSO) of 96.3%. (RX3053 (Beer et al., 2021).)

[redacted] (*See* PFF ¶ 439.) [redacted]; and the Cohen study found the PET-CT approach is not well suited to be a primary screening modality for the general population also because it is financially and operationally impractical (Conroy (Exact/Thrive) Tr. 1707–08). (See PFF ¶ 1700.)

Dr. Lengauer also admitted that a diagnostic full-body PET-CT confers a higher radiation exposure than a standard CT; the radiation exposure from diagnostic PET-CT and follow-up imaging tests in the participants without cancer is a recognized source of potential harm associated with the DETECT-A CancerSEEK protocol; investigators of the DETECT-A trial recognized that the diagnostic PET-CT scans are not well suited to be the primary screening modality for the general population, in part because of a low disease prevalence and a relatively high rate of incidental findings; and even after the full-body PET-CT scan, there may be a need to do additional biopsies to further characterize the cancer. (*See* Lengauer (Exact/Thrive) Tr. 248–50; PFF ¶ 1724; *see also* PFF ¶¶ 152–152.2.)

Respondents also note that Exact/Thrive's CancerSEEK test cannot be a substitute for GRAIL's Galleri test because while the Galleri test can detect a molecular cancer signal of origin, CancerSEEK is unable to identify the cancer signal of origin. Instead, CancerSEEK uses further invasive testing in the form of a whole body PET-CT scan (Lengauer (Exact/Thrive) Tr. 190, 270} RX3419 (Lennon et al., 2020); Cote Tr. 3811–14.)

3562. [redacted]

Response to Finding No. 3562:

The proposed finding is inaccurate and misleading to the extent it suggests that Galleri's determination of the cancer signal of origin is inaccurate or that the Galleri test has a low specificity.

To the contrary, Galleri v1 demonstrated a superb cancer signal of origin prediction accuracy of 93%. (PFF ¶ 389 (RX3430 (Liu et al., 2020) at 1, 9; RX0744 (GRAIL) at 68; RX3869 (Cote Expert Report) ¶ 143).) CCGA3, the third CCGA sub-study, reported that Galleri v2 demonstrated a cancer signal of origin prediction accuracy of 88.7%. (PFF ¶ 393 (RX3408 (Klein et al., 2021) at 10; RX3869 (Cote Expert Report) ¶ 144).) GRAIL demonstrated this performance in a prospective clinical trial environment as well, with PATHFINDER. In the PATHFINDER trial, Galleri returned an overall CSO accuracy (for both first and second CSO) of 96.3%. (RX3053 (Beer et al., 2021).)

By contrast, the CancerSEEK assay does not identify the cancer signal of origin, which is why it is combined with a whole-body PET-CT. (PFF ¶ 419 (RX3869 (Cote Expert Report) ¶ 174).) Contrary to Dr. Lengauer's assertion that PET-CT scanning is more accurate than a molecular cancer signal of origin, full-body PET-CT is a fairly poor tool for attempting to find a cancer. This is reflected in Exact/Thrive's own study. Of the 53 patients identified by PET-CT as having imaging concerning for cancer in Exact/Thrive's DETECT-A study, only 15 were determined to have cancer, with only a 28.3% detection rate. (*See* PFF ¶¶ 426.3–426.4.)

[redacted]

Similarly, Galleri also has a superior specificity (and accordingly, lower false positive rate) than the CancerSEEK test. Specifically, the results of the CCGA2 study, published in Annals of Oncology in March 2020, showed that Galleri was capable of detecting more than 50 cancer types at a specificity of 99.3% and a false-positive rate of less than 1% across the more than 50 cancer types. (PFF ¶ 388; RX3430 (Liu et al., 2020) at 1, 10.) Similarly, CCGA3 ultimately reported that GRAIL's Galleri v2 test achieved a specificity of 99.5% across more than 50 cancer types, a false-positive rate of 0.5%, and a signal of origin prediction accuracy of 88.7%. (PFF ¶ 392; RX3408 (Klein et al., 2021) at 10; RX3869 (Cote Expert Report) ¶ 144.)

By contrast, CancerSEEK Exact/Thrive's CancerSEEK test in development was shown to have a specificity of 95.3% using a single blood test in the DETECT-A study. (PFF ¶¶ 173

("Specificity . . . measures the proportion of actual negative samples that are correctly identified as such", so that a 95.3% specificity corresponds to a true negative rate of 95.3% and a false positive rate of 100% minus 95.3%), 428, 431 ("In the DETECT-A study, CancerSEEK obtained [a] specificit[y] of 95.3% in its baseline blood test (that is, with a single blood test).").) [redacted] (*See also* RX3419 (Lennon et al., 2020) at 8 & Table 2; PFF ¶¶ 431–432.)

Contrary to Dr. Lengauer's insinuation in the cited testimony that a molecular cancer signal of origin is "unsafe", as Dr. Ofman testified, the high CSO accuracy (together with Galleri's extremely high specificity of more than 99.5%) allow Galleri to avoid the "diagnostic odyssey" that can result from false positive results: "So the test, if it's a multicancer early detection test, has to have a very low false positive rate because you're looking for so many different kinds of cancer. And that will contribute to what we call a high positive predictive value. Positive predictive value is the most important clinical measure that a doctor needs to know about when using this test. And PPV really refers to, of those with a positive result, how many actually have cancer. And so these are really important that these numbers, the very low false positive rate and a much higher PPV than what is typically seen with single-cancer screening tests. Finally, for any multicancer screening test, it has to be able to predict the tissue

of origin in order to direct an efficient and focused workup. Otherwise, doctors really won't know what to do with the result." (Ofman (GRAIL) Tr. 3289.)

The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938–39, 1963, 3561, 3578 and 3580, which Respondents incorporate herein.

3563. [redacted]

Response to Finding No. 3563:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938–39, 1963 and 3561–62, which Respondents incorporate herein.

Further, the proposed finding is inaccurate insofar as it suggests that [redacted] The suggestion is also irrelevant, because [redacted]

3564. [redacted]

Response to Finding No. 3564:

The proposed finding is irrelevant and further demonstrates that GRAIL applies criteria to define "competitors" and "competitive threats" that are broader than would be used for determining a relevant antitrust product market. Any [redacted] would necessarily concern products that are not in Complaint Counsel's proposed product market. Complaint Counsel's proposed market includes only "MCED tests" and excludes any standard-of-care screening tests. Galleri is not meant as an alternative or replacement to standard cancer screening procedures, but rather as a complement to recommended screenings, designed to detect more cancers earlier while minimizing the harms that may come from a false positive result. (PFF ¶ 358.)

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 35), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

(3) Grail's MCED Test Will Require Additional Scanning

3565. Grail's CEO, Hans Bishop, testified at trial that certain patients may undergo a body scan to identify the cancer tissue of origin. (Bishop (Grail) Tr. 1387).

Response to Finding No. 3565:

The proposed finding is misleading. Mr. Bishop testified that "[with] certain patients [a doctor] may choose" to do a scan, "but it's not a necessary requirement for many patients." Bishop (GRAIL) Tr. 1387.) Moreover, the proposed finding is misleading to the extent it conflates CancerSEEK's ***full-body*** PET-CT scan with the less frequent scan Mr. Bishop was referring to. CancerSEEK requires a full-body PET-CT scan in every positive case and even

after the full-body PET-CT scan, there may be a need to do additional biopsies to further characterize the cancer. (*See* Lengauer (Exact/Thrive) Tr. 248–50; PFF ¶ 1724.) Mr. Bishop's testimony indicates that is not the case with Galleri, as its ability to detect cancer signal of origin "can reduce the need for unnecessary work-ups, including unnecessary whole-body imaging, which is expensive and sometimes comes with exposure to radiation." (Bishop (GRAIL) Tr. 1388.)

Dr. Lengauer also admitted that a diagnostic full-body PET-CT confers a higher radiation exposure than a standard CT; the radiation exposure from diagnostic full-body PET-CT and follow-up imaging tests in the participants without cancer is a recognized source of potential harm associated with the DETECT-A CancerSEEK protocol; investigators of the DETECT-A trial recognized that the diagnostic full-body PET-CT scans are not well suited to be the primary screening modality for the general population, in part because of a low disease prevalence and a relatively high rate of incidental findings; and even after the full-body PET-CT scan, there may be a need to do additional biopsies to further characterize the cancer. (*See* Lengauer (Exact/Thrive) Tr. 248–50; PFF ¶ 1724; *see also* PFF ¶¶ 152–152.2.)

3566. Grail's CEO, Hans Bishop, testified that "ultimately patients will then get a biopsy, but that step needs . . . to have a diagnostic confirmation." (Bishop (Grail) Tr. 1387).

Response to Finding No. 3566:

The proposed finding is misleading to the extent it conflates CancerSEEK's required full-body PET-CT in every positive case to a more targeted diagnostic confirmation required after Galleri's cancer signal of origin identification. Respondents also incorporate their responses to CCFF ¶ 3565 herein.

3567. Galleri does not predict tumor of origin for fifty cancer types. (Ofman (Grail) Tr. 3433). As Dr. Ofman testified, for colon and rectum cancers, Galleri predicts a single tissue of

origin, rather than five cancer types. (Ofman (Grail) Tr. 3434). Dr. Ofman elaborated that the tissue of origin classifier is grouped into 24 categories. (Ofman (Grail) Tr. 3453).

Response to Finding No. 3567:

The proposed finding is misleading to the extent it suggests that the utility of the cancer signal of origin determination is diminished because the classifier is grouped into 24 categories rather than 50 cancer types. The 24 categories of classifier will still yield a more targeted follow-up and "reduce the need for unnecessary work-ups, including unnecessary whole-body imaging, which is expensive and sometimes comes with exposure to radiation." (Bishop (GRAIL) Tr. 1388.)

3568. [redacted] (PX4207 (Grail) at 040 (Competitive Intelligence Updates: Deep Dive, June 9, 2020) (*in camera*)). [redacted] (PX4207 (Grail) at 040 (Competitive Intelligence Updates: Deep Dive, June 9, 2020) (*in camera*)).

Response to Finding No. 3568:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 1938–39, 1963, 3561–62, and 3565–67, which Respondents incorporate herein.

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 40), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3569. Respondents' expert, Dr. Richard Cote, testified at trial that a physician may need to perform a targeted follow-up screening test on individuals who take the Galleri test. (Cote Tr. 3802-3803).

Response to Finding No. 3569:

The proposed finding is misleading to the extent it conflates CancerSEEK's required full-body PET-CT in every positive case with the more targeted follow-up Dr. Cote describes here. As discussed, full-body PET-CT is a fairly poor tool for cancer signal of origin determination. (*See* PFF ¶¶ 426.3–426.4.) [redacted]; *see also* PFF ¶¶ 152–152.2); and its financial and operational impracticalities (Conroy (Exact/Thrive) Tr. 1707–08; PFF ¶ 1700.) In addition, there may be a need to do additional biopsies to further characterize the cancer after the PET-CT scan. (*See* Lengauer (Exact/Thrive) Tr. 248–50; PFF ¶ 1724.)

The targeted follow-up Dr. Cote described dose not entail the same set of issues. For instance, if the cancer signal of origin returned is bladder cancer, Dr. Cote testified that he "wouldn't expect reliance on imaging studies but, rather, on evaluation of urine for the presence of cancer cells and even including a procedure known as uroscopy, where the lining of the bladder is actually directly visualized by a urologist." (Cote Tr. 3803.)

C. HARM TO GRAIL'S RIVALS WILL LEAD TO DECREASED INNOVATION IN THE U.S. MCED TEST MARKET

3570. Respondents' own expert, Dr. Carlton, testified that harm to innovation is "a concern you should worry about" when examining the effects of a merger. (PX7134 (Carlton Dep. at 82-83)). Additionally, Respondents' expert, Dr. Katz, testified that if innovation is "stifled," "that would be in my view a bad thing." (PX7145 (Katz Dep. at 39-41)).

Response to Finding No. 3570:

The proposed finding is inaccurate and misleading insofar as it suggests that the Transaction will harm or stifle innovation; the opposite is true. Dr. Carlton testified to this effect: "My view is that this transaction will not harm innovative competition"; he added that "the transaction will accelerate the approval of Galleri. That could have an effect on the

marketplace, and induce more people to innovate. (PX7134 (Carlton Dep. at 84–85).) Illumina relies on its customers to invest in costly R&D to generate demand for Illumina's products, including in applications that have not yet been developed or possibly even conceived, creating a future stream of sequencing sales and profits. (*See, e.g.*, Berry (Illumina) Tr. 811 ("Our mission remains to . . . enable all attributes of our technology to drive accessibility and utilization across as many use cases as possible, and certainly pricing is a key element of that, a key enabler of that, and so continuing to drive down the price of sequencing is something that we are absolutely relentlessly continuing to pursue."); [redacted] To realize those future profits, Illumina must incentivize customers to invest, which requires that Illumina maintain its reputation as a supporter of innovation by its customers in products that use Illumina's NGS technology. (RX6000 (Carlton Trial Dep. at 33–35, 186, 188).) As Dr. Aravanis explained, attempting to foreclose a GRAIL rival "would be very detrimental" because "our business is based on customers using our platforms for their applications, developing new applications" and "[w]ere we to do something like foreclose on a customer's business . . . we would jeopardize the existing customer relationships", and "at a kind of reputational level, to do something like that . . . is not consistent with our mission and values." (Aravanis (Illumina) Tr. 1922–23; 1931–32.)

In fact, substantial evidence shows that the Transaction will spur greater innovation through the large efficiencies it will generate (*e.g.*, PFF ¶¶ 1136–45), and it has already catalyzed excitement and investment in the liquid biopsy field (*e.g.*, PFF ¶¶ 928, 933). Thus, the proposed finding is a red herring in that there is no dispute that innovation benefits consumers and should be allowed to flourish. However, it is not the Transaction that threatens innovation in MCED testing, but rather Complaint Counsel's misguided effort to unwind it.

3571. [redacted] (PX7138 (Scott Morton Trial Dep. at 32) (*in camera*)).

Response to Finding No. 3571:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3570, which Respondents incorporate herein. The proposed finding is also inaccurate and misleading to the extent it is intended to imply that Dr. Scott Morton conducted any reliable analysis of Illumina's pre-merger and post-merger incentives, taking into account real world constraints on Illumina's conduct and incentives such as reputational constraints, competitive constraints the Open Offer. She did not. (*E.g.*, PFF ¶¶ 138, 808-814, 913-915, 972, 1077.) Respondents further note that while there is no evidence that there is any MCED tests comparable to GRAIL in development and that would launch in the foreseeable future, Illumina's post-merger incentives remain the same as they were pre-merger. (*E.g.*, PFF ¶ 857.) The proposed finding also ignores the substantial evidence showing that the Transaction will spur greater innovation through the large efficiencies it will generate (*e.g.*, PFF ¶¶ 1136–45), and that it has already catalyzed excitement and investment in the liquid biopsy field (*e.g.*, PFF ¶¶ 928, 933).

3572. [redacted] (PX7138 (Scott Morton Trial Dep. at 32-33) (*in camera*)).

Response to Finding No. 3572:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3570 and 3571, which Respondents incorporate herein.

3573. [redacted] (PX6090 (Scott Morton Report) ¶¶ 171-73 (*in camera*)).

Response to Finding No. 3573:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3570 and 3571, which Respondents incorporate herein. The proposed finding is also a red herring in that there is no dispute that innovation benefits consumers and should be allowed to flourish. However, it is the Transaction that will spur greater innovation (*e.g.*, PFF ¶¶ 928, 933, 1136–45), and it is Complaint Counsel's misguided attempt to unwind the Transaction that threatens innovation.

3574. Dr. William Cance, Chief Medical and Scientific Officer of the American Cancer Society, testified that "multiple companies and institutions developing and improving [MCED] technology is very important." (PX7086 (Cance (American Cancer Society) Dep. at 100-101)).

Response to Finding No. 3574:

Respondents have no specific response other than to note that the proposed finding is a red herring in that there is no dispute that innovation benefits consumers and should be allowed to flourish. However, it is the Transaction that will spur greater innovation (*e.g.*, PFF ¶¶ 928, 933, 1136–45), and it is Complaint Counsel's misguided attempt to unwind the Transaction that threatens innovation.

3575. Respondents' own expert, Dr. Richard Abrams, testified, "if there are multiple laboratories and companies developing better and better products, that would be a great advantage to me as a physician and, most importantly, to my patients." (PX7137 (Abrams Dep. at 73)). Dr. Abrams testified that one way MCED tests will "get better and better" is through competition among multiple companies, adding that "[c]ompetition is America." (PX7137 (Abrams Dep. at 75-76)).

Response to Finding No. 3575:

Respondents have no specific response other than to note that the proposed finding is a red herring in that there is no dispute that innovation benefits consumers and should be allowed to flourish. However, it is the Transaction that will spur greater innovation (*e.g.*, PFF ¶¶ 928,

933, 1136–45), and it is Complaint Counsel's misguided attempt to unwind the Transaction that threatens innovation.

3576. As the CEO of Freenome explained, he is "focused on beating the competitor, which is cancer," and "there's room for a lot of folks if we take that approach and that we have a fair and level playing field to achieve it." (Nolan (Freenome) Tr. 2727).

Response to Finding No. 3576:

The proposed finding is incomplete, and misleading to the extent it suggests that the playing field will not be fair and level after the Transaction for the reasons explained in Respondents' responses to CCFF ¶ 3570, which Respondents incorporate herein. The proposed finding is also incomplete and misleading to the extent it suggests that Freenome is developing and likely to launch an MCED that would compete with Galleri at any point in the foreseeable future, for the reasons explained in Respondents' responses to CCFF ¶¶ 378 and 3571, which are incorporated herein. Further, Mr. Nolan testified that Freenome is [redacted] (PX7094 (Nolan (Freenome) Dep. at 307); PFF ¶¶ 459–72.) [redacted]

1. Entry to Participate in the MCED Race Requires Investment in R&D, with Fixed Investments—R&D and Clinical—to Launch an MCED Test

3577. [redacted]

[redacted] (PX6090 (Scott Morton Report) ¶¶ 155-56 (*in camera*)). [redacted]

(PX6090 (Scott Morton Report) ¶ 156 (*in camera*)).

Response to Finding No. 3577:

The proposed finding is inaccurate, incomplete and misleading by suggesting that any of Complaint Counsel's putative MCED test developers are currently, or anywhere close to, competing with Galleri, for the reasons explained in Respondents' responses to CCFF ¶¶ 378 and 3571, which are incorporated herein. Dr. Scott Morton's assertions to the contrary are merely unsupported claims of an economic expert who is not qualified to opine on MCED development.

3578. [redacted] (PX6090 (Scott Morton Report) ¶ 156 (*in camera*)). [redacted] (PX6090 (Scott Morton Report) ¶ 157 (*in camera*)).

Response to Finding No. 3578:

The proposed finding is inaccurate, incomplete and misleading by suggesting that any of Complaint Counsel's putative MCED test developers are currently, or anywhere close to, competing with Galleri, for the reasons explained in Respondents' responses to CCFF ¶¶ 378 and 3571, which are incorporated herein. Dr. Scott Morton's assertions to the contrary are merely unsupported claims of an economic expert who is not qualified to opine on MCED development.

3579. [redacted] (PX6090 (Scott Morton Report) 160 (*in camera*)). [redacted] (PX6090 (Scott Morton Report) ¶ 160 *(in camera*)).

Response to Finding No. 3579:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 378, 3571 and 3577, which are incorporated herein. The proposed finding also highlights one of the reasons Illumina has an incentive to support all development of clinical tests on its NGS platforms—a successful test that has performance dimensions important to patients or clinicians would catalyze and expand demand for Illumina's NGS products, giving it greater opportunity for upstream sales than would be the case without such a test in the marketplace.

3580. [redacted] (PX6090 (Scott Morton Report) ¶ 159 (*in camera*)).

Response to Finding No. 3580:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 378, 3571 and 3577, which are incorporated herein.

3581. [redacted] (PX7138 (Scott Morton Trial Dep. at 31-32) (*in camera*)).

Response to Finding No. 3581:

The proposed finding is inaccurate and misleading to the extent it is intended to imply that Dr. Scott Morton conducted any reliable analysis of Illumina's pre-merger and post-merger incentives, taking into account real world constraints on Illumina's conduct and incentives such as reputational constraints, competitive constraints the Open Offer. She did not. (*E.g.*, PFF ¶¶ 138, 808-814, 913-915, 972, 1077.) Respondents further note that while there is no evidence

that there is any MCED tests comparable to GRAIL in development and that would launch in the foreseeable future, Illumina's post-merger incentives remain the same as they were pre-merger. (*E.g.*, PFF ¶ 857.) The proposed finding also overlooks that Illumina's NGS business is expected to be the dominant driver of Illumina's profits well into the future, and currently accounts for more than 90% of its revenues and profits. (PFF ¶ 22.) As Mr. deSouza explained, [redacted] (deSouza (Illumina) Tr. 2291.) Because Illumina's "core business is to sell sequencers and consumables", its "strong incentive is to continue to be successful selling sequencers and consumables into the market segments that we serve." (deSouza (Illumina) Tr. 2378.) Dr. Aravanis similarly testified that "Illumina's business is based on growing sequencing markets" by "lowering the cost, allowing people to do more sequencing" and "has also been driven by new applications that are developed", and "Illumina is hoping for more of those applications to be developed" on its platforms, which creates "a strong incentive for us to continue to decrease cost, and that's our plan." (Aravanis (Illumina) Tr. 1922.) Even [redacted]

Further, due to the royalty GRAIL owed to Illumina pre-Transaction, the same purported incentive to favor GRAIL existed prior to the Transaction's close. In light of the pre-merger royalty and equity stake, under Complaint Counsel's own theory of Illumina's incentives, Illumina "makes much more money if a customer uses the GRAIL test than if it uses that of" a

GRAIL rival, which means "there already is an incentive to favor GRAIL" and "therefore, the merger" has no effect on Illumina's dealings with putative GRAIL rivals. (RX6000 (Carlton Trial Dep. at 93–94).) [redacted]

Further, the proposed finding is misleading and incomplete in its presentation of MCED test development as a "race" for the reasons explained in Respondents' response to CCFF ¶ 3577, which are incorporated herein.

3582. [redacted] Gao (Singlera) Tr. 2888-2889; [redacted]

Response to Finding No. 3582:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that any test developers are developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted] Helio, and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for anywhere near as many cancers as Galleri simultaneously in the foreseeable future (PFF ¶¶ 701–706). Further, the proposed finding relies on IH testimony, which Respondents had no

opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3583. [redacted] (PX7053 (Fesko (Natera) IHT at 28) (*in camera*)).

Response to Finding No. 3583:

The proposed finding is incomplete, misleading and inaccurate. There is no evidence besides the unsubstantiated and implausible say-so of Natera's testifying executives, who lack credibility (*E.g.*, PFF ¶ 1881.), that [redacted]. (*E.g.*, PFF ¶¶ 703.8–703.13.) The proposed finding is also misleading and inaccurate to the extent that it suggests that [redacted]. The evidence suggests that [redacted] (PFF ¶¶ 509–10.) There is no evidence based on [redacted]. (PFF ¶ 511 (RX3869 (Cote Expert Report) ¶ 227; [redacted]).) Respondents

incorporate their responses to CCFF ¶ 420 herein. Further, the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3584. Singlera spends approximately $30 million annually on research and development. (PX7042 (Gao (Singlera) IHT at 22)).

Response to Finding No. 3584:

The proposed finding is incomplete and misleading to the extent that it suggests that Singlera is developing and likely to launch an MCED test comparable to Galleri at any point in the foreseeable future, which is false. Dr. Gao testified that Singlera is "far away" from starting clinical trials for PanSeer in the United States, and that it is "still not in the really starting clinical trial state." (Gao (Singlera) Tr. 2926; PX7102 (Gao (Singlera) Dep. at 113–14, 81–82; PFF ¶ 536.1.) By Dr. Gao's own calculation, PanSeer is at least eight to ten years away from potential launch in the United States, and Singlera does not currently have any clinical trials relating to screening for multiple cancers listed on clinicaltrials.gov. (PFF ¶¶ 536.1-36.2.) Accordingly, [redacted] Respondents incorporate their responses to CCFF ¶ 447. Further, the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3585. Singlera's Dr. Gao testified at trial that Singlera has spent between $60 million to $100 million on research and development efforts related to the PanSeer test. (Gao (Singlera) Tr. 2888-2889).

Response to Finding No. 3585:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 447 and 3584, which Respondents incorporate herein.

3586. Singlera is working to "reduce cost, improve accuracy, and improve convenience" of its test. **(**PX7042 (Gao (Singlera) IHT at 100).

Response to Finding No. 3586:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 447 and 3584, which Respondents incorporate herein. Further, the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3587. [redacted]

Response to Finding No. 3587:

The proposed finding is incomplete, misleading and inaccurate. It mischaracterizes the cited document, [redacted] (*E.g.*, PX8305 at 063.) The document discusses [redacted] The proposed finding is also misleading to the extent that it suggests that [redacted]

[redacted]

[redacted] **Respondents incorporate their responses to CCFF ¶ 426.**

3588. [redacted]

Response to Finding No. 3588:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' responses to CCFF ¶¶ 447 and 3587, which Respondents incorporate herein

3589. [redacted]

Response to Finding No. 3589:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' responses to CCFF ¶¶ 447 and 3587, which Respondents incorporate herein.

3590. [redacted]

Response to Finding No. 3590:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' responses to CCFF ¶¶ 447 and 3587, which Respondents incorporate herein.

3591. [redacted]

Response to Finding No. 3591:

The proposed finding is incomplete and misleading to the extent that it suggests that Exact/Thrive is anywhere close to launching an MCED test that will compete with Galleri in the foreseeable future. Galleri detects more than 50 cancer types (PFF ¶ 61), while Dr. Lengauer testified that the DETECT-A study of CancerSEEK only detected cancers of 10 organs (Lengauer (Exact/Thrive) Tr. 245; RX3869 (Cote Expert Report) ¶ 177; PFF ¶¶ 429–430.1). [redacted] By contrast, CancerSEEK must use a whole body PET-CT scan to attempt to localize any detected cancers. (*See* Lengauer (Exact/Thrive) Tr. 248; RX3419 (Lennon et al., 2020) at 3; PFF ¶¶ 419, 425, 739, 760, 841.3, 1723–24.) Dr. Lengauer also observes that the DETECT-A study of CancerSEEK only detected cancers of 10 organs, as opposed to the more than 50 cancer types that Galleri detects. (PFF ¶ 429 (Lengauer (Exact/Thrive) Tr. 245; RX3869 (Cote Expert Report) ¶ 177).) Dr. Lengauer also testified that CancerSEEK obtained a 30% sensitivity rate in the DETECT-A trial, as opposed to the 51.5% sensitivity rate of Galleri. (PFF ¶¶ 725 (RX3409 (Klein et al., 2021) at 5; RX3419 (Lennon et al., 2020) at 7; RX3115 (Chen et al., 2020) at 4).) Thus, there is little overlap between Galleri and CancerSEEK and little evidence to indicate that CancerSEEK will serve as a close substitute to Galleri, either now or in the foreseeable future. (PFF ¶ 421.)

Further, the proposed finding supports Respondents' point that investment has poured into liquid biopsy / cancer test development since the announcement of the Transaction, not least by Exact. [redacted] The

timing and size of Exact's investments in cancer detection is directly contrary to Complaint Counsel's speculation that the Transaction will disincentivize investment in the area. Indeed, Exact signed its agreement to acquire Thrive, and then consummated that transaction, all after Illumina announced its acquisition of GRAIL. (PFF ¶ 929.1.)

3592. [redacted] (PX4250 (Grail) at 012 ([redacted]) (*in camera*)). [redacted] (PX4054 (Grail) at 004 [redacted] (*in camera*)).

Response to Finding No. 3592:

The proposed finding is incomplete and misleading. [redacted]

[redacted] Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 41), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

The proposed finding is also incomplete and misleading to the extent that it suggests that the described "Competitive Threats to Galleri" are actual competitors to Galleri or GRAIL. [redacted]

Most of the putative MCED developers identified by Complaint Counsel, including Guardant, Freenome, [redacted] Helio, and [redacted], do not expect (and none can reasonably be expected) to launch a test capable of screening for more than one cancer simultaneously in the foreseeable future (PFF ¶¶ 701–706) and Galleri is the only multi-cancer early detection test capable of detecting anywhere near 50 cancer types on the market (PFF ¶ 698). Respondents also incorporate their responses to CCFF ¶ 398 herein.

The proposed finding is also inaccurate, incomplete and misleading to the extent that it suggests that GRAIL is planning to incorporate cfRNA, proteins or biofluids as an analyte into its Galleri test. To the contrary, GRAIL has locked version 2 of Galleri, which is the version currently on the market, and is working on an updated version of Galleri that meets current performance standards while sequencing fewer regions of the genome, thereby reducing the cost

of the test. (PFF ¶ 1607 (Ofman (GRAIL) Tr. 3301–03.) Respondents also note that there is no evidence that an MCED test using proteins or other biofluids (urine) as analytes would use NGS technology, nor have Complaint Counsel contended that such a test would be within the alleged product market.

Complaint Counsel chose not to discuss PX4250 at trial, (CC Exhibit Index at 41), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

Respondents also incorporate their responses to CCFF ¶¶ 306, 312, 413 and 761 herein.

3593. [redacted]

[redacted]

(PX6090 (Scott Morton Report) ¶ 161 (*in camera*)).

Response to Finding No. 3593:

The proposed finding is inaccurate, incomplete and misleading to the extent it suggests that the Transaction will hinder investment in the cancer screening market or in any way limit the development of such developers. The evidence is to the contrary, which [redacted] The proposed finding is also a red herring in that there is no dispute that innovation benefits consumers and should be allowed to flourish. However, substantial evidence shows that the Transaction will spur greater innovation through the large efficiencies it will generate (*e.g.*, PFF ¶¶ 1136–45), and it has already catalyzed excitement and investment in the liquid biopsy field (*e.g.*, PFF ¶¶ 928, 933). Thus, it is not the

Transaction that threatens innovation in MCED testing, but rather Complaint Counsel's misguided effort to unwind it. Respondents further incorporate their responses to CCFF ¶ 3577 herein.

a) The Transaction Will Give Illumina the Ability and Incentive to Raise Rivals Costs, Which Will Lower or Eliminate the Incentive for Grail's Rivals to Invest in R&D Related to MCED Tests and Slow Innovation

3594. Dr. Scott Morton testified that Illumina's acquisition of GRAIL will deprive consumers of the benefits from the scientific activity and investment involved in the race to develop an MCED test. (PX7138 (Scott Morton Trial Dep. at 20)).

Response to Finding No. 3594:

The proposed finding is inaccurate and misleading to the extent it is intended to imply that Dr. Scott Morton conducted any reliable analysis of Illumina's pre-merger and post-merger incentives, taking into account real world constraints on Illumina's conduct and incentives such as reputational constraints, competitive constraints the Open Offer. She did not. (*E.g.*, PFF ¶¶ 138, 808-814, 913-915, 972, 1077.) Respondents further note that while there is no evidence that there is any MCED tests comparable to GRAIL in development and that would launch in the foreseeable future, Illumina's post-merger incentives remain the same as they were pre-merger. (*E.g.*, PFF ¶ 857.) The proposed finding also ignores the substantial evidence showing that the Transaction will spur greater innovation through the large efficiencies it will generate (*e.g.*, PFF ¶¶ 1136–45), and that it has already catalyzed excitement and investment in the liquid biopsy field (*e.g.*, PFF ¶¶ 928, 933).

3595. [redacted] (PX7138 (Scott Morton Trial Dep. at 82) (*in camera*)).

Response to Finding No. 3595:

The proposed finding is inaccurate and misleading for the reasons explained in Respondents' response to CCFF ¶ 3594, which Respondents incorporate herein.

3596. [redacted] (PX7138 (Scott Morton Trial Dep. at 82-83) (*in camera*)).

Response to Finding No. 3596:

The proposed finding is inaccurate and misleading for the reasons explained in Respondents' response to CCFF ¶ 3594, which Respondents incorporate herein.

3597. Further, Dr. Scott Morton concluded in her report that [redacted] (PX6090 (Scott Morton Report) ¶ 12 (*in camera*)).

Response to Finding No. 3597:

The proposed finding is inaccurate and misleading for the reasons explained in Respondents' response to CCFF ¶ 3594, which Respondents incorporate herein.

3598. According to Illumina's former CEO and board member Jay Flatley, prior to the spin-off of Grail, Illumina was hesitant to "go after markets . . . using a subsidiary of Illumina . . . that could compete more favorably with existing customers [Illumina] had in the marketplace." (PX7057 (Flatley (Illumina) IHT at 166)).

Response to Finding No. 3598:

The proposed finding is incomplete and misleading in that it omits and mischaracterizes Mr. Flatley's testimony and the relevant facts. Mr. Flatley made it clear that he was not talking about the MCED space when referring to Illumina's hesitancy to "go after markets . . . using a subsidiary of Illumina". Rather, he explained that this concern related to Illumina competing with customers in mature, existing markets , but those same considerations did not apply to a nascent space like the MCED space. As to the MCED space, Mr. Flatley explained that, "this

market did not exist – it still doesn't exist" and Illumina "had decided that we were going to focus on enabling new markets in – and in those cases Illumina could put application and sample prep products into the market. And we've done that in our history. We did it in, you know – in the DTC area. We did it with a company called Helix that we spun out. We were doing it here. And those activities were to create markets where they otherwise would not get created or take many, many more years to get created. And so that's why" Illumina participated in nascent markets but not in mature markets. (PX7057 (Flatley (Illumina) IHT at 166–68.)

Further, the Proposed Finding is incomplete and misleading because Illumina's views at the time of the spin-off of GRAIL in 2017 are irrelevant to evaluating the effects of the Transaction on competition today, including because the evidence shows Illumina firmly believes the Transaction will not harm any of its customers, Illumina has no incentive to harm any customer, and the terms of the Open Offer guarantee Illumina cannot anticompetitively disadvantage any for profit oncology customer. (PFF ¶¶ 847–51, 1000–57.) The surge of investment in NGS-based liquid biopsy tests since the announcement of the Illumina/GRAIL merger agreement further rebuts any notion that the Transaction risks deterring Illumina customers from developing tests for Illumina's platform. (PFF ¶¶ 927–42.) Respondents further incorporate their responses to CCFF ¶ 57. Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3599. According to Mr. Flatley, Illumina determined that its customers might not want to participate in markets where Illumina had a presence, in part "because they'd believe that Illumina could always underprice them if we wanted to." (PX7057 (Flatley (Illumina) IHT at 167)).

Response to Finding No. 3599:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3598, which Respondents incorporate herein.

3600. [redacted] (PX7105 (Getty (Guardant) Dep. at 72-73) (*in camera*)). Mr. Getty explained that "as a public company . . . profitability is critical to our shareholders. And very quickly we would find it very difficult to invest in the R&D necessary or the commercialization necessary to make, you know, improvements and impact patients' lives." (PX7105 (Getty (Guardant) Dep. at 33)).

Response to Finding No. 3600:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3570, which are incorporated herein. The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that any test developers are developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. Further, the proposed finding amounts to speculation divorced from fact, including because the Open Offer prevents any anticompetitive conduct, with the backstop of arbitration by which the arbitrator is empowered to award of injunctive and monetary relief that can go as far as necessary to restore the pre-merger status quo. (*E.g.*, PFF ¶¶ 1021–23.)

3601. The cost of producing an MCED test is "highly indexed" to the cost of sequencing. (Getty (Guardant) Tr. 2518).

Response to Finding No. 3601:

The proposed finding is inaccurate, incomplete and misleading. The evidence is clear that NGS costs will be a very small part of future MCED test revenues and profits. (PFF ¶¶ 879–915.) Both Illumina [redacted] internal documents project this. (PFF ¶ 885.) Dr. Aravanis testified that "it became clear to the leadership at GRAIL and the R&D team that we

were quickly approaching a point where sequencing cost would be immaterial. In fact, things like the blood tube would end up being more expensive . . . ." (PX7104 (Aravanis (Illumina) Dep. at 205–06); [redacted]) Further, the Open Offer commits Illumina to decreasing its sequencing prices for its highest throughput product by at least 43% by 2025. (PFF ¶ 1023.)

3602. Dr. Gao, Board Member, Founder, and Scientific Advisor for Singlera, expressed that "Illumina can jack up the price of [its] reagent or machine . . . and then we will not be able to compete." (PX7042 (Gao (Singlera) IHT at 130)).

Response to Finding No. 3602:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3570. Further, the proposed finding amounts to speculation divorced from fact, including because the Open Offer prevents any anticompetitive conduct, with the backstop of arbitration by which the arbitrator is empowered to award of injunctive and monetary relief that can go as far as necessary to restore the pre-merger status quo. (*E.g.*, PFF ¶¶ 1021–23.) Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3603. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 194) (*in camera*)).

Response to Finding No. 3603:

The proposed finding is inaccurate, incomplete and misleading. [redacted]

[redacted]

[redacted]

[redacted] The proposed finding is also inaccurate, incomplete and misleading as there are alternatives to Illumina's NGS platform, and Respondents incorporate their responses to CCFF ¶ 3597. The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that any test developers are developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. Further, the proposed finding amounts to speculation divorced from fact, including because the Open Offer prevents any such conduct, with the backstop of arbitration by which the arbitrator is empowered to award of injunctive and monetary relief that can go as far as necessary to restore the pre-merger status quo. (*E.g.*, PFF ¶¶ 1021–23.) Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3604. [redacted] (PX8324 (Roche) at 005 [redacted] (*in camera*)).

Response to Finding No. 3604:

The proposed finding is inaccurate, incomplete and misleading in that it the proposed finding amounts to speculation divorced from fact, including because the Open Offer prevents

any such conduct, with the backstop of arbitration by which the arbitrator is empowered to award of injunctive and monetary relief that can go as far as necessary to restore the pre-merger status quo. (*E.g.*, PFF ¶¶ 1021–23.)

3605. (PX8324 (Roche) at 005 (*in camera*)).

Response to Finding No. 3605:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' response to CCFF ¶ 3604, which are incorporated herein.

3606. Helio's Chahine warned, "if investors see this as a foregone conclusion that Grail and Illumina are going to win the [MCED test development] category and investment dries up, then absolutely, it could have negative consequences for innovation in the category." (PX7077 (Chahine (Helio) Dep. at 62)).

Response to Finding No. 3606:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' response to CCFF ¶ 3570, which are incorporated herein. In fact, substantial evidence shows that the Transaction will spur greater innovation through the large efficiencies it

will generate (*e.g.*, PFF ¶¶ 1136–45), and it has already catalyzed excitement and investment in the liquid biopsy field (*e.g.*, PFF ¶¶ 928, 933). Thus, it is not the Transaction that threatens innovation in MCED testing, but rather Complaint Counsel's misguided effort to unwind it.

3607. Mr. Chahine elaborated:

[redacted]

(PX7077 (Chahine (Helio) Dep. at 56) (*in camera*)).

Response to Finding No. 3607:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' response to CCFF ¶¶ 3570 and 3606, which are incorporated herein.

3608. Guardant's Mr. Getty stated that the company is "in a bit of a freeze because if you believe [Illumina] [is] going to, you know, increase your price across your portfolio, then the question becomes why, why would you pursue future tests. You know, there's no way to be successful there. So it -- unfortunately, the acquisition largely slows down innovation not just at Guardant but across the entire industry because everyone else is just as reliant on Illumina as well." (PX7040 (Getty (Guardant) IHT at 147)).

Response to Finding No. 3608:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' response to CCFF ¶ 3570, which are incorporated herein. Further, the proposed finding amounts to speculation divorced from fact, including because the Open Offer prevents any anticompetitive conduct, with the backstop of arbitration by which the arbitrator is empowered to award of injunctive and monetary relief that can go as far as necessary to restore the pre-merger status quo. (*E.g.*, PFF ¶¶ 1021–23.) The proposed finding is also inaccurate, incomplete and misleading to the extent that it suggests that any test developers are developing

and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3609. Further, Mr. Getty warned that one implication of Illumina's acquisition of Grail was that:

> [I]n a more sort of nefarious potential, you have a competitor who controls essentially your margins, and so, you know – and they – and internally Illumina obviously, you know, wants the most profitable product and can do things at a lower cost because they are the manufacturer of the reagent, and so not only could they copy what we were doing, they could do it at a lower cost, maximize their own profitability, and slowly squeeze us into a position of being completely uncompetitive or, you know, *potentially not able to support the innovation that we would need or the innovation we'd want to pursue*.

(PX7040 (Getty (Guardant) IHT at 135) (emphasis added)).

Response to Finding No. 3609:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' response to CCFF ¶¶ 3570 and 3608, which are incorporated herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3610. Bill Getty of Guardant testified that Illumina could "provide favored status or development opportunities to their internal partners in GRAIL, which would convey potentially a lack of opportunity for us to advance our technology at a faster rate, and . . . thus hurt us competitively." (PX7105 (Getty (Guardant) Dep. at 69-71)).

Response to Finding No. 3610:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' response to CCFF ¶¶ 3570 and 3608, which are incorporated herein.

3611. Guardant's Bill Getty testified that without access to Illumina's latest technology, Guardant will not be able to offer patients the best performing or the lowest cost test. (PX7105 (Getty (Guardant) Dep. at 74-75)).

Response to Finding No. 3611:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' response to CCFF ¶¶ 3570 and 3608, which are incorporated herein.

3612. Mr. Getty described the scenario where "the profitability is squeezed for other manufacturers such that over time, those manufacturers are rendered nonexistent. And ultimately then innovation slows down because there's no advantage for Illumina to advance their technology such that patients will be negatively impacted." (PX7105 (Getty (Guardant) Dep. at 76)).

Response to Finding No. 3612:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' response to CCFF ¶¶ 3570 and 3608, which are incorporated herein.

3613. [redacted]

Response to Finding No. 3613:

The proposed finding is inaccurate, incomplete and misleading. [redacted]

[redacted] (PFF ¶¶703-704.)

3614. [redacted]

Response to Finding No. 3614:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3583 and 3613, which are incorporated herein. Further, the proposed finding amounts to speculation divorced from fact, including because the Open Offer prevents any anticompetitive conduct, with the backstop of arbitration by which the arbitrator is empowered to award of injunctive and monetary relief that can go as far as necessary to restore the pre-merger status quo. (*E.g.*, PFF ¶¶ 1021–23.)

3615. [redacted]

Response to Finding No. 3615:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3583 and 3613, which are incorporated herein. Further, the proposed finding amounts to speculation divorced from fact, including because the Open Offer prevents any anticompetitive conduct, with the backstop of arbitration by which the arbitrator is empowered to award of injunctive and monetary relief that can go as far as necessary to restore the pre-merger status quo. (*E.g.*, PFF ¶¶ 1021–23.) Further, Mr. Fesko is not a credible source of information concerning Illumina's conduct, and his (and Natera's) claims bout Illumina's conduct in the U.S. NIPT market, in which Natera has long remained the market leader, are refuted by the facts, as explained below in response to CCFF ¶¶ 4125-4137, which are incorporated herein by reference. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3616. [redacted]

Response to Finding No. 3616:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3583, 3613 and 3615. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3617. [redacted]

Response to Finding No. 3617:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3583, 3613 and 3615. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3618. [redacted]

Response to Finding No. 3618:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3583, 3613 and 3615. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3619. [redacted]

[redacted]

Response to Finding No. 3619:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3583, 3613 and 3615. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3620. [redacted]

[redacted]

Response to Finding No. 3620:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3583, 3613 and 3615. Further, the proposed finding relies

on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3621. [redacted]

Response to Finding No. 3621:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3583, 3613 and 3615.

3622. Singlera's Dr. Gao testified at trial that he is concerned about the impact of Illumina's acquisition of Grail on Singlera's ability to raise money from investors. (Gao (Singlera) Tr. 2902).

Response to Finding No. 3622:

The proposed finding amounts to speculation divorced from fact, including because the Open Offer prevents any anticompetitive conduct, with the backstop of arbitration by which the arbitrator is empowered to award of injunctive and monetary relief that can go as far as necessary to restore the pre-merger status quo, and because Illumina has every incentive to support its customers post-Transaction. (E.g., PFF ¶¶ 857-864, 1021–23.) The proposed finding is also misleading in that substantial evidence shows that the Transaction has already catalyzed excitement and investment in the liquid biopsy field (*e.g.*, PFF ¶¶ 928, 933).

3623. Dr. Gao explained how Singlera's negotiations with Illumina could impact investment in Singlera: "Illumina will now play hardball for negotiation, and that either will take us longer time to negotiate or even convince any investor this is worthy, economically, you know, feasible. I think we will be at a disadvantage to convince any investor to invest in us." (PX7042 (Gao (Singlera) IHT at 130)).

Response to Finding No. 3623:

The proposed finding amounts to speculation divorced from fact, including because the Open Offer prevents any anticompetitive conduct, with the backstop of arbitration by which the arbitrator is empowered to award of injunctive and monetary relief that can go as far as necessary to restore the pre-merger status quo, and because Illumina has every incentive to support its customers post-Transaction. (*E.g.*, PFF ¶¶ 857-864, 1021–23.) The proposed finding is also misleading in that substantial evidence shows that the Transaction has already catalyzed excitement and investment in the liquid biopsy field (e.g., PFF ¶¶ 928, 933). Additionally, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3624. According to Dr. Gao, an inability to raise money from investors will be "very damaging" to Singlera, as the company would have to "lay off people, and then maybe narrow down other things." (Gao (Singlera) Tr. 2902).

Response to Finding No. 3624:

The proposed finding amounts to speculation divorced from fact, including because the Open Offer prevents any anticompetitive conduct, with the backstop of arbitration by which the arbitrator is empowered to award of injunctive and monetary relief that can go as far as necessary to restore the pre-merger status quo, and because Illumina has every incentive to support its customers post-Transaction. (E.g., PFF ¶¶ 857-864, 1021–23.) The proposed finding is also misleading in that substantial evidence shows that the Transaction has already catalyzed excitement and investment in the liquid biopsy field (e.g., PFF ¶¶ 928, 933).

3625. Dr. Gao testified, "[t]here's no incentive for Illumina to support . . . people other than GRAIL." (PX7042 (Gao (Singlera) IHT at 90)).

Response to Finding No. 3625:

The proposed finding amounts to speculation divorced from fact, including because the Open Offer prevents any anticompetitive conduct, with the backstop of arbitration by which the arbitrator is empowered to award of injunctive and monetary relief that can go as far as necessary to restore the pre-merger status quo, and because Illumina has every incentive to support its customers post-Transaction. (E.g., PFF ¶¶ 857-864, 1021–23.) The proposed finding is also misleading in that substantial evidence shows that the Transaction has already catalyzed excitement and investment in the liquid biopsy field (e.g., PFF ¶¶ 928, 933). The proposed finding is also irrelevant, incomplete and misleading because third parties are not reliable sources of Illumina's own incentives. Indeed, it is telling and a reflection of Complaint Counsel's double standard approach that it argues the speculation of a small number of ***third party*** executives regarding Illumina's supposed post-Transaction incentives is proof of those incentives, whereas the testimony of Illumina's ***own executive leaders*** as to Illumina's incentives are given no weight. Additionally, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3626. Dr. Gao elaborated, Illumina will have "no incentive to faithfully negotiate with anyone, not only Singlera, on how their machine will be used or priced." (PX7042 (Gao (Singlera) IHT at 130)).

Response to Finding No. 3626:

The proposed finding amounts to speculation divorced from fact, including because the Open Offer prevents any anticompetitive conduct, with the backstop of arbitration by which the arbitrator is empowered to award of injunctive and monetary relief that can go as far as necessary to restore the pre-merger status quo, and because Illumina has every incentive to support its

customers post-Transaction. (E.g., PFF ¶¶ 857-864, 1021–23.) The proposed finding is also misleading in that substantial evidence shows that the Transaction has already catalyzed excitement and investment in the liquid biopsy field (e.g., PFF ¶¶ 928, 933). The proposed finding is also irrelevant, incomplete and misleading because third parties are not reliable sources of Illumina's own incentives. Indeed, it is telling and a reflection of Complaint Counsel's double standard approach that it argues the speculation of a small number of ***third party*** executives regarding Illumina's supposed post-Transaction incentives is proof of those incentives, whereas the testimony of Illumina's ***own executive leaders*** as to Illumina's incentives are given no weight. Additionally, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3627. [redacted]

Response to Finding No. 3627:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that Roche is developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. The proposed finding also ignores that Dr. Fielder testified that [redacted]

[redacted] Respondents incorporate their responses to CCFF ¶ 462 herein. Further, the proposed finding is inaccurate, incomplete and misleading to suggest that there are no alternative suppliers to Illumina; Respondents incorporate their responses to CCFF ¶ 3597 herein. Ms. Perettie testified that [redacted] (PX7068 (Perettie) FMI-Roche) IHT at 58 (*in camera*).) Further, the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3628. [redacted]

Response to Finding No. 3628:

The proposed finding is irrelevant, incomplete and misleading for the reasons Respondents explain in their responses to CCFF ¶ 3627. Further, the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3629. [redacted]

[redacted]

Response to Finding No. 3629:

The proposed finding is irrelevant, incomplete and misleading for the reasons Respondents explain in their responses to CCFF ¶ 3627. Further, if anything, the proposed finding shows (along with other substantial evidence) that there are alternatives to Illumina's platform for cancer detection test developers, and Respondents incorporate their responses to CCFF ¶ 3597 herein. The proposed finding is also misleading to the extent it is intended to suggest the Transaction will diminish innovation. To the contrary, substantial evidence shows that the Transaction will spur greater innovation through the large efficiencies it will generate (*e.g.*, PFF ¶¶ 1136–45), and it has already catalyzed excitement and investment in the liquid biopsy field (*e.g.*, PFF ¶¶ 928, 933). Thus, it is not the Transaction that threatens innovation in MCED testing, but rather Complaint Counsel's misguided effort to unwind it. Further, the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3630. [redacted]

Response to Finding No. 3630:

The proposed finding is irrelevant, incomplete and misleading for the reasons Respondents explain in their responses to CCFF ¶ 3627. Further, if anything, the proposed

finding shows (along with other substantial evidence) that there are alternatives to Illumina's platform for cancer detection test developers, and Respondents incorporate their responses to CCFF ¶ 3597 herein. The proposed finding is also misleading to the extent it is intended to suggest the Transaction will diminish innovation. To the contrary, substantial evidence shows that the Transaction will spur greater innovation through the large efficiencies it will generate (*e.g.*, PFF ¶¶ 1136–45), and it has already catalyzed excitement and investment in the liquid biopsy field (*e.g.*, PFF ¶¶ 928, 933). Thus, it is not the Transaction that threatens innovation in MCED testing, but rather Complaint Counsel's misguided effort to unwind it. Further, the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3631. [redacted]

Response to Finding No. 3631:

The proposed finding is irrelevant, incomplete and misleading for the reasons Respondents explain in their responses to CCFF ¶ 3627. Further, if anything, the proposed finding shows (along with other substantial evidence) that there are alternatives to Illumina's platform for cancer detection test developers, and Respondents incorporate their responses to CCFF ¶ 3597 herein. The proposed finding is also misleading to the extent it is intended to suggest the Transaction will diminish innovation. To the contrary, substantial evidence shows that the Transaction will spur greater innovation through the large efficiencies it will generate (*e.g.*, PFF ¶¶ 1136–45), and it has already catalyzed excitement and investment in the liquid

biopsy field (*e.g.*, PFF ¶¶ 928, 933). Thus, it is not the Transaction that threatens innovation in MCED testing, but rather Complaint Counsel's misguided effort to unwind it.

3632. [redacted] (Lengauer (Third Rock Ventures) Tr. 196-99 (*in camera*)).

Response to Finding No. 3632:

The proposed finding amounts to speculation divorced from fact, including because the Open Offer prevents any anticompetitive conduct, with the backstop of arbitration by which the arbitrator is empowered to award of injunctive and monetary relief that can go as far as necessary to restore the pre-merger status quo, and because Illumina has every incentive to support its customers post-Transaction. (E.g., PFF ¶¶ 857-864, 1021–23.) The proposed finding is also misleading in that Illumina does not have any incentive to try to make its sequencing systems optimized for Galleri but not for a third-party test; Illumina has not optimized any of its products for Galleri; and Illumina does not have any pattern or practice of optimizing its sequencers for particular applications. (PFF ¶¶ 1319; 1666.) The proposed finding is also misleading in that substantial evidence shows that the Transaction has already catalyzed excitement and investment in the liquid biopsy field (e.g., PFF ¶¶ 928, 933). The proposed finding is also inaccurate, incomplete and misleading to the extent that it suggests that Exact/Thrive is developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. The proposed finding is also irrelevant, incomplete and misleading because third parties are not reliable sources of Illumina's own incentives. Indeed, it is telling and a reflection of Complaint Counsel's double standard approach that it argues the speculation of a small number of ***third party*** executives regarding Illumina's supposed post-Transaction incentives is proof of those

incentives, whereas the testimony of Illumina's ***own executive leaders*** as to Illumina's incentives are given no weight.

3633. [redacted]

(Lengauer (Third Rock Ventures) Tr. 197-98 (*in camera*)).

Response to Finding No. 3633:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3632, which are incorporated herein.

3634. [redacted]

(PX7051 (Lengauer (Third Rock Ventures) IHT at 92-93. 189-91) (*in camera*)).

Response to Finding No. 3634:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3632, which are incorporated herein. Further, the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3635. [redacted] (Lengauer (Third Rock Ventures) Tr. 98 (*in camera*)).

Response to Finding No. 3635:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3632, which are incorporated herein.

3636. [redacted] (Lengauer (Third Rock Ventures) Tr. 200 (*in camera*)).

Response to Finding No. 3636:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3632, which are incorporated herein.

3637. [redacted] (Lengauer (Third Rock Ventures) Tr. 196-99 (*in camera*)).

Response to Finding No. 3637:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3632, which are incorporated herein.

3638. [redacted]

For additional evidence on MCED test developers concerns with the Illumina-Grail transaction, see Section VIII.A.2.c. (Concerns Regarding Illumina's Acquisition of Grail Expressed by Illumina Customers).

Response to Finding No. 3638:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3632, which are incorporated herein. Further, the proposed finding relies on IH testimony, which Respondents had no opportunity to cross

examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

2. MCED Developers Are Currently Competing—and Expect to Continue to Compete—on the Basis of Innovation, Not Just Price

3639. [redacted] (PX7138 (Scott Morton Trial Dep. at 30) (*in camera*)).

Response to Finding No. 3639:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that any test developers are developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. [redacted] are unsupported claims of an economic expert who is not qualified to opine on MCED development.

3640. [redacted] (PX7138 (Scott Morton Trial Dep. at 352) (*in camera*)).

Response to Finding No. 3640:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that any test developers are developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. [redacted] are unsupported claims of an economic expert who is not qualified to opine on MCED development.

3641. [redacted]

[redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 16 (*in camera*)).

Response to Finding No. 3641:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that any test developers are developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. [redacted] are unsupported claims of an economic expert who is not qualified to opine on MCED development.

3642. [redacted] (RX6004 (Katz Trial Dep. at 105) (*in camera*)).

Response to Finding No. 3642:

The proposed finding is incomplete and misleading in that it omits Dr. Katz's full testimony. [redacted]

3643. As Chief Medical and Scientific Officer for the American Cancer Society, Dr. William Cance, explained, "I don't believe we will have one test be 100 percent accurate and zero percent inaccurate. So, therefore, multiple companies and institutions developing and improving this technology is very important." (PX7086 (Cance (American Cancer Society) Dep. at 101)).

Response to Finding No. 3643:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that any test developers are developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. The proposed finding is also a red herring in

that there is no dispute that innovation benefits consumers and should be allowed to flourish. However, it is the Transaction that will spur greater innovation (*e.g.*, PFF ¶¶ 928, 933, 1136–45), and it is Complaint Counsel's misguided attempt to unwind the Transaction that threatens innovation.

3644. [redacted]

Response to Finding No. 3644:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that any test developers are developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. Further, the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

a) Despite Grail's First-Mover Advantage, Other MCED Developers Will Have the Incentive to "Leapfrog" Grail by Offering Better Technology

3645. [redacted]

[redacted]

(PX6090 (Scott Morton Report) ¶ 222 (*in camera*)).

Response to Finding No. 3645:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that any test developers are developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. [redacted] are unsupported claims of an economic expert who is not qualified to opine on MCED development. Further, the proposed finding highlights the differentiation among tests in development which further undercuts the conclusion that any in development will be substitutes for Galleri, and also highlights one of the reasons Illumina has an incentive to support all development of clinical tests on its NGS platforms—a successful test that has performance dimensions important to patients or clinicians would catalyze and expand demand for Illumina's NGS products, giving it greater opportunity for upstream sales than would be the case without such a test in the marketplace. (*E.g.*, PFF ¶¶ 826, [redacted], 849.)

3646. [redacted] (Bishop (Grail) Tr. 1447-48 (*in camera*); PX7083 (Bishop (Grail) Dep. at 70-71)).

Response to Finding No. 3646:

Respondents have no specific response.

3647. Grail CEO, Hans Bishop, emphasized that "one of the exciting things about the horizon scanning we do and the [MCED test development] field in general is the number of different approaches different companies are taking." (PX7069 (Bishop (Grail) IHT at 154-156)).

Response to Finding No. 3647:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that any test developers are developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. Further, the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3648. Mr. Bishop explained that there are a "number of different approaches different companies are taking," including multiomics as a way to try "to get to the highest-performing technology." (PX7069 (Bishop (Grail) IHT at 154-56)).

Response to Finding No. 3648:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that any test developers are developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. Further, the proposed finding relies on IH testimony, which Respondents had no opportunity to cross examine, and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3649. Grail previously pursued other approaches to detecting cancer, including mutations and aneuploidy in cfDNA, but later decided to focus on the use of methylation sites in cfDNA as its method for the Galleri test. (PX4082 (Grail) at 099 (Email from B. Cornelius, Latham & Watkins LLP, to C. Gartin, Morgan Stanley, et al., attaching Grail 2020 S-1/Amended, Sept. 17, 2020); PX7069 (Bishop (Grail) IHT at 123-24)).

Response to Finding No. 3649:

Respondents have no specific responses except to note that the fact that in its early stage development GRAIL explored different approaches for a potential MCED test does not support any of Complaint Counsel's contentions concerning innovation competition.

3650. Dr. William Cance, Chief Medical and Scientific Officer of the American Cancer Society declared:

> Having multiple approaches to compare against one another can ultimately lead to better clinical outcomes for patients and more cost-effective approaches to cancer detection for the benefit of patients. A good example of the importance of multiple approaches to innovation is the development and efficacy of COVID vaccinations from Pfizer, Moderna, Johnson & Johnson, AstraZeneca, Novavax, and others. At this stage, it is unclear whether analyzing DNA mutations, DNA methylation patterns, chromosomal variations, RNA variations, protein markers, or some other method for detecting cancer in the blood will prove most effective.

(PX8398 (Cance (American Cancer Society) Decl. ⁋ 11)).

Response to Finding No. 3650:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that any test developers are developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. The proposed finding is also a red herring in that there is no dispute that innovation benefits consumers and should be allowed to flourish. However, it is the Transaction that will spur greater innovation (*e.g.*, PFF ¶¶ 928, 933, 1136–45), and it is Complaint Counsel's misguided attempt to unwind the Transaction that threatens innovation.

3651. [redacted] (PX6090 (Scott Morton Report) ¶ 160 (*in camera*)).

Response to Finding No. 3651:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that any test developers are developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their

responses to CCFF ¶¶ 378, 3577 and 3639 herein. [redacted] are unsupported claims of an economic expert who is not qualified to opine on MCED development. Further, the proposed finding highlights the differentiation among tests in development which further undercuts the conclusion that any in development will be substitutes for Galleri, and also highlights one of the reasons Illumina has an incentive to support all development of clinical tests on its NGS platforms—a successful test that has performance dimensions important to patients or clinicians would catalyze and expand demand for Illumina's NGS products, giving it greater opportunity for upstream sales than would be the case without such a test in the marketplace. (*E.g.*, PFF ¶¶ 826, [redacted], 849.)

3652. In testimony, Dr. Vogelstein affirmed,

> Researchers and ultimately the public benefit from having multiple firms and companies developing tests employing nucleic acid sequencing for the earlier detection of cancer. The greater the number of teams of researchers working with nucleic acid sequencing technologies such as Illumina's to identify cancer-specific differences in nucleic acids in the blood, the greater the chances of new discoveries that lead to more accurate, more effective, and more cost-effective earlier detection tests being developed.

(PX7101 (Vogelstein (Johns Hopkins University) Dep. at 71)).

Response to Finding No. 3652:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that any test developers are developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. The proposed finding is also a red herring in that there is no dispute that innovation benefits consumers and should be allowed to flourish. However, it is the Transaction that will spur greater innovation (*e.g.*, PFF ¶¶ 928, 933, 1136–45), and it is Complaint Counsel's misguided attempt to unwind the Transaction that threatens innovation.

3653. With respect to which technology will be most successful for detecting cancer in blood, Dr. Vogelstein testified that he has "a sense it will be based on massively parallel sequencing" but other than that he doesn't know which will be most successful because "there's so many analytes and ways of analyzing cell-free DNA using massively parallel sequencing." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 80-81)).

Response to Finding No. 3653:

Respondents have no specific responses other than to note that there are numerous routes that might be pursued in the cancer detection testing space. None of the MCED tests developers cited by Complaint Counsel have ascertained the specific features of any MCED test that they may launch in the future, although it is clear that none is on a path to launching a test, like Galleri, that can detect 50 cancer types and cancer of origin in a single blood draw. (PFF ¶¶ 836–38.)

3654. With respect to technologies used for cancer detection, Dr. Vogelstein testified that "[t]here are many different analytes that can be detected in blood, many different characteristics of DNA, and I don't know which will be superior because no one, including Thrive or us that I know of, has yet done the kinds of studies that will indicate which tests will be superior in actual practice in a prospective trial." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 48-49)).

Response to Finding No. 3654:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that any test developers are likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. In particular, Exact/Thrive's test will not compete with Galleri in the near future. Galleri detects more than 50 cancer types (PFF ¶ 61), while Dr. Lengauer testified that the DETECT-A study of CancerSEEK only detected cancers of 10 organs (Lengauer (Exact/Thrive) Tr. 245; RX3869 (Cote Expert Report) ¶ 177; PFF ¶¶ 429–430.1).

[redacted]

[redacted] By contrast, CancerSEEK must use a whole body PET-CT scan to attempt to localize any detected cancers. (*See* Lengauer (Exact/Thrive) Tr. 248; RX3419 (Lennon et al., 2020) at 3; PFF ¶¶ 419, 425, 739, 760, 841.3, 1723–24.) Dr. Lengauer also observes that the DETECT-A study of CancerSEEK only detected cancers of 10 organs, as opposed to the more than 50 cancer types that Galleri detects. (PFF ¶ 429 (Lengauer (Exact/Thrive) Tr. 245; RX3869 (Cote Expert Report) ¶ 177).) Dr. Lengauer also testified that CancerSEEK obtained a 30% sensitivity rate in the DETECT-A trial, as opposed to the 51.5% sensitivity rate of Galleri. (PFF ¶¶ 725 (RX3409 (Klein et al., 2021) at 5; RX3419 (Lennon et al., 2020) at 7; RX3115 (Chen et al., 2020) at 4).) [redacted] (PFF ¶ 421.)

Further, contrary to the proposed finding, GRAIL's PATHFINDER study is a prospective study that enrolled 6,662 participants in the U.S., to whom results were returned. This prospective trial allowed GRAIL to evaluate the implementation of Galleri in clinical practice. Its results were positive and largely confirmed previous studies. (PFF ¶¶ 394–402.) While Thrive's DETECT-A study was prospective, it only detected 10 cancers; no subsequent data has shown the test can detect more. (PFF ¶¶ 429–430.)

3655. [redacted]
(PX7051 (Lengauer (Third Rock Ventures) IHT at 179) (*in camera*)).

Response to Finding No. 3655:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that Exact/Thrive is developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to

CCFF ¶¶ 378, 3577, 3639 and 3654 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3656. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 179) (*in camera*)).

Response to Finding No. 3656:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that Exact/Thrive is developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577, 3639 and 3654 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3657. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 179) (*in camera*)).

Response to Finding No. 3657:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that Exact/Thrive is developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577, 3639 and 3654 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3658. [redacted]

[redacted] (PX7058 (Conroy (Exact) IHT at 114-15) (*in camera*)).

Response to Finding No. 3658:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that Exact/Thrive (or any other test developer identified by Complaint Counsel) is developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577, 3639 and 3654 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3659. [redacted] (Conroy (Exact) Tr. 1558-59 (*in camera*)).

Response to Finding No. 3659:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that Exact/Thrive is developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577, 3639 and 3654 herein.

3660. [redacted] (Conroy (Exact) Tr. 1558-59 (*in camera*)).

Response to Finding No. 3660:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that Exact/Thrive is developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577, 3639 and 3654 herein.

3661. Singlera's Dr. Gao testified that "continuous improvement, innovation, to reduce cost, improve accuracy and improve convenience will always be [ ] nonstop of any company." (PX7042 (Gao (Singlera) IHT at 100)).

Response to Finding No. 3661:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that Singlera is developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. Dr. Gao has also testified that Singlera is "far away" from starting clinical trials for PanSeer in the United States, and that it is "still not in the really starting clinical trial state." (Gao (Singlera) Tr. 2926; PX7102 (Gao (Singlera) Dep. at 113–14, 81–82; PFF ¶ 536.1.) By Dr. Gao's own calculation, PanSeer is at least eight to ten years away from potential launch in the United States, and Singlera does not currently have any clinical trials relating to screening for multiple cancers listed on clinicaltrials.gov. (PFF ¶¶ 536.1-36.2.) Accordingly, [redacted] The proposed finding is also a red herring in that there is no dispute that innovation benefits consumers and should be allowed to flourish. However, it is the Transaction that will spur greater innovation (*e.g.*, PFF ¶¶ 928, 933, 1136–45), and it is Complaint Counsel's misguided attempt to unwind the Transaction that threatens innovation. Further, the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3662. Dr. Gao elaborated that innovation is "the number one [priority for Singlera's executives], the soul of our company" because Singlera "ha[s] to innovate to survive" as a company. (PX7042 (Gao (Singlera) IHT at 100-01)).

Response to Finding No. 3662:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that Singlera is developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577, 3639 and 3661 herein. The proposed finding is also a red herring in that there is no dispute that innovation benefits consumers and should be allowed to flourish. However, it is the Transaction that will spur greater innovation (*e.g.*, PFF ¶¶ 928, 933, 1136–45), and it is Complaint Counsel's misguided attempt to unwind the Transaction that threatens innovation. The proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3663. [redacted]

Response to Finding No. 3663:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that any Natera (or any test developer) is developing and likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. [redacted]

[redacted] and that Natera is unlikely to accelerate the development of a cancer screening test for multiple cancer types or to add a new cancer type to an existing screening test, [redacted]. (PFF ¶¶ 509–10.) Respondents incorporate their responses to CCFF ¶ 420 herein. The proposed finding is also a red herring in that there is no dispute that innovation benefits consumers and should be allowed to flourish. However, it is the Transaction that will spur greater innovation (*e.g.*, PFF ¶¶ 928, 933, 1136–45), and it is Complaint Counsel's misguided attempt to unwind the Transaction that threatens innovation. The proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3664. [redacted]

Response to Finding No. 3664:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that any test developers are likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. Further, the proposed finding highlights the differentiation among tests in development which further undercuts the conclusion that any in development will be substitutes for Galleri, and also highlights one of the reasons Illumina has an incentive to support all development of clinical tests on its NGS platforms—a successful test that has performance

dimensions important to patients or clinicians would catalyze and expand demand for Illumina's NGS products, giving it greater opportunity for upstream sales than would be the case without such a test in the marketplace. (*E.g.*, PFF ¶¶ 826, [redacted], 849.)

3665. [redacted]

Response to Finding No. 3665:

The proposed finding is inaccurate, incomplete and misleading to the extent that it suggests that any test developers are likely to launch an MCED test that will compete with Galleri at any point in the foreseeable future; Respondents incorporate their responses to CCFF ¶¶ 378, 3577 and 3639 herein. Further, the proposed finding highlights the differentiation among tests in development which further undercuts the conclusion that any in development will be substitutes for Galleri, and also highlights one of the reasons Illumina has an incentive to support all development of clinical tests on its NGS platforms—a successful test that has performance dimensions important to patients or clinicians would catalyze and expand demand for Illumina's NGS products, giving it greater opportunity for upstream sales than would be the case without such a test in the marketplace. (*E.g.*, PFF ¶¶ 826, [redacted], 849.) [redacted] (PFF ¶ 438.2.) [redacted] (PFF ¶ 439.) No test in development has demonstrated the ability to identify cancer signal of origin without the aid of a PET-CET scan. (PFF ¶ 684.2.)

3666. Guardant plans to differentiate its own MCED test from others based on the company's "legacy of innovation" being the "first liquid biopsy to be approved by the FDA in a different context but in the context of treatment selection." (PX7105 (Getty (Guardant) Dep. at 41)).

Response to Finding No. 3666:

The proposed finding is misleading and incomplete insofar as it suggests that Guardant is developing and likely to launch an MCED test comparable to Galleri at any point in the foreseeable future, which is not true and contradicted by the evidence. [redacted]

[redacted] Respondents incorporate their responses to CCFF ¶ 426.

3667. Bill Getty, Senior Vice President of Commercial at Guardant, emphasized that Guardant "will do what [it has] always done, which is improve the performance of [its] assay in order to remain competitive." (PX7105 (Getty (Guardant) Dep. at 41-42)).

Response to Finding No. 3667:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3666, which are incorporated herein.

3668. Mr. Getty elaborated that Guardant's focus on improving the performance of its MCED test will in turn provide "greater benefit for patients and also is a compelling value of proposition to physicians." (PX7105 (Getty (Guardant) Dep. at 41-42)).

Response to Finding No. 3668:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' responses to CCFF ¶ 3666, which are incorporated herein.

D. ILLUMINA'S ANALYSIS AND BEHAVIOR IN OTHER MARKETS IN WHICH IT IS VERTICALLY INTEGRATED CORROBORATES EVIDENCE SHOWING ILLUMINA WILL HAVE THE ABILITY AND INCENTIVE TO DISADVANTAGE POTENTIAL COMPETITORS TO GRAIL

1. Illumina Identified Tools When It Launched and Spun Off Grail

a) When Illumina Created a Grail as a Majority-Controlled Entity, Illumina Gave Grail Exclusive Discounts and Special Assistance

(1) Illumina Created Grail as an Independent Company That Was Majority Owned by Illumina

3669. The team that started Grail began work on Grail in 2015 as a part of Illumina. (deSouza (Illumina) Tr. 2194-95).

Response to Finding No. 3669:

Respondents have no specific response.

3670. Illumina executives explained that Grail was separately incorporated in the beginning of 2016. (deSouza (Illumina) Tr. 2194-95); Flatley (Illumina) Tr. 4090)).

Response to Finding No. 3670:

Respondents have no specific response.

3671. Grail remained an Illumina-affiliated entity after it was incorporated. (deSouza (Illumina) Tr. 2198-99; Flatley (Illumina) Tr. 4092; *See also* PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 8 (RFA No. 5)).

Response to Finding No. 3671:

Respondents have no specific response.

3672. "Illumina admits that it formed GRAIL in January of 2016, and at that time held a majority of the voting shares of GRAIL." (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 8 (RFA No. 5)).

Response to Finding No. 3672:

Respondents have no specific response.

3673. Illumina prepared questions and answers relating to the formation of Grail for "a presentation to investors about GRAIL and what [Illumina was] doing in forming GRAIL." (PX2543 (Illumina) (Illumina, GRAIL FAQs, Jan. 11, 2016); deSouza (Illumina) Tr. 2196-97).

Response to Finding No. 3673:

Respondents have no specific response.

3674. The presentation Illumina prepared for investors explains that "Illumina [is] starting another company vs. expanding its own business to include these new services" because Grail was a major R&D endeavor "requiring trials which will sequence more individuals than any program announced to date, but with the potential for significant returns." (PX2543 (Illumina) at 001-02 (Illumina, GRAIL FAQs, Jan. 11, 2016); deSouza (Illumina) Tr. 2195-96).

Response to Finding No. 3674:

Respondents have no specific response.

3675. The presentation Illumina prepared for investors notes that "GRAIL is majority owned by Illumina, but the independent company structure will allow [them] to run as a true start-up." (PX2543 (Illumina) at 002 (Illumina, GRAIL FAQs, Jan. 11, 2016)).

Response to Finding No. 3675:

Respondents have no specific response.

3676. The presentation Illumina prepared for investors notes that "[t]he business of GRAIL will be very different than Illumina's core business." (PX2543 (Illumina) at 002 (Illumina, GRAIL FAQs, Jan. 11, 2016)).

Response to Finding No. 3676:

Respondents have no specific response.

(2) At the Time It Created Grail, Illumina Purposefully Avoided Focusing on Overlapping Markets With Its Customers

3677. Jay Flatley – then the CEO of Illumina – explained to Jeff Huber that when forming Grail, "[i]n order to avoid competition with Illumina customers already focused on determining tumor mutational status from a draw (liquid biopsies), minimal residual disease, or therapeutic response monitoring, Python [Grail] will focus entirely on asymptomatic individuals." (PX2218 (Illumina) at 001 (Email from J. Flatley, Illumina, to J. Huber, Illumina, Feb. 22, 2016).

Response to Finding No. 3677:

The proposed finding is misleading and incomplete insofar as it is intended to suggest that the conditions described in Mr. Flatley's email have not changed since 2015 and are relevant to an evaluation of the Transaction's competitive effects. Respondents note that as Illumina's contemporaneous internal documents noted, in 2015, Illumina believed that "no customer has the ability to implement a pan-cancer screening test responsibly and economically anytime in the next 5 years"; therefore, to accelerate the growth of the segment, Illumina "felt an imperative to organize an entity" focused on that moon-shot mission. (PFF ¶ 980.2 (RX1088 (Illumina) at 7; (Flatley (Illumina) Dep. at 111–12).) These considerations from the time of GRAIL's formation no longer exist for many reasons, including because the cost of sequencing has come down

substantially since 2015. (PFF ¶¶ 21, 981.) Further, since that time, Illumina entered the oncology therapy selection space, launching its TSO500 test in 2018, and has concluded and shown through its actions in therapy selection that it can support and encourage the development of its customers' oncology tests while competing alongside those customers. (PFF ¶¶ 964-973.) Innovation is flourishing in therapy selection, as it is in NIPT, another downstream application in which Illumina both competes with and supports third party test developers. (PFF ¶¶ 950-973.)

3678. Mr. Flatley also explained to Mr. Huber that when forming Grail, "[i]n order to avoid competition with Illumina customers already focused on cancer risk testing (e.g. BRCA testing), Python [Grail] will focus on the detection of somatic mutations in ctNDA and ctRNA rather than on inherited mutations in tissues." (PX2218 (Illumina) at 001 (Email from J. Flatley to J. Huber, Feb. 22, 2016).

Response to Finding No. 3678:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' response to CCFF ¶ 3677, which Respondents incorporate herein.

3679. Mr. Flatley testified that if Grail competed "in markets that already existed, then customers wouldn't want to participate in those markets because they'd believe that Illumina could always underprice them if we wanted to." (PX7057 (Flatley (Illumina) IHT at 166–68)).

Response to Finding No. 3679:

The proposed finding is misleading and incomplete for the reasons explained in Respondents' response to CCFF ¶ 3677, which Respondents incorporate herein

(3) While Illumina Had Majority-Ownership, Grail Received Preferential Treatment

(a) Grail's Supply Agreement with Illumina Included Significant Discounts

3680. While Illumina was the majority owner, Grail had access to deeper discounts on Illumina consumables and instruments than other Illumina customers. (deSouza (Illumina) Tr. 2198-99).

Response to Finding No. 3680:

The proposed finding is irrelevant because any special pricing and other benefits Illumina may have provided to GRAIL in its original supply agreement when GRAIL was formed and controlled by Illumina are irrelevant to evaluating the effects of the Transaction on competition. (PFF ¶ 979.) [redacted] (PFF ¶¶ 980–980.4.)

In addition, the proposed finding is incorrect to the extent it suggests that GRAIL required and received deeper discounts to complete its development of Galleri. That is not true. As Dr. Aravanis explained, "the pricing benefits that GRAIL had during the first year [of its existence], which were then eliminated for the majority of its life, ended up having . . . minimal benefit" because "[i]t turned out that the sequencing cost was not that significant in the development of these tests." (PX7065 (Aravanis (Illumina) IHT at 63–64.) In fact, the prices that Illumina charged GRAIL during the time frame of Galleri's development after Illumina no longer held a controlling stake in GRAIL, and today, as well as the price reductions it modelled for GRAIL as part of its modelling the Transaction, serve as the basis for the pricing now available to all test developers through the Open Offer and its universal grid. (PFF ¶ 1023.6.) [redacted] (PFF ¶¶ 886–97.)

3681. [redacted] (PX2550 (Illumina) at 001, 037 [redacted] (*in camera*)).

Response to Finding No. 3681:

Respondents have no specific response.

3682. [redacted] (PX2550 (Illumina) at 001, 008–09, 038 [redacted] (*in camera*); *see also* PX2183 (Illumina) at 004 (Email from N. Naclerio, Illumina, to A. Pierce, Illumina, et al., attaching Python: Board Approval, Dec. 20, 2015)).

Response to Finding No. 3682:

The proposed finding is irrelevant and incorrect for the reasons explained in CCFF ¶¶ 23, 3680, which Respondents incorporate herein. Respondents further note that Complaint Counsel chose not to discuss the cited documents at trial, (CC Exhibit Index at 11, 23), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3683. [redacted] (PX7079 (Flatley (Illumina) Dep. at 132) (*in camera*)). (*See also* PX2712 (Illumina) at 042 (Email from P. Scagnetti, Illumina, to M. Nguyen, Illumina, attaching Illumina, Python Update, Dec. 12, 2015) ("Discount on Illumina products: 75% (with MFN) discount from list price on select products for us in the Python Field")).

Response to Finding No. 3683:

The proposed finding is irrelevant and incorrect for the reasons explained in CCFF ¶¶ 23, 3680, which Respondents incorporate herein. Respondents further note that Complaint Counsel chose not to discuss PX2712 at trial, (CC Exhibit Index at 29), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3684. [redacted] (PX2553 (Illumina) at 062 (Illumina, GRAIL Financial Update, Oct. 26, 2016) (*in camera*)).

Response to Finding No. 3684:

The proposed finding is irrelevant and incorrect for the reasons explained in CCFF ¶¶ 23, 3680, which Respondents incorporate herein.

3685. By the end of 2015, Illumina recognized that the "[c]ost of sequencing" and "[c]linical validation and utility evidence" were two of the "[m]ost significant barriers and drivers of liquid biopsy innovation and adoption." (PX2557 (Illumina) at 032 (Illumina, Minutes of the Meeting of the Board of Directors of Illumina, Inc., Dec. 20, 2015)).

Response to Finding No. 3685:

The proposed finding is irrelevant and incorrect for the reasons explained in CCFF ¶¶ 23, 3680, which Respondents incorporate herein. The proposed finding is incomplete and misleading to the extent it suggests that, even today, more than seven years after the cited document was generated, the amount of sequencing required for an MCED test renders it cost prohibitive. This is incorrect. As Illumina's contemporaneous internal documents noted, in 2015, Illumina believed that "no customer has the ability to implement a pan-cancer screening test responsibly and economically anytime in the next 5 years"; therefore, to accelerate the growth of the segment, Illumina "felt an imperative to organize an entity" focused on that moon-shot mission. (PFF ¶ 980.2 (RX1088 (Illumina) at 7; (Flatley (Illumina) Dep. at 111–12).) These considerations from the time of GRAIL's formation no longer exist for many reasons, including because the cost of sequencing has come down substantially since 2015. (PFF ¶¶ 21, 981.)

The proposed finding also is incorrect to the extent it suggests that cancer detection today requires "sequenc[ing] at depths". Illumina's assumptions in 2015 about the volume of sequencing required to develop a cancer screening test were significantly higher than what is

actually required (PFF ¶ 981 (Flatley (Illumina) Dep. at 118–20).) For example, GRAIL's Galleri test does not use "ultra-deep sequencing", but relies on targeted methylation for cancer signal detection and localization. *(See, e.g.*, PFF ¶¶ 56, 345, 384, 981, 1289.)

Respondents further note that Complaint Counsel chose not to discuss the cited document at trial, (CC Exhibit Index at 23), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3686. A 2015 Illumina document stated: "our unique advantage is that we can sequence at depths today that would be cost-prohibitive to others" and that Illumina thus had "the technology and cost structure to do [ultra-deep sequencing to detect ctDNA] years before anyone else." (PX2005 (Illumina) at 005 (Illumina, ScreenCo: Early Cancer Detection on a Global Scale, 2015)).

Response to Finding No. 3686:

The proposed finding is irrelevant and incorrect for the reasons explained in CCFF ¶¶ 23, 3680 and 3685, which Respondents incorporate herein.

3687. Illumina regarded the discounts to Grail as "forward pricing"—lower pricing based on where Illumina expected pricing to be "two or three years" or more into the future. (PX7089 (Naclerio (Illumina) Dep. at 250-251) (acknowledging that Grail's initial agreements with Illumina involved forward pricing and defining the term); PX2412 (Illumina) at 007 (Email from J. Flatley, Illumina, to J. Bird, Sutter Hill Ventures, attaching Project Python: Summary of Key Commercial Terms, Dec. 19, 2015) (discussing the exclusivity provision between Illumina and Grail from paragraphs 2.19 to 2.19.b.v.)).

Response to Finding No. 3687:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 23, 3677, 3679–80, 3685–86, which Respondents incorporate herein.

3688. Illumina expected that the "Special Pricing" Illumina gave to Grail in the 2016 supply and commercialization agreement would result in "~$100M savings" to Grail "over [the] first 3 years[.]" (PX2183 (Illumina) at 004 (Email from N. Naclerio, Illumina, to A. Pierce, Illumina, et al,, attaching Python: Board Approval, Dec. 20, 2015)).

Response to Finding No. 3688:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 23, 3677, 3679–80, 3685–86, which Respondents incorporate herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 11), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3689. A 2016 Grail presentation to Illumina's board contained a slide titled "GRAIL Moats: Why We Can Do This and Others Can't." One reason listed was "Economic advantage for product development/clinical plans enabled by Illumina equipment & reagent discount (~$350M value vs. retail through 2021)." (PX4044 (Grail) at 025 (Email from J. Huber, Grail, to R. Nelsen, Illumina, et al, attaching GRAIL Illumina BoD Update, Oct. 27, 2016)).

Response to Finding No. 3689:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 23, 3677, 3679–80, 3685–86, which Respondents incorporate herein.

3690. Dr. Aravanis explained this special pricing enabled Illumina "to have early research and development happen sooner." (PX7065 (Aravanis (Illumina) IHT at 37)).

Response to Finding No. 3690:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 23, 3677, 3679–80, 3685–86, which Respondents incorporate herein.

3691. Dr. Aravanis further explained that this special pricing enabled Grail's work." (PX7065 (Aravanis (Illumina) IHT at 39)).

Response to Finding No. 3691:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 23, 3677, 3679–80, 3685–86, which Respondents incorporate herein.

3692. Dr. Naclerio testified that it would have been difficult for Grail to develop its MCED test without forward pricing. (PX7060 (Naclerio (Illumina) IHT at 201-02)).

Response to Finding No. 3692:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 23, 3677, 3679–80, 3685–86, which Respondents incorporate herein.

(b) Illumina's Discounts to Grail as an Affiliated Entity Were Exclusive

3693. At the time of Grail's formation, Grail had no competitors, as "ctNA companies [were] currently focused in therapy selection [and were] not yet pursing screening." (PX2554 (Illumina) at 014 (Email from J. Owens, Illumina, to P. Scagnetti, Illumina, et al., attaching Illumina, Python Board Slides, Oct. 26, 2015); *see also* PX2543 (Illumina) at 001 (Illumina, GRAIL FAQs, Jan. 11, 2016) ("We do not believe GRAIL is competing with the customers we're enabling in the liquid biopsy space. We don't believe any of our customers have the ability to economically deploy this test in the next five years, due to the scale of clinical trial work required."); PX7060 (Naclerio (Illumina) IHT at 172-73) (explaining that at the time Grail first started exploring the option of starting Grail, there were not "any companies who had quite the audacious goal of saying let's – let's go right to screening asymptomatic people for cancer."); PX7107 (deSouza (Illumina) Dep. at 182) (explaining that he was "not aware of any" Grail competitors "at that time")).

Response to Finding No. 3693:

Respondents have no specific response.

3694. Illumina, however, already recognized the potential for competition between Grail and cancer detection test developers that would likely seek to develop an early detection test but would need Illumina's NGS platform to do so. In valuing Grail, Dr. Nick Naclerio—at the time Illumina's Senior Vice President of Corporate and Venture Development—described Illumina as "giving NewCo [Grail] a (time bounded) monopoly." (PX2026 (Illumina) at 002 (Email from N. Naclerio, Illumina, to R. Klausner, Illumina, and M. Stapley, Illumina, Aug. 19, 2015)).

Response to Finding No. 3694:

The proposed finding is not supported by the cited evidence, which Complaint Counsel takes entirely out of context. Nothing in the cited document suggests that Illumina "recognized the potential for competition between Grail and cancer detection test developers" or that such hypothetical developers would "need Illumina's NGS platform to do so." For one thing, the cited document makes clear that Dr. Naclerio was expressing his viewpoints on issues relating to GRAIL, not the viewpoint of Illumina. Indeed, in the same document, two of Illumina's then top executives, Dr. Rick Klausner, Illumina's former Chief Medical Officer, and Marc Stapley, its CFO, called Dr. Naclerio's email "inflammatory" and Dr. Klausner commented that he "strongly but respectfully disagree[s]". (PX2026 (Illumina) at 001.) The suggestion by Complaint Counsel that Dr. Naclerio's one-off late night email, which was responded to as such by other Illumina executives, reflects the "recogni[tion of Illumina" as to GRAIL's value and the factors impacting that value, is absurd. Further, the evidence at the time indicates Illumina did not think developers would need Illumina's NGS platform. As Dr. Nick Naclerio explained in response to a separate email about modeling the value of GRAIL at the time of its formation, he felt that the model should assume that "[Illumina] may lose some business over this . . . [because] they might switch to other, other suppliers." (PX7060 (Naclerio (Illumina) IHT at 221).) Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 4), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3695. In another email related to valuing Grail, Dr. Naclerio noted that Illumina "should also footnote that this model assumes that we have not forgone any revenue over the next 8 years by exclusively enabling Python for this market. If we assume that others (FMI, Natera, Guardant, etc) would have purchased instruments and reagents to go after the same opportunity had we not partnered exclusively with Python, we should net that out from our upside[.]" (PX2043 (Illumina) at 001 (Email from N. Naclerio, Illumina, to J. Owens,

Illumina, and P. Scagnetti, Illumina, Oct. 27, 2015); *see also* PX7060 (Naclerio (Illumina) IHT at 219-20)).

Response to Finding No. 3695:

The proposed finding is misleading and incomplete. As Dr. Naclerio explained when shown this email:

> I don't have the whole model in front of me or anything. I'm just sort of inferring what, you know, I wrote five years ago, but . . . I tend to be the ultra conservative, let's make sure we put all the cards on the table, all the risks on the table . . . [and] if we give this discount for this narrow application to GRAIL exclusively, we have to be at least prepared for the fact that someone else might say: Oh, now that GRAIL is doing this, I want to do this, too. Let me go to Life Tech or BGI and see if I can cut a deal with them instead and do the same thing. And so all I'm saying is . . . we should at least make a note in the model that there's some risk that this could cost us some business from one of our other oncology customers should they decide to switch to another platform in order to get that same level of discounting and . . . choose to compete head on with GRAIL.

(PX7060 (Naclerio (Illumina) IHT at 222–23).)

3696. Dr. Naclerio explained at Illumina had "agreed [that it] would not give another company that same deal, so in other words, such [a] deep discount." (PX7060 (Naclerio (Illumina) IHT at 221).

Response to Finding No. 3696:

The proposed finding is irrelevant, incomplete and misleading.

First, any special pricing and other benefits Illumina may have provided to GRAIL in its original supply agreement when GRAIL was formed and controlled by Illumina are irrelevant to evaluating the effects of the Transaction on competition. (PFF ¶ 979.) At the time of GRAIL's formation, the objective of creating a cancer screening test was a moonshot concept, and Illumina believed that without deep discounting, it would be impossible for GRAIL to develop a cancer screening test. (PFF ¶¶ 980–980.4.) As Dr. Aravanis explained, "the pricing benefits that GRAIL had during the first year [of its existence], which were then eliminated for the majority of its life, ended up having . . . minimal benefit" because "[i]t turned out that the sequencing cost

was not that significant in the development of these tests." (Aravanis IH at 63-64.) In fact, the prices that Illumina charged GRAIL during the time frame of Galleri's development after Illumina no longer held a controlling stake in GRAIL, and today, as well as the price reductions it modelled for GRAIL as part of its modelling the Transaction, serve as the basis for the pricing now available to all test developers through the Open Offer and its universal grid. Notably, the deal model modelled GRAIL as a stand-alone company, and, contrary to the suggestion in the finding, it forecasted that GRAIL would earn healthy margins with the arm's-length pricing and cost reductions available to it (and now available to all cancer screening test developers). (PFF ¶ 1023.6.) Second, the proposed finding fails to note that under its original supply agreement with Illumina, GRAIL was required to pay Illumina a substantial royalty on all future net sales (of 10-20%), which no other customer was required to pay to Illumina. (PX2550 (Illumina) at 14.) Third, there is nothing anticompetitive about Illumina collaborating with GRAIL on terms it has not and would not enter into with an arm's-length customer; to the contrary, that is an efficiency of vertical integration that benefits competition and consumers. To the extent the proposed finding is meant to suggest otherwise, it is wrong.

3697. [redacted]
(PX2550 (Illumina) at 001, 019 [redacted] (*in camera*)).

Response to Finding No. 3697:

The proposed finding is irrelevant and misleading for the reasons explained in CCFF ¶ 3697 , which Respondents incorporate herein. Respondents further note that Complaint

Counsel chose not to discuss this document at trial, (CC Exhibit Index at 23), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3698. Illumina understood that its 2016 supply and commercialization agreement with Grail provided that "Illumina will not launch, invest in, or provide special discounts to competitive business," which thereby gave Grail "Limited Exclusivity in the field of blood based cancer screening[.]" (PX2183 (Illumina) at 004 (Email from N. Naclerio, Illumina, to A. Pierce, Illumina, et al., attaching Python: Board Approval, Dec. 20, 2015)).

Response to Finding No. 3698:

The proposed finding is irrelevant and misleading for the reasons explained in CCFF ¶ 3697, which Respondents incorporate herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 11), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

(c) Illumina offered Grail Exclusive Discounts Because of Illumina's Equity Interest in Grail and the Royalty Payments Grail Owed to Illumina

3699. The 2016 presentation Illumina prepared for investors explained that Illumina is not "enabling our customers to sequence at the lower cost that we are giving Grail" because Illumina owned more than "50% of Grail and we get a significant royalty and our customers wouldn't be able to give us those type of economics." (PX2543 (Illumina) at 001 (Illumina, GRAIL FAQs, Jan. 11, 2016); deSouza (Illumina) Tr. 2199).

Response to Finding No. 3699:

The proposed finding is irrelevant and misleading for the reasons explained in CCFF ¶ 3697, which Respondents incorporate herein.

3700. Mr. deSouza agreed at trial that, due to the royalty payment and Illumina's equity interest in Grail, it made financial sense for Illumina to provide a discount to Grail. (deSouza (Illumina) Tr. 2198-99).

Response to Finding No. 3700:

The proposed finding is irrelevant and misleading for the reasons explained in CCFF ¶ 3697, which Respondents incorporate herein.

3701. Mr. deSouza agreed at trial that Illumina was compensated for the discount it provided Grail through a combination of the cash Grail paid Illumina for sequencers and consumables, royalty, and equity. (deSouza (Illumina) Tr. 2200).

Response to Finding No. 3701:

The proposed finding is irrelevant and misleading for the reasons explained in CCFF ¶ 3697, which Respondents incorporate herein.

3702. For Illumina to provide the same level of discount to other customers, those customers would also need to have the same combination of sales to Illumina, royalty paid to Illumina, plus equity paid to Illumina. (PX7107 (deSouza (Illumina) Dep. at 196)).

Response to Finding No. 3702:

The proposed finding is irrelevant and misleading for the reasons explained in CCFF ¶ 3697, which Respondents incorporate herein.

3703. [redacted] (PX7079 (Flatley (Illumina) Dep. at 134-35) (*in camera*)).

Response to Finding No. 3703:

The proposed finding is irrelevant and misleading for the reasons explained in CCFF ¶ 3697, which Respondents incorporate herein. The proposed finding is also misleading in that it omits Mr. Flatley's contextual testimony. The quoted testimony was [redacted] (PX7079 at 134-135.)

(d) Illumina and Grail Collaborated on Development Projects and Designed Custom, Exclusive Products

3704. When Illumina owned more than 50% of Grail, Illumina and Grail collaborated on project development, assay development, software and data analysis, and supply chain management. (PX2541 (Illumina) at 008 (Interim Review K2-GRAIL, Feb. 2, 2017)).

Response to Finding No. 3704:

The proposed finding is incomplete and misleading. The K2 collaboration referenced was not related to an MCED test, but a potential therapy selection test. As Dr. Aravanis explained, [redacted] Therefore, to be [redacted], "the technical improvements that GRAIL made to this one technical approach around these names here, K2/Napa, would be shared with Illumina so as to not have redundant research and development around that approach." (PX7065 (Aravanis (Illumina) IHT at 56–60.) Dr. Aravanis also explained that, to achieve those operational efficiencies, Illumina made "some minor alterations to the reagents for the purposes of developing this assay", and ultimate, "the discussion about the K2/Napa activity was a very minor, minor part of the R&D activities at GRAIL and a very minor, minor part of the R&D activities at Illumina when put in context of the overall R&D activities and overall activities of the company almost – again, kind of a very early, minor activity in the company's history . . . ." (PX7065 (Aravanis (Illumina) IHT at 61–62.)

Further, there is nothing anticompetitive about Illumina collaborating with GRAIL in ways it has not and would not with an arm's-length customer; to the contrary, that is an efficiency of vertical integration that benefits competition and consumers. To the extent the proposed finding is meant to suggest otherwise, it is wrong. Further, under the Open Offer, upon

customer request, Illumina must enter into a development agreement on commercially reasonable terms relating to the design or modification of sequencing products to optimize interoperability with the customer's tests. (*See* PFF ¶¶ 1005, 1008, 1010.) Illumina has not historically collaborated with customers on such optimization, and so, in this regard, customers who see value in optimization are better off under the Open Offer than they were under the pre-Transaction status quo. (PFF ¶¶ 1010.3–10.10.)

Respondents also incorporate their responses to CCFF ¶ 47 herein.

3705. Illumina collaborated with Grail on "extraction methodology to improve library yields" as well as collaborated with Grail on the development of library prep and sequencing kits. Some of these kits were "built specifically for GRAIL." (PX2541 (Illumina) at 010, 017 (Interim Review K2-GRAIL, Feb. 2, 2017)).

Response to Finding No. 3705:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 47 and 3704, which Respondents incorporate herein.

3706. Illumina created reagent kits "[p]urpose built for GRAIL" to accommodate Grail's high throughput ctDNA sequencing. (PX2541 (Illumina) at 008, 017 (Interim Review K2-GRAIL, Feb. 2, 2017)).

Response to Finding No. 3706:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 47 and 3704, which Respondents incorporate herein.

3707. An Illumina presentation reveals that, after its spinoff, Grail had concerns that it was receiving kits from Illumina "from different lots." (PX2541 (Illumina) at 017 (Interim Review K2-GRAIL, Feb. 2, 2017)).

Response to Finding No. 3707:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 47 and 3704, which Respondents incorporate herein.

3708. Prior to its spinoff, Grail's [k]its were purpose built specifically for GRAIL to support single lot shipments and ease of qualification into GRAIL laboratory." (PX2541 (Illumina) at 017 (Interim Review K2-GRAIL, Feb. 2, 2017)).

Response to Finding No. 3708:

The proposed finding is incomplete and misleading for the reasons explained in

Respondents' responses to CCFF ¶¶ 47 and 3704, which Respondents incorporate herein.

b) After Illumina's Sale of Its Majority Interest in Grail, Illumina "Leveled" the Playing Field Between Grail and Its Competitors

(1) Illumina Sold Its Majority Interest in Grail as Part of Grail's Series B Financing

3709. In early 2017, Grail initiated its Series B financing to raise over $1 billion. (deSouza (Illumina) Tr. 2202). During Grail's Series B financing, Illumina made the decision to reduce its ownership interest in Grail. (deSouza (Illumina) Tr. 2202). Post-Series B financing, Illumina's ownership interest in Grail reduced from a majority ownership interest to less than 20% of Grail. (deSouza (Illumina) Tr. 2202).

Response to Finding No. 3709:

Respondents have no specific response.

3710. [redacted] (PX4291 (Grail) [redacted] (*in camera*).

Response to Finding No. 3710:

Respondents have no specific response.

3711. To effectuate its spinoff of Grail, Illumina "had to give up" its seats on Grail's board of directors; Flatley "had to step out of" the role as Grail's chairman; and Illumina "truly had to kick [Grail] off and treat them under commercial agreements like any other customer[.]" (PX7057 (Flatley (Illumina) IHT at 158–60)).

Response to Finding No. 3711:

Respondents have no specific response.

(a) Illumina Decreased Its Ownership in Grail to Allow Grail to Raise More Capital

3712. At the time when Illumina considered spinning off Grail, Illumina determined that Grail's "technology needed to have a much higher level of investment than we originally thought." (PX7057 (Flatley (Illumina) IHT at 158–60)).

Response to Finding No. 3712:

The proposed finding is irrelevant because the considerations resulting in Illumina's decision to spin off GRAIL are not pertinent to the Transaction, and it is misleading to the extent it is meant to suggest otherwise. At the time of the spin-off, GRAIL was embarking on a moon-shot mission that required the flexibility and freedom to fail of a start-up, while Illumina was in the early stages of its clinical transformation. (*E.g.*, PFF ¶¶ 1324; Febbo (Illumina) Tr. 4334, 4344 (explaining that, "approximately seven years ago, [Illumina] went through a clinical transformation project", developing systems and capabilities to produce and run clinical tests at scale).) Since then, Illumina has invested substantially in developing its clinical capabilities, and GRAIL is at a stage of its development where it needs to move from a start-up with game-changing technology to a global diagnostic company. (Febbo (Illumina) Tr. 4334 (explaining that Illumina now has more experience scaling clinical testing than any other organization).) Illumina is optimally positioned to accelerate that transformation, and is committed to investing upwards of $1 billion to generate the clinical evidence necessary to secure broad payor coverage for Galleri. (*Id.*; PFF ¶¶ 1121-1122, 1163, 1389.)

3713. [redacted] (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 9 (RFA No. 6) (*in camera*)).

Response to Finding No. 3713:

Respondents have no specific response.

(b) Illumina Decreased Its Ownership in Grail to Increase Shareholder Value

3714. According to Jay Flatley "probably [the] single biggest factor in considering de-consolidating" was Illumina's desire to "[a]void significant dilution" of Illumina's earnings. (PX7079 (Flatley (Illumina) Dep. at 146–47)).

Response to Finding No. 3714:

The proposed finding is irrelevant and misleading for the reasons explained in CCFF ¶ 3712, which Respondents incorporate herein.

3715. During "the time when [Flatley] was chairman … half the loss of GRAIL was debited to [Illumina's] income statement, so … we were diluting our income statement." (PX7057 (Flatley (Illumina) IHT at 158–60)).

Response to Finding No. 3715:

The proposed finding is irrelevant and misleading for the reasons explained in CCFF ¶ 3712, which Respondents incorporate herein.

3716. When Illumina had a majority stake in Grail, "Illumina had to consolidate the losses of GRAIL in proportion to [Illumina's] ownership." (PX7057 (Flatley (Illumina) IHT at 158–60)).

Response to Finding No. 3716:

The proposed finding is irrelevant and misleading for the reasons explained in CCFF ¶ 3712, which Respondents incorporate herein.

3717. While deSouza testified that multiple reasons factored into Illumina's decision to reduce its ownership percentage in Grail; he agreed with Jay Flatley that one reason was that Illumina felt that it created more shareholder value for Illumina to lower its stake in Grail and, as custodians of shareholder money, Illumina needed to assess what was going to drive returns for shareholders. (deSouza (Illumina) Tr. 2202-03).

Response to Finding No. 3717:

The proposed finding is irrelevant and misleading for the reasons explained in CCFF ¶ 3712, which Respondents incorporate herein.

3718. [redacted]

[redacted] (PX2862 (Illumina) at 005 (Email from M. Stapley, Illumina, to J. Flatley, Illumina, F. deSouza, Illumina, P. Scagnetti, Illumina, D. Moriarty, Illumina, R. Chambers, Illumina, M. Bouchard, Illumina, S. Davies, Illumina, C. Dadswell, Illumina, W. Valencia, Illumina, Dec. 7, 2016, attaching "Grail Series B Overview," Dec. 7, 2016) (*in camera*)).

Response to Finding No. 3718:

The proposed finding is irrelevant and misleading for the reasons explained in CCFF ¶ 3712, which Respondents incorporate herein. Respondents further note that Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witness during discovery or at trial in this case (CC Exhibit Index at 23), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3719. When Flatley and other Illumina leaders "realized how much [Illumina was] going to have to spend and [Illumina] took a look at how much more dilution that was going to cause Illumina, [Illumina] decided that was untenable" because Illumina's "shareholders would not tolerate that level of dilution[.]" (PX7057 (Flatley (Illumina) IHT at 158–60)).

Response to Finding No. 3719:

The proposed finding is irrelevant and misleading for the reasons explained in CCFF ¶ 3712, which Respondents incorporate herein.

3720. A "benefit for Illumina" that resulted from spinning off Grail was "avoiding the significant dilution [Illumina] otherwise incur[s] based on GRAIL's necessary expenditures." (PX7079 (Flatley (Illumina) Dep. at 147)).

Response to Finding No. 3720:

The proposed finding is irrelevant and misleading for the reasons explained in CCFF ¶ 3712, which Respondents incorporate herein.

3721. Another one of the financial benefits of spinning off Grail was a "[o]ne-time $500 million cash inflow" to Illumina "from the sale of [Illumina's] equity [position]" in Grail. (PX7079 (Flatley (Illumina) Dep. at 147–48)).

Response to Finding No. 3721:

The proposed finding is irrelevant and misleading for the reasons explained in CCFF ¶ 3712, which Respondents incorporate herein.

(c) Illumina Decreased Its Ownership Percentage in Grail to Allow It to Operate More Nimbly and ATTRACT TALENT

3722. [redacted] (PX7066 (Freidin (Grail) IHT at 21) (*in camera*)).

Response to Finding No. 3722:

The proposed finding is irrelevant and misleading for the reasons explained in CCFF ¶ 3712, which Respondents incorporate herein. Further, contrary to the suggestion in the proposed finding, Mr. Freidin testified that the Transaction would allow GRAIL to feel secure about its future funding and it would de-risk capital needs and accelerate GRAIL's ability to put capital to work. (Freidin (GRAIL) Tr. 2999.)

3723. Nick Naclerio also explained that as an independent company Grail was "able to raise money and attract people in way that would be difficult for Illumina, at the time, you know, to have done." (PX7089 (Naclerio (Illumina) Dep. at 254)). Naclerio also said that operating as an independent company would allow it to attract "high-price talent" and investment as well be more "nimble." (PX7089 (Naclerio (Illumina) Dep. at 252-53)).

Response to Finding No. 3723:

The proposed finding is irrelevant and misleading for the reasons explained in CCFF ¶ 3712, which Respondents incorporate herein. Further, contrary to the suggestion in the proposed finding,. Dr. Naclerio explained that the considerations at the time of the deconsolidation of GRAIL do not apply today: "It's a very different situation today. I mean now GRAIL is a big, mature, multibillion-dollar company. So nobody is getting granted 5 percent equity anymore. So, no, I would say GRAIL has kind of matured to be sort of in the same class as Illumina with respect to equity incentives." (PX7089 (Nalcerio (Illumina) Dep. at 274).)

(d) Illumina Decreased Its Ownership Percentage in Grail to "Level the Playing Field" for Tts Other Customers Developing Early Cancer Detection Tests

3724. At the time of the Series B financing, other companies were beginning to get interested in developing liquid biopsy tests. (deSouza (Illumina) Tr. 2202).

Response to Finding No. 3724:

Respondents have no specific response.

3725. At the time of the Series B, companies were trying different approaches to do early cancer detection. (deSouza (Illumina) Tr. 2203).

Response to Finding No. 3725:

Respondents have no specific response except to note that Mr. deSouza testified that the same would be true independent of whether Illumina spun GRAIL out or not. (deSouza (Illumina) Tr. 2204.)

3726. Mr. deSouza was responsible for attending investor calls. (PX7107 (deSouza (Illumina) Dep. at 246)).

Response to Finding No. 3726:

Respondents have no specific response.

3727. During calls with investors, it is important to be truthful and accurate. (PX7107 (deSouza (Illumina) Dep. at 246)).

Response to Finding No. 3727:

Respondents have no specific response.

3728. In fact there are "laws you might break" if you are not and there may also be a "reputational impact." (PX7107 (deSouza (Illumina) Dep. at 246)).

Response to Finding No. 3728:

Respondents have no specific response.

3729. Illumina ordinary course documents from this period also corroborate the rationale that Illumina executives provided for decreasing its ownership percentage of Grail. Notably, Illumina explained that it was going to operate Grail at "Arms length" and that it wanted

> "Grail to fuel a technology arms race in liquid biopsy" and expected "[m]any other customers may pursue the same opportunity." (PX2624 (Illumina) at 009 (Email from D. Moriarty, Illumina, to J. Benson, Illumina, D. Baker, Illumina, Jan. 11, 2017, attaching "Grail Series B Overview," Jan. 5, 2017)).

Response to Finding No. 3729:

The proposed finding is incomplete and misleading. Respondents note that the document describes an "arms race" in "liquid biopsy" generally not MCED specifically. Further, under "Arms length", the document notes that "Grail has no field restrictions", which Illumina's former CEO Jay Flatley explained was significant because it meant that Grail could compete in liquid biopsy fields other than MCED, whereas before the spin-off Grail was limited to developing an MCED test, and "there were no customers in the screening market". (PX7057 (Flatley (Illumina) Dep. at 174–75).) Thus, the context of the document makes clear that it is not discussing MCED development specifically, but liquid biopsy applications generally. Further, to the extent that the proposed finding is meant to suggest that the cited document supports Complaint Counsel's claim that Illumina's ownership of GRAIL deterred investment in MCED development, it is misleading, in that the document does not say anything to that effect, there is no support for the claim, and events since the Illumina/GRAIL merger was announced (including a surge in investment in liquid biopsy) disprove the claim. (*E.g.*, PFF ¶¶ 928-929.)

Respondents also note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 26), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3730. Mr. deSouza testified that, when Illumina sold its shares in Grail in 2017, Illumina "didn't want to be tied to just one approach":

> "[W]e wanted to see which approach would work so that we could figure out in the end what was the right way to go, because it wasn't clear to anybody in the

> market which way to go, and we didn't want to be tied to just one approach. So it gave us the opportunity to assess which way the market was going to go and which technology would work."

(deSouza (Illumina) Tr. 2204).

Response to Finding No. 3730:

Respondents have no specific response.

3731. Jay Flatley – CEO of Illumina at the time – corroborated Mr. deSouza's testimony and explained that Illumina did not want to enter a new market through its subsidiary because "then customers wouldn't want to participate in those markets because they'd believe that Illumina would always underprice them if [it] wanted to." As such, if Grail wanted to enter into a new market "they'd have to do it on a level play field with the existing customers in the market. We thought that was fair to [Grail] and fair to our existing customers." (PX7057 (Flatley (Illumina) IHT at 167-168)).

Response to Finding No. 3731:

The proposed finding is incomplete and misleading because it omits Mr. Flatley's testimony contextualizing this point. Mr. Flatley explained that this point refers to the fact that, at the time, "if GRAIL has the constraints taken off it in terms of field of use, they could now compete against customers where in the earlier format [before the spin-off] they could not have because the field was constrained." (PX7057 (Flatley (Illumina) Dep. at 174).) Mr. Flatley went on to explain that, prior to the spin-off, the question regarding the creation of an entity that would compete with customers more broadly in liquid biopsy was not a consideration because GRAIL was constrained to developing only an MCED test, "there were no customers in the screening market" and "there was a market that didn't exist and still doesn't, so there are no customers in the screening market." (PX7057 (Flatley (Illumina) Dep. at 175).)

(2) After Illumina Relinquished Its Majority Ownership It Operated at Arms-Length to Grail

3732. Illumina understood that [redacted] (PX2862 (Illumina) at 005 (Email from M. Stapley, Illumina, to J. Flatley, Illumina, F. deSouza, Illumina, P. Scagnetti, Illumina, D. Moriarty,

Illumina, R. Chambers, Illumina, M. Bouchard, Illumina, S. Davies, Illumina, C. Dadswell, Illumina, W. Valencia, Illumina, Dec. 7, 2016, attaching "Grail Series B Overview," Dec. 7, 2016) (*in camera*)).

Response to Finding No. 3732:

Respondents have no specific response, except note that Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witness during discovery or at trial in this case (CC Exhibit Index at 23), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3733. Illumina understood that the [redacted]. (PX2862 (Illumina) at 005 (Email from M. Stapley, Illumina, to J. Flatley, Illumina, F. deSouza, Illumina, P. Scagnetti, Illumina, D. Moriarty, Illumina, R. Chambers, Illumina, M. Bouchard, Illumina, S. Davies, Illumina, C. Dadswell, Illumina, W. Valencia, Illumina, Dec. 7, 2016, attaching "Grail Series B Overview," Dec. 7, 2016) (*in camera*)).

Response to Finding No. 3733:

Respondents have no specific response, except note that Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witness during discovery or at trial in this case (CC Exhibit Index at 23), and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

3734. Illumina decided not to "have a board seat on Grail" because "[t]o avoid accounting for GRAIL's losses as an equity method investment, it required them to be truly independent." (PX2406 (Illumina) at 005 (Email from J. Flatley, Illumina, to E. Endicott, Illumina, M.c Stapley, Illumina, F. deSouza, Illumina, R. Chambers, Illumina, D. Moriarty, Illumina, S. Davies, Illumina, P. Scagnetti, Illumina, M. Bouchard, Illumina, L. Zinser, Illumina, Jan. 2, 2017)).

Response to Finding No. 3734:

Respondents have no specific response.

(3) After Illumina Sold Its Majority Interest in Grail, Illumina Took Steps to Achieve Parity between Grail and Illumina's Other Customers

3735. At the time of Grail's Series B financing, Jay Flatley, Executive Chairman of Illumina, had executive responsibility for the Series B financing. (deSouza (Illumina) Tr. 2209). In edits to a draft Q&A to investors, Mr. Flatley wrote in response to the question "[b]y creating and unleashing Grail have you created a competitor for your customers?" that the Series B financing "actually leveled the playing field" because "[p]reviously Grail had access to technology and pricing that was preferential to our customers, albeit just for the asymptomatic screening market. Today, GRAIL has access to technology on same terms and price as other large customers, and is funding to perform large scale studies." (PX2406 (Illumina) at 005 (Email from J. Flatley, Illumina, to E. Endicott, Illumina, M. Stapley, Illumina, F. deSouza, Illumina, R. Chambers, Illumina, D. Moriarty, Illumina, S. Davies, Illumina, P. Scagnetti, Illumina, M. Bouchard, Illumina, L. Zinser, Illumina, Jan. 2, 2017); (deSouza (Illumina) Tr. 2210-11)).

Response to Finding No. 3735:

The proposed finding is irrelevant and misleading for the reasons explained in CCFF ¶ 3697, which Respondents incorporate herein. The proposed finding is also misleading in that it omits Mr. Flatley's testimony concerning what he meant by the quoted language. Mr. Flatley explained that what he meant with this language is that "if GRAIL has the constraints taken off it in terms of field of use, it could now compete against customers where in the earlier format [before the spin-off] they could not have because the field was constrained." (PX7079 (Flatley (Illumina) Dep. at 174.) Mr. Flatley went on to explain that, prior to the spin-off, the question regarding the creation of an entity that would compete with customers more broadly in liquid biopsy was not a consideration because GRAIL was constrained to developing only an MCED test, "there were no customers in the screening market" and "there was a market that didn't exist and still doesn't, so there are no customers in the screening market." (PX7079 (Illumina) Dep. at 175.)

Further, the proposed finding is also misleading to the extent it suggests that GRAIL will receive access to sequencing instruments and core consumables, as well as associated services,

that are unavailable to other putative MCED test developers. This is incorrect. Any customer that signs the Open Offer shall have the same access to services that GRAIL or any other For-Profit Entity has access to, at the same prices. (PFF ¶ 1004; [redacted]; Berry (Illumina) Tr. 865–66; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.)). Similarly, the Open Offer provides customers the same access to purchase sequencing instruments and core consumables to which GRAIL has access. (PFF ¶ 1005; [redacted]; Berry (Illumina) Tr. 878–79; deSouza (Illumina) Tr. 2434–35, 2437–38; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) Further, the timing of the access to these services and sequencing products shall be the same for GRAIL as it is for its putative rivals: the Open Offer requires that "Customer shall have access to the Supplied Products for purchase that GRAIL . . . has access, within 5 days of when GRAIL . . . is offered such access (if not earlier) for purchase." (PFF ¶ 1005.1; RX3935 (Illumina) at 2.)

In addition, the proposed finding overlooks the fact that the prices that Illumina charged GRAIL during the time frame of Galleri's development after Illumina no longer held a controlling stake in GRAIL, and today, as well as the price reductions it modelled for GRAIL as part of its modelling the Transaction, serve as the basis for the pricing now available to all test developers through the Open Offer and its universal grid. Notably, the deal model modelled GRAIL as a stand-alone company, and forecasted that GRAIL would earn healthy margins with the arm's-length pricing and cost reductions available to it (and now available to all cancer screening test developers). (PFF ¶ 1023.6.)

3736. Jay Flatley's testimony also corroborates his ordinary course documents. He testified that "what [Illumina] did not want to do was essentially provide a very high discount rate to an entity that was inside of Illumina that would then go compete with our existing customers. And so, you know, if they were going to do that, they would have to do it at market pricing." (PX7057 (Flatley (Illumina) IHT at 165)).

Response to Finding No. 3736:

The proposed finding is incomplete and misleading for the reasons explained in

Respondents' responses to CCFF ¶¶ 3697 and 3735, which Respondents incorporate herein.

3737. Flatley explained that Illumina's sale of Grail's shares in 2017 made Grail "an arm's length entity to Illumina," which meant that Illumina "would treat [Grail] like [Illumina] would any other customer at that point in time." (PX7079 (Flatley (Illumina) Dep. at 148–49)).

Response to Finding No. 3737:

The proposed finding is incomplete and misleading for the reasons explained in

Respondents' responses to CCFF ¶¶ 3697 and 3735, which Respondents incorporate herein.

3738. As a result, the deeper discounts Illumina provided to Grail "went away" after the Series B financing. (deSouza (Illumina) Tr. 2207).

Response to Finding No. 3738:

The proposed finding is incomplete and misleading for the reasons explained in

Respondents' responses to CCFF ¶¶ 3697 and 3735, which Respondents incorporate herein.

3739. [redacted] (PX2862 (Illumina) at 007 (Email from M. Stapley, Illumina, to J. Flatley, Illumina, F. deSouza, Illumina, P. Scagnetti, Illumina, D. Moriarty, Illumina, R. Chambers, Illumina, M. Bouchard, Illumina, S. Davies, Illumina, C. Dadswell, Illumina, W. Valencia, Illumina, Dec. 7, 2016, attaching "Grail Series B Overview," Dec. 7, 2016) (*in camera*)).

Response to Finding No. 3739:

The proposed finding is incomplete and misleading for the reasons explained in

Respondents' responses to CCFF ¶¶ 3697 and 3735, which Respondents incorporate herein.

3740. As former CEO, Jay Flatley testified at his deposition, after the Series B financing, Illumina was "not involved with GRAIL at an operation level" and did not "have a strategic agreement about any operational work[.]" (PX7079 (Flatley (Illumina) Dep. at 49)).

Response to Finding No. 3740:

Respondents have no specific response.

3741. [redacted]

(PX2541 (Illumina) at 008 (Interim Review K2-GRAIL, Feb. 2, 2017) (*in camera*)); *see also* PX6090 (Scott Morton Report) ¶ 208 (*in camera*); PX2712 (Illumina) at 042 (Email from P. Scagnetti, Illumina, to M. Nguyen, Illumina, Dec. 3, 2019, attaching "Python Update," Dec. 12, 2015) (explaining that Illumina was helping with "Joint development and IP" prior to the spin off)).

Response to Finding No. 3741:

The proposed finding is incomplete and misleading.

First, the only witness questioned about the cited document was Mr. deSouza, and as to that document, he testified: [redacted] starting with Mr. Aravanis. (DeSouza Dep. 243-244.) Complaint Counsel nonetheless chose not to ask Mr. Aravanis or any other witness about that document.

Second, Dr. Aravanis made clear in his testimony that the K2 collaboration referenced in the cited exhibit was not an MCED test, but a potential therapy selection test. As Dr. Aravanis explained, the K2 project was formed due to the fact that one of the approaches to cancer screening that GRAIL was exploring at this early stage of its development (but ultimately never pursued) also might have uses for a therapy selection test that Illumina was exploring (but ultimately never pursued). Therefore, [redacted] (Aravanis IH Tr. 56-60.) Dr. Aravanis also explained that, to achieve those operational efficiencies, Illumina made "some minor alterations to the reagents for the purposes of developing this assay", and ultimate, "the discussion about the K2/Napa activity was a very minor, minor part of the R&D activities at GRAIL and a very minor, minor part of the R&D activities at Illumina when put in context of the overall R&D activities and overall activities of the company almost – again, kind of a very early, minor activity in the company's history . . . ." (Id. at 61-62.)

Third, there is nothing anticompetitive about Illumina collaborating with GRAIL in ways it has not and would not with an arm's-length customer; to the contrary, that is an efficiency of vertical integration that benefits competition and consumers. To the extent the proposed finding is meant to suggest otherwise, it is wrong. Further, under the Open Offer, upon customer request, Illumina must enter into a development agreement on commercially reasonable terms relating to the design or modification of sequencing products to optimize interoperability with the customer's tests. (See PFF ¶¶ 1005, 1008, 1010.) Illumina has not historically collaborated with customers on such optimization (*see, e.g.*, RFF ¶ 2988), and so, in this regard, customers

who see value in optimization are better off under the Open Offer than they were under the pre-Transaction status quo.

3742. After Grail's Series B fundraising, when Illumina reduced its Grail ownership stake below 50 percent, Illumina and Grail no longer collaborated on development of library prep and sequencing kits. (deSouza (Illumina) Tr. 2456).

Response to Finding No. 3742:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3742, which Respondents incorporate herein.

c) After Illumina "Leveled the Playing Field," Other Illumina Customers Successfully Developed Asymptomatic Cancer Tests

3743. As Jay Flatly explained in his draft Q&A statements to investors, Illumina expected that its decision to grant Grail "access to technology on same terms and price as other large customers … will accelerate the liquid biopsy market for all." PX2406 (Illumina) at 005 (Email from J. Flatley, Illumina, to E. Endicott, Illumina, M. Stapley, Illumina, F. deSouza, Illumina, R. Chambers, Illumina, D. Moriarty, Illumina, S. Davies, Illumina, P. Scagnetti, Illumina, M. Bouchard, Illumina, L. Zinser, Illumina, Jan. 2, 2017); deSouza (Illumina) Tr. 2211)).

Response to Finding No. 3743:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 3697 and 3735, which Respondents incorporate herein.

3744. Since Grail's Series B financing, the number of companies developing liquid biopsy tests has increased. (*See* deSouza (Illumina) Tr. 2212-15; PX2544 (Illumina) at 019 (Email from T. Peterson, JPMorgan, to F. deSouza, Illumina, Sept. 5, 2019, attaching JPMorgan, "Transcript of JPM Life Sciences CEO Conference Call," Sept. 3, 2019)).

Response to Finding No. 3744:

The proposed finding is incomplete and misleading to the extent it suggests that Illumina spinning off GRAIL caused an increase in development of liquid biopsy tests that would not have occurred but for the spin-off. The suggestion makes no sense, including because GRAIL has always been focused on one application, its MCED test Galleri, while the increase in liquid biopsy test development has been across many fields, and Illumina has always encouraged such

development through innovation and cost reductions. Further, there is no basis for such a suggestion, and it is refuted by substantial evidence, including the massive surge in investment in liquid biopsy since the Illumina/GRAIL merger was announced. (*E.g.*, PFF ¶¶ 928-929.)

3745. In a September 3, 2019 investor conference call that was part of a JPM Life Sciences CEO conference call series, Mr. deSouza told investors: "In liquid biopsy [Illumina was] one of the catalysts of that space as a whole when we incubated Grail internally and then spun it out. We're continuing to work and I think now we're tracking over 70 companies that are doing liquid biopsy in some form or another." (PX2544 (Illumina) at 019 (Email from T. Peterson, JPMorgan, to F. deSouza, Illumina, Sept. 5, 2019, attaching JPMorgan, "Transcript of JPM Life Sciences CEO Conference Call," Sept. 3, 2019)).

Response to Finding No. 3745:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3744, which Respondents incorporate herein.

3746. In the period after the Series B financing, Illumina supported companies developing liquid biopsy tests. (*See* deSouza (Illumina) Tr. 2214; PX2544 (Illumina) at 019 (Email from T. Peterson, JPMorgan, to F. deSouza, Illumina, Sept. 5, 2019, attaching JPMorgan, "Transcript of JPM Life Sciences CEO Conference Call," Sept. 3, 2019)).

Response to Finding No. 3746:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3744, which Respondents incorporate herein.

3747. In the September 3, 2019 JPM Life Sciences CEO conference call, Mr. deSouza stated that, of the 70 companies that are doing liquid biopsy, "[w]e continue to support them in some cases, it's making sure that they have access to the best of our workflow even on the front end or on the back end. In some cases it's planning with them what their path to a regulated offering could be, cleared offering. And so we're continuing to work with them in a number of different ways to enhance their ability to expand their market, because, what's good for them is obviously good for us too." (PX2544 (Illumina) at 019 (Email from T. Peterson, JPMorgan, to F. deSouza, Illumina, Sept. 5, 2019, attaching JPMorgan, "Transcript of JPM Life Sciences CEO Conference Call," Sept. 3, 2019)).

Response to Finding No. 3747:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3744, which Respondents incorporate herein.

3748. Indeed, since the time of the Series B financing, MCED developers have invested in MCED testing and are now poised to commercialize a successful MCED test. (*See supra* Section VI. (Competitors Are Racing to Develop MCED Tests)).

Response to Finding No. 3748:

The proposed finding is inaccurate for the reasons explained in Respondents' responses to CCFF ¶¶ 1902–2606 and 3744, which Respondents incorporate herein.

2. Illumina Identified and Used Similar Tools in the Oncology Therapy Selection Market

3749. As Illumina's SVP and General Manager of the Americas business unit, Mr. Daly was responsible for overseeing all commercial operations, including sales, marketing, customer service, and field service support. (PX7109 (Daly (Singular Genomics) Dep. at 15)).

Response to Finding No. 3749:

Respondents have no specific response.

3750. When testifying regarding [redacted]

(PX7109 (Daly (Singular Genomics) Dep. at 93) (*in camera*)).

Response to Finding No. 3750:

The proposed finding is irrelevant, incomplete and misleading. It is of no moment to the issues before the Court that in the early days of its IVD technology and its therapy selection strategy, Illumina "evaluated" the impact of IVD partnerships on its profits. Illumina had invested substantial amounts in its IVD technology, there were few IVD kitted tests even commercially available, and Illumina had not yet even received FDA authority to market a higher-throughput IVD system. The evaluation Illumina undertook of different potential approaches to this new technology and mode of distribution is what any profit maximizing firm would do when considering a major strategic decision such as the one Illumina faced when it first considered how and to what extent to enable third party kits on its new IVD systems.

What matters to understanding Illumina's incentives are the choices Illumina made, not the strategies some within Illumina evaluated along the way. [redacted] (PFF ¶ 971.3.) Today, Illumina has collaboration agreements in place with Roche, PGDx and numerous other test developers in therapy selection pursuant to which these formidable competitors are developing IVD tests that will compete with Illumina's own therapy selection test. (PFF ¶ 966.) Illumina provides customer support to its therapy selection rivals, and investment and innovation has increased in in recent years. (PFF ¶ 967.) In fact, the therapy selection market is thriving. Further, the Open Offer requires Illumina, on a customer's request, to enter into a separate standardized agreement with the customer to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33; [redacted]; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; [redacted]

[redacted].) These requirements in the Open Offer prevent Illumina from withholding support as MCED test developers seek FDA approval. (PFF ¶ 1035; RX6002 (Guerin-Calvert Trial Dep. at 74).)

Respondents also note that the cited testimony also states that "[redacted]" (PX7109 (Daly (Singular Genomics) Dep. at 94.)

3751. When asked whether [redacted] (PX7109 (Daly (Singular Genomics) Dep. at 94) (*in camera*)).

Response to Finding No. 3751:

The proposed finding is irrelevant, inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3750, which Respondents incorporate herein.

a) Illumina Withheld Agreements to Prevent Competitors in the Therapy Selection Space from Cannibalizing Illumina's Therapy Selection Product

(1) Therapy Selection Tests Use an Array of Datapoints to Help Determine the Best Treatment for a Patient's Cancer

3752. A therapy selection test is a test "looking at the DNA [or some other analyte] of a patient out of tissue or blood, using Next-Generation Sequencing technology to… produc[e] the data that is giving the oncologist information on whether the patient is more likely to [] respond to one treatment or another." (PX7112 (Bailey (PGDx) Dep. at 16-17)).

Response to Finding No. 3752:

Respondents have no specific response.

3753. [redacted] (PX7118 (Fiedler (FMI) Dep. at 54); (PX7061 (Davy (Illumina) IHT at 153) (*in camera*)).

Response to Finding No. 3753:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3754. [redacted] (PX7061 (Davy (Illumina) IHT at 153) (*in camera*)).

Response to Finding No. 3754:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

(2) Illumina Developed an Oncology Therapy Selection Test That Uses Its NGS platform

3755. Illumina has a therapy selection test called TruSight Oncology or TSO-500. (PX7063 (Berry (Illumina) IHT at 25)).

Response to Finding No. 3755:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3756. [redacted] (PX2035 (Illumina) at 017 (Illumina, Oncology Testing 5-Year Strategy Refresh, 2020) (*in camera*)); Leite (Illumina) Tr. 2074-75); *see* PX0091 at 018 (Illumina Source Book, Aug. 2020)).

Response to Finding No. 3756:

Respondents have no specific response but note that the Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial

in this case, (CC Exhibit Index at 15), and therefore should not be entitled to rely on it to establish anything beyond the words on the page.

3757. The TSO-500 uses Illumina's NGS platform. (Leite (Illumina) Tr. 2076-77).

Response to Finding No. 3757:

Respondents have no specific response.

3758. The TSO-500 test interrogates tumors from patients who are actively being managed for oncology or cancer care where physicians have specific questions as to how to treat the tumors. (Leite (Illumina) Tr. 2074).

Response to Finding No. 3758:

Respondents have no specific response.

3759. The TSO-500 is also capable of indicating tumor mutation burden—a scoring system for determining if a patient is likely to respond to immunotherapies. (Leite (Illumina) Tr. 2078; PX7052 (Leite (Illumina) IHT at 120)).

Response to Finding No. 3759:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3760. [redacted] (PX7052 (Leite (Illumina) IHT at 121-22 (*in camera*)).

Response to Finding No. 3760:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3761. [redacted]

[redacted]

(PX7052 (Leite (Illumina) IHT at 120-21) (*in camera*); (*See also* Leite (Illumina) Tr. 2079 (Mr. Leite testifying that TMB was a selling point for TSO-500)).

Response to Finding No. 3761:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3750, which Respondents incorporate herein, and also because, by charging fees for IVD rights, Illumina was following market practice, **as other platform suppliers** [redacted] **also charge for such rights**. (PPF ¶ 973.) IVD rights have value, and there is nothing anticompetitive about charging fees for things of value. Further, the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3762. Mr**.** Leite was Illumina's former Vice President of oncology product marketing and market development. (PX7052 (Leite (Illumina) IHT at 21)).

Response to Finding No. 3762:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3763. [redacted]

[redacted] (PX7063 (Berry (Illumina) IHT at 25-26, 27) (*in camera*)).

Response to Finding No. 3763:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3764. [redacted] (PX7063 (Berry (Illumina) IHT at 27) (*in camera*)); PX7080 (Silvis (Tempus) Dep. at 47) (*in camera*))).

Response to Finding No. 3764:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3765. Illumina has created different versions of TSO-500 – a liquid biopsy and tissue version. (Leite (Illumina) Tr. 2077-78).

Response to Finding No. 3765:

Respondents have no specific response.

3766. The "kit content" provided on the TSO500 ctDNA assay "is the same as the TSO500 tissue." (PX2004 (Illumina) at 003 (Email from A. Gutierrez, Illumina, to J. Godsey, Illumina, attaching "TSO500 FAQ slides," July 13, 2020.

Response to Finding No. 3766:

Respondents have no specific response.

3767. Ms. Berry testified that some of Illumina's "customers are seeking to deploy [TSO-500] as a laboratory-developed test." (PX7063 (Berry (Illumina) IHT at 26)).

Response to Finding No. 3767:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3768. The TSO-500 test is an IVD test. (Leite (Illumina) Tr. 2076).

Response to Finding No. 3768:

Respondents have no specific response.

3769. The Illumina reagents used for the TSO-500 test are unique reagents designed for the TSO-500 specific use case. (PX7063 (Berry (Illumina) IHT at 33)).

Response to Finding No. 3769:

Respondents have no specific response except that, to the extent the proposed finding is meant to suggest that Illumina has core consumables that are unique to TSO-500 use cases, that is incorrect and not supported by the cited testimony. Ms. Berry's testimony makes clear that she was referring to the fact that, in addition to its core consumables that are used for a range of applications, Illumina (like many other third parties) has some library preparation reagent products that it sells, of which TSO-500 is one. Respondents also note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3770. [redacted] (PX2120 (Illumina) at 019 [redacted] (*in camera*))).

Response to Finding No. 3770:

Respondents have no specific response but note that Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this

case, (CC Exhibit Index at 8), and therefore should not be entitled to rely on it to establish anything beyond the words on the page.

3771. eORB stands for "The Executive Opportunity Review Board" and it's made up of Illumina's CEO, Francis deSouza, and his direct reports. (PX7052 (Leite (Illumina) IHT at 32-34)).

Response to Finding No. 3771:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3772. [redacted] (PX7043 (Gunn (Roche) IHT at 38) (*in camera*); PX7112 (Bailey (PGDx) Dep. at 33, 35); PX7040 (Getty (Guardant) IHT at 99)).

Response to Finding No. 3772:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3773. [redacted] (PX7043 (Gunn (Roche) IHT at 54) (*in camera*)); PX7118 (Fiedler (FMI) Dep. at 19-20) (*in camera*)); PX7049 (Bailey (PGDx) IHT at 29)); PX7040 (Getty (Guardant) IHT at 56) (*in camera*)).

Response to Finding No. 3773:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

(3) [redacted]

3774. [redacted] (PX7052 (Leite (Illumina) IHT at 211) (*in camera*)).

Response to Finding No. 3774:

The proposed finding is misleading and inaccurate to the extent it is intended to suggest that Mr. Leite was testifying as to diagnostic tests generally. He was not. Rather, as the cited testimony makes clear, he was referring specifically to the distribution dynamics in the therapy selection space. The proposed finding is also irrelevant for this reason, as the same dynamics indisputably do not apply to MCED testing. (PFF ¶¶ 1416-17, 677.) Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3775. [redacted] (PX7040 (Getty (Guardant) IHT at 82) (*in camera*)). [redacted] (PX7040 (Getty (Guardant) IHT at 82) (*in camera*)).

Response to Finding No. 3775:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 3774, which Respondents incorporate herein. The proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(a) [redacted]

3776. [redacted] (PX2123 (Illumina) at 002 (Email from G. Hampton, Illumina, to J. Leite et al., Illumina, attaching slides, Dec. 5, 2018 (*in camera*)).

Response to Finding No. 3776:

Respondents have no specific response.

3777. [redacted] (PX2123 (Illumina) at 007 (Email from G. Hampton, Illumina, to J. Leite et al., Illumina, attaching slides, Dec. 5, 2018 (*in camera*)).

Response to Finding No. 3777:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to Proposed Findings CCFF ¶ 3750, which Respondents incorporate herein.

3778. [redacted] (PX7052 (Leite (Illumina) IHT at 167-68) (*in camera*)).

Response to Finding No. 3778:

The proposed finding is misleading and inaccurate to the extent it is intended to suggest that Mr. Leite was testifying as to diagnostic tests generally. He was not. Rather, as the cited testimony makes clear, he was referring specifically to the distribution dynamics in the therapy selection space. The proposed finding is also irrelevant for this reason, as the same dynamics indisputably do not apply to MCED testing. (PFF ¶¶ 1416-17, 677.) Respondents further note

that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

Respondents incorporate their responses to Proposed Findings CCFF ¶ 3760 herein.

3779. [redacted] (PX2123 (Illumina) at 004 (Email from G. Hampton, Illumina, to J. Leite et al., Illumina, attaching slides, Dec. 5, 2018 (*in camera*)).

Response to Finding No. 3779:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to Proposed Findings CCFF ¶ 3750, which Respondents incorporate herein.

3780. [redacted] (PX7052 (Leite (Illumina) IHT at 184) (*in camera*)); [redacted] (PX2095 (Illumina) at 004 [redacted] (*in camera*)).

Response to Finding No. 3780:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to Proposed Findings CCFF ¶ 3750, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

Respondents incorporate their responses to Proposed Findings CCFF ¶ 3760 herein.

3781. [redacted] (PX7112 (Bailey (PGDx) Dep. at 89) (*in camera*)).

Response to Finding No. 3781:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to Proposed Findings CCFF ¶ 3750, which Respondents incorporate herein.

3782. [redacted] (PX7112 (Bailey (PGDx) Dep. at 89) (*in camera*)).

Response to Finding No. 3782:

Respondents have no specific response.

(4) An IVD Agreement is a De Facto Requirement to Create a Kitted Decentralized Test

3783. [redacted] (PX7052 (Leite (Illumina) IHT at 52) (*in camera*)).

Response to Finding No. 3783:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

Respondents incorporate their responses to Proposed Findings CCFF ¶ 3760 herein.

3784. [redacted] (PX7052 (Leite (Illumina) IHT at 53-54) (*in camera*)).

Response to Finding No. 3784:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

Respondents incorporate their responses to Proposed Findings CCFF ¶ 3760 herein.

3785. [redacted] (PX7049 (Bailey (PGDx) IHT at 43) (*in camera*)). [redacted] (PX8351 (Roche) at 003 [redacted] (*in camera*)); PX7068 (Perettie (FMI-Roche) IHT at 81) (*in camera*)).

Response to Finding No. 3785:

Respondents have no specific response except note that the Open Offer requires Illumina to enter into such an IVD agreement if the test developer requests one (PFF ¶ 1026), and further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

Respondents incorporate their responses to Proposed Findings CCFF ¶ 3760 herein.

3786. Ms. Bailey, PGDx's CEO, testified that PGDx needed an IVD agreement from Illumina to "initiate the development plans, study plans and process to submit a product to the FDA." (PX7112 (Bailey (PGDx) Dep. at 37)).

Response to Finding No. 3786:

The proposed finding is misleading and incomplete in that it fails to mention that, when Illumina and PGDx initially discussed a potential IVD agreement, PGDx insisted on unequal terms that would have disadvantaged other Illumina IVD partners; that Illumina was also concerned at the time with the high degree of heterogeneity in the TMB measurement

methodology which caused a lack of standardization in the industry; that, after leadership at PGDx changed, Illumina and PGDx entered into an IVD agreement which today includes TMB rights; and that PGDx has not been deterred from attracting investment in its therapy selection business. (PFF ¶¶ 966, 970, 1545.)

3787. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 81-82) (*in camera*)).

Response to Finding No. 3787:

Respondents have no specific response except note that the Open Offer requires Illumina to enter into such an IVD agreement if the test developer requests one (PFF ¶ 1026), and further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

Respondents incorporate their responses to Proposed Findings CCFF ¶ 3760 herein.

3788. [redacted] (PX7049 (Bailey (PGDx) IHT at 42-43) (*in camera*)).

Response to Finding No. 3788:

Respondents have no specific response except note that the Open Offer requires Illumina to enter into such an IVD agreement if the test developer requests one (PFF ¶ 1026), and further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents

had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3789. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 82) (*in camera*)).

Response to Finding No. 3789:

Respondents have no specific response except note that the Open Offer requires Illumina to enter into such an IVD agreement if the test developer requests one (PFF ¶ 1026), and further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

Respondents incorporate their responses to Proposed Findings CCFF ¶ 3760 herein.

3790. Mr. Leite testified that "IVD Agreements"—co-development agreements or collaboration agreements where Illumina would provide access to its NGS platform so that the IVD test provider could validate its assays on Illumina's instruments, secure quality agreements with Illumina, and secure supply agreements with Illumina that would supply the IVD provider during their development period. (Leite (Illumina) Tr. 2081).

Response to Finding No. 3790:

Respondents have no specific response except note that the Open Offer requires Illumina to enter into such an IVD agreement if the test developer requests one (PFF ¶ 1026).

3791. The IVD Agreements that Dr. Leite negotiated also included provisions related to "a quality agreement, as well as an Illumina development of a software module to include the partner's assay manifest, as well as reporting capability into [Illumina's] instrument." (Leite (Illumina) Tr. 2082).

Response to Finding No. 3791:

Respondents have no specific response except note that the Open Offer requires Illumina to enter into such an IVD agreement if the test developer requests one (PFF ¶ 1026).

3792. According to Dr. Leite, an IVD Agreement provision related to Illumina's software module was necessary because:

> IVD platforms are by definition what's called a locked box. So to preserve the integrity of the data flow and the audit trail, nothing about the instruments may be changed by the user to ensure the integrity of the clinical data being generated.
>
> So a partner would contract with Illumina to have their assay included as part of that software system and have the report be reported out. This is common practice in the industry.

(Leite (Illumina) Tr. 2082-83).

Response to Finding No. 3792:

Respondents have no specific response except note that the Open Offer requires Illumina to enter into such an IVD agreement if the test developer requests one (PFF ¶ 1026).

3793. IVD platforms are a locked box due to FDA requirements related to maintaining data integrity and the ability to audit results on the platform. (Leite (Illumina) Tr. 2082-83).

Response to Finding No. 3793:

Respondents have no specific response.

3794. [redacted] (PX7049 (Bailey (PGDx) IHT at 102) (*in camera*)).

Response to Finding No. 3794:

Respondents have no specific response except note that the Open Offer requires Illumina to enter into such an IVD agreement if the test developer requests one (PFF ¶ 1026), and further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3795. [redacted] (PX7049 (Bailey (PGDx) IHT at 102-03) (*in camera*)).

Response to Finding No. 3795:

Respondents have no specific response except note that the Open Offer requires Illumina to enter into such an IVD agreement if the test developer requests one (PFF ¶ 1026), and further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3796. Ms. Bailey testified that inquiries regarding the existence an IVD agreement with Illumina was a "standard request by the agency to see that were was in fact that direct relationship between manufacture of platform and manufacture of content, and so not having that [agreement] required [PGDx] to find and collaborate with the FDA on a different path to be able to demonstrate to them that we could in fact control for quality end to end without having that agreement in place." (PX7049 (Bailey (PGDx) IHT at 98)).

Response to Finding No. 3796:

Respondents have no specific response except note that the Open Offer requires Illumina to enter into such an IVD agreement if the test developer requests one (PFF ¶ 1026), and further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3797. [redacted] (PX7049 (Bailey (PGDx) IHT at 42-43) (*in camera*)).

Response to Finding No. 3797:

Respondents have no specific response except note that the Open Offer requires Illumina to enter into such an IVD agreement if the test developer requests one (PFF ¶ 1026), and further

note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3798. [redacted] (PX7040 (Getty (Guardant) IHT at 90-91) (*in camera*)).

Response to Finding No. 3798:

Respondents have no specific response except note that the Open Offer requires Illumina to enter into such an IVD agreement if the test developer requests one, as well as any documentation requested by the FDA of Illumina concerning its sequencing products (PFF ¶¶ 1026, 1035), and further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

3799. [redacted] (PX7040 (Getty (Guardant) IHT at 92) (*in camera*) ([redacted])).

Response to Finding No. 3799:

Respondents have no specific response except note that the Open Offer requires Illumina to enter into such an IVD agreement if the test developer requests one (PFF ¶ 1026), and further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

(5) Illumina Only Wanted to Allow "Partnerships" with Companies Who Are Complementary and Not Competitive

3800. In negotiating IVD agreements, Dr. Leite and his colleagues considered whether a customer's oncology therapy selection tests would compete with the TSO-500. (Leite (Illumina) Tr. 2083-84).

Response to Finding No. 3800:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to Proposed Findings CCFF ¶ 3750, which Respondents incorporate herein.

Respondents incorporate their responses to Proposed Findings CCFF ¶ 3760 herein.

3801. [redacted] (PX2102 (Illumina) at 004 [redacted] (*in camera*)).

Response to Finding No. 3801:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to Proposed Findings CCFF ¶ 3750, which Respondents incorporate herein.

3802. [redacted] (PX2102 (Illumina) at 004 [redacted] Feb. 4, 2019 (*in camera*) (see image inset)).

[redacted]

Response to Finding No. 3802:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to Proposed Findings CCFF ¶ 3750, which Respondents incorporate herein.

3803. [redacted] (PX2677 (Illumina) at 001 (Email from D. Daly, Illumina, to N. Berry, Illumina, Feb. 6, 2019 (*in camera*) ([redacted])).

Response to Finding No. 3803:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to Proposed Findings CCFF ¶ 3750, which Respondents incorporate herein.

3804. [redacted] (PX2203 (Illumina) at 001 (Email from J. Leite, Illumina, to J. Mayew, J. Eidel, Illumina, Apr. 4, 2018) (*in camera*)).

Response to Finding No. 3804:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to Proposed Findings CCFF ¶ 3750, which Respondents incorporate herein.

3805. As part of Illumina's strategy, Dr. Leite and his colleagues considered competitive factors in determining Illumina's negotiation strategy, such as:

> [T]he value of inclusion of partners that were developing solutions close to ours. We considered a term called "cannibalization" -- in other words, what would be the sales of Illumina TSO-500 in the absence of these partners versus the presence of these partners—to try and decide at least a framework for summing up what the value of that partnership should be.

(Leite (Illumina) Tr. 2085).

Response to Finding No. 3805:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to Proposed Findings CCFF ¶ 3750, which Respondents incorporate herein.

3806. Dr. Leite testified that Illumina took into account the net loss in TSO-500 sales that might result from a partnership with a customer:

> And so we certainly wanted to quantify from a financial loss perspective what would be the worst case scenario, and we knew that that had to be our floor and that anything that we could gain from a partnership consideration in terms of up-front payments or total deal value should at least look to mitigate some of that risk.

(Leite (Illumina) Tr. 2087).

Response to Finding No. 3806:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to Proposed Findings CCFF ¶ 3750, which Respondents incorporate herein.

3807. In negotiating IVD agreements, Dr. Leite testified that Illumina dictates which tests gain an IVD agreement and accept customer proposals only if they made financial sense for Illumina. (Leite (Illumina) Tr. 2187).

Response to Finding No. 3807:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to Proposed Findings CCFF ¶¶ 3750 and 3761, which Respondents incorporate herein.

3808. When negotiating with oncology therapy selection test developers, Dr. Leite testified at trial that "the ability to maximize penetration into the oncology market was always a consideration. As part of our strategy, we considered the value of inclusion of partners that were developing solutions close to ours. We considered a term called 'cannibalization' – in other words, what would be the sales of Illumina TSO-500 in the absence of these partners versus the presence of these partners – to try and decide at least a framework for summing up what the value of that partnership should be." (Leite (Illumina) Tr. 2084-85).

Response to Finding No. 3808:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to Proposed Findings CCFF ¶¶ 3750 and 3761, which Respondents incorporate herein.

b) [redacted]

(1) [redacted]

3809. [redacted]

[redacted] (RX0485 (Roche) at 060 [redacted] (*in camera*)); Leite (Illumina) Tr. 2105-06 (*in camera*)).

Response to Finding No. 3809:

Respondents have no specific response.

3810. [redacted] (RX0485 (Roche) at 060 [redacted] (*in camera*)).

Response to Finding No. 3810:

Respondents have no specific response.

3811. [redacted] (RX0485 (Roche) at 060 [redacted]

Response to Finding No. 3811:

Respondents have no specific response.

3812. [redacted] (*in camera*)).

Response to Finding No. 3812:

Respondents have no specific response.

(a) The AVENIO Kits

3813. "The AVENIO kits are a packaged solution [] able to run a sequencing assay on the Illumina platform." (PX7043 (Gunn (Roche) IHT at 37)).

Response to Finding No. 3813:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3814. [redacted] (PX7043 (Gunn (Roche) IHT at 37-38) (*in camera*)).

Response to Finding No. 3814:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3815. [redacted] (PX7043 (Gunn (Roche) IHT at 38-39) (*in camera*)).

Response to Finding No. 3815:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3816. The AVENIO kits have the regulatory classification of research use only (RUO) which "is an official regulatory classification, [meaning] that [] labs can use them for research purposes, and they have to – there are instructions for use. They are provided as a kit, and they are used in that context." (PX7074 (Gunn (Roche) IHT at 51)).

Response to Finding No. 3816:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3817. Because the AVENIO kits are RUO only, for labs to run the AVENIO kits in their own labs they must operate it as a laboratory developed test. Meaning, they have to validate it within their own workflow, and they have to validate the results that come off it." (PX7074 (Gunn (Roche) IHT at 51)).

Response to Finding No. 3817:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3818. [redacted] (PX7074 (Gunn (Roche) IHT at 53-54) (*in camera*)).

Response to Finding No. 3818:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(b) FoundationOne Assays

3819. FoundationOne is a tissue-based therapy selection test. (PX7068 (Perettie (FMI-Roche) IHT at 25)).

Response to Finding No. 3819:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3820. The FoundationOne test was launched in 2012. FoundationOne CDx is the FDA-approved test companion diagnostic version of FoundationOne. (PX7068 (Perettie (FMI-Roche) IHT at 24-25)).

Response to Finding No. 3820:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3821. The FoundationOne CDx test is a "tissue-based test that [] looks for 324 genes that are associated with cancer… [FMI is] able to inform the oncologist or the biopharma partner and the patient which genes [the test has] found in their individual cancer. And that enables a treatment decision." (PX7068 (Perettie (FMI-Roche) IHT at 25)).

Response to Finding No. 3821:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3822. The FoundationOne test can measure tumor mutational burden or TMB. (PX7068 (Perettie (FMI-Roche) IHT at 27)).

Response to Finding No. 3822:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3823. TMB is "a number of genes that form a biomarker that are indicative of patients that would respond to cancer immunotherapy." (PX7068 (Perettie (FMI-Roche) IHT at 27)).

Response to Finding No. 3823:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3824. FMI had the ability to measure TMB from a research and development standpoint since 2017, but it was not until 2019 that it was officially FDA approved. (PX7068 (Perettie (FMI-Roche) IHT at 27)).

Response to Finding No. 3824:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3825. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 28 (*in camera*))). [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 28 (*in camera*))).

Response to Finding No. 3825:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3826. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 32) (*in camera*)).

Response to Finding No. 3826:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3827. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 32 (*in camera*))).

Response to Finding No. 3827:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3828. When FoundationOne was initially launched it was launched as a laboratory developed test or "LDT." (PX7068 (Perettie (FMI-Roche) IHT at 34)).

Response to Finding No. 3828:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3829. "A laboratory developed test is a test that passes a CLIA certification or New York certification… It is a test that can be used in clinical practice, but [] it [has] a slightly – a lower bar than going through an FDA process." (PX7068 (Perettie (FMI-Roche) IHT at 34-35)).

Response to Finding No. 3829:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3830. "LDTs can be used to guide treatment decision in the clinic." "[W]ith an LDT, there's a certain number of things you do to add or subtract genes… that require some validation not at the same rigor [as] FDA [approval]." (PX7068 (Perettie (FMI-Roche) IHT at 35)).

Response to Finding No. 3830:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3831. Today, the FoundationOne test is an in vitro diagnostic test. (PX7068 (Perettie (FMI-Roche) IHT at 35)).

Response to Finding No. 3831:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3832. An in vitro diagnostic or IVD is "a test that has passed that rigor to have an FDA approval and used to guide treating physicians and patients." (PX7068 (Perettie (FMI-Roche) IHT at 36)).

Response to Finding No. 3832:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3833. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 33 (*in camera*))).

Response to Finding No. 3833:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3834. IVDs and LDTs are governed differently. "[F]or an LDT, you have the ability to make more rapid changes to it. It doesn't go through a process of intense review with the FDA. Instead, it's a much lighter process to make changes than you would with an IVD." (PX7068 (Perettie (FMI-Roche) IHT at 36)).

Response to Finding No. 3834:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(2) [redacted]

3835. The AVENIO test kits require an NGS platform to be used. (PX7043 (Gunn (Roche) IHT at 54)). Specifically, "the AVENIO kits and all kits actually have to be designed with the platform in mind, and so Roche developed the AVENIO kits with the direct purpose of running them on the Illumina NextSeq instrument." (PX7043 (Gunn (Roche) IHT at 54)).

Response to Finding No. 3835:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3836. [redacted] (RX0485 (Roche) at 060 [redacted] (*in camera*))).

Response to Finding No. 3836:

The proposed finding is inaccurate, incomplete and misleading to the extent it is intended to suggest that there are no NGS platforms other than Illumina's that can support a genomic profiling test such as FMI's. The suggestion is false, as there are a number of NGS platforms that can support such tests. (*E.g.*, PFF ¶¶ 581, 592-93.)

3837. "Comprehensive genomic profiling tests are tests that look at a wide range of mutations of tumor tissue to understand, connect what genomic mutations happens to the tumor to decide on a treatment plan. And the word 'comprehensive' is because it's not just one mutation that is checked, but it's a wide range of mutations." (PX7118 (Fiedler (FMI) Dep. at 18)).

Response to Finding No. 3837:

Respondents have no specific response.

3838. Mr. Fielder testified that Illumina's products are essential to FMI's comprehensive genomic profiling tests "because the design of the test is based on the Illumina technology. The Illumina technology has one central element. It is called 'hybrid capturing' where you connect, prepare the gene in the way that you can selectively look at mutations, and that is a unique offering at this stage for Illumina." (PX7118 (Fiedler (FMI) Dep. at 19)).

Response to Finding No. 3838:

The proposed finding is inaccurate, incomplete and misleading to the extent it is intended to suggest that there are no NGS platforms other than Illumina's that can support a genomic profiling test such as FMI's. The suggestion is false, as there are a number of NGS platforms that can support such tests. (*E.g.*, PFF ¶¶ 581, 592-93.)

3839. [redacted] (PX7118 (Fiedler (FMI) Dep. at 19-20 (*in camera*))).

Response to Finding No. 3839:

The proposed finding is inaccurate, incomplete and misleading to the extent it is intended to suggest that there are no NGS platforms other than Illumina's that can support a genomic profiling test such as FMI's. The suggestion is false, as there are a number of NGS platforms that can support such tests. (*E.g.*, PFF ¶¶ 581, 592-93.)

3840. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 23) (*in camera*)).

Response to Finding No. 3840:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3841. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 90) (*in camera*)).

Response to Finding No. 3841:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3842. [redacted] (*See* PX7068 (Perettie (FMI-Roche) IHT at 90-91) (*in camera*) ([redacted])).

Response to Finding No. 3842:

The proposed finding is misleading and inaccurate to the extent it is intended to suggest that the reagents specific to Roche's therapy selection test are the core consumable reagents that are purchased from Illumina, which is incorrect. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(3) [redacted]

3843. [redacted] (PX2095 (Illumina) at 003 (Email from J. Leite, Illumina, to G. Hampton, et al., Dec. 5, 2018) (*in camera*); Leite (Illumina) Tr. 2105-06 (*in camera*)).

Response to Finding No. 3843:

Respondents have no specific response.

3844. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 80-81) (*in camera*)).

Response to Finding No. 3844:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3845. [redacted] (PX8351 (Roche) at 011 [redacted] (*in camera*))).

Response to Finding No. 3845:

Respondents have no specific response.

3846. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 81) (*in camera*)).

Response to Finding No. 3846:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(4) [redacted]

3847. [redacted] (PX7043 (Gunn (Roche) IHT at 38) (*in camera*) ([redacted]).

Response to Finding No. 3847:

Respondents have no specific response except note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3848. [redacted]

[redacted] (PX7068 (Perettie (FMI-Roche) IHT at 38 (*in camera*))). [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 39 (*in camera*))).

Response to Finding No. 3848:

Respondents have no specific response.

3849. [redacted]

[redacted]

(PX7068 (Perettie (FMI-Roche) IHT at 38-39 (*in camera*))).

Response to Finding No. 3849:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3850. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 39 (*in camera*))).

Response to Finding No. 3850:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(5) [redacted]

3851. [redacted] (PX2095 (Illumina) at 003 (Email from J. Leite, Illumina, to G. Hampton, Illumina, et al., attaching slides, Dec. 5, 2018) (*in camera*); *see* PX2089 (Illumina) (Email from T. Dodge, Illumina, to D. Daly, Illumina, et al., Aug. 31, 2018) (*in camera*); Leite (Illumina) Tr. 2105-06 (*in camera*); PX7061 (Davy (Illumina) IHT at 153) (*in camera*)).

Response to Finding No. 3851:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.).

3852. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 81) (*in camera*)).

Response to Finding No. 3852:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.).

3853. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 17-18, 80-81) (*in camera*)).

Response to Finding No. 3853:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.).

3854. [redacted]

[redacted] (PX7061 (Davy (Illumina) IHT at 154) (*in camera*)).

Response to Finding No. 3854:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.).

3855. [redacted] (Leite (Illumina) Tr. 2102 (*in camera*)). [redacted] (Leite (Illumina) Tr. 2102 (*in camera*); *see* PX2095 (Illumina) at 001 (Email from J. Leite, Illumina, to G. Hampton, Illumina, et al., attaching slides, Dec. 5, 2018) (*in camera*)).

Response to Finding No. 3855:

Respondents have no specific response.

3856. [redacted] (*See* PX2119 (Illumina) at 002-003 (Email from K. Davy, Illumina, to G. Hampton, Illumina, attaching slides, Feb. 12, 2018) (*in camera*) ([redacted]); PX7052 (Leite (Illumina) IHT at 26-27) (*in camera*) ([redacted]); PX2117 (Illumina) [redacted] (*in camera*)).

Response to Finding No. 3856:

The proposed finding is incomplete, misleading and inaccurate. The evidence refutes the inferences that Complaint Counsel seeks to draw from Illumina's interactions with Roche concerning an IVD agreement. It is of no moment that, in the early days of its IVD technology and its therapy selection strategy, Illumina "evaluated" the impact of IVD partnerships on its profits. Illumina had invested substantial amounts in its IVD technology, there were few IVD

kitted tests even commercially available, and Illumina had not yet even received FDA authority to market a higher-throughput IVD system. The evaluation Illumina undertook of different potential approaches to this new technology and mode of distribution is what any profit maximizing firm would do when considering a major strategic decision such as the one Illumina faced when it first considered how and to what extent to enable third party kits on its new IVD systems. What matters to understanding Illumina's incentives are the choices Illumina made, not the strategies some within Illumina evaluated along the way. [redacted] (PFF ¶¶ 971.4-971.5)

3857. [redacted] (PX2123 (Illumina) at 003 (Email from K. Davy, Illumina, to K. Keegan, Illumina, attaching slides, Dec. 9, 2018) (*in camera*)).

[redacted]

[redacted]

(PX2123 (Illumina) at 003 (Email from K. Davy, Illumina, to K. Keegan, Illumina, attaching slides, Dec. 9, 2018) (*in camera*); *see* PX2095 (Illumina) at 003 (Email from J. Leite, Illumina, to G. Hampton, Illumina, et al., attaching slides, Dec. 5, 2018) (*in camera*) ([redacted]).

Response to Finding No. 3857:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Further, the proposed finding excludes the testimony contextualizing the quoted language in the cited document that makes clear the documents do not have relevance to the issues before the Court. As John Leite, who was directly involved in the discussions with Roche, testified, [redacted]

[redacted]

(PX7052 (Leite (Illumina) IHT at 171.)

3858. [redacted]
(PX2095 (Illumina) at 003 (Email from J. Leite, Illumina, to G. Hampton, Illumina, et al., attaching slides, Dec. 5, 2018) (*in camera*)).

Response to Finding No. 3858:

The proposed finding is incomplete, misleading, inaccurate and irrelevant for the reasons explained in Respondents' responses to CCFF ¶¶ 3856 and 3857, which Respondents incorporate herein.

3859. [redacted] (PX7052 (Leite (Illumina) IHT at 170-71) (*in camera*)).

Response to Finding No. 3859:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3860. [redacted] (PX2120 (Illumina) at 004,

006 [redacted] (*in camera*); *see* PX7052 (Leite (Illumina) IHT at 119) ("IO" refers to immuno-oncology, within the field of immunotherapy.)).

[redacted]

(PX2120 (Illumina) at 006 [redacted] (*in camera*)).

Response to Finding No. 3860:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3861. [redacted]

(PX2119 (Illumina) at 003 (Email from K. Davy, Illumina, to G. Hampton, Illumina, attaching slides, Feb. 12, 2018) (*in camera*)).

Response to Finding No. 3861:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3862. (PX2120 (Illumina) at 006 (*in camera*)).

Response to Finding No. 3862:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3863. (PX2120 (Illumina) at 010 (*in camera*)).

Response to Finding No. 3863:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3864. [redacted]

[redacted]

(PX2120 (Illumina) at 009 [redacted] (*in camera*)).

Response to Finding No. 3864:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3865. [redacted] (PX2120 (Illumina) at 004 [redacted] (*in camera*)).

[redacted]

Response to Finding No. 3865:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3866. [redacted] (PX2120 (Illumina) at 004 [redacted] (*in camera*)).

Response to Finding No. 3866:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3867. [redacted] (PX2120 (Illumina) at 004 [redacted] (*in camera*)).

Response to Finding No. 3867:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3868. [redacted] (PX2120 (Illumina) at 007 [redacted] (*in camera*)).

Response to Finding No. 3868:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3869. [redacted] (PX2120 (Illumina) at 007 [redacted] (*in camera*))).

Response to Finding No. 3869:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3870. [redacted] (PX2095 (Illumina) at 002 (Email from J. Leite, Illumina, to G. Hampton, Illumina, attaching slides, Dec. 5, 2018) (*in camera*)). [redacted] (PX7052 (Leite (Illumina) IHT at 161-62) (*in camera*); *see* Leite (Illumina) Tr. 2104-05, 2107 (*in camera*)).

Response to Finding No. 3870:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

Respondents further note that the proposed finding relies on IH testimony [which is hearsay and]

which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3871. [redacted] (PX2123 (Illumina) at 006 (Email from K. Davy, Illumina, to K. Keegan, Illumina, attaching slides, Dec. 9, 2018) (*in camera*)).

Response to Finding No. 3871:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3872. [redacted] (PX2122 (Illumina) at 003 (Email from G. Hampton, Illumina, to J. Leite, Illumina, et al., attaching slides, Dec. 5, 2018) (*in camera*) (*see* image inset)).

[redacted]

Response to Finding No. 3872:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3873. [redacted] (PX2123 (Illumina) at 008 (Email from K. Davy, Illumina, to K. Keegan, Illumina, attaching slides, Dec. 9, 2018) (*in camera*)).

Response to Finding No. 3873:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3874. [redacted] (PX2095 (Illumina) at 001 (Email from J. Leite, Illumina, to G. Hampton, Illumina, attaching slides, Dec. 5, 2018) (*in camera*)).

Response to Finding No. 3874:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3875. [redacted] (PX7052 (Leite (Illumina) IHT at 159-60) (*in camera*)).

Response to Finding No. 3875:

Respondents have no specific response except to refer to RRFF ¶ 3847.

3876. [redacted] (PX7052 (Leite (Illumina) IHT at 165) (*in camera*)). [redacted] (PX7052 (Leite (Illumina) IHT at 165-66) (*in camera*)).

Response to Finding No. 3876:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3877. [redacted] (PX7052 (Leite (Illumina) IHT at 167) (*in camera*) ([redacted])).

Response to Finding No. 3877:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3878. [redacted] (PX7052 (Leite (Illumina) IHT at 174-75) (*in camera*); *see* PX2095

(Illumina) at 004 (Email from J. Leite, Illumina, to G. Hampton, Illumina, attaching slides, Dec. 5, 2018) (*in camera*)). [redacted] (PX7052 (Leite (Illumina) IHT at 175) (*in camera*)).

Response to Finding No. 3878:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3879. [redacted] (PX7052 (Leite (Illumina) IHT at 176) (*in camera*); *see* PX2095 (Illumina) at 006 (Email from J. Leite, Illumina, to G. Hampton, Illumina, attaching slides, Dec. 5, 2018) (*in camera*)).

Response to Finding No. 3879:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3880. [redacted] (PX7052 (Leite (Illumina) IHT at 179-80) (*in camera*); *see* PX2095 (Illumina) at 008 (Email from J. Leite, Illumina, to G. Hampton, Illumina, attaching slides, Dec. 5, 2018) (*in camera*)).

Response to Finding No. 3880:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3881. [redacted] (Leite (Illumina) Tr. 2107-08 (*in camera*)).

Response to Finding No. 3881:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3882. [redacted] (PX7052 (Leite (Illumina) IHT at 180-81) (*in camera*)).

Response to Finding No. 3882:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3883. [redacted] (PX2095 (Illumina) at 008 (Email from J. Leite, Illumina, to G. Hampton, Illumina, attaching slides, Dec. 5, 2018) (*in camera*)).

[redacted]

(PX2123 (Illumina) at 008 (Email from K. Davy, Illumina, to K. Keegan, Illumina, attaching slides, Dec. 9, 2018) (*in camera*)).

Response to Finding No. 3883:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3884. [redacted] (PX2095 (Illumina) at 003 (Email from J. Leite, Illumina, to G. Hampton, Illumina, et al., Dec. 5, 2018) (*in camera*); Leite (Illumina) Tr. 2106-07 (*in camera*)).

Response to Finding No. 3884:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3885. [redacted] (PX2095 (Illumina) at 003 (Email from J. Leite, Illumina, to G. Hampton, Illumina, attaching slides, Dec. 5, 2018) (*in camera*)). [redacted]

[redacted] (PX7052 (Leite (Illumina) IHT at 172-73) (*in camera*)).

Response to Finding No. 3885:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3886. [redacted] (Leite (Illumina) Tr. 2106-07 (*in camera*)).

Response to Finding No. 3886:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3887. [redacted] (PX2095 (Illumina) at 003 (Email from J. Leite, Illumina, to G. Hampton, et al., attaching slides, Dec. 5, 2018) (*in camera*); Leite (Illumina) Tr. 2105-07 (*in camera*)).

Response to Finding No. 3887:

Respondents have no specific response.

(a) [redacted]

3888. [redacted] (PX2199 (Illumina) at 001 (Email from J. Leite, Illumina, to K. Davy, Illumina, et al., July 22, 2019) (*in camera*) ([redacted]

[redacted]).

Response to Finding No. 3888:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3889. [redacted] (PX7052 (Leite (Illumina) IHT at 180-81) (*in camera*)).

Response to Finding No. 3889:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3890. [redacted] (PX7052 (Leite (Illumina) IHT at 186-87); PX2102 (Illumina) at 001 [redacted] (*in camera*)).

Response to Finding No. 3890:

Responds have no specific response except to note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3891. [redacted] (PX7052 (Leite (Illumina) IHT at 186) (*in camera*)).

Response to Finding No. 3891:

Responds have no specific response except to note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3892. [redacted] (PX2102 (Illumina) at 004 (*in camera*)). [redacted] (PX7052 (Leite (Illumina) IHT at 188) (*in camera*)).

Response to Finding No. 3892:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3893. [redacted] (PX2102 (Illumina) at 005 (*in camera*)). [redacted] (PX7052 (Leite (Illumina) IHT at 191) (*in camera*)).

Response to Finding No. 3893:

Respondents have no specific response except to refer to RRFF ¶ 3847. The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3894. [redacted] (PX2102 (Illumina) at 005 (*in camera*)). [redacted] (PX2102 at 007-009 [redacted] (*in camera*))).

[redacted]

Response to Finding No. 3894:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3895. [redacted] (*See* PX2124 (Illumina) at 002-003 [redacted] (*in camera*)).

Response to Finding No. 3895:

Respondents have no specific response.

3896. [redacted] (PX2125 (Illumina) at 005 [redacted] (*in camera*); *see* PX2124 (Illumina) at 003 [redacted] (*in camera*)).

Response to Finding No. 3896:

Respondents have no specific response.

3897. [redacted] (PX2124 (Illumina) at 003 [redacted] (*in camera*))). [redacted] (PX2124 (Illumina) at 003 [redacted] (*in camera*)); PX2125 (Illumina) at 005 [redacted] (*in camera*)).

[redacted]

(PX2125 (Illumina) at 005 [redacted] (*in camera*)).

Response to Finding No. 3897:

Respondents have no specific response.

3898. [redacted] (Leite (Illumina) Tr. 2110-11 (*in camera*)). [redacted] (Leite (Illumina) Tr. 2110-11 (*in camera*)).

Response to Finding No. 3898:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3899. [redacted] (Leite (Illumina) Tr. 2107-09 (*in camera*)).

Response to Finding No. 3899:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3900. [redacted] (Leite (Illumina) Tr. 2107-09, 2111-12 (*in camera*); PX2199 (Illumina) at 001 (Email from K. Keegan, Illumina, to J. Leite and K. Davy, Illumina, July 22, 2019) (*in camera*)). [redacted] (Leite (Illumina) Tr. 2107-09, 2111-12 (*in camera*); PX2199 (Illumina)at 001 (Email from J. Leite, Illumina, to K. Davy, et. al, Illumina, July 22, 2019 (*in camera*)). [redacted]

(PX2199 (Illumina) at 001 (Email from J. Leite, Illumina, to K. Davy, Illumina, et al., July 22, 2019) (*in camera*)).

Response to Finding No. 3900:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3901. [redacted] (PX2199 (Illumina) at 001 (Email from K. Keegan, Illumina, to J. Leite, et. al, Illumina, July 22, 2019) (*in camera*)).

Response to Finding No. 3901:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3902. [redacted] (Leite (Illumina) Tr. 2115 (*in camera*)).

Response to Finding No. 3902:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3903. [redacted] (Leite (Illumina) Tr. 2114 (*in camera*); PX2199 (Illumina) at 001 (Email from K. Keegan, Illumina, to J. Leite, et. al, Illumina, July 22, 2019) (*in camera*)).

Response to Finding No. 3903:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3904. [redacted] (Leite (Illumina) Tr. 2118 (*in camera*); PX2199 (Illumina) at 001 (Email from K. Keegan, Illumina, to J. Leite, et. al, Illumina,

July 22, 2019) (*in camera*)). [redacted] (Leite (Illumina) Tr. 2115 (*in camera*)).

Response to Finding No. 3904:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3905. [redacted] (Leite (Illumina) Tr. 2116 (*in camera*)).

Response to Finding No. 3905:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3906. [redacted] (*See* Leite (Illumina) Tr. 2120-21 (*in camera*)). [redacted] (Leite (Illumina) Tr. 2120-21 (*in camera*)).

Response to Finding No. 3906:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3907. [redacted] (PX2209 (Illumina) (*in camera*); Leite (Illumina) Tr. 2117-19 (*in camera*)). [redacted] (Leite (Illumina) Tr. 2119-20 (*in camera*); PX2209 (Illumina) (*in camera*)).

Response to Finding No. 3907:

Respondents have no specific response.

3908. [redacted] (PX2209 (Illumina) at 017 [redacted] (*in camera*)).

Response to Finding No. 3908:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3909. [redacted] (PX2209 (Illumina) at 017 [redacted] (*in camera*)).

Response to Finding No. 3909:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3910. [redacted] (PX7052 (Leite (Illumina) IHT at 202-04) (*in camera*)); PX2209 (Illumina) at 005 [redacted] (*in camera*)).

Response to Finding No. 3910:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3911. [redacted] (PX7052 (Leite (Illumina) IHT at 203) (*in camera*)).

Response to Finding No. 3911:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3912. [redacted] (PX2209 (Illumina) at 005 [redacted] (*in camera*)).

Response to Finding No. 3912:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3913. [redacted] (PX7052 (Leite (Illumina) IHT at 203) (*in camera*)).

Response to Finding No. 3913:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3914. [redacted] (PX7052 (Leite (Illumina) IHT at 205-06) (*in camera*)).

Response to Finding No. 3914:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3915. [redacted] (PX7052 (Leite (Illumina) IHT at 206) (*in camera*)).

Response to Finding No. 3915:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3916. [redacted] (PX7052 (Leite (Illumina) IHT at 208) (*in camera*)).

Response to Finding No. 3916:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and]

which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3917. [redacted] (PX2209 (Illumina) at 009 [redacted] (*in camera*)).

[redacted]

Response to Finding No. 3917:

Respondents have no specific response.

3918. [redacted] (PX7052 (Leite (Illumina) IHT at 209) (*in camera*)).

Response to Finding No. 3918:

Respondents have no specific response.

3919. [redacted] (PX7052 (Leite (Illumina) IHT at 209) (*in camera*); PX2209 (Illumina) at 009 [redacted] (*in camera*)).

Response to Finding No. 3919:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3920. [redacted] (PX2209 (Illumina) at 014 [redacted] (*in camera*)).

Response to Finding No. 3920:

Respondents have no specific response.

3921. [redacted] (PX2209 (Illumina) at 017 [redacted] (*in camera*)).

[redacted]

Response to Finding No. 3921:

Respondents have no specific response.

3922. [redacted] (Leite (Illumina) Tr. 2120-21 (*in camera*); PX2209 (Illumina) at 017 [redacted] (*in camera*)).

Response to Finding No. 3922:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3923. [redacted] (Leite (Illumina) Tr. 2122-24 (*in camera*); PX2209 (Illumina) at 006 [redacted] (*in camera*)). [redacted] (Leite (Illumina) Tr. 2123 (*in camera*)).

Response to Finding No. 3923:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3924. [redacted] (PX7052 (Leite (Illumina) IHT at 215) (*in camera*)).

Response to Finding No. 3924:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3925. [redacted] (PX7052 (Leite (Illumina) IHT at 213) (*in camera*); PX2209 (Illumina) at 017 [redacted] (*in camera*)).

Response to Finding No. 3925:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3926. [redacted] (PX7052 (Leite (Illumina) IHT at 213) (*in camera*)).

Response to Finding No. 3926:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3927. [redacted] (PX7052 (Leite (Illumina) IHT at 214) (*in camera*)).

Response to Finding No. 3927:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3928. [redacted] (PX7052 (Leite (Illumina) IHT at 218) (*in camera*); PX2199 (Illumina) at 001 (Email from K. Davy, Illumina, to K. Keegan, et. al, Illumina, July 22, 2019 (*in camera*)).

Response to Finding No. 3928:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3929. [redacted] (PX7052 (Leite (Illumina) IHT at 218-19) (*in camera*); PX2199 (Illumina) at 001 (Email from K. Keegan, Illumina, to J. Leite, et. al Illumina, July 22, 2019) (*in camera*)).

Response to Finding No. 3929:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3930. [redacted] (PX2199 (Illumina) at 001 (Email from K. Keegan, Illumina to J. Leite, et. al, Illumina, July 22, 2019) (*in camera*)).

Response to Finding No. 3930:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3931. [redacted] (PX7052 (Leite (Illumina) IHT at 222-23) (*in camera*); PX2199 (Illumina) at 001 (Email from K. Keegan, Illumina to J. Leite, et. al, Illumina, July 22, 2019) (*in camera*)).

Response to Finding No. 3931:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3932. [redacted]

(PX7052 (Leite (Illumina) IHT at 223) (*in camera*); PX2199 (Illumina) at 001 (Email from K. Keegan, Illumina to J. Leite, et. al, Illumina, July 22, 2019) (*in camera*)).

Response to Finding No. 3932:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3933. [redacted] (PX8351 (Roche) (*in camera*)). [redacted] (PX8351 (Roche) at 003 (*in camera*)).

Response to Finding No. 3933:

Respondents have no specific response.

3934. [redacted] (PX8351 (Roche) at 003 (*in camera*)).

Response to Finding No. 3934:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3935. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 82-83) (*in camera*); PX8351 (Roche) at 003 [redacted] (*in camera*)).

Response to Finding No. 3935:

Respondents have no specific response except to refer to RRFF ¶ 3847.

3936. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 83) (*in camera*)).

Response to Finding No. 3936:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3937. [redacted] (PX8351 (Roche) at 012 (Distributed NGS Kits Group Level Discussions with Illumina, Sept. 2019) (*in camera*)).

Response to Finding No. 3937:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein.

3938. [redacted] (PX8351 (Roche) at 015, 016 [redacted] (*in camera*)).

Response to Finding No. 3938:

Respondents have no specific response.

3939. [redacted] (Leite (Illumina) Tr. 2126 (*in camera*)). [redacted] (Leite (Illumina) Tr. 2126-27 (*in camera*)).

Response to Finding No. 3939:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3856, which Respondents incorporate herein. Further, it omits that Mr. Leite testified that "[g]iven the considerations of the up-front investment that Illumina had made into the development of their Dx instruments, the desire to accelerate value creation using those platforms, . . . a decision was made that partnerships are the more favorable path". (Leite (Illumina) Tr. 2124-25.) While Illumina was looking to offset the risk of partnership, Roche ultimately agreed to pay "a fraction of [Illumina was] asking for". (Leite (Illumina) Tr. 2125-26.) [redacted]

3940. [redacted] (Leite (Illumina) Tr. 2124-26 (*in camera*)).

Response to Finding No. 3940:

Respondents have no specific response except to refer to RRFF ¶ 3939.

(6) [redacted]

3941. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 83) (*in camera*)).

Response to Finding No. 3941:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3942. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 85) (*in camera*)).

Response to Finding No. 3942:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3943. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 39-40, 84) (*in camera*); PX7052 (Leite (Illumina) IHT at 134) (*in camera*)).

Response to Finding No. 3943:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3944. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 85) (*in camera*)).

Response to Finding No. 3944:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3945. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 84-85) (*in camera*)).

Response to Finding No. 3945:

The proposed finding is misleading to the extent it suggests Roche "had to" provide anything to Illumina as though it was coerced into doing so. The record does not support that suggestion. Rather, the parties negotiated mutually agreeable terms, which is reflected in the agreement, pursuant to which Roche today is investing in and developing its IVD tests. (PFF ¶¶ 966-67.) Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3946. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 84) (*in camera*)).

Response to Finding No. 3946:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3947. [redacted] (PX8351 (Roche) at 003 (*in camera*)).

Response to Finding No. 3947:

Respondents have no specific response.

3948. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 86) (*in camera*) ([redacted]

[redacted]).

Response to Finding No. 3948:

The proposed finding is vague, and therefore misleading, as to the types of information Roche shares with Illumina when a sequencer stops working. Further, to the extent the proposed finding is meant to suggest that customers must share confidential information with Illumina and that such information could be shared with GRAIL post-merger, the suggestion is false and overlooks both the firewall in the Open Offer and the fact that Roche testified it was secure in its supply agreement and had no concerns about the Transaction in light of that agreement. (*E.g.*, PFF ¶ 986.) Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3949. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 85) (*in camera*)).

Response to Finding No. 3949:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶¶ 3856 and 3939, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3950. [redacted]

[redacted] (PX7052 (Leite (Illumina) IHT at 201) (*in camera*)).

Response to Finding No. 3950:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3951. [redacted] (PX7052 (Leite (Illumina) IHT at 201-02) (*in camera*) ([redacted])

Response to Finding No. 3951:

Respondents have no specific response except note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3952. [redacted] (PX2290 (Illumina) at 005-006 [redacted] (*in camera*); PX2625 (Illumina) at 003, 087 [redacted] (*in camera*)).

Response to Finding No. 3952:

Respondents have no specific response.

3953. The standardized IVD partnership agreement in the Open Offer requires, for IVD rights to all platforms, a tech access fee of $25 million, development milestone payments of $1 million to $5 million per IVD test kit, and a revenue sharing royalty of 6 percent. (PX0087 at 021, 041 (Illumina IVD Test Kit Agreement – All Platforms, dated Mar. 30, 2021)).

Response to Finding No. 3953:

Respondents have no specific response.

(a) [redacted]

3954. [redacted] (PX8351 (Roche) at 006 [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 88-89) (*in camera*)).

Response to Finding No. 3954:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶¶ 3856 and 3939, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3955. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 89) (*in camera*)).

Response to Finding No. 3955:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶¶ 3856 and 3939, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3956. [redacted]

[redacted] (PX2507 (Illumina) at 001 (Email from S. Young, Illumina, to T. Zaleski, Illumina, et al., Aug. 20, 2019) (*in camera*)). [redacted] (PX2507 (Illumina) at 001 (Email from S. Young, Illumina, to T. Zaleski, Illumina, et al., Aug. 20, 2019) (*in camera*)).

Response to Finding No. 3956:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶¶ 3856 and 3939, which Respondents incorporate herein.

3957. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 89) (*in camera*)). [redacted] (PX2199 (Illumina) at 001 (Email from K. Keegan, Illumina, to J. Leite and K. Davy, Illumina, July 22, 2019) (*in camera*); Leite (Illumina) Tr. 2116-8).

Response to Finding No. 3957:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶¶ 3856 and 3939, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3958. According to Mr. Leite, Illumina required these up-front payments and other fees because "there was a potential for downside risk that we needed to offset through some financial consideration." (Leite (Illumina) Tr. 2163).

Response to Finding No. 3958:

The proposed finding is incomplete, misleading, and inaccurate for the reasons explained in Respondents' responses to CCFF ¶ 3939, which Respondents incorporate herein. Respondents further note that in licensing IVD rights in a field of use and charging fees for those rights, Illumina has simply followed market practice in the industry. (PFF ¶ 973.)

c) [redacted]

(1) [redacted]

3959. PGDx has two therapy selection products: Elio Tissue Complete and Elio Plasma Resolve. (PX7049 (Bailey (PGDx) IHT at 28-30)).

Response to Finding No. 3959:

Respondents have no specific response except note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3960. Ms. Bailey, PGDx's CEO, testified that what PGDx is trying to solve for is "putting it closer [to the patient] so results can be delivered faster and becomes more standard of care, and ultimately… more patients receive [a therapy selection] test." (PX7049 (Bailey (PGDx) IHT at 25)).

Response to Finding No. 3960:

Respondents have no specific response except note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(a) Elio Tissue Complete Test

3961. [redacted] (PX7049 (Bailey (PGDx) IHT at 26); PX7112 (Bailey (PGDx) Dep. at 25-6) (*in camera*)).

Response to Finding No. 3961:

Respondents have no specific response. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3962. [redacted] (PX7049 (Bailey (PGDx) IHT at 141) (*in camera*)).

Response to Finding No. 3962:

Respondents have no specific response. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3963. Elio Tissue Complete is a distributed in vitro diagnostic (IVD) test meaning PGDx's customers can run the test in their own lab. (PX7049 (Bailey (PGDx) IHT at 94)).

Response to Finding No. 3963:

The proposed finding is not supported by the cited evidence. Ms. Bailey testified that the Elio Tissue Complete is a "distributed IVD"; she did not specify what this means. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3964. PGDx's Elio Tissue Complete test uses Illumina's NextSeq instrument. (PX7049 (Bailey (PGDx) IHT at 29)).

Response to Finding No. 3964:

Respondents have no specific response. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(b) Elio Plasma Resolve Test

3965. PGDx began development of the Elio Plasma Resolve test in 2017. (PX7049 (Bailey (PGDx) IHT at 135-36)).

Response to Finding No. 3965:

Respondents have no specific response. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3966. The Elio Plasma Resolve test "is a 33 gene liquid biopsy kit" and "runs out of a blood sample." The Elio Plasma Resolve test is "intended to be pan-cancer in nature" and "report[s] microsatellite instability which is related to immune-oncology therapies." (PX7049 (Bailey (PGDx) IHT at 28)).

Response to Finding No. 3966:

Respondents have no specific response. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3967. The Elio Plasma Resolve test "works very similarly to [] the elio tissue complete test with the primary exception being that the DNA is extracted out of a blood sample." (PX7049 (Bailey (PGDx) IHT at 134-35)).

Response to Finding No. 3967:

Respondents have no specific response. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3968. Because Elio Plasma Resolve can measure microsatellite instability or "MSI" it can be used to indicate for immuno-oncology therapies. (PX7049 (Bailey (PGDx) IHT at 138)).

Response to Finding No. 3968:

Respondents have no specific response. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3969. Elio Plasma Resolve cannot measure tumor mutation burden or "TMB" because the panel is "not big enough to do that accurately." (PX7049 (Bailey (PGDx) IHT at 138-39)).

Response to Finding No. 3969:

Respondents have no specific response. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3970. PGDx's Elio Plasma Resolve test uses next-generation sequencing to analyze the blood sample. Specifically, the Elio Plasma Resolve test runs on the Illumina NextSeq platform. (PX7049 (Bailey (PGDx) IHT at 32-33, 135)).

Response to Finding No. 3970:

Respondents have no specific response. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3971. Elio Plasma Resolve is not FDA cleared. (PX7112 (Bailey (PGDx) Dep. at 28)).

Response to Finding No. 3971:

The proposed finding is not supported by the cited evidence, which does not describe the Elio Plasma Resolve's FDA status. Respondents have no specific response. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3972. The Elio Plasma Complete test will not fall under the November 2020 Illumina IVD agreement as "that agreement is restricted to the NextSeq platform." PGDx "would have to negotiate and extension or addendum to encompass [] rights to the NovaSeq platform." (PX7049 (Bailey (PGDx) IHT at 162)).

Response to Finding No. 3972:

Respondents have no specific response except note that Open Offer requires Illumina, on a customer's request, to enter into a separate standardized agreement with the customer to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33.) Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(2) [redacted]

3973. [redacted] (PX7112 (Bailey (PGDx) Dep. at 21-22) (*in camera*)).

Response to Finding No. 3973:

Respondents have no specific response.

3974. During the development process of Elio Plasma Resolve, PGDx did not look at any next generation sequencers other than Illumina's because Illumina has a "broad install base, quality of reads, and the impact of that on performance of the panel, and because it was always the strategy and plan to take the product through the FDA. There are really only two registered instruments with the FDA, the Illumina instruments – I should say two companies that have registered instruments, Illumina and Thermo." (PX7049 (Bailey (PGDx) IHT at 139-40)).

Response to Finding No. 3974:

Respondents have no specific response. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3975. Ms. Bailey testified that PGDx has not considered Thermo Fisher as its next-generation supplier because of "technical reasons around the need for depth of sequence and quality expectations around Illumina's instrument." (PX7049 (Bailey (PGDx) IHT at 140)).

Response to Finding No. 3975:

The proposed finding is incomplete and misleading. Ms Bailey later testified that "Thermo [Fisher] is" a "viable alternative[] to Illumina's NG[S] instruments". (PX7049 (Bailey (PGDx) IHT at 155).) She also noted that PGDx was "talking with or communicating with other NGS providers", specifically Element Biosciences. (PX7049 (Bailey (PGDx) IHT at 154).) She considered Element "an example of a company that is designing and developing a new sequencing platform" with a "strategy [that] is well aligned to [PGDx's]". (PX7049 (Bailey (PGDx) IHT at 154).) She said that PGDx was "looking at options". (PX7049 (Bailey (PGDx) IHT at 155).) Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3976. [redacted] (PX7112 (Bailey (PGDx) Dep. at 22) (*in camera*) ([redacted]).

Response to Finding No. 3976:

The proposed finding, relating to the purported costs of Illumina NGS products used in PGDx's therapy selection test, is irrelevant, given the substantial evidence that the costs of Illumina's NGS products continue to decline and will make up a small percentage of downstream revenues of Galleri or any equally efficient MCED test. (PFF ¶¶ 1246.)

3977. [redacted]

[redacted] (PX7049 (Bailey (PGDx) IHT at 38) (*in camera*)).

Response to Finding No. 3977:

Respondents have no specific response. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3978. [redacted] (PX7049 (Bailey (PGDx) IHT at 153-54) (*in camera*)).

Response to Finding No. 3978:

The proposed finding is incomplete and misleading without further context. Switching between Illumina's platform and alternative platforms is feasible. There are alternative methods of switching between platforms that are less costly (should that be a concern for a test developer), including concurrent development on multiple platforms. (PFF ¶ 645.) Illumina's own model contemplates that a portion of test developers will switch to an alternative sequencing platform developer in the process of upgrading Illumina instruments. (PFF ¶ 646.1) Respondents also refer to PFF ¶¶ 647–74. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3979. [redacted] (PX7049 (Bailey (PGDx) IHT at 169) (*in camera*)).

Response to Finding No. 3979:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' response to CCFF¶ 3978, which Respondents incorporate herein. Further, the

proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3980. [redacted] (PX7052 (Leite (Illumina) IHT at 151-52) (*in camera*)).

Response to Finding No. 3980:

Respondents have no specific response. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(3) [redacted]

(a) [redacted]

3981. Ms. Bailey testified that Illumina's TSO500 is a competitor of the Elio Tissue Complete test. (PX7112 (Bailey (PGDx) Dep. at 33)).

Response to Finding No. 3981:

Respondents have no specific response.

3982. Ms. Bailey testified that Elio Tissue Complete competes with the TSO500 "on content." "The gene content on the panels is very similar, and both are comprehensive across different classes of variants that have mutations relevant to multiple cancer types." (PX7112 (Bailey (PGDx) Dep. at 34)).

Response to Finding No. 3982:

Respondents have no specific response.

3983. Both Elio Tissue Complete and TSO500 are approximately 500 gene panels. (PX7112 (Bailey (PGDx) Dep. at 34)).

Response to Finding No. 3983:

Respondents have no specific response.

3984. Additionally, Elio Tissue Complete and TSO500 compete on "workflow performance" and "turnaround time." (PX7112 (Bailey (PGDx) Dep. at 35) ("Q. Are there any other features

that the Elio Tissue Complete will compete with the TSO500 on? A. I mean, from a laboratory perspective, it competes on things like workflow performance, but I think the more obvious, competitive nature, it's just the clinical content on the panel itself. Q. Do they compete in regards to turnaround time? A. Yes.")).

Response to Finding No. 3984:

Respondents have no specific response.

3985. Elio Tissue Complete and TSO500 compete on the indication of tumor mutation burden (TMB). (PX7112 (Bailey (PGDx) Dep. at 35)).

Response to Finding No. 3985:

The proposed finding is not supported by the cited evidence. The cited evidence merely states that "the TSO500 [can] indicate for TMB"; it does not state that the two tests compete as such.

3986. [redacted] (PX7063 (Berry (Illumina) IHT at 84-85) (*in camera*)).

Response to Finding No. 3986:

The proposed finding is incomplete and misleading. It leaves out Ms. Berry's additional testimony providing context for the referenced testimony. In it, she explained that her

[redacted]

[redacted] (PX7063 (Berry (Illumina) IHT at 86-87) (*in camera*).) Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3987. [redacted] (PX7063 (Berry (Illumina) IHT at 85) (*in camera*)).

Response to Finding No. 3987:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' response to CCFF ¶ 3986, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3988. [redacted] (PX7063 (Berry (Illumina) IHT at 85) (*in camera*)).

Response to Finding No. 3988:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' response to CCFF ¶ 3986, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no

opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3989. Ms. Bailey testified that PGDx's 500-gene liquid biopsy test will be competitive with the TSO500 liquid biopsy. (PX7049 (Bailey (PGDx) IHT at 159).)

Response to Finding No. 3989:

Respondents have no specific response except note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3990. PGDx plans to launch its 500-gene liquid biopsy test in Q3 2021. (PX7049 (Bailey (PGDx) IHT at 159-60) ("Q. When will PGDx be launching this plasma resolve test with 500 genes? A. Within the next quarter.")).

Response to Finding No. 3990:

Respondents have no specific response except note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(4) [redacted]

3991. [redacted] (PX7112 (Bailey (PGDx) Dep. at 72) (*in camera*)). At this time, Mr. Doug Ward was the CEO of PGDx. (PX7112 (Bailey (PGDx) Dep. at 42)).

Response to Finding No. 3991:

Respondents have no specific response.

3992. In 2017, PGDx was asking Illumina for "access to the platform and the parameters around codeveloping [PGDx's] test on [Illumina's] platform in the IVD software mode to be submitted to the FDA." (PX7112 (Bailey (PGDx) Dep. at 42-43)).

Response to Finding No. 3992:

Respondents have no specific response.

3993. Ms. Bailey testified that it was her understanding that in 2017 Illumina was "not willing to enter into [an IVD] agreement." (PX7112 (Bailey (PGDx) Dep. at 43)). Ms. Bailey was made aware of Illumina's reaction "through leadership discussions at the time with Doug [Ward] and Jay [Foust] and [PGDx's] head of regulatory's work to discuss with the FDA alternate approaches." (PX7112 (Bailey (PGDx) Dep. at 43)). More specifically, Ms. Bailey testified that Illumina refused PGDx and IVD agreement "because of the development of the TSO500 test. It would be a competitive test on [Illumina's] platform." (PX7112 (Bailey (PGDx) Dep. at 43); PX7049 (Bailey (PGDx) IHT at 96-97); PX2764 (Illumina) at 001 (Email from J. Leite, Illumina, to M. Kreitzinger, Illumina, et al., Feb. 28, 2018)).

Response to Finding No. 3993:

The proposed finding is incomplete, misleading and inaccurate. The evidence refutes the inferences that Complaint Counsel seeks to draw from Illumina's interactions with PGDx concerning an IVD agreement. It is of no moment that, in the early days of its IVD technology and its therapy selection strategy, Illumina "evaluated" the impact of IVD partnerships on its profits. Illumina had invested substantial amounts in its IVD technology, there were few IVD kitted tests even commercially available, and Illumina had not yet even received FDA authority to market a higher-throughput IVD system. The evaluation Illumina undertook of different potential approaches to this new technology and mode of distribution is what any profit maximizing firm would do when considering a major strategic decision such as the one Illumina faced when it first considered how and to what extent to enable third party kits on its new IVD systems. What matters to understanding Illumina's incentives are the choices Illumina made, not the strategies some within Illumina evaluated along the way. [redacted]

[redacted] Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3994. Ms. Bailey testified that Illumina's development of TSO500 impacted PGDx's ability to secure an IVD agreement from Illumina because the TSO500 "product would be developed and launched on the same platform and was quite comparable in content to what [PGDx was] developing, and it was more a desire not to enable the standard path forward for Elio Tissue Complete through the FDA submission." (PX7112 (Bailey (PGDx) Dep. at 45-46); PX7049 (Bailey (PGDx) IHT at 97-98)).

Response to Finding No. 3994:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no

opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3995. Ms. Bailey testified that the feedback she heard as to why Illumina refused PGDx and IVD agreement prior to November 2020 was "because of the development of the TSO500 test that would be a competitive test on that platform." In other words, because Illumina had a competitive test to PGDx's Elio Tissue Complete Illumina "didn't want to sign a partnership agreement that would have put in place the more standard co-development agreement that would have been supplied as part of [PGDx's] FDA submission process." (PX7049 (Bailey (PGDx) IHT at 97)).

Response to Finding No. 3995:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3996. Illumina initially rejected PGDx's request for IVD rights for PGDx's therapy selection test on the grounds that it would "devalue our competitive position significantly." (PX2764 (Illumina) at 001 (Email from J. Leite, Illumina, to M. Kreitzinger, Illumina, et al., Feb. 28, 2018); PX7049 (Bailey (PGDx) IHT at 96-97) (testifying that PGDx believed Illumina did not initially provide PGDx with IVD rights because Illumina's "TSO500 test that would be a competitive test on that platform")).

Response to Finding No. 3996:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3997. [redacted]

[redacted] (PX2764 (Illumina) at 001 (Email from J. Leite, Illumina, to M. Kreitzinger, Illumina, et al., Feb. 28, 2018); Leite (Illumina) Tr. 2093-94 (*in camera*)).

Response to Finding No. 3997:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein.

3998. PGDx did not enter into an IVD agreement with Illumina in 2017. (PX7112 (Bailey (PGDx) Dep. at 44)).

Response to Finding No. 3998:

Respondents have no specific response.

3999. When Illumina refused to provide PGDx an IVD agreement in 2017 PGDx had "discussions with the FDA, [which] were motivated based on patient care needs in the market, and [] a desire to regulate some of the lab-developed tests of this kind in the market to enable a path forward. But because [PGDx] didn't have some of the standard things in place like the IVD agreement, it required multiple [] pre-sub meetings and discussions to align on an alternate path" to FDA clearance. (PX7112 (Bailey (PGDx) Dep. at 46-47)).

Response to Finding No. 3999:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein.

4000. [redacted]

Response to Finding No. 4000:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Further, the

proposed finding is misleading in that Ms. Berry's testimony makes clear she lacked personal knowledge as to the PGDx relationship, for which she was not responsible. (PX7063 (Berry) IHT at 81-83.)

4001. [redacted]

Response to Finding No. 4001:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶¶ 3993 and 4001, which Respondents' incorporate herein.

4002. [redacted] (PX7052 (Leite (Illumina) IHT at 136-37) (*in camera*)).

Response to Finding No. 4002:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4003. [redacted]

[redacted] (*See* PX2617 (Illumina) at 005 (Email from M. Bornstein, Illumina, to Legal Contracts, Illumina, attaching IVD Test Kit Development Agreement, Nov. 4, 2020) [redacted]) (*in camera*); PX7049 (Bailey (PGDx) IHT at 123-24) (*in camera*) ([redacted]).

Response to Finding No. 4003:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(a) Because PGDx Could Not Get an IVD Agreement from Illumina PGDx Found a Novel Way to Gain FDA Approval by Running the Elio Tissue Complete Test in RUO Mode with a Quality Control Software

4004. When Illumina refused to provide PGDx with an IVD agreement, PGDx had discussions with the FDA on pursuing another viable path. (PX7049 (Bailey (PGDx) IHT at 96-97) ("the broad understanding within the company at the time I joined it, actually, was that PGDx had sought an IVD agreement with Illumina and was unable to obtain one and then began the discussions with the FDA on what another viable path might look like.")). [redacted] (PX7112 (Bailey (PGDx) Dep. at 48-49); PX7049 (Bailey (PGDx) IHT at 96-99) (*in camera*)).

Response to Finding No. 4004:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4005. [redacted] (PX7049 (Bailey (PGDx) IHT at 98-99) (*in camera*)).

Response to Finding No. 4005:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4006. [redacted] (PX7049 (Bailey (PGDx) IHT at 103-04 (*in camera*))). [redacted] (PX7049 (Bailey (PGDx) IHT at 103-04 (*in camera*))).

Response to Finding No. 4006:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4007. [redacted] (PX7049 (Bailey (PGDx) IHT at 104 (*in camera*)). [redacted]

[redacted] (PX7049 (Bailey (PGDx) IHT at 104 (*in camera*))).

Response to Finding No. 4007:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4008. [redacted] (PX7049 (Bailey (PGDx) IHT at 105) (*in camera*)).

Response to Finding No. 4008:

Respondents have no specific response.

4009. More specifically, PGDx's direct collaboration with the FDA took between six to twelve months with "multiple months of alignment meetings with [] the FDA on the approach itself and then probably another three to six months of product development around the software device." (PX7112 (Bailey (PGDx) Dep. at 51)).

Response to Finding No. 4009:

Respondents have no specific response.

4010. [redacted] (PX7049 (Bailey (PGDx) IHT at 104-05) (*in camera*)).

Response to Finding No. 4010:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4011. [redacted] (PX7049 (Bailey (PGDx) IHT at 105-06) (*in camera*)).

Response to Finding No. 4011:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(i) PGDx's Customers and Investors Raised Concerns About PGDx Not Having an IVD Agreement Which Pushed PGDx to Reengage Negotiations with Illumina

4012. Ms. Bailey testified that PGDx's customers reacted to the Elio Tissue Complete workaround test running in RUO mode "fine" "from a workflow perspective." But "there [were] some usability enhancements if you are in the IVD software mode in the sense that it's a straightforward dropdown to select the test. But [running the Elio Tissue Complete test in RUO mode] is not [] extremely cumbersome, it's not just as straightforward as the other path." (PX7112 (Bailey (PGDx) Dep. at 51)).

Response to Finding No. 4012:

Respondents have no specific response.

4013. Ms. Bailey testified that "concern expressed by several prospective customers around why we needed the workaround and what our relationship was with Illumina that caused some concern in utilizing the test." (PX7112 (Bailey (PGDx) Dep. at 51-52)). Ms. Bailey learned of this concern by "direct feedback" from customers as "usually a member of [PGDx's] sales team, or, in some cases, customer support team that would hear the feedback and get questions directly from customers." (PX7112 (Bailey (PGDx) Dep. at 52)).

Response to Finding No. 4013:

Respondents have no specific response.

4014. Ms. Bailey testified that customers were concerned about PGDx's workaround and the relationship PGDx had with Illumina because "there was mention by Illumina representatives in those laboratories that PGDx didn't have a license to the platform or that

they could be violating terms and conditions of their relationship by utilizing our test." (PX7112 (Bailey (PGDx) Dep. at 52)).

Response to Finding No. 4014:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein.

4015. Ms. Bailey testified that besides a license and the ability to use Illumina's products there were no concerns from customers about the results of the RUO software workaround test. (PX7112 (Bailey (PGDx) Dep. at 52)).

Response to Finding No. 4015:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein.

4016. Ms. Bailey testified that there was a concern regarding licensing of the Illumina platform which "was prompted by discussions with those laboratory [customers] from members of the Illumina field team." (PX7112 (Bailey (PGDx) Dep. at 53)). Specifically, "there was mention by Illumina representatives in those laboratories that PGDx didn't have a license to the platform or that they could be violating terms and conditions of their relationship by utilizing [PGDx's] test." (PX7112 (Bailey (PGDx) Dep. at 52)).

Response to Finding No. 4016:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein.

4017. The PGDx customer concern was "prompted by discussions with those laboratories from members of the Illumina field team." (PX7112 (Bailey (PGDx) Dep. at 53)).

Response to Finding No. 4017:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein.

4018. Ms. Bailey testified that the concern she "typically heard expressed was more whether the customer would be violating anything around the terms and conditions of their contractual relationship with Illumina by using [PGDx's] product that had a workaround approach." (PX7112 (Bailey (PGDx) Dep. at 53)).

Response to Finding No. 4018:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein.

4019. PGDx's pharmaceutical customers did not want to pursue an Illumina IVD rights workaround telling PGDx that "they would not consider a companion diagnostic program with [PGDx] without an IVD co-development agreement." (PX7049 (Bailey (PGDx) IHT at 111)).

Response to Finding No. 4019:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein.

4020. Customers indicated to Dr. Leite in negotiations that they placed value on the reputational signal that an IVD agreement with Illumina would send to payers and pharmaceutical companies. (Leite (Illumina) Tr. 2183).

Response to Finding No. 4020:

Respondents have no specific response.

4021. [redacted] (*in camera*)).

Response to Finding No. 4021:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein.

4022. [redacted]

[redacted]

[redacted]

(PX7049 (Bailey (PGDx) IHT at 108-09) (*in camera*)).

Response to Finding No. 4022:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4023. The concern raised by prospective PGDx partners about PGDx's Elio Tissue Complete workaround test was that Illumina would change the platform in some way to make PGDx's tissue test harder to run. (PX7049 (Bailey (PGDx) IHT at 110)).

Response to Finding No. 4023:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4024. The concerns raised by PGDx's customers about the Elio Tissue Complete workaround test impacted PGDx's ability to get pharmaceutical partnerships. (PX7049 (Bailey (PGDx) IHT at 111-12)). Ms. Bailey testified that there are "numerous examples of prospective partners saying they would not consider a companion diagnostic program with [PGDx] without an IVD co-development agreement" with Illumina. (PX7049 (Bailey (PGDx) IHT at 111-12)).

Response to Finding No. 4024:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4025. Ms. Bailey testified that PGDx's pharmaceutical partners had concerns about "commercial risk" and PGDx was "told directly by multiple pharma partners that they would not enter into a companion diagnostic agreement with PGDx without [an IVD] agreement in place" with Illumina. (PX7112 (Bailey (PGDx) Dep. at 53-54)).

Response to Finding No. 4025:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4026. [redacted] (PX7049 (Bailey (PGDx) IHT at 118) (*in camera*)).

Response to Finding No. 4026:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4027. [redacted] (PX7049 (Bailey (PGDx) IHT at 118) (*in camera*)).

Response to Finding No. 4027:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4028. These pharma partners were large and important customers of PGDx. (PX7112 (Bailey (PGDx) Dep. at 54)).

Response to Finding No. 4028:

Respondents have no specific response.

4029. [redacted] (PX7049 (Bailey (PGDx) IHT at 119) (*in camera*)).

Response to Finding No. 4029:

Respondents have no specific response except note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4030. [redacted] (PX7049 (Bailey (PGDx) IHT at 120) (*in camera*)).

Response to Finding No. 4030:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4031. It's important for a test to have companion diagnostic capabilities "in the sense that it demonstrates very clearly the clinical utility. Typically, companion diagnostics are supported by a clinical trial positive outcome around the drug efficacy or other means of demonstrating that that patient subset will have a [] better response to the therapy." (PX7112 (Bailey (PGDx) Dep. at 30)).

Response to Finding No. 4031:

Respondents have no specific response.

4032. Ms. Bailey testified that concerns raised by customers regarding the Elio tissue complete workaround test "had a more direct impact to business on the pharma side and among investors." (PX7049 (Bailey (PGDx) IHT at 111-12)). When PGDx went to market without IVD rights from Illumina, PGDx's prospective investors told PGDx "that they would not make an investment without [PGDx] having the IVD co-development agreement with Illumina." (PX7049 (Bailey (PGDx) IHT at 111-12)).

Response to Finding No. 4032:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4033. When PGDx went to market without IVD rights from Illumina, PGDx's pharmaceutical customers did not want to pursue an Illumina IVD rights workaround telling PGDx that "they would not consider a companion diagnostic program with [PGDx] without an IVD co-development agreement." **(**PX7049 (Bailey (PGDx) IHT at 111-12)).

Response to Finding No. 4033:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4034. PGDx's CEO, Ms. Bailey, testified that reduced investment decreases PGDx's ability to fund its research and development projects. (PX7112 (Baily (PGDx) Dep. at 195)).

Response to Finding No. 4034:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4035. [redacted] (PX7049 (Bailey (PGDx) IHT at 128) (*in camera*)).

Response to Finding No. 4035:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4036. [redacted] (PX7049 (Bailey (PGDx) IHT at 117-18) (*in camera*)). [redacted] (PX7049 (Bailey (PGDx) IHT at 117-18) (*in camera*)).

Response to Finding No. 4036:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4037. The concerns raised by pharmaceutical partners, strategic lab customers, and investors regarding the Elio Tissue Complete workaround test drove PGDx to seek an IVD agreement with Illumina. (PX7112 (Bailey (PGDx) Dep. at 54-55) ("Q. Did these pharma partners' concerns drive PGDx to seek an IVD agreement with Illumina? A. In part. I would say the – those concerns – the feedback expressed by some strategic customers in the lab segment, as well as investors, led PGDx to negotiate the IVD agreement.")).

Response to Finding No. 4037:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein.

(ii) Illumina Knows Whether a Customer Is Using PGDx's Test Because of the Reagents They Have to Purchase from Illumina to Run PGDx's Test on Illumina's sequencer

4038. A PGDx customer wanting to run the Elio Tissue Complete test would have to buy the Illumina reagents to run the test directly from Illumina. (PX7049 (Bailey (PGDx) IHT at 175)).

Response to Finding No. 4038:

The proposed finding is not supported by the cited evidence. Ms. Bailey testified that PGDx does not "buy any Illumina reagents to put in its test kit", and that "the customer" "buys the Illumina reagents directly from Illumina". She did not testify that this has to be the case. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4039. Ms. Bailey testified that because of the "lack of IVD kits on the market outside of PGDx's it is not hard for Illumina to figure out" whether a company ordering Dx reagents is using PGDx's test. (PX7049 (Bailey (PGDx) IHT at 175)). In other words, a customer just ordering the Dx reagents from Illumina would signal that they are using a PGDx test. (PX7049 (Bailey (PGDx) IHT at 175)).

Response to Finding No. 4039:

The proposed finding is incorrect, as Illumina has several IVD partnerships, and Ms. Baily therefore overstates what information Illumina can glean simply from a customer ordering Dx reagents. (PFF ¶ 966.) Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4040. Ms. Bailey testified that some of PGDx's customers tell Illumina what test they are running when purchasing Dx reagents. Specifically, Ms. Bailey mentioned two examples of this occurring: "one that [told us] they were choosing to partner with us for this content over TSO500, so it was discussed openly with the customer, and then the other one was a lab using our test actually as a orthogonal method, a method to compare against for something else they were developing. And when they went to order the DX reagents they described what tests they intended to run on the NextSeq platform." (PX7049 (Bailey (PGDx) IHT at 176)).

Response to Finding No. 4040:

Respondents have no specific response except note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4041. Illumina made it difficult for PGDx's customers to buy Illumina Dx reagents needed to run PGDx's test because the test was not subject to an Illumina IVD agreement. Ms. Bailey testified that "on the laboratory [customer] side [PGDx had] a couple instances where the field sales team for Illumina when the customer would go to order the Dx reagents say PGDx is not licensed to have those products on our platform and make it difficult to order them." (PX7049 (Bailey (PGDx) IHT at 111-12)).

Response to Finding No. 4041:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶ 3993, which Respondents' incorporate herein. The proposed finding is further misleading in that it suggests that Illumina has told customers that PGDx is not licensed for the products today, rather than prior to the execution of the Illumina/PGDx IVD agreement, at which time it is in fact the case that PGDx was not licensed to use Illumina's IVD NGS products. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4042. Illumina's sales team knew which customers were running PGDx's test because there is "typically [] somebody like a field application specialist who is in the laboratory who knows what the lab is intending to run and validate and so when that comes up and they know it's our test." (PX7049 (Bailey (PGDx) IHT at 112-13)).

Response to Finding No. 4042:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶¶ 3993 and 4041, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4043. When asked how Illumina would know which of its customers are using Illumina reagents to run PGDx's Elio Tissue Complete workaround test Ms. Bailey explained that Illumina doesn't know "from a centralized corporate standpoint" as the reagents are "an orderable part number, in [a] catalogue. But what can happen is one of two things, either that's a part

number that the customer has never needed before because they've never run an IVD cleared product on the platform and so they need to negotiate pricing with Illumina and establish that to be able to order it. Or… a local sales rep or a local support rep is in trying to support the customer and what tests they are onboarding and then they are told what test the lab is planning to run." (PX7049 (Bailey (PGDx) IHT at 113-14)).

Response to Finding No. 4043:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039 and 4041, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(iii) [redacted]

4044. [redacted]
(PX7063 (Berry (Illumina) IHT at 98) (*in camera*); PX2310 (Illumina) (Email from N. Berry, Illumina, to J. Leite, Illumina, and S. Young, Illumina, May 12, 2020 (*in camera*))).

Response to Finding No. 4044:

The proposed finding is incomplete and misleading in that it omits Ms. Berry's additional testimony explaining that [redacted] (PX7063 (Berry

(Illumina) IHT at 99-100.) The proposed finding is also incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039 and 4041, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4045. [redacted] (PX2310 (Illumina) (Email from N. Berry, Illumina, to J. Leite, Illumina, and S. Young, Illumina, May 12, 2020 (*in camera*))).

Response to Finding No. 4045:

Respondents have no specific response.

4046. [redacted] (PX7063 (Berry (Illumina) IHT at 98-99) (*in camera*)).

Response to Finding No. 4046:

The proposed finding is also incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4047. [redacted] (PX7063 (Berry (Illumina) IHT at 99) (*in camera*)). [redacted] (PX7063 (Berry (Illumina) IHT at 99) (*in camera*)).

Response to Finding No. 4047:

The proposed finding is incomplete and misleading. It mischaracterizes Ms. Berry's testimony, as explained in Respondents' response to CCFF ¶¶ 4044. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4048. [redacted] (PX7063 (Berry (Illumina) IHT at 100) (*in camera*) [redacted].

Response to Finding No. 4048:

The proposed finding is incomplete and misleading. It mischaracterizes Ms. Berry's testimony, as explained in Respondents' response to CCFF ¶¶ 4044. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4049. [redacted] (PX2310 (Illumina) (Email from N. Berry, Illumina, to J. Leite, Illumina, and S. Young, Illumina, May 12, 2020 (*in camera*)) [redacted] (PX7063 (Berry (Illumina) IHT at 101) (*in camera*)).

Response to Finding No. 4049:

The proposed finding is also incomplete, misleading and inaccurate for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on

IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4050. [redacted] (PX7063 (Berry (Illumina) IHT at 104-05 (*in camera*)) [redacted].

Response to Finding No. 4050:

The proposed finding is incomplete and misleading. It mischaracterizes Ms. Berry's testimony, as explained in Respondents' response to CCFF ¶¶ 4044. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(5) [redacted]

4051. [redacted] (PX2200 (Illumina) at 002 (Email from J. Leite, Illumina, to M. Van Oene et al., Illumina, Nov. 3, 2020 (*in camera*)); PX7049 (Bailey (PGDx) IHT at 95, 125) (*in camera*);. PX2617 (Illumina) at 002 (Email from M. Bronstein, Illumina, to LegalContracts@illumina.com, Nov. 4, 2020) (*in camera*))).

Response to Finding No. 4051:

Respondents have no specific response except note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4052. [redacted] (PX7052 (Leite (Illumina) IHT at 139 (*in camera*))).

Response to Finding No. 4052:

Respondents have no specific response except note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4053. [redacted] (*See* PX2200 (Illumina) at 001 (Email from M. Bornstein, Illumina, to N. Berry et al., Illumina, Nov. 3, 2020 (*in camera*)) [redacted].

Response to Finding No. 4053:

Respondents have no specific response except to the extent the proposed finding is meant to suggest that PGDx had to expend additional resources as a result of some raising rivals' cost strategy by Illumina, that is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4054. [redacted] (PX7049 (Bailey (PGDx) IHT at 121, 124) (*in camera*)).

Response to Finding No. 4054:

Respondents have no specific response except to the extent the proposed finding is meant to suggest that the fees charged by Illumina for IVD rights, which have value, is some raising rivals' cost strategy by Illumina, that is patently untrue for the reasons explained in Respondents'

response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4055. [redacted] (PX7049 (Bailey (PGDx) IHT at 121-23) (*in camera*) [redacted] *See* PX2211 (Illumina) at 001 (Email from M. Bornstein, Illumina, to J. Goswami, Illumina, Nov. 3, 2020 (*in camera*) [redacted]).

Response to Finding No. 4055:

Respondents have no specific response except to the extent the proposed finding is meant to suggest that the fees charged by Illumina for IVD rights, which have value, is some raising rivals' cost strategy by Illumina, that is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(a) [redacted]

4056. [redacted] (PX7049 (Bailey (PGDx) IHT at 121) (*in camera*)).

Response to Finding No. 4056:

Respondents have no specific response except to the extent the proposed finding is meant to suggest that the fees charged by Illumina for IVD rights, which have value, is some raising rivals' cost strategy by Illumina, that is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4057. [redacted] (PX2211 (Illumina) at 001 (Email from M. Bornstein, Illumina, to J. Goswami et al., Illumina, Nov. 3, 2020 (*in camera*)); PX2617 (Illumina) at 020, 041 (Email from M. Bronstein, Illumina, to LegalContracts@illumina.com, Nov. 4, 2020) (*in camera*)).

Response to Finding No. 4057:

Respondents have no specific response except to the extent the proposed finding is meant to suggest that the fees charged by Illumina for TMB rights, which have value and for which other test developers with IVD agreements compensate Illumina, is some raising rivals' cost strategy by Illumina, that is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no

opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(b) [redacted]

4058. [redacted] (PX2617 (Illumina) at 005 (Email from M. Bronstein, Illumina, to LegalContracts@illumina.com, Nov. 4, 2020) (*in camera*)).

Response to Finding No. 4058:

The proposed finding is misleading. In fact, PGDx's operative IVD agreement gives PGDx rights to commercialize a test that reports tumor mutation burden, contrary to the suggestion in the proposed finding. (PFF ¶ 970.4)

4059. [redacted] (PX7049 (Bailey (PGDx) IHT at 123) (*in camera*)).

Response to Finding No. 4059:

Respondents have no specific response except to the extent the proposed finding is meant to suggest that the fees charged by Illumina for TMB rights, which have value and for which other test developers with IVD agreements compensate Illumina, is some raising rivals' cost strategy by Illumina, that is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4060. [redacted] (PX7049 (Bailey (PGDx) IHT at 123) (*in camera*) [redacted]

[redacted]).

Response to Finding No. 4060:

Respondents have no specific response except to the extent the proposed finding is meant to suggest that the fees charged by Illumina for TMB rights, which have value and for which other test developers with IVD agreements compensate Illumina, is some raising rivals' cost strategy by Illumina, that is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4061. [redacted] (PX2617 (Illumina) at 044 (Email from M. Bronstein, Illumina, to LegalContracts@illumina.com, Nov. 4, 2020) (*in camera*)).

Response to Finding No. 4061:

Respondents have no specific response except to the extent the proposed finding is meant to suggest that the fees charged by Illumina for TMB rights, which have value and for which other test developers with IVD agreements compensate Illumina, is some raising rivals' cost strategy by Illumina, that is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4062. The Elio Tissue Complete test would be at a disadvantage if it could not indicate for TMB. (PX7112 (Bailey (PGDx) Dep. at 26)).

Response to Finding No. 4062:

Respondents have no specific response except to the extent the proposed finding is meant to suggest that the fees charged by Illumina for TMB rights, which have value and for which other test developers with IVD agreements compensate Illumina, is some raising rivals' cost strategy by Illumina, that is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4063. [redacted]
(PX7049 (Bailey (PGDx) IHT at 150-152) (*in camera*).

Response to Finding No. 4063:

Respondents have no specific response except to the extent the proposed finding is meant to suggest that the fees charged by Illumina for TMB rights, which have value and for which other test developers with IVD agreements compensate Illumina, is some raising rivals' cost strategy by Illumina, that is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4064. [redacted]
(PX7049 (Bailey (PGDx) IHT at 123-24) (*in camera*)).

Response to Finding No. 4064:

The proposed finding is misleading and inaccurate, in that it appears intended to suggest that the fees charged by Illumina for TMB rights, which have value and for which other test developers with IVD agreements compensate Illumina, is some raising rivals' cost strategy by Illumina, which is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4065. [redacted] (PX7049 (Bailey (PGDx) IHT at 124, 147) (*in camera*)).

Response to Finding No. 4065:

The proposed finding is misleading and inaccurate, in that it appears intended to suggest that the fees charged by Illumina for TMB rights, which have value and for which other test developers with IVD agreements compensate Illumina, is some raising rivals' cost strategy by Illumina, which is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4066. [redacted] (PX7049 (Bailey (PGDx) IHT at 138, 141) (*in camera*)).

Response to Finding No. 4066:

The proposed finding is misleading and inaccurate, in that it appears intended to suggest that the fees charged by Illumina for TMB rights, which have value and for which other test developers with IVD agreements compensate Illumina, is some raising rivals' cost strategy by Illumina, which is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4067. [redacted] (PX7049 (Bailey (PGDx) IHT at 124 (*in camera*) [redacted]).

Response to Finding No. 4067:

The proposed finding is misleading and inaccurate, in that it appears intended to suggest that the fees charged by Illumina for TMB rights, which have value and for which other test developers with IVD agreements compensate Illumina, is some raising rivals' cost strategy by Illumina, which is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4068. [redacted] (Leite (Illumina) Tr. 2099-2100 (*in camera*)).

Response to Finding No. 4068:

The proposed finding is misleading. In fact, PGDx's operative IVD agreement gives PGDx rights to commercialize a test that reports tumor mutation burden, contrary to the

suggestion in the proposed finding. (PFF 970.4) Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4069. [redacted] (PX2211 (Illumina) at 001 (Email from M. Bornstein, Illumina, to J. Goswami et al., Illumina, Nov. 3, 2020 (*in camera*))).

Response to Finding No. 4069:

The proposed finding is misleading and inaccurate, in that it appears intended to suggest that the fees charged by Illumina for TMB rights, which have value and for which other test developers with IVD agreements compensate Illumina, is some raising rivals' cost strategy by Illumina, which is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4070. [redacted] Leite (Illumina) Tr. 2100 (*in camera*)).

Response to Finding No. 4070:

Respondents have no specific response, except to note that the proposed finding demonstrates that TMB rights have value, and there is nothing anticompetitive about charging for something of value, which is market practice in the IVD field. (*E.g.*, PFF ¶ 973.)

(c) [redacted]

4071. [redacted] (PX7049 (Bailey (PGDx) IHT at 125) (*in camera*)).

Response to Finding No. 4071:

Respondents have no specific response except to the extent the proposed finding is meant to suggest that the fees charged by Illumina for TMB rights, which have value and for which other test developers with IVD agreements compensate Illumina, is some raising rivals' cost strategy by Illumina, that is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4072. [redacted] (PX2211 (Illumina) at 001 (Email from M. Bornstein, Illumina, to J. Goswami et al., Illumina, Nov. 3, 2020 (*in camera*)); PX7049 (Bailey (PGDx) IHT at 125 (*in camera*)). *See* PX7112 (Bailey (PGDx) Dep. at 86 (*in camera*)) [redacted]).

Response to Finding No. 4072:

Respondents have no specific response except to the extent the proposed finding is meant to suggest that the fees charged by Illumina for TMB rights, which have value and for which other test developers with IVD agreements compensate Illumina, is some raising rivals' cost strategy by Illumina, that is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(d) [redacted]

4073. [redacted] (PX2211 (Illumina) at 001 (Email from M. Bornstein, Illumina, to J. Goswami et al., Illumina, Nov. 3, 2020 (*in camera*)); PX2617 (Illumina) at 020, 041 (Email from M. Bronstein, Illumina, to LegalContracts@illumina.com, Nov. 4, 2020) (*in camera*)).

Response to Finding No. 4073:

Respondents have no specific response except to the extent the proposed finding is meant to suggest that the fees charged by Illumina for TMB rights, which have value and for which other test developers with IVD agreements compensate Illumina, is some raising rivals' cost strategy by Illumina, that is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4074. [redacted] (PX2211 (Illumina) at 001 (Email from M. Bornstein, Illumina, to J. Goswami et al., Illumina, Nov. 3, 2020 (*in camera*))).

Response to Finding No. 4074:

Respondents have no specific response except to the extent the proposed finding is meant to suggest that the fees charged by Illumina for TMB rights, which have value and for which other test developers with IVD agreements compensate Illumina, is some raising rivals' cost

strategy by Illumina, that is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4075. [redacted]
(PX2211 (Illumina) at 001 (Email from M. Bornstein, Illumina, to J. Goswami, et al. Illumina, Nov. 3, 2020 (*in camera*))).

Response to Finding No. 4075:

Respondents have no specific response except to the extent the proposed finding is meant to suggest that the fees charged by Illumina for TMB rights, which have value and for which other test developers with IVD agreements compensate Illumina, is some raising rivals' cost strategy by Illumina, that is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(e) [redacted]

4076. [redacted] (PX7049 (Bailey (PGDx) IHT at 128) (*in camera*)).

Response to Finding No. 4076:

The proposed finding is misleading and inaccurate, in that it appears intended to suggest that the fees charged by Illumina for IVD rights, which have value and for which other test developers with IVD agreements compensate Illumina, is some raising rivals' cost strategy by Illumina, which is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4077. [redacted] (PX7112 (Bailey (PGDx) Dep. at 86) (*in camera*)).

Response to Finding No. 4077:

The proposed finding is misleading and inaccurate, in that it appears intended to suggest that the fees charged by Illumina for IVD rights, which have value and for which other test developers with IVD agreements compensate Illumina, is some raising rivals' cost strategy by Illumina, which is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4078. [redacted] (PX7112 (Bailey (PGDx) Dep. at 86) (*in camera*)).

Response to Finding No. 4078:

The proposed finding is misleading and inaccurate, in that it appears intended to suggest that the fees charged by Illumina for IVD rights, which have value and for which other test

developers with IVD agreements compensate Illumina, is some raising rivals' cost strategy by Illumina, which is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4079. [redacted] (PX7049 (Bailey (PGDx) IHT at 128) (*in camera*)).

Response to Finding No. 4079:

The proposed finding is misleading and inaccurate, in that it appears intended to suggest that the fees charged by Illumina for IVD rights, which have value and for which other test developers with IVD agreements compensate Illumina, is some raising rivals' cost strategy by Illumina, which is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4080. [redacted] (PX7049 (Bailey (PGDx) IHT at 128-129); PX7112 (Bailey (PGDx) Dep. at 86-87) (*in camera*)).

Response to Finding No. 4080:

The proposed finding is misleading and inaccurate, in that it appears intended to suggest that the fees charged by Illumina for IVD rights, which have value and for which other test developers with IVD agreements compensate Illumina, is some raising rivals' cost strategy by Illumina, which is patently untrue for the reasons explained in Respondents' response to CCFF ¶¶ 3993, 4039, 4041 and 4044, which Respondents' incorporate herein. Respondents further

note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

3. Illumina Identified and Used Similar Tools in the NIPT Market

a) NIPT Overview

4081. [redacted] (PX7113 (Rabinowitz (Natera) Dep. at 36) (*in camera*)).

Response to Finding No. 4081:

Respondents have no specific response.

4082. Dr. Dennis "Lo was the first scientist to discover the presence of circulating fetal DNA in a pregnant mother's blood." (PX4613 (Grail) at 002 (E-mail from V. Bajaj, Grail, to science_organization@grailbio.com, May 31, 2017)).

Response to Finding No. 4082:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 54), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

4083. NIPT was one of the first applications of NGS in a clinical setting. (PX7089 (Naclerio (Illumina) Dep. at 42)).

Response to Finding No. 4083:

Respondents have no specific response.

4084. [redacted] (PX7071 (Song (Omniome) IHT at 66–67) (*in camera*)).

Response to Finding No. 4084:

Respondents have no specific response.

4085. [redacted] (PX7071 (Song (Omniome) IHT at 67) (*in camera*)).

Response to Finding No. 4085:

Respondents have no specific response.

4086. [redacted] (PX7071 (Song (Omniome) IHT at 67–68) (*in camera*)).

Response to Finding No. 4086:

Respondents have no specific response.

4087. [redacted] (PX7071 (Song (Omniome) IHT at 68) (*in camera*)).

Response to Finding No. 4087:

Respondents have no specific response.

4088. [redacted] (PX7054 (Rabinowitz (Natera) IHT at 36–38) (*in camera*)).

Response to Finding No. 4088:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

4089. [redacted] (PX7113 (Rabinowitz (Natera) Dep. at 36-37) (*in camera*)).

Response to Finding No. 4089:

Respondents have no specific response.

4090. NIPT has largely replaced invasive tests like amniocentesis and CVS. (PX7113 (Rabinowitz (Natera) Dep. at 22-23)).

Response to Finding No. 4090:

Respondents have no specific response.

b) Illumina Acquired Verinata in 2013

4091. In 2010, prior to the launch of the first NIPT test and prior to its acquisition of Verinata, Illumina considered different options of how it would participate in the NIPT market. (PX2266 (Illumina) at 002 (E-mail from K. Dobie, Illumina, to N. Naclerio, Illumina, attaching "Opportunity Review Board Meeting Minutes 100930," Oct. 8, 2010)).

Response to Finding No. 4091:

Respondents have no specific response.

4092. One option for participating in the NIPT market that Illumina's Opportunity Review Board considered in 2010 was to become an "arms dealer." (PX2266 (Illumina) at 002 (E-mail from K. Dobie, Illumina, to N. Naclerio, Illumina, attaching "Opportunity Review Board Meeting Minutes 100930,"Oct. 8, 2010)). Being an "arms dealer" referred to selling instruments to NIPT companies and allowing the NIPT companies to compete among themselves. (PX7060 (Naclerio (Illumina) IHT at 48)).

Response to Finding No. 4092:

The proposed finding is irrelevant, incomplete and misleading. It omits the fact that Dr. Naclerio also testified that being an "arms dealer" and participating in the NIPT space was not "an either-or because . . . we were always going to sell the instruments no matter what" (PX7060 (Naclerio (Illumina) IHT at 50), and subsequent events have borne that out—since Illumina acquired Verinata, the number of NIPT tests conducted by Verinata's rivals on Illumina's platforms in the U.S. has more than doubled between 2015 and 2019, output has expanded, and, critically, Verinata's share of NIPT sales has *decreased* while rival sales have *increased*. (PFF ¶ 956 & Figure 7.) Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

4093. Another option for participating in the NIPT market that Illumina's Opportunity Review Board considered in 2010 was to become a "consolidator." (PX2266 (Illumina) at 002 (E-mail from K. Dobie, Illumina, to N. Naclerio, Illumina, attaching "Opportunity Review Board Meeting Minutes 100930,"Oct. 8, 2010)). Becoming the "consolidator" referred to Illumina acquiring a NIPT company and competing in NIPT itself. (PX7060 (Naclerio (Illumina) IHT at 48)).

Response to Finding No. 4093:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 4092, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

4094. Dr. Naclerio testified that prior to Illumina's acquisition of Verinata, "[i]t was clear that NIPT was going to be a really big business." (PX7060 (Naclerio (Illumina) IHT at 51)).

Response to Finding No. 4094:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

4095. Before being acquired by Illumina, Verinata "competed with some of [Illumina's] other customers." (PX7057 (Flatley (Illumina) IHT at 15)).

Response to Finding No. 4095:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

4096. Illumina acquired Verinata in 2013. (PX7089 (Naclerio (Illumina) Dep. at 41, 80–81)).

Response to Finding No. 4096:

Respondents have no specific response.

4097. Illumina paid approximately $450 million to acquire Verinata. (PX7060 (Naclerio (Illumina) IHT at 56)). The sum Illumina paid for Verinata was "a very big deal" to Illumina at the time. (PX7060 (Naclerio (Illumina) IHT at 56)).

Response to Finding No. 4097:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

4098. At the time of Illumina's acquisition of Verinata, "[r]apid NIPT adoption [was] a common phenomenon across [the United States.]" (PX2432 (Illumina) at 002 (E-mail from N. Naclerio, Illumina, to E. Cheung, Illumina, et al., Feb. 1, 2013)).

Response to Finding No. 4098:

The proposed finding is incomplete and misleading to the extent it is meant to suggest that the market developments in the years following Illumina's acquisition of Verinata, including the explosion of NIPT entry and output, would have occurred even if Illumina had not acquired Verinata. There is no basis for such a suggestion, and substantial evidence refutes it. As Dr. Naclerio testified as to the cited document, while adoption of NIPT in its first few years of availability may have been rapid "compared to the usual glacial pace at which diagnostics move", it "subsequently exploded" after the Verinata acquisition. (PX7060 (Naclerio (Illumina) IHT at 97-98.) Further, the proposed finding omits the undisputed fact that, prior to the acquisition, the NIPT field was limited by a confusing and uncertain intellectual property landscape, as each of Verinata, Sequenom, Ariosa and Natera sued one another to enjoin their rivals from practicing their respective NIPT patents. (PFF ¶ 1099.) After acquiring Verinata, Illumina sought to settle all of the litigation in order to broadly license the NIPT IP and open the field. (*Id.*) Illumina settled Verinata's litigation with Sequenom, and as part of that settlement,

Illumina and Sequenom created a patent pool, where NIPT competitors could pay a single test fee and practice the key IP for NIPT from five different entities. (*Id.*)

As Dr. Naclerio explained, "Illumina was seeing this huge potential market being sort of held back by super high prices, and a lot of uncertainty about who owns the IP and that sort of thing. So the idea with buying Verinata was that we could help to accelerate the market by coming out with a solution that any lab could use to do NIPT testing." (PX7089 (Naclerio (Illumina) Dep. at 49–50).) "So our strategy was, you know, get the litigation settled, and then turn around and make the technology available to other labs across the country, and around the world, in order to grow the market and bring down the prices." (PX7089 (Naclerio (Illumina) Dep. at 58–59).) Dr. Naclerio further noted that, prior to the Verinata acquisition, the price of an NIPT was holding back its widespread adoption, and Illumina realized that "if we can drive the price down . . . this could become something that's not just hundreds of thousands of tests a year but something that's millions of tests per year". (PX7060 (Naclerio IH) at 54.) And that is exactly what happened, as evidenced by unrefuted market data. (PFF ¶¶ 950-963.)

(1) Background on NIPT Intellectual Property Disputes

4099. Prior to Illumina's acquisition of Verinata, there was IP-related litigation among the NIPT companies. (PX7060 (Naclerio (Illumina) IHT at 51)).

Response to Finding No. 4099:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

4100. There came a time when it appeared that Verinata's IP would "be the stronger IP." (PX7060 (Naclerio (Illumina) IHT at 52)).

Response to Finding No. 4100:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

4101. It appeared that the IP disputes were "settling out in favor of Verinata." (PX7089 (Naclerio (Illumina) Dep. at 50)).

Response to Finding No. 4101:

The proposed finding is incomplete and misleading. Dr. Naclerio further testified that he meant, "[i]n other words, Verinata was looking like they were going to have probably one of the stronger, if not the strongest, intellectual property portfolio", and that Sequenom's "technology was very similar and their IP portfolio was probably the second best". (PX7089 (Naclerio (Illumina) Dep. at 50-51.)

4102. In an October 2012 board presentation, Dr. Naclerio proposed that Illumina could "[a]cquire [a] dominant IP position" by acquiring Verinata. (PX2270 (Illumina) at 012 (Email from N. Naclerio, Illumina, to A. Pierce et al., Illumina, attaching "Corporate & Venture Development Update," Oct. 25, 2012)).

Response to Finding No. 4102:

The proposed finding is incomplete and misleading. As Dr. Naclerio made clear in his testimony and the overwhelming weight of the evidence demonstrates, Illumina's rationale for acquiring Verinata was to grow the NIPT market and make it more broadly available, and that is exactly what occurred. Prior to the acquisition, the NIPT field was limited by a confusing and uncertain intellectual property landscape, as each of Verinata, Sequenom, Ariosa and Natera sued one another to enjoin their rivals from practicing their respective NIPT patents. (PFF ¶ 1099.) After acquiring Verinata, Illumina sought to settle all of the litigation in order to broadly license the NIPT IP and open the field. (*Id.*) Illumina settled Verinata's litigation with

Sequenom, and as part of that settlement, Illumina and Sequenom created a patent pool, where NIPT competitors could pay a single test fee and practice the key IP for NIPT from five different entities. (*Id.*)

As Dr. Naclerio explained, "Illumina was seeing this huge potential market being sort of held back by super high prices, and a lot of uncertainty about who owns the IP and that sort of thing. So the idea with buying Verinata was that we could help to accelerate the market by coming out with a solution that any lab could use to do NIPT testing." (PX7089 (Naclerio (Illumina) Dep. at 49–50).) "So our strategy was, you know, get the litigation settled, and then turn around and make the technology available to other labs across the country, and around the world, in order to grow the market and bring down the prices." (PX7089 (Naclerio (Illumina) Dep. at 58–59).)

Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 14) and did not elicit any testimony regarding the specific language it relies upon with Dr. Naclerio or any other witness who was shown this document in any deposition or IH (*see* PX7060 (Naclerio (Illumina) IHT at 63–78; PX7089 (Naclerio (Illumina) Dep. at 126–30)), and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

c) NIPT Market Overview

(1) Market Participants at the Time of Illumina's Acquisition of Verinata

4103. At the time that Illumina acquired Verinata, four companies provided NIPT in the United States: Sequenom, Verinata, Ariosa, and Natera. (PX7060 (Naclerio (Illumina) IHT at 44)).

Response to Finding No. 4103:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

4104. At the time that Illumina acquired Verinata, all four companies that provided NIPT in the United States used Illumina's NGS platform. (PX7060 (Naclerio (Illumina) IHT at 44-45)).

Response to Finding No. 4104:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

4105. Illumina considered a Natera IVD to be competitive with Illumina's own NIPT product. (PX2219 (Illumina) at 024 (Illumina, Review of 2013 Strategic Discussion Topics, Nov. 17, 2014)).

Response to Finding No. 4105:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 34), or in any deposition, and should not be entitled to rely on it to establish anything beyond the words on the page.

4106. Illumina's ordinary course documents identified Sequenom, Ariosa/Labcorp, Verinata, and Natera as the U.S. "players" in NIPT. (PX2270 (Illumina) at 008 (Illumina, Corporate & Venture Development Update, Oct. 25, 2012) (noting "Illumina is currently the platform supplier to all of the major NIPD players")).

Response to Finding No. 4106:

Respondents have no specific response.

(a) Sequenom

4107. Sequenom launched the first NIPT test in 2011. (PX7071 (Song (Omniome) IHT at 65-66)).

Response to Finding No. 4107:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

4108. Sequenom's NIPT method relied on random shotgun sequencing. (PX7071 (Song (Omniome) IHT at 65-66)).

Response to Finding No. 4108:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

4109. Sequenom was acquired by Labcorp in 2016. (PX7122 (Eisenberg (Labcorp) Dep. at 76–77)).

Response to Finding No. 4109:

Respondents have no specific response.

(b) Verinata

4110. Verinata launched its NIPT test in early 2012. (PX7071 (Song (Omniome) IHT at 66)).

Response to Finding No. 4110:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

4111. Verinata's NIPT method relied on random shotgun sequencing. (PX2270 (Illumina) at 007 (Illumina, Corporate & Venture Development Update, Oct. 25, 2012)).

Response to Finding No. 4111:

Respondents have no specific response.

(c) Ariosa

4112. Ariosa, another NIPT company, was founded in late 2009. (PX7071 (Song (Omniome) IHT at 61)).

Response to Finding No. 4112:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

4113. Ariosa launched its NIPT test in 2012. (PX7071 (Song (Omniome) IHT at 64)).

Response to Finding No. 4113:

Respondents have no specific response but note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

4114. Ariosa's NIPT test relied on Illumina's NGS platform. (PX7071 (Song (Omniome) IHT at 66)).

Response to Finding No. 4114:

Respondents have no specific response except to note that Ariosa switched its NIPT test from an NGS-based approach to a microarray-based approach, and claimed to have achieved lower cost and decreased turnaround time for the test. (PFF ¶ 653.) Respondents further note that the proposed finding relies on IH testimony [which is hearsay and] which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

4115. Dr. Song testified that Ariosa was able to price its NIPT test $2,000 lower than the two existing NIPT tests because "[Ariosa] had developed a targeted approach where [its] consumption of Illumina sequencing reagents was . . . tenfold lower" than the existing NIPT tests from Sequenom and Verinata. (PX7071 (Song (Omniome) IHT at 69–70)).

Response to Finding No. 4115:

The proposed finding is incomplete and misleading. Dr. Song's say-so as to the cost differences between its test and the NIPT tests of Sequenom and Verinata is unsubstantiated, and other testimony calls it into question. For example, Dr. Naclerio testified that Ariosa "had that claim" that targeted sequencing required less sequencing but that it was not clear "it ever really panned out", and that "everybody in the end was within a factor of two, despite Ariosa's claim that theoretically they could use much less sequencing". (PX7089 (Naclerio (Illumina) Dep. at 126.) Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4116. Ariosa's ability to use less sequencing for NIPT was "not well received by Illumina." (PX7071 (Song (Omniome) IHT at 70)).

Response to Finding No. 4116:

The proposed finding is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 4115, which Respondents incorporate herein. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(d) Natera

4117. Natera first launched Panorama in March 2013. (Rabinowitz (Natera) Tr. 289).

Response to Finding No. 4117:

Respondents have no specific response.

4118. [redacted] (Rabinowitz (Natera) Tr. 352 (*in camera*)).

Response to Finding No. 4118:

Respondents have no specific response.

4119. [redacted] (Rabinowitz (Natera) Tr. 315-318 (*in camera*)).

Response to Finding No. 4119:

Respondents have no specific response.

4120. At the time Natera launched Panorama, Verinata, Sequenom, and Ariosa were also providing NIPT tests in the United States. (Rabinowitz (Natera) Tr. 290).

Response to Finding No. 4120:

Respondents have no specific response.

4121. [redacted] (Rabinowitz (Natera) Tr. 327 (*in camera*)).

Response to Finding No. 4121:

Respondents have no specific response.

4122. [redacted] (Rabinowitz (Natera) Tr. 327 (*in camera*)).

Response to Finding No. 4122:

Respondents have no specific response.

4123. [redacted] (PX2759 (Illumina) at 005 (*in camera*)).

Response to Finding No. 4123:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 31), or in any deposition, and therefore,

the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

(2) [redacted]

4124. [redacted] (PX2077 (Illumina) at 004 (Strategic approach to shaping the NIPT market, Mar. 11, 2013)). [redacted] (PX2077 (Illumina) at 004 (Strategic approach to shaping the NIPT market, Mar. 11, 2013)).

Response to Finding No. 4124:

The proposed finding is misleading and contrary to the weight of the evidence. After Illumina acquired Verinata, Dr. Naclerio proposed that Illumina settle the various patent litigation and then turn around and license Verinata's IP to other labs across the country, and around the world, in order to grow the NIPT market and bring down the prices. (PX7089 (Naclerio (Illumina) Dep. at 58–59).) As Dr. Naclerio testified, "what I was describing was . . . a fairly maybe, you might say, complicated and nuanced strategy, and I think the feeling and I think the feeling of the board was that we better have some consultants come in and make sure that Nick's not crazy." (PX7089 (Naclerio (Illumina) Dep. at 68).) To that end, Illumina hired McKinsey to vet this plan. (PX7089 (Naclerio (Illumina) Dep. at 68).)

[redacted] (*See, e.g.*, PX7089 (Naclerio (Illumina) Dep. at 157 (explaining that similar language regarding Natera in another document was "I think this is, again, sour grapes between Verinata and Natera that we had to keep pushing back on."); PX7060

(Naclerio (Illumina) IHT at 95–96, 99).) During the course of McKinsey's strategic review, both the McKinsey consultants and some of the executives at Verinata had tried to steer Illumina towards a different strategy, unlike what Dr. Naclerio proposed:

> The people who came from Verinata, who had been in a bitter, bitter commercial and legal fight with Ariosa and Sequenom, had a hard time swallowing that we were going to then treat Ariosa and Sequenom the same way we treat them, you know, so you could imagine them saying, Oh, now that we're part of Illumina, let's put these other guys out of business, let's do whatever. ***And you know, that was clearly not our plan***. And the McKinsey guys I think similarly were like, 'Hey, you guys, you know, other people with a patent portfolio like yours can extract a lot more value . . .'
>
> And you know, what you'll see throughout this whole process if you look at all these documents is a back-and-forth between those views and the views of the Illumina management . . . which was that we were going to open up the market, that we were going to treat everyone the same. We weren't going to treat Verinata any better than anyone else. . . . [W]hat we did pursue was the treating everybody the same and opening up the market and driving down prices.

(PX7060 (Naclerio (Illumina) IHT at 91–92).)

[redacted] (PFF ¶¶ 950-963.)

4125. [redacted]

Response to Finding No. 4125:

The proposed finding is inaccurate, misleading and contrary to the weight of the evidence. Contemporaneous statements also show that Dr. Rabinowitz's cited testimony is provably false: Dr, Rabinowitz is quoted in an October 2014 GenomeWeb article stating that ***it was Natera*** that "opted to end its agreement with Quest after the reference lab asked for reduced pricing on the test". (RX2408 (Illumina) at 4.) [redacted]

[redacted]

Progenity. Natera did not lose Progenity as a lab customer because of Illumina, but rather that Progenity terminated the relationship because of the poor quality of Natera's test and services, and after Progenity did so, Natera engaged in what Progenity characterized as a campaign of retribution against Progenity. Specifically, in 2013, Natera and Progenity entered into a test services agreement under which Natera would provide Progenity with Natera's NIPT test, Panorama, for Progenity to market and sell to Progenity's customers. (RX3586 (Compl., Progenity, Inc. v. Natera, Inc., 20-cv-01252) ¶ 12; PX7113 (Rabinowitz (Natera) Dep. at 155.) Eventually, Natera sued Progenity for alleged infringement of certain Natera patents, which Progenity characterized as the "continuation of Natera's campaign to seek retribution against Progenity for rejecting Natera's technology six years ago and developing its own superior technology that competes with Natera." (RX3586 (Compl., Progenity, Inc. v. Natera, Inc., 20-cv-01252) ¶ 11.) Progenity then sued Natera and sought a declaratory judgment that Progenity's NIPT test did not infringe certain Natera patents. (RX3586 (Compl., Progenity, Inc. v. Natera, Inc., 20-cv-01252) ¶ 1.) [redacted] (RX3586 (Compl., Progenity, Inc. v. Natera, Inc., 20-cv-01252) ¶ 16; PX7113 (Rabinowitz (Natera) Dep. at 161).) [redacted]

[redacted]. (RX3586 (Compl., Progenity, Inc. v. Natera, Inc., 20-cv-01252) ¶ 17; [redacted].) In internal Illumina emails from 2014, Gautam Kollu (who came to Illumina from Natera) explained that Natera's SNP-based approach required more pre-sequencing steps, which introduce complexity, leading to more lab errors and more failed samples. (RX2389 (Illumina) at 1.) Kollu said that Progenity estimated that Panorama would require three times the hands on time that verifi does. (RX2389 (Illumina) at 1.) [redacted] (RX3586 (Compl., Progenity, Inc. v. Natera, Inc., 20-cv-01252) ¶ 29; PX7113 (Rabinowitz (Natera) Dep. at 162).) [redacted] (RX3586 (Compl., Progenity, Inc. v. Natera, Inc., 20-cv-01252) ¶ 29; [redacted].) Internal Illumina documents reflecting Illumina's conversations with Progenity are consistent with Progenity's allegations and predate the litigation between Natera and Progenity. In a 2013 email among Illumina employees discussing Progenity, Illumina sales representatives mentioned that Progenity was "unhappy with [turnaround time] and other service issues" regarding Natera's test. (RX2385 (Illumina) at 1.) [redacted] (RX3586 (Compl., Progenity, Inc. v. Natera, Inc., 20-cv-01252) ¶¶ 30-31; PX7113 (Rabinowitz (Natera) Dep. at 164-66).)

[redacted] (RX2459 (Illumina) at 1) (emphasis added).

BioReference Laboratory. The evidence also shows that Natera did not lose BioReference as a lab customer because of Illumina. BioReference's issues with Natera began as early as 2013, when it sent a letter to customers that it could no longer provide Natera's Panorama NIPT, because state laws required Natera to directly bill for the test, and Natera was not contracted with any Medicaid plan. (RX2316 (Illumina) at 3.) Then, in June 2015, BioReference informed Illumina that it was not happy with Natera but didn't intend to shift its business away from them "in fear that Natera will simpl[y] go into those docs and flip business". (RX2523 (Illumina) at 1.) By February 2016, BioReference was ready to end its relationship with Natera. BioReference again informed Illumina they were unhappy with Natera and indicated an interest in switching to Illumina. (RX2383 (Illumina) at 1.) That December, Natera sued BioReference for breach of their licensing agreement after BioReference launched its internalized NIPT, ClariTest. (RX2412 (Illumina) at 1; *Natera, Inc. v. Bio-Reference Laboratories, Inc.*, 16-cv-09514 (S.D.N.Y. filed Dec. 9, 2016), ECF No. 1.) Illumina noted that Natera and BRL were "going to war" with each other and that "Natera has gone full nuclear on the whole marketplace and dissing every technology that is not theirs." (RX2384 (Illumina) at 1.) By the following January, Natera had terminated its distribution agreement with BRL and shifted to a direct model for clinicians who ordered through BRL. (RX2412 (Illumina) at 1.)

Quest. The evidence shows that Natera did not lose Quest as a lab customer because of Illumina. When Quest ended its relationship with Natera, it did not switch to Illumina; rather, it

signed an agreement with Sequenom. (RX2520 (Illumina) at 1.) Internal Illumina emails indicate that Quest left Natera because of the same performance issues that existed with the Progenity-Natera relationship. (RX2386 (Illumina) at 1.) [redacted] (RX2392 (Illumina) at 1.) In addition, JP Morgan analyst Tycho Peterson said that he heard from Quest that it ended its partnership with Natera because Natera was "promising to cap out of pocket expenses for Panorama at ~$200" which he notes is "illegal in some markets." (RX1857 (Illumina) at 2.) Further, Rabinowitz is quoted in an October 2014 GenomeWeb article stating that ***it was Natera*** that "opted to end its agreement with Quest after the reference lab asked for reduced pricing on the test". (RX2408 (Illumina) at 4.) Rabinowitz added that "[w]e would much rather go direct and see very good margins" and "[t]he reality is that the gross margins that we see from the biggest labs are very low." (RX2408 (Illumina) at 4.)

Thus, simply put, Dr. Rabinowitz did not tell the truth in his testimony. His assertions about Illumina's conduct, which Complaint Counsel adopted unquestioningly, are unreliable and demonstrably false.

4126. [redacted]

Response to Finding No. 4126:

The proposed finding is inaccurate, misleading and contrary to the weight of the evidence for the reasons explained in Respondents' responses to CCFF ¶ 4125, [redacted]

[redacted] (*E.g.*, PFF ¶ 1881.) His assertions about Illumina's conduct, which Complaint Counsel adopted unquestioningly, are unreliable and demonstrably false.

4127. [redacted]

Response to Finding No. 4127:

The proposed finding is inaccurate, misleading and contrary to the weight of the evidence for the reasons explained in Respondents' responses to CCFF ¶ 4125, [redacted] (*E.g.*, PFF ¶ 1881.) His assertions about Illumina's conduct, which Complaint Counsel adopted unquestioningly, are unreliable and demonstrably false. Further, Respondents note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4128. [redacted]

Response to Finding No. 4128:

The proposed finding is inaccurate, misleading and contrary to the weight of the evidence. [redacted]. (PX7060 (Naclerio (Illumina) Dep. at 187–88).))

Neither Complaint Counsel nor Natera provided any evidence to verify Dr. Rabinowitz's claims, which are without any basis, as Dr. Rabinowitz has no personal knowledge of Illumina's supply and reagent manufacturing processes such that he would know whether or not Illumina "monkey[ed]" with the supply or quality of reagents. Contrary to Dr. Rabinowitz's baseless assertion, other Illumina customers testified that Illumina has never "monkeyed" with supply. (PFF ¶ 986.3 (Fiedler (FMI) Tr. 4471).) Now, if Illumina "monkeyed" with supply by providing lower quality instruments or consumables or by delaying a purchase order (which it would not do and has never done, and Complaint Counsel has not shown otherwise), Illumina would be in breach of the Open Offer. (PFF ¶ 1092.1 (Berry (Illumina) Tr. 878–79).)

4129. [redacted]

[redacted]

Response to Finding No. 4129:

The proposed finding is inaccurate, misleading and contrary to the weight of the evidence for the reasons explained in Respondents' responses to CCFF ¶ 4125, which Respondents incorporate herein. [redacted] (*E.g.*, PFF ¶ 1881.) His assertions about Illumina's conduct, which Complaint Counsel adopted unquestioningly, are unreliable and demonstrably false.

4130. [redacted]

Response to Finding No. 4130:

The proposed finding is inaccurate, misleading and contrary to the weight of the evidence for the reasons explained in Respondents' responses to CCFF ¶ 4125, [redacted] (*E.g.*, PFF ¶ 1881.) His assertions about Illumina's conduct, which Complaint Counsel adopted unquestioningly, are unreliable and demonstrably false.

4131. [redacted]

Response to Finding No. 4131:

The proposed finding is inaccurate, misleading and contrary to the weight of the evidence for the reasons explained in Respondents' responses to CCFF ¶ 4125, [redacted] (*E.g.*, PFF ¶ 1881.) His assertions about Illumina's conduct, which Complaint Counsel adopted unquestioningly, are unreliable and demonstrably false.

4132. [redacted]

Response to Finding No. 4132:

The proposed finding is inaccurate, misleading and contrary to the weight of the evidence. [redacted] (*E.g.*, PFF ¶ 1881.) His assertions about Illumina's conduct, which Complaint Counsel adopted unquestioningly, are unreliable and demonstrably false.

Respondents further note that the proposed finding relies on IH testimony which Respondents

had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4133. [redacted]

Response to Finding No. 4133:

The proposed finding is inaccurate, misleading and contrary to the weight of the evidence for the reasons explained in Respondents' response to CCFF ¶ 4132. Respondents further note that Mr. Fesko lacks sufficient personal knowledge [redacted] (*E.g.*, PFF ¶ 1881.) [redacted] (PX7111 (Fesko (Natera) Dep. at 124.) His assertions about Illumina's conduct, which Complaint Counsel adopted unquestioningly, are unreliable and demonstrably false.

4134. [redacted]

Response to Finding No. 4134:

The proposed finding is inaccurate, misleading and contrary to the weight of the evidence for the reasons explained in Respondents' response to CCFF ¶ 4132. Respondents further note that Dr. Rabinowitz lacks sufficient personal knowledge [redacted] (*E.g.*, PFF ¶ 1881.) His assertions about Illumina's conduct, which Complaint Counsel adopted unquestioningly, are unreliable and demonstrably false. Respondents further note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4135. [redacted]

Response to Finding No. 4135:

The proposed finding is inaccurate, misleading and contrary to the weight of the evidence for the reasons explained in Respondents' response to CCFF ¶ 4132. Respondents further note that [redacted] (*e.g.*, PFF ¶ 1881), and its executive's assertions about Illumina's conduct, which Complaint Counsel adopted unquestioningly, are unreliable and demonstrably false.

4136. [redacted]

[redacted]

Response to Finding No. 4136:

The proposed finding is inaccurate, misleading and contrary to the weight of the evidence for the reasons explained in Respondents' response to CCFF ¶ 4132. Respondents further note that [redacted] (*e.g.*, PFF ¶ 1881), and its executive's assertions about Illumina's conduct, which Complaint Counsel adopted unquestioningly, are unreliable and demonstrably false.

4137. [redacted]

Response to Finding No. 4137:

The proposed finding is inaccurate, misleading and contrary to the weight of the evidence for the reasons explained in Respondents' response to CCFF ¶¶ 4128, 4129, 4132, [redacted] (PFF ¶¶ 950-963.)

(a) [redacted]

4138. [redacted]

Response to Finding No. 4138:

[redacted]

(PX7060 (Naclerio (Illumina) IHT at 152-56).) Illumina had only one instrument that had been cleared by the FDA, the MiSeqDx. (PX7060 (Naclerio (Illumina) IHT at 148-49).) Because of its throughput, the MiSeqDx could not be used for NIPT testing. (PX7060 (Naclerio (Illumina) IHT at 148-49).) [redacted] (PX7060 (Naclerio (Illumina) IHT at 152-56).)

[redacted] (*e.g.*, PFF ¶ 1881), and its executive's assertions about Illumina's conduct, which Complaint Counsel adopted unquestioningly, are unreliable and demonstrably false.

4139. [redacted]

Response to Finding No. 4139:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 4138, which Respondents incorporate herein. Respondents further note that [redacted] (RX3969 (Illumina) at 16.)

4140. [redacted]

Response to Finding No. 4140:

The proposed finding is incomplete and misleading. [redacted] (*See* PX7060 (Naclerio (Illumina) IHT at 152-56).)

4141. [redacted]

Response to Finding No. 4141:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4138-4140, which Respondents incorporate herein.

4142. [redacted]

Response to Finding No. 4142:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4138-4140, which Respondents incorporate herein. The proposed finding is also misleading in that it glosses over the commercial reality that an IVD kitted NIPT is unprecedent and extremely complicated and came with the risk of "ethical blowback". (PX7089 (Naclerio (Illumina) Dep. at 45).) [redacted] (PX7089 (Naclerio (Illumina) Dep. at 52).) Thus, there is nothing wrong or remotely anticompetitive with the fact that Illumina has taken a careful, considered approach to evaluating how to enable IVD kitted NIPT tests on its IVD sequencers, particularly also in light of the fact that the FDA determined not to require IVD tests, and the NIPT market has been extremely successful without any IVD tests available.

4143. [redacted]

Response to Finding No. 4143:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4138-4142, which Respondents incorporate herein.

4144. [redacted]

Response to Finding No. 4144:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4138-4142, which Respondents incorporate herein.

4145. [redacted] (PX7060 (Naclerio (Illumina) IHT at 154-155) (*in camera*)).

Response to Finding No. 4145:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4138-4142, which Respondents incorporate herein.

4146. [redacted] (PX7060 (Naclerio (Illumina) IHT at 127-128) (*in camera*)).

Response to Finding No. 4146:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4138-4142, which Respondents incorporate herein.

4147. [redacted] (PX2265 (Illumina) at 002 (E-mail from J. Eidel, Illumina, to C. Henry, Illumina, Dec. 11, 2015) (*in camera*)).

Response to Finding No. 4147:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4138-4142, which Respondents incorporate herein.

4148. [redacted] (PX7060 (Naclerio (Illumina) IHT at 154-155) (*in camera*)).

Response to Finding No. 4148:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4138-4142, which Respondents incorporate herein.

4149. [redacted] (PX7089 (Naclerio (Illumina) Dep. at 243-244) (*in camera*)).

Response to Finding No. 4149:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4138-4142, which Respondents incorporate herein. Furthermore, the proposed finding ignores relevant context. The distributed IVDs referenced in the cited testimony were [redacted] (PX7089 (Naclerio (Illumina) Dep. at 246).) Dr. Naclerio went on to explain that [redacted] (PX7089 (Naclerio (Illumina) Dep. at 244).)

4150. [redacted]

Response to Finding No. 4150:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4132, 4138-4142, which Respondents incorporate herein.

4151. [redacted]

Response to Finding No. 4151:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4132, 4138-4142, which Respondents incorporate herein.

4152. [redacted] (PX2267 (Illumina) (Email from J. Eidel (Illumina) to J. Flatley et al., Nov. 14, 2015) (*in camera*)).

Response to Finding No. 4152:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4132, 4138-4142, which Respondents incorporate herein.

4153. [redacted] (PX2265 (Illumina) at 002 (Email from J. Eidel (Illumina) to C. Henry et al., Dec. 11, 2015) (*in camera*)).

Response to Finding No. 4153:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4132, 4138-4142, which Respondents incorporate herein.

4154. [redacted]

Response to Finding No. 4154:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4132, 4138-4142, which Respondents incorporate herein.

4155. [redacted]

Response to Finding No. 4155:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4132, 4138-4142, which Respondents incorporate herein.

4156. [redacted]

Response to Finding No. 4156:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4132, 4138-4142, which Respondents incorporate herein. The proposed finding is also inaccurate. Notably, it relies on the testimony of Mr. Fesko, a biased witness, for the proposition that Illumina has been working on obtaining FDA approval for an NIPT IVD for at least seven years, rather than any direct evidence to prove the claim—because there is none. [redacted]

(Febbo (Illumina) Tr. 4382. Unlike Mr. Fesko, Dr. Febbo is actually a subject matter expert in FDA processes and has deep experience in NGS-based FDA submissions, while Mr. Fesko and Dr. Rabinowitz have none. [redacted]

[redacted] (Febbo Febbo (Illumina) Tr. 4383.) Further, Dr. Febbo explained that Illumina had started to look at potentially pursuing an IVD approval for NIPT when it acquired Verinata, but then decided not to until more recently due to changed policy at the FDA and the unavailability of an FDA-authorized IVD sequencer that was suitable for NIPT. He explained, "after we acquired Verinata, at some point, the FDA notified all laboratory-developed tests producing NIPT tests to consider submission as an IVD to the agency. At Illumina, when we evaluated our path to an IVD, at that point Verinata's lab and now Illumina's lab was using a sequencer, the HiSeq sequencer, that was considered not compatible with supporting a pMA due to the way it was developed as a research-use-only sequencer. [redacted] (Febbo (Illumina) Tr. 4382-83.)

Dr. Febbo's testimony on this topic is reliable and informed by substantial experience and personal; Mr. Fesko's testimony amounts to baseless speculation by business executives who lack experience and personal knowledge on the topic, and can carry no weight. Indeed, cross-examination of Mr. Fesko showed he was not telling the truth and was testifying about events as to which he had no personal knowledge. [redacted]

[redacted] (PX7111 (Fesko (Natera) Dep. at 117-118, 120.) [redacted] (PX7111 (Fesko (Natera) Dep. at 120.) Remarkably, that was his ***only*** basis for this claim about Illumina's regulatory efforts. [redacted] (*Id.* at 121-123.)

Thus, after making blanket assertions about Illumina's FDA efforts, Mr. Fesko was forced to admit the facts that Dr. Febbo explained in his testimony, which contextualize why Illumina started its current NIPT IVD approval project when it did after talking about potentially pursuing an IVD earlier in the history of the NIPT marketplace. Mr. Fesko clearly is not a reliable source of information on the topic of Illumina's regulatory prowess and activities, and has proven he will stretch the truth and testify without personal knowledge in order to unfairly and inaccurately cast Illumina in a bad light.

4157. [redacted]

Response to Finding No. 4157:

The proposed finding is incomplete, misleading and inaccurate for the reasons explained in Respondents' responses to CCFF ¶¶ 4132, 4138-4142 and 4156, which Respondents incorporate herein.

4158. [redacted] (PX2075 (Illumina) at 007 (Natera Executive Summary, Sept. 30, 2016) (*in camera*)).

Response to Finding No. 4158:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4132, 4138-4142 and 4156, which Respondents incorporate herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 7), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

4159. [redacted] (PX7060 (Naclerio (Illumina) IHT at 159–160) (*in camera*)).

Response to Finding No. 4159:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4132, 4138-4142 and 4156, which Respondents incorporate herein.

4160. [redacted] (PX2761 (Illumina) (Email from A. Wellend, Illumina, to S. Rohatgi, Illumina, Jun. 20, 2017) (*in camera*)).

Response to Finding No. 4160:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4132, 4138-4142 and 4156, which Respondents incorporate herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 31), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

4161. [redacted] (PX2761 (Illumina) (Email from A. Wellend, Illumina, to S. Rohatgi, Illumina, Jun. 20, 2017) (*in camera*)).

Response to Finding No. 4161:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4132, 4138-4142 and 4156, which Respondents incorporate herein. Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 31), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

(b) [redacted]

4162. [redacted]

Response to Finding No. 4162:

[redacted] (PFF ¶¶ 950-963; 1880.) It also omits the fact that Illumina helped open the NIPT field to innovation by clearing IP hurdles through the formation of a patent pool, which removed IP uncertainty and settled patent litigation that had been impeding innovation in the field. (PFF ¶ 1099.) [redacted] (*E.g.*, PFF ¶ 1881.)

4163. [redacted]

Response to Finding No. 4163:

[redacted] (PFF ¶¶ 950-963; 1880.) It also omits the fact that Illumina helped open the NIPT field to innovation by clearing IP hurdles through the formation of a patent pool, which removed IP uncertainty and settled patent litigation that had been impeding innovation in the field. (PFF ¶ 1099.) [redacted]

[redacted] (*E.g.*, PFF ¶ 1881.)

4164. [redacted]

Response to Finding No. 4164:

The proposed finding is incomplete, misleading and inaccurate. It omits the reality that, since Illumina's acquisition of Verinata, Natera has been the U.S. market leader in NIPT, Natera has boasted about the amount of R&D and innovation it has engaged in to maintain its market leading status in NIPT, and the NIPT market has been and remains highly competitive and characterized by substantial new entry and R&D investment. (PFF ¶¶ 950-963; 1880.) It also omits the fact that Illumina helped open the NIPT field to innovation by clearing IP hurdles through the formation of a patent pool, which removed IP uncertainty and settled patent litigation that had been impeding innovation in the field. (PFF ¶ 1099.) [redacted] (*E.g.*, PFF ¶ 1881.)

VIII. RESPONDENTS' BEAR THE BURDEN TO PROVE THAT COUNTERVAILING FACTORS ARE SUFFICIENT TO RESOLVE POTENTIAL HARMS: RESPONDENTS DO NOT MEET THIS BURDEN

A. ILLUMINA'S OPEN OFFER IS INSUFFICIENT TO RESOLVE POTENTIAL HARMS

1. A Structural Remedy is the Only Way to Adequately Protect Customers

4165. [redacted] (PX7136 (Guerin-Calvert dep. at 106) (*in camera*)).

Response to Finding No. 4165:

The proposed finding is incomplete and misleading. As her testimony makes clear, [redacted] Respondents further note that behavioral remedies have been used by the FTC and DOJ since the 1970s in a wide variety of industries and cases, and that a retrospective study by the FTC of many consent decrees in horizontal and vertical mergers found that behavioral remedies were effective in the mergers studied. (PFF ¶ 1078.1; RX6002 (Guerin-Calvert Trial Dep. at 81–82, 105).)

4166. [redacted] (PX7136 (Guerin-Calvert Dep. at 106-07) (*in camera*)).

Response to Finding No. 4166:

The proposed finding is incomplete and misleading. As her testimony makes clear, [redacted]

[redacted]

4167. Ms. Guerin-Calvert testified at her trial deposition that whether a behavioral or conduct remedy is appropriate is "case-specific" and "[t]here may be a vertical merger where a behavioral remedy is not effective." (RX6002 (Guerin-Calvert Trial Dep. at 117)).

Response to Finding No. 4167:

The proposed finding is incomplete and misleading in that it has no relevance to the issues in this case. The fact that behavioral remedies *may not always* be appropriate is not relevant for assessing whether *the Open Offer* is effective to address the alleged competitive harm in this case. Ms. Guerin-Calvert explained that the Open Offer effectively addresses Complaint Counsel's allegation that Illumina will have the incentive and ability to anticompetitively disadvantage GRAIL's rivals following the Transaction. (PFF ¶ 99; RX6002 (Guerin-Calvert Trial Dep. at 20–21).)

In fact, the Open Offer provides the economically necessary terms to prevent the alleged anticompetitive harms from the Transaction in both the short term and the long term. (PFF ¶ 997.1; RX6002 (Guerin-Calvert Trial Dep. at 21–22).) The Open Offer provides a comprehensive set of protections for Illumina's customers including access, pricing and quality of products and services, cooperation for FDA regulatory approval, and rights to develop distributable IVD kits on Illumina's FDA-regulated systems. (PFF ¶ 997.3; RX6002 (Guerin-Calvert Trial Dep. at 22, 94–95).) The Open Offer provides for effective monitoring and enforceability mechanisms, and extrinsic aspects of the Open Offer (like its public availability, its stated commitment to allay concerns about the Transaction and its availability to a large number of customers) will increase the Open Offer's enforceability. (PFF ¶ 998; RX6002

(Guerin-Calvert Trial Dep. at 22).) Further, the Open Offer represents an improvement for customers over the pre-merger status quo. (PFF ¶ 999; RX6002 (Guerin-Calvert Trial Dep. at 37, 52–53, 57); *see also* RX6000 (Carlton Trial Dep. at 48).) Further, the Open Offer provides powerful enforcement mechanisms through the guarantee of baseball style arbitration for any dispute arising under it, wherein the arbitrator is expressly empowered to order "*any relief necessary to restore the status quo prior to Illumina's breach*, including monetary and/or injunctive relief, and is required to decide any dispute based on the principle that the purpose of the Open Offer is to prevent the Transaction from disadvantaging any GRAIL putative rival. (PFF ¶¶ 1055–56.)

Finally, behavioral remedies like the Open Offer have been used by the FTC and DOJ since the 1970s in a wide variety of industries and cases, and a retrospective study by the FTC of many consent decrees in horizontal and vertical mergers found that behavioral remedies were effective in the mergers studied. (PFF ¶ 1078.1; RX6002 (Guerin-Calvert Trial Dep. at 81–82, 105).)

4168. [redacted] (PX7136 (Guerin-Calvert Dep. at 20) (*in camera*)).

Response to Finding No. 4168:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 4167, which Respondents incorporate herein.

4169. [redacted] (PX7136 (Guerin-Calvert Dep. at 21) (*in camera*)).

Response to Finding No. 4169:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 4167, which Respondents incorporate herein.

4170. [redacted] (PX7136 (Guerin-Calvert Dep. at 21-22) (*in camera*)).

Response to Finding No. 4170:

Respondents have no specific response except to note that in Ms. Guerin-Calvert's opinion, the Open Offer provides the economically necessary terms to prevent the alleged anticompetitive harms from the transaction in both the short term and the long term. (PFF ¶ 997.1; RX6002 (Guerin-Calvert Trial Dep. at 21–22).) Respondents further incorporate their responses to CCFF ¶ 4167 herein.

4171. [redacted] (PX7138 (Scott Morton Trial Dep. at 79) (*in camera*)).

Response to Finding No. 4171:

The proposed finding is inaccurate, incomplete, and misleading. Behavioral remedies have been used by the FTC and DOJ since the 1970s in a wide variety of industries and cases, and a retrospective study by the FTC of many consent decrees in horizontal and vertical mergers found that behavioral remedies were effective in the mergers studied. (PFF ¶ 1078.1; RX6002 (Guerin-Calvert Trial Dep. at 81–82, 105).) Further, [redacted] the Open Offer's provisions are extremely robust and they ensure that Illumina's incentives are to support GRAIL's rivals while disabling Illumina from using any of the purported "foreclosure tools" alleged by Complaint Counsel. (PFF ¶ 1082.2–1082.4; *see* RX6002 (Guerin-Calvert Trial Dep. at 20–22, 108–09; RX6000 (Carlton Trial Dep. at 84–85).) For example, the Open Offer, as a private contract, creates an incentive for Illumina customers to

take advantage of it and enforce it. (PFF ¶ 1082.4; RX6000 (Carlton Trial Dep. at 84).) Also, as Dr. Scott Morton acknowledged, [redacted]

The record evidence shows that the Open Offer's enforcement provisions are robust and address the alleged harms. Specifically, the Open Offer contains enforcement provisions including a biannual audit and a commitment to binding arbitration in the event of a dispute. (PFF ¶ 1043; deSouza (Illumina) Tr. at 2405, 2438; PX0064 (Illumina) at 10–11; RX3935 (Illumina) at 3.) The audit and arbitration provisions of the Open Offer play complementary roles to address the alleged harms. (PFF ¶ 1045; RX6002 (Guerin-Calvert Trial Dep. at 89–90).) The audit provision assures customers that they will have access to the necessary information to ensure that Illumina abides by its obligations, and the arbitration provision allows for a mechanism to resolve any disputes that could arise. (PFF ¶ 1045; RX6002 (Guerin-Calvert Trial Dep. at 89–90).) The enforcement terms of the Open Offer provide Illumina's clinical oncology customers with effective monitoring and enforcement mechanisms to ensure compliance with the Open Offer terms and to effectuate its purpose of ensuring that Illumina cannot materially disadvantage GRAIL rivals post-merger. (PFF ¶ 1044; RX6002 (Guerin-Calvert Trial Dep. at 22–23).) The very public aspect of the Open Offer can also bolster compliance. (PFF ¶ 1044; *see* RX6002 (Guerin-Calvert Trial Dep. at 22–23).) The arbitration provision has real teeth in that it empowers the arbitrator to order "*any relief necessary to restore the status quo prior to Illumina's breach*, including monetary and/or injunctive relief, and requires the arbitrator to decide any dispute based on the principle that the purpose of the Open Offer is to prevent the

Transaction from disadvantaging any GRAIL putative rival. (PFF ¶¶ 1055–56.) Further, the enforcement provisions of the Open Offer represent an improvement over the pre-merger status quo because, as Dr. Scott Morton acknowledged, [redacted]

4172. [redacted] (PX7138 (Scott Morton Trial Dep. at 81) (*in camera*)).

Response to Finding No. 4172:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 4171, which Respondents incorporate herein. Further, [redacted] the Open Offer's terms are comprehensive and include commitments relating to price decreases, product improvements, product optimization and other terms that ensure there will be no anticompetitive conduct, regardless of any changes in the marketplace over its duration. For example, the Open Offer's provisions on pricing for new Supplied Products or new versions of materially improved Supplied Products require that the prices are "commercially reasonable" and empower an arbitrator to evaluate the commercial reasonableness of the prices, with the ability to order injunctive relief and monetary damages that bolster Illumina's incentives to treat customers fairly going forward. (PFF ¶ 1079.1; RX3935 (Illumina) at 2–3.) Similarly, rather than prescribing specific types of assistance, the FDA provision requires Illumina to provide whatever documentation is needed for FDA approval. (PFF ¶ 1083.2; RX6002 (Guerin-Calvert Trial Dep. at 103–04).) This allows the provision to be effective even if FDA requirements change over time. (PFF ¶ 1083.2; *see* RX6002 (Guerin-

Calvert Trial Dep. at 104).) Illumina has a contract with Deloitte Consulting to operationalize the terms of the Open Offer, which will help guarantee Illumina's compliance with the Open Offer's provisions. (PFF ¶ 1017.3; Berry (Illumina) Tr. [redacted], 894–97; PX7135 (Rock Dep. at 90).)

Further, as outlined in Respondents' Post-Trial Brief, Dr. Scott Morton's innovation market approach to analyzing the Illumina-GRAIL transaction is misplaced. (*See* Resps.' Post-Trial Br. at 70–71.) Even if such an approach were acceptable, Dr. Scott Morton did not perform the necessary analysis for an innovation market and Complaint Counsel has offered no evidence to prove that Galleri and other putative MCED tests in development comprise an innovation market. (*See* Resps.' Post-Trial Br. at 72.)

4173. As noted in the Department of Justice's 2020 Merger Remedies Manual, when a remedy requires that a supplier help its customers compete against itself, "it is unlikely to exert much effort to ensure the products or inputs it supplies are of high quality, arrive as scheduled, match the order specifications, and satisfy other conditions that are necessary to preserve competition." (RX3702 (U.S. Dep't of Justice, Antitrust Division, Merger Remedies Manual (Sept. 2020) at 14.

Response to Finding No. 4173:

The proposed finding is incomplete and misleading. Behavioral remedies like the Open Offer have been used by the FTC and DOJ since the 1970s in a wide variety of industries and cases, and a retrospective study by the FTC of many consent decrees in horizontal and vertical mergers found that behavioral remedies were effective in the mergers studied. (PFF ¶ 1078.1; RX6002 (Guerin-Calvert Trial Dep. at 81–82, 105); RX3865 (Guerin-Calvert Expert Report) ¶ 94; RX3322 (FTC) at 8; RX3675 (FTC).) Further, the very source cited in the proposed finding also notes that "a stand-alone conduct remedy may be appropriate to consider" when "requiring a structural divestiture might remedy the competitive concerns only at the cost of

unnecessarily sacrificing significant efficiencies" (RX3702 (U.S. Dep't of Justice, Antitrust Division, Merger Remedies Manual (Sept. 2020) at § III.B.2), which is the case here.

4174. One key issue with remedying mergers through long-term supply agreements is that "[c]ontractual terms are difficult to define and specify with the requisite foresight and precision". (RX3702 (U.S. Dep't of Justice, Antitrust Division, Merger Remedies Manual (Sept. 2020) at 14)).

Response to Finding No. 4174:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 4172–73, which Respondents incorporate herein.

a) The Open Offer Cannot Change Illumina's Strong Incentives to Favor Grail

4175. [redacted] (PX7138 (Scott Morton Trial Dep. at 74-75) (*in camera*)).

Response to Finding No. 4175:

The proposed finding is inaccurate, incomplete, and misleading, including for the reasons explained in Respondents' responses to CCFF ¶ 4121, which Respondents incorporate herein. [redacted] who did not study the Open Offer and its impact on Illumina's incentives but merely assumed it is ineffective based on unreliable, selective anecdotal testimony from certain third parties (*see* Resps.' Post-Trial Br. at 264–65; PFF ¶¶ 2010–16), the Open Offer's provisions in their totality reinforce Illumina's incentives to support GRAIL's putative rivals. (PFF ¶ 1082.2–1082.4; *see* RX6002 (Guerin-Calvert Trial Dep. at 20–22, 108–09; RX6000 (Carlton Trial Dep. at 84–85).) The Open Offer, as a private contract, creates an incentive for Illumina customers to take advantage of it and enforce it. (PFF ¶ 1082.4; RX6000 (Carlton Trial Dep. at 84).) Further, as Dr. Scott Morton acknowledged,

[redacted]

[redacted] The weight of the evidence shows that the Open Offer's provisions are extremely robust and they ensure that Illumina's incentives are to support GRAIL's rivals while disabling Illumina from using any of the purported "foreclosure tools" alleged by Complaint Counsel. (PFF ¶ 1082.2–1082.4; *see* RX6002 (Guerin-Calvert Trial Dep. at 20–22, 108–09; RX6000 (Carlton Trial Dep. at 84–85).)

4176. [redacted] (PX7138 (Scott Morton Trial Dep. at 74-75) (*in camera*)).

Response to Finding No. 4176:

The proposed finding is inaccurate, incomplete, and misleading, including for the reasons explained in Respondents' responses to CCFF ¶¶ 4121 and 4175, which Respondents incorporate herein.

4177. Singlera's Dr. Gary Gao testified that Illumina has an "inherent conflict of interest" when it comes to Grail:

> [I]f GRAIL was not started by Illumina, Illumina has no stake in any screening company. Things could be different. Then Illumina will wish many company succeed so they can supply the machine and reagent. But because of GRAIL, Illumina may want to have GRAIL succeed, other company slow down. There's no incentive for Illumina to support other people other than GRAIL.

(PX7042 (Gao (Singlera) IHT at 89-90)).

Response to Finding No. 4177:

The proposed finding is inaccurate, incomplete, and misleading, including for the reasons explained in Respondents' responses to CCFF ¶¶ 4121 and 4175, which Respondents incorporate herein. Moreover, the proposed finding has no probative weight, as biased third parties claiming

they know Illumina's incentives are not credible sources for understanding Illumina's post-merger incentives. Further, Dr. Gao testified that he was "not even aware of the first open [...] offer until [his] lawyer told [him]", let alone the amended version. (PFF ¶ 1895; Gao (Singlera) Tr. 2952 ("Q. And are you aware that that open offer was amended as of just last week to make certain improvements to it? A. Sir, to be frank, I am not even aware of the first open -- open offer until my lawyer told me, and I am not even aware of the one if you don't tell me a week ago.").) Thus, Dr. Gao's testimony should be given little weight since he ignores the effects of the Open Offer, which Singlera had an opportunity to sign (*see* deSouza (Illumina) Tr. 2338), on Illumina's incentive and ability to foreclose potential GRAIL rivals. Moreover, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4178. [redacted]

Response to Finding No. 4178:

The proposed finding is inaccurate, incomplete, and misleading, including for the reasons explained in Respondents' responses to CCFF ¶¶ 4121 and 4175, which Respondents incorporate herein. Moreover, the proposed finding has no probative weight, as biased third parties claiming they know Illumina's incentives are not credible sources for understanding Illumina's post-merger incentives. Further, [redacted], as explained in the responses to CCFF ¶¶ 4533–34, 4708, 4729, 4809, 4844–45 and 4933, which respondents incorporate herein**.**

4179. [redacted]

Response to Finding No. 4179:

The proposed finding is inaccurate, incomplete, and misleading, including for the reasons explained in Respondents' responses to CCFF ¶¶ 4121, 4175 and 4178, which Respondents incorporate herein.

4180. [redacted] (PX6090 (Scott Morton Report) ¶ 306 (*in camera*)).

Response to Finding No. 4180:

The proposed finding is inaccurate, incomplete, and misleading, including for the reasons explained in Respondents' responses to CCFF ¶¶ 4121 and 4175.

4181. [redacted] (*See* PX6091 (Scott Morton Rebuttal Report) ¶¶ 98-100 (*in camera*)).

Response to Finding No. 4181:

The proposed finding is inaccurate, incomplete, and misleading, including for the reasons explained in Respondents' responses to CCFF ¶¶ 4121 and 4175.

4182. Pre-Acquisition, Illumina claimed its objective was to "maximize customer success and satisfaction." (PX7076 (Berry (Illumina) Dep. at 105-06)).

Response to Finding No. 4182:

The proposed finding is incomplete and misleading. While it is true that one of Illumina's objectives pre-acquisition was to maximize customer success, the same is true post-acquisition. (*See* PFF ¶¶ 802 –22.)

4183. [redacted]

[redacted]

Response to Finding No. 4183:

The proposed finding is inaccurate, incomplete, and misleading, including for the reasons explained in Respondents' responses to CCFF ¶¶ 4121 and 4175, which Respondents incorporate herein. Moreover, the proposed finding has no probative weight, as biased third parties claiming they know Illumina's incentives are not credible sources for understanding Illumina's post-merger incentives.

4184. [redacted]

Response to Finding No. 4184:

The proposed finding is inaccurate, incomplete, and misleading, including for the reasons explained in Respondents' responses to CCFF ¶¶ 4121, 4175 and 4183, which Respondents incorporate herein.

4185. Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)).

Response to Finding No. 4185:

The proposed finding is inaccurate, incomplete, and misleading, including for the reasons explained in Respondents' responses to CCFF ¶¶ 4121 and 4175, which Respondents incorporate herein. Moreover, the proposed finding has no probative weight, as biased third parties claiming

they know Illumina's incentives are not credible sources for understanding Illumina's post-merger incentives. Further, [redacted] In its negotiations with Illumina, Guardant never indicated to Illumina that Guardant viewed its amended supply agreement as, in substance, unenforceable or worthless. (PFF ¶ 1075.5; Getty (Guardant) Tr. 2669.)

4186. Mr. Getty testified that he does not think a contract between Guardant and Illumina could eliminate Illumina's incentives to favor Grail. (PX7105 (Getty (Guardant) Dep. at 79-80)).

Response to Finding No. 4186:

The proposed finding is inaccurate, incomplete, and misleading, including for the reasons explained in Respondents' responses to CCFF ¶¶ 4121, 4175 and 4185, which Respondents incorporate herein.

4187. Mr. Getty expressed concern about Illumina post-acquisition, testifying:

> [I]n the future state, if you– if your competitor is part of your own organization and you actually want them to be highly competitive, then you have all the incentive in the world to optimize their information ahead of their competitive set and you have potentially– not potentially– you likely have significant financial ties associated with that competitive advantage.

(PX7105 (Getty (Guardant) Dep. 100-01)).

Response to Finding No. 4187:

The proposed finding is inaccurate, incomplete, and misleading, including for the reasons explained in Respondents' responses to CCFF ¶¶ 4121, 4175 and 4185, which Respondents incorporate herein.

4188. Mr. Getty testified that the acquisition would shift Illumina's incentives:

> [T]he assumption here is that, again, it's in [Illumina's] best interest to keep Guardant happy as a customer. However, if your business is no longer sequencing, then why is it that you would want to keep Guardant happy per se, right. You would want to actually move them out of the market so you could have a bigger share of the market. That's the underlying concern at the heart of all of this.

(PX7040 (Getty (Guardant) IHT at 189)).

Response to Finding No. 4188:

The proposed finding is inaccurate, incomplete, and misleading, including for the reasons explained in Respondents' responses to CCFF ¶¶ 4121, 4175 and 4185, which Respondents incorporate herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4189. [redacted]

Response to Finding No. 4189:

The proposed finding is incomplete and misleading. [redacted]

[redacted] The Open Offer is 12-year supply agreement. (PFF ¶ 1000; Berry (Illumina) Tr. 690–91, 861, 874–75; Conroy (Exact/Thrive) Tr. 1725; deSouza (Illumina) Tr. 2402; PX0064 (Illumina) at 5.) The Open Offer provides MFN pricing relative to both GRAIL and any other For-Profit Entity. (PFF ¶¶ 1017–18; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 7–8.) And the Open Offer assures an uninterrupted supply of core consumables. (*See* PFF ¶¶ 1000, 1005, 1007, 1009, 1011, 1037; [redacted]; Berry (Illumina) Tr. 690–91, 861, 864, 874–75, 878–79, 883; Conroy (Exact/Thrive) 1725; deSouza (Illumina) Tr. 2402, 2434–35, 2437–38; PX0064 (Illumina) at 5–6, 9; RX3935 (Illumina) at 2; RX6002 (Guerin-Calvert Trial Dep. at 59–60, 77–79.)

[redacted] The Open Offer provides exactly that: As Ms. Berry testified, "the customer [who signs the Open Offer] is free to . . . leave [the agreement] at any time", but Illumina is not. (Berry (Illumina) Tr. 862–63.)

4190. [redacted]

[redacted]

Response to Finding No. 4190:

Respondents incorporate their responses to CCFF ¶ 4189 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4191. At trial, Guardant's Mr. Getty testified that he expects Illumina's incentives towards Guardant will change when Illumina becomes a competitor to Guardant rather than only a supplier. (Getty (Guardant) Tr. 2681-82). Mr. Getty explained the changing incentives, "[C]urrently the [MCED test] marketplace has been estimated to be, you know, $50 billion-plus. . . It's the largest market available to probably [Illumina and Guardant]" and, for Illumina, "the incentives will be there in order to tap into that much larger market than what is available today because that's going to increase shareholder value ostensibly." (Getty (Guardant) Tr. 2681-82).

Response to Finding No. 4191:

The proposed finding is inaccurate, incomplete, and misleading, including for the reasons explained in Respondents' responses to CCFF ¶¶ 4121, 4175 and 4185, which Respondents incorporate herein.

4192. Respondents' economic expert, Dr. Willig, testified, "if the incentives aren't right, then the contract is not going to be successful . . . the parties try to build in the protection that they think they can get into the contract, but the real details of how the business is going to work evolve from appropriate business incentives shared by the parties." (PX7132 (Willig Dep. at 289-290)).

Response to Finding No. 4192:

The proposed finding is irrelevant, since, as the testimony makes clear, Dr. Willig's testimony was from another case involving another contract wholly unrelated to the Open Offer and the issues in this case, and in this case, Illumina has powerful incentives to comply with the Open Offer. Dr. Willig in no way testified that Illumina does not have incentives to comply with the Open Offer, and any claim that Illumina does not have such incentives is incomplete, and

misleading, including for the reasons explained in Respondents' responses to CCFF ¶¶ 4121, 4171 and 4175.

4193. [redacted] (PX6090 (Scott Morton Report) ¶ 229 (*in camera*); PX6091 (Scott Morton Rebuttal Report) ¶ 102 (*in camera*)).

Response to Finding No. 4193:

The proposed finding is inaccurate, incomplete, and misleading, including for the reasons explained in Respondents' responses to CCFF ¶¶ 4121, 4175 and 4185, which Respondents incorporate herein. Further, the evidence shows that the Open Offer contains the economically necessary set of terms to prevent the alleged competitive harms arising from the merger in both the short and the long term. (PFF ¶ 1077; RX6002 (Guerin-Calvert Trial Dep. at 21–22).) [redacted] the theory of incomplete contracts does not, from an economic standpoint, mean that contracts cannot be written or that parties cannot enter into contracts that address unforeseen circumstances. (PFF ¶ 1078; RX6002 (Guerin-Calvert Trial Dep. at 99–102); RX6000 (Carlton Trial Dep. at 50, 84–85).) Dr. Scott Morton's opinion that the Open Offer is inadequate because it cannot anticipate every contingency that could arise ignores the fact that this is true of all contracts, and not true here. (PFF ¶ 1078.2; RX6000 (Carlton Trial Dep. at 49–50).) In fact, Dr. Scott Morton assumes that, absent the merger, sophisticated contracts could be written that would enable the efficiencies of the merger but places no confidence in the Open Offer's ability to protect GRAIL rivals, even though the Open Offer is a private contract that is privately enforceable and has very robust monitoring and enforcement mechanisms. (PFF ¶ 1078.2; RX6000 (Carlton Trial Dep. at 49–50).) Under the theory of incomplete contracts, economists can still evaluate the terms of the Open Offer to

determine whether the terms provide customers with adequate protection. (PFF ¶ 1078.3; RX6002 (Guerin-Calvert Trial Dep. at 100–01).) Economists have evaluated the Open Offer and concluded that it is a comprehensive contract that sufficiently addresses and anticipates issues that are likely to arise over time. (PFF ¶ 1078.3; RX6002 (Guerin-Calvert Trial Dep. at 21–22, 103–04); RX6000 (Carlton Trial Dep. at 84–85).)

Moreover, the 12-year term is consistent with what is normally provided in consent decrees that the FTC and the DOJ have approved historically. (PFF ¶ 1000.3; RX6002 (Guerin-Calvert Trial Dep. at 28); *see, e.g.*, RX3082 (*In re Broadcom Ltd.* Decision and Order) at 11; RX3664 (*In re Sycamore Partners II* Analysis of Agreement Containing Consent Order) at 4).) The 12-year term was chosen to assure customers that Illumina was absolutely invested in maintaining longstanding relationships with these customers as a technology provider. (PFF ¶ 1000.2; Berry (Illumina) Tr. 862.) And the 12-year term allows customers to plan for the long term. (PFF ¶ 1000.6; [redacted]; RX6002 (Guerin-Calvert Trial Dep. at 28–29).)

2. Illumina Failed to Assuage Customers' Concerns Regarding the Grail Acquisition

a) Illumina Sought Long Term Supply Agreements with Grail's Key Competitors

(1) Illumina's Initial Outreach to Customers Re Illumina's Acquisition of Grail

4194. In September 2020, Illumina's Nicole Berry was "involved in a proactive reach-out program with a select group of customers" to discuss Illumina's proposed acquisition of Grail. (PX7063 (Berry (Illumina) IHT at 123-24)).

Response to Finding No. 4194:

Respondents have no specific response except to note that [redacted]

[redacted]

[redacted]

Finally, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4195. Illumina created a "stratification of customers that would be prioritized for proactive reach-out." (*See* PX7063 (Berry (Illumina) IHT at 124); *see also* PX2302 (Illumina) (Email from N. Berry, Illumina to C. Fiedler and M. Gallad, Illumina, Sept. 21, 2020)).

Response to Finding No. 4195:

Respondents incorporate their responses to CCFF ¶ 4194 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4196. In a September 21, 2020 email, Ms. Berry explained to Mr. Fiedler and Mr. Gallad that Illumina has "identified a number of customers whom we believe it would be good to reach out proactively regarding the GRAIL announcement." (PX2302 (Illumina) at 001 (Email from N. Berry, Illumina to C. Fiedler and M. Gallad, Illumina, Sept. 21, 2020)).

Response to Finding No. 4196:

Respondents incorporate their responses to CCFF ¶ 4194 herein.

4197. Ms. Berry's email broke down Illumina customers into "Tier 1 customers" and "Tier 2 customers." (PX2302 (Illumina) at 001-002 (Email from N. Berry, Illumina to C. Fiedler and M. Gallad, Illumina, Sept. 21, 2020)).

Response to Finding No. 4197:

The proposed finding is incomplete and misleading. All of the companies in Ms. Berry's email were "flagged for a proactive call", whether identified as "Tier 1" or "Tier 2". (PX2302 (Illumina) at 2.) Respondents also incorporate their responses to CCFF ¶ 4194.

4198. Ms. Berry's email stated that "Tier 1 customers" were to be contacted by "Francis [deSouza] and MVO, [Mark Van Oene], to assist with, as either our largest onc[ology] testing customers or those specifically participating in the early detection space." (PX2302 (Illumina) at 001 (Email from N. Berry, Illumina to C. Fiedler and M. Gallad, Illumina, Sept. 21, 2020)).

Response to Finding No. 4198:

Respondents incorporate their responses to CCFF ¶¶ 4194 and 4197 herein.

4199. [redacted] (PX2302 (Illumina) at 001-002 (Email from N. Berry, Illumina to C. Fiedler and M. Gallad, Illumina, Sept. 21, 2020) (*in camera*)).

Response to Finding No. 4199:

Respondents incorporate their responses to CCFF ¶¶ 4194 and 4197 herein.

4200. In Ms. Berry's September 21, 2020 email, she highlighted in yellow below the "Tier 1 customers" chart that

> The primary purpose of these calls is to assure these customers that the GRAIL transaction will have no impact on Illumina's relationship with the customer, explain to the customer how the transaction will benefit them, and that upon closing of the transaction Illumina will offer the customer a long-term extension of its supply agreement that guarantees access to Illumina's platforms, consumables and service/repair, price decreases, volume discounts and any innovations/improvements to Illumina's instruments and consumables.

(PX2302 (Illumina) at 002 (Email from N. Berry, Illumina to C. Fiedler and M. Gallad, Illumina, Sept. 21, 2020)).

Response to Finding No. 4200:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina worked to assuage customers' concerns about the merger and assure customers that their relationship with Illumina would not change post-acquisition.

4201. [redacted] (Berry (Illumina) Tr. 938 (*in camera*)).

Response to Finding No. 4201:

The proposed finding is incomplete and misleading. Later in her testimony, Ms. Berry provided context for this response. [redacted]

4202. [redacted] (Berry (Illumina) Tr. 753) (*in camera*)).

Response to Finding No. 4202:

Respondents incorporate their responses to CCFF ¶¶ 4194 and 4201 herein. Further, the proposed finding is evidence that Illumina worked to assuage potential GRAIL rivals' concerns about the merger.

4203. [redacted] (Berry (Illumina) Tr. 753-55) (*in camera*)).

Response to Finding No. 4203:

The proposed finding is incomplete and misleading. Ms. Berry testified that [redacted] Respondents also incorporate their responses to CCFF ¶¶ 4194 and 4197. Further, the proposed finding is evidence that Illumina worked to assuage potential GRAIL rivals' concerns about the merger.

(2) Ms. Berry's Contribution to the Customer Outreach List

4204. Although Ms. Berry denied creating the tiers of customers she wrote about in her September 21, 2020 email, Ms. Berry testified that she contributed by "filling out a spreadsheet where I provided inputs. That would then translate to a subsequent stratification." (PX7063 (Berry (Illumina) IHT at 125)).

Response to Finding No. 4204:

The proposed finding is incomplete and misleading. Ms. Berry did not "den[y] creating the tiers of customers". She testified that she provided inputs to a spreadsheet to help decide which customers "should be prioritized for proactive reach-out". (PX7063 (Berry (Illumina) IHT at 125.) [redacted]

[redacted] Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4205. Ms. Berry's "inputs" included information about Illumina customers' "annual revenue," "priority" category, "freeform inputs," and "commentary." (PX7063 (Berry (Illumina) IHT at 125)).

Response to Finding No. 4205:

Respondents incorporate their responses to CCFF ¶ 4204 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4206. Illumina's "priority" classification indicated "whether [Illumina] felt that a specific customer should be prioritized for proactive reach-out. And if so, by whom, because we -- I believe -- my recollection is that we had -- we had proactive reach-out for a couple of different layers, if you will, or priority groups, but those reach-outs would be done by different people." (PX7063 (Berry (Illumina) IHT at 126)).

Response to Finding No. 4206:

Respondents incorporate their responses to CCFF ¶ 4204 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4207. Illumina customers that had business in the oncology space were prioritized for reach-out calls by Illumina executives regarding Illumina's proposed acquisition of Grail. (PX7063 (Berry (Illumina) IHT at 127)).

Response to Finding No. 4207:

Respondents incorporate their responses to CCFF ¶¶ 4197, 4203 and 4204 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4208. After Illumina decided which customers to reach out to, Illumina "scheduled calls and executed those calls via videoconference." (PX7063 (Berry (Illumina) IHT at 129-30)).

Response to Finding No. 4208:

Respondents have no specific response. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4209. Illumina reached out to Foundation Medicine, Natera, Guardant Health, Invitae, Thrive, Freenome, Exact Sciences, and LabCorp. (PX7063 (Berry (Illumina) IHT at 130)).

Response to Finding No. 4209:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina worked to assuage customers' concerns about the merger. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4210. Several Illumina executives participated on these calls including Ms. Nicole Berry, Ms. Kathy Davy, the customer's Illumina account manager, an Illumina commercial organization member, Mr. Francis deSouza, and Mr. Mark Van Oene. (PX7063 (Berry (Illumina) IHT at 130-31)).

Response to Finding No. 4210:

Respondents incorporate their responses to CCFF ¶ 4203 herein and also note that the proposed finding is evidence that Illumina worked to assuage customers' concerns about the merger. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(3) Illumina's Ms. Berry, the Signatory on Long-Term Supply Agreements, Expressed Concerns with Illumina Purchasing Grail

4211. [redacted] (*See* PX0064 at 002 (Illumina, Open Offer Letter, Mar. 29, 2021); *see, e.g.*, PX2538

(Illumina) at 004 [redacted]

Response to Finding No. 4211:

Respondents have no specific response.

4212. Nicole Berry, Illumina's Senior Vice President and General Manager of the Americas Commercial Region, testified at trial that she first learned about Illumina's proposed acquisition of Grail in March 2020. (PX7063 (Berry (Illumina) IHT at 110); Berry (Illumina) Tr. 687)).

Response to Finding No. 4212:

Respondents have no specific response.

4213. In March 2020, Ms. Berry "attended a portion of a leadership meeting during which M&A candidates were being discussed, and [she] saw GRAIL's name on the list." (PX7063 (Berry (Illumina) IHT at 110)).

Response to Finding No. 4213:

Respondents have no specific response.

4214. When Ms. Berry first heard about the proposed acquisition, she had concerns. (PX7063 (Berry (Illumina) IHT at 110); Berry (Illumina) Tr. 687).

Response to Finding No. 4214:

The proposed finding is incomplete and misleading. Ms. Berry explained that she had concerns "*at that particular point in time early on*" and that at the time, she "didn't really that that deep[ly] about it". (PX7063 (Berry (Illumina) IHT at 111 (emphasis added); Berry (Illumina) Tr. 687 (saying she had concerns "*at the time*" of the announcement of the acquisition (emphasis added)).) Further, the only concern Ms. Berry identified was that the announcement of the acquisition "would cause [her team] to have to, you know, spend time and effort resolving [customers'] concerns", which would "take time away from what [Ms. Berry and her team] are

primarily responsible for, which is maximizing, you know, revenue growth and customer satisfaction". (PX7063 (Berry (Illumina) IHT at 111–12.)

In any event, in light of these early concerns, Ms. Berry and her team [redacted] Based on what was learned in this outreach, Illumina developed the Open Offer to present to all of its U.S. oncology customers to address concerns raised by both Complaint Counsel and certain customers that the Illumina-GRAIL transaction would allow Illumina to foreclose GRAIL rivals. (PFF ¶¶ 990–91; *see* Berry (Illumina) Tr. 688–89, 709–10, 857, [redacted]; deSouza (Illumina) Tr. 2338–39, 2401; Goswami (Illumina) Tr. 3207; PX0064 (Illumina) at 1; [redacted].). The Open Offer fully and effectively addresses the concerns that Illumina will have the incentive and ability to anticompetitively disadvantage GRAIL's rival. (PFF ¶ 997; RX6002 (Guerin-Calvert Trial Dep. at 20–21).)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4215. Ms. Berry testified that her concerns over Illumina acquiring Grail included "if and when this acquisition came to pass that some of our customers, you know, would have a reaction that would be– would cause us to have to, you know, exert a lot of time and effort in terms of talking them through it and manage it." (PX7063 (Berry (Illumina) IHT at 110-11)).

Response to Finding No. 4215:

Respondents incorporate their responses to CCFF ¶ 4214 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4216. Ms. Berry testified that she thought customers would have a reaction to Illumina's acquisition of Grail because "it's a big acquisition" and "customers would [] have questions about, you know, how this acquisition would relate to, you know, their– the commercial relationship that they have established with [Illumina]." (PX7063 (Berry (Illumina) IHT at 111)).

Response to Finding No. 4216:

Respondents incorporate their responses to CCFF ¶ 4214 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4217. Ms. Berry testified that she anticipated questions from customers about whether Illumina's acquisition of Grail "meant any changes to the commercial relationship that [Illumina] had together, you know, built and were engaged in prior to the acquisition taking place." (PX7063 (Berry (Illumina) IHT at 112)).

Response to Finding No. 4217:

Respondents incorporate their responses to CCFF ¶ 4214 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4218. Ms. Berry testified that the customers she anticipated would need clarification about Illumina's commercial relationship "would primarily relate to customers in, you know, the– that participate in the oncology space . . . because GRAIL is an oncology-focused company." (PX7063 (Berry (Illumina) IHT at 112-13)).

Response to Finding No. 4218:

Respondents incorporate their responses to CCFF ¶ 4214 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4219. Ms. Berry testified that when she learned of the acquisition, she thought Illumina's oncology customers would have questions about Illumina's proposed acquisition of Grail because these customers also offer oncology products. (PX7063 (Berry (Illumina) IHT at 113)).

Response to Finding No. 4219:

Respondents incorporate their responses to CCFF ¶ 4214 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4220. [redacted] (PX2569 (Illumina) at 008 (Illumina, *Executive Session* Presentation, Apr. 28, 2020 (*in camera*))).

Response to Finding No. 4220:

The proposed finding is incomplete and misleading. For example, at trial, Mr. deSouza

[redacted]

[redacted] Moreover, to the extent that customers have any concerns about the relationship between Illumina and its customers post-acquisition, the Open Offer was created to allay those concerns and ensure that Illumina treats its customers fairly relative to GRAIL and to each other. (*See* PFF ¶¶ 997–1057.)

4221. [redacted] (PX7063 (Berry (Illumina) IHT at 115); *see* PX2157 (Illumina) (Text message exchange between G. Weightman, Illumina, and N. Berry, Illumina, June 4, 2020) (*in camera*)).

Response to Finding No. 4221:

Respondents have no specific response.

4222. [redacted] (PX2283 (Illumina) at 001 (Text from K. Davy, Illumina, to N. Berry, Illumina, June 4, 2020) (*in camera*)).

Response to Finding No. 4222:

The proposed finding is incomplete and misleading. At trial, Ms. Berry provided context for this answer: [redacted]

She also testified that Illumina's acquisition of GRAIL will "[a]bsolutely not" change how Illumina interacts with its customers: "I'm speaking on behalf of Illumina, but importantly speaking on behalf of me and my team, we remain absolutely committed to doing what we can to bring new technologies to market to continue to drive expansion in accessibility of genomics

technology to be applied in a wide variety of many important ways . . . and ensuring customers are absolutely satisfied with their use of Illumina products." (Berry (Illumina) Tr. 838.) Respondents also incorporate their responses to CCFF ¶ 4214.

4223. [redacted] (PX2283 (Illumina) at 001 (Text from K. Davy, Illumina, to N. Berry, Illumina, June 4, 2020) (*in camera*)).

Response to Finding No. 4223:

The proposed finding is incomplete and misleading. At trial, Ms. Berry provided context for this answer: [redacted] Respondents also incorporate their responses to CCFF ¶ 4214.

4224. [redacted] (PX7061 (Davy (Illumina) IHT at 240) (*in camera*)).

Response to Finding No. 4224:

Respondents incorporate their responses to CCFF ¶¶ 4214 and 4222–23 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4225. [redacted] (PX7061 (Davy (Illumina) IHT at 234) (*in camera*)).

Response to Finding No. 4225:

Respondents incorporate their responses to CCFF ¶¶ 4214 and 4222–23 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4226. [redacted] (PX2157 (Illumina) (Text message exchange between G. Weightman, Illumina, and N. Berry, Illumina, June 4, 2020) (*in camera*); *see* PX7063 (Berry (Illumina) IHT at 117-23)).

Response to Finding No. 4226:

Respondents have no specific response.

4227. [redacted] (PX2157 (Illumina) (Text message exchange between G. Weightman, Illumina, and N. Berry, Illumina, June 4, 2020) (*in camera*)).

Response to Finding No. 4227:

Respondents also incorporate their responses to CCFF ¶¶ 4214, 4230 and 4233 herein.

4228. Ms. Berry understood Ms. Weightman's question to mean "pretty much exactly what it says, you know, would our customers, you know, be, quote-unquote, upset, if you will, if we started competing on service." (PX7063 (Berry (Illumina) IHT at 118)).

Response to Finding No. 4228:

Respondents also incorporate their responses to CCFF ¶ 4214, 4230 and 4233 herein.

4229. When Ms. Weightman used the phrase "competing on service," Ms. Berry understood her to mean "participat[ing] in the oncology testing market by offering a service in addition to products, supplying products." (PX7063 (Berry (Illumina) IHT at 118)).

Response to Finding No. 4229:

Respondents incorporate their responses to CCFF ¶¶ 4214, 4230 and 4233 herein.

4230. Ms. Berry testified that she agreed with Ms. Weightman's statement that post-acquisition Illumina would be competing with its customers because "if a third party's perception . . . that the only outcome of Illumina acquiring GRAIL and offering oncology testing services was simply that we would be offering oncology testing services, then that would concern me . . . ." (PX7063 (Berry (Illumina) IHT at 119)).

Response to Finding No. 4230:

The proposed finding is incomplete and misleading. Ms. Berry said that she agreed "to a certain extent" but that she thought Ms. Weightman's statement was an "overgeneralization" because "it fail[ed] to recognize all of the benefits that [Illumina's acquisition of GRAIL] would have on the market overall and [on] other players in the space." (PX7063 Berry (Illumina) IHT at 119.) Further, Ms. Berry explained that she agreed only to the extent that if a "third party's *perception* . . . was simply that [Illumina] would be offering oncology testing services, then that would concern me, *if customers of other third parties didn't appreciate the full story and all of the outcomes that would be enabled through Illumina's acquisition of GRAIL and subsequent participation in the oncology testing space*." (PX7063 Berry (Illumina) IHT at 119–20.) She further testified that "there is *no basis* for perceived competition" between Illumina and its customers. (PX7063 Berry (Illumina) IHT at 120.) Respondents also incorporate their responses to CCFF ¶¶ 4214, 4220 and 4233 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4231. Ms. Berry testified that "[i]n this context, 'service' refers to Illumina processing samples in our laboratory and returning results to the originator of the samples, similar to the Verinata model that I described earlier." (PX7063 (Berry (Illumina) IHT at 118-19)).

Response to Finding No. 4231:

Respondents incorporate their responses to CCFF ¶¶ 4214, 4230 and 4233 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4232. Ms. Berry testified that she agreed with Ms. Weightman that post-acquisition of Grail, Illumina would start competing on service with its customers. (PX7063 (Berry (Illumina) IHT at 119-20)).

Response to Finding No. 4232:

Respondents incorporate their responses to CCFF ¶¶ 4214, 4220, 4230 and 4233 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4233. In a text message dated June 4, 2020, between Ms. Berry and Gretchen Weightman, Illumina's general manager of the Asia Pacific region, Ms. Weightman asked "How much does [G]rail compete with your customers? Would it piss off a ton of your customers if we start competing on service?" Ms. Berry responded "Of course. It would be disastrous." PX2157 (Illumina) at 001 (Mobile text chain between N. Berry, Illumina, and G. Weightman, Illumina, June 4, 2020). [redacted] (Berry (Illumina) Tr. 740) (*in camera*).

Response to Finding No. 4233:

The proposed finding is incomplete and misleading. When asked about the text message at trial, Ms. Berry provided context: [redacted]

[redacted] Respondents also incorporate their responses to CCFF ¶¶ 4214, 4220 and 4230 herein.

4234. Ms. Berry testified at trial that when she learned about the potential acquisition of Grail in March 2020, she had concerns that her "customers, generally speaking, would perceive this as a shift in Illumina's strategy . . ." (Berry (Illumina) Tr. 687).

Response to Finding No. 4234:

Respondents incorporate their responses to CCFF ¶ 4214 herein.

4235. Ms. Berry testified that she believed customers would have questions about how the acquisition would impact their commercial relationship with Illumina. (Berry (Illumina) Tr. 688).

Response to Finding No. 4235:

Respondents incorporate their responses to CCFF ¶ 4214 herein.

4236. In particular, Ms. Berry testified that customer questions regarding the proposed acquisition of Grail would come from oncology customer since public information "clearly identifies [Grail] as being in the oncology testing space." (Berry (Illumina) Tr. 688).

Response to Finding No. 4236:

Respondents incorporate their responses to CCFF ¶ 4214 herein.

4237. Ms. Berry testified that, in June 2020, she [redacted] Berry (Illumina) Tr. 740-41) (*in camera*)).

Response to Finding No. 4237:

Respondents incorporate their responses to CCFF ¶ 4214 herein.

4238. [redacted] (PX2160 (Illumina) at 006 (Email from T. Boyaniwsky, Illumina, to M. Van Oene, Illumina, and N. Berry, Illumina, et al, attaching Commercial All Hands_3Q20_DRAFT_v2.pptx, Oct. 28, 2020) (*in camera*)).

Response to Finding No. 4238:

Respondents incorporate their responses to CCFF ¶¶ 4214 and 4220 herein.

b) Illumina Sent Letters to a Subset of Its Oncology Customers in Early October 2020 to Announce the Transaction and Provided Information About Illumina's Supply of NGS Products Moving Forward

4239. After Illumina made initial phone calls to select customers, including Guardant, FMI, Natera, Invitae, Thrive, Freenome, and Exact, Illumina followed up by sending letters. (PX7063 (Berry (Illumina) IHT at 130-31)).

Response to Finding No. 4239:

The proposed finding is complete and misleading. [redacted] Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4240. [redacted] (Berry (Illumina) Tr. 755) (*in camera*)). [redacted] (Berry (Illumina) Tr. 755-56) (*in camera*)).

Response to Finding No. 4240:

The proposed finding is incomplete and misleading. [redacted]

4241. On October 9, 2020 Ms. Berry sent letters to Illumina's MCED customers to announce its proposed merger with Grail and provide certain assurances about the Illumina-Grail transaction. (PX7063 (Berry (Illumina) IHT at 131); *see e.g.*, PX2068 (Illumina) at 002-003 (Email from N. Berry, Illumina, to S. George, Invitae, attaching letter of intent, Oct. 9, 2020) (*in camera*)).

Response to Finding No. 4241:

Respondents incorporate their responses to CCFF ¶ 4240 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4242. Ms. Berry testified that Illumina's legal team drafted the October 9, 2020 letter of intent. (PX7063 (Berry (Illumina) IHT at 132)).

Response to Finding No. 4242:

The proposed finding relates to irrelevant subject matter because it is immaterial who drafted the letters of intent. Ms. Berry signed the letters and the letters represented the positions of Illumina as a whole. [redacted] Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4243. [redacted] (Berry (Illumina) Tr. 938) (*in camera*).

Response to Finding No. 4243:

The proposed finding is incomplete and misleading. Later in her testimony, Ms. Berry provided context for this response. [redacted] incorporate their responses

4244. [redacted] (Berry (Illumina) Tr. 938) (*in camera*).

Response to Finding No. 4244:

Respondents incorporate their responses to CCFF ¶ 4243 herein.

4245. Ms. Berry testified that she was not aware of any other time that Illumina has sent a letter of intent relating to an Illumina acquisition to Illumina's customers. (PX7063 (Berry (Illumina) IHT at 141)).

Response to Finding No. 4245:

The proposed finding relates to irrelevant subject matter because Ms. Berry's awareness of previously sent letters of intent for other acquisitions is immaterial to the content, purpose or effect of the letters of intent sent to Illumina customers in October 2020. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4246. [redacted] (PX2303 (Illumina) (Email from N. Berry, Illumina, to G. Otte, Freenome, attaching letter of intent, Oct. 9, 2020); PX2645 (Illumina) [redacted] (*in camera*); PX8349 (Tempus) (Illumina letter to Tempus Labs, Inc. ("Tempus"), Oct. 9, 2020); *see also* PX7056 (Silvis (Tempus) IHT at 66) (*in camera*)).

Response to Finding No. 4246:

Respondents incorporate their responses to CCFF ¶¶ 4239–40 herein.

4247. [redacted] (*See e.g.*, PX2068 (Illumina) at 002 [redacted]

Response to Finding No. 4247:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina worked to assuage customers' concerns about the merger and assure customers that their relationship with Illumina would not change post-acquisition.

4248. After customers raised concerns that Illumina may share their competitively sensitive information with Grail post-acquisition, Illumina sent out revised letters a few weeks later, adding that Illumina will not share customers' confidential information with Grail. (PX7063 (Berry (Illumina) IHT at 134-135)). Ms. Berry sent Illumina's second letter of intent to select customers on October 20, 2020. (*See e.g.*, PX2067 (Illumina) at 002-003 (Email from N. Berry, Illumina to S. George, Invitae, attaching letter of intent, Oct. 20, 2020)).

Response to Finding No. 4248:

Respondents have no specific response except to note that the proposed finding is confirms that Illumina worked to assuage customers' concerns about the merger and assure customers that their relationship with Illumina would not change post-acquisition. In fact, [redacted]

4249. [redacted] (*See* PX2658 (Illumina) at 001 (Email from N. Berry, Illumina, to L. Leigh, Illumina, Oct. 28, 2020) (*in camera*); PX2643 (Illumina) at 002-003 (Email from N. Berry, Illumina, to S. Chapman, Natera, Oct. 20, 2020) (*in camera*)); PX2067 (Illumina) at 002-003 (Email from N. Berry, Illumina to S. George, Invitae, attaching letter of intent, Oct. 20, 2020); PX2664 (Illumina) at 002 (Email from N. Berry, Illumina, to K. Fiedler, FMI, Oct. 20, 2020) (*in camera*); PX2655 (Illumina) [redacted] (*in camera*); PX2642 (Illumina) at 002-003 (Email from N. Berry, Illumina, to M. Eisenberg, LabCorp, Oct. 20, 2020) (*in camera*); PX2653 (Illumina) at 002-003 (Email from N. Berry, Illumina, to A. Elliott, Ambry, Oct. 20, 2020) (*in camera*); PX2650 (Illumina) at 002-003 (Email from N. Berry, Illumina, to D. Spetzler, Caris, Oct. 20, 2020) (*in camera*)).

Response to Finding No. 4249:

Respondents incorporate their responses to CCFF ¶¶ 4239–40 herein.

4250. [redacted] (Berry (Illumina) Tr. 756-57) (*in camera*)).

Response to Finding No. 4250:

Respondents incorporate their responses to CCFF ¶¶ 4239–40 herein.

(1) Customers Reactions to Illumina's Letters of Intent

(a) Freenome

4251. [redacted] (PX7055 (Otte (Freenome) IHT at 102-03) (*in camera*)).

Response to Finding No. 4251:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina worked to assuage customers' concerns about the merger and assure customers that their relationship with Illumina would not change post-acquisition. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4252. [redacted] (PX7055 (Otte (Freenome) IHT at 103-04) (*in camera*)).

Response to Finding No. 4252:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina worked to assuage customers' concerns about the merger and assure customers that their relationship with Illumina would not change post-acquisition. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no

opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4253. [redacted] (PX7055 (Otte (Freenome) IHT at 103-04) (*in camera*)).

Response to Finding No. 4253:

The proposed finding is incomplete and misleading. Specifically, Mr. Otte testified that [redacted] a binding commitment in the form of the Open Offer. (*See* PFF ¶¶ 992–1057.) Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4254. [redacted] (PX7055 (Otte (Freenome) IHT at 103-04) (*in camera*)).

Response to Finding No. 4254:

Respondents incorporate their responses to CCFF ¶ 4253 herein.

4255. [redacted]

[redacted] (PX7055 (Otte (Freenome) IHT at 113-15) (*in camera*)).

Response to Finding No. 4255:

Respondents have no specific response except to note that [redacted] Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶ 4253 herein.

4256. [redacted] (PX7055 (Otte (Freenome) IHT at 113-14) (*in camera*)).

Response to Finding No. 4256:

The proposed finding is misleading including because [redacted] Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶ 4253 herein.

4257. [redacted]
(PX7055 (Otte (Freenome) IHT at 113-14) (*in camera*)).

Response to Finding No. 4257:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina worked to assuage customers' concerns about the merger and assure customers that their relationship with Illumina would not change post-acquisition. [redacted] Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4258. [redacted]

[redacted] (*in camera*)).

Response to Finding No. 4258:

The proposed finding is inaccurate, incomplete and misleading. [redacted] Additionally, the Open Offer provides customers with protections relating to IP. For example, under the Open Offer, Illumina commits to give customers a right under Illumina's core intellectual property to use its sequencing instruments and core consumables. (PFF ¶ 1036; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.) Under the Open Offer, Illumina also commits that it will not have the right to cease shipments of the products solely on the basis of a claim of infringement of Illumina's intellectual property rights. (PFF ¶ 1037; Berry (Illumina) Tr. 864; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.)

[redacted]

[redacted]

[redacted] Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4259. [redacted]

(PX7055 (Otte (Freenome) IHT at 113-6) (*in camera*)).

Response to Finding No. 4259:

The proposed finding is incomplete and misleading to the extent that it suggests that Illumina's work to assure its customers that they would be treated fairly ended with the first letter of intent. To the contrary, based on what was learned in this customer outreach, Illumina developed the Open Offer to extend to all of its U.S. oncology customers to address concerns raised by both Complaint Counsel and certain customers that the Illumina-GRAIL transaction would allow Illumina to foreclose GRAIL rivals. (PFF ¶¶ 990–91; *see* Berry (Illumina) Tr. 688–89, 709–10, 857, [redacted]; deSouza (Illumina) Tr. 2338–39, 2401; Goswami (Illumina) Tr. 3207; PX0064 (Illumina) at 1; [redacted].).

The Open Offer specifically addressed Freenome's concerns, and in fact, provided additional protections. [redacted]

[redacted] The Open Offer is *12-year* supply agreement. (PFF ¶ 1000; Berry (Illumina) Tr. 690–91, 861, 874–75; Conroy (Exact/Thrive) Tr. 1725; deSouza (Illumina) Tr. 2402; PX0064 (Illumina) at 5.) The Open Offer provides MFN pricing relative to both GRAIL and any other For-Profit Entity. (PFF ¶¶ 1017–18; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 7–8.) And the Open Offer assures an uninterrupted supply of core consumables. (*See* PFF ¶¶ 1000, 1005, 1007, 1009, 1011, 1037; [redacted]; Berry (Illumina) Tr. 690–91, 861, 864, 874–75, 878–79, 883; Conroy (Exact/Thrive) 1725; deSouza (Illumina) Tr. 2402, 2434–35, 2437–38; PX0064 (Illumina) at 5–6, 9; RX3935 (Illumina) at 2; RX6002 (Guerin-Calvert Trial Dep. at 59–60, 77–79.)

[redacted] The Open Offer provides that customers can terminate the supply relationship with Illumina at any time and without specifying any reason. (PFF ¶ 1001; Berry (Illumina) Tr. 862–63; deSouza (Illumina) Tr. 2402; PX0064 (Illumina) at 10.). It also requires that "Illumina cannot terminate this Supply Agreement for convenience during the Term." (PFF ¶ 1002; PX0064 (Illumina) at 10; *see also* (Berry (Illumina) Tr. 863; deSouza (Illumina) Tr. 2402.) [redacted], but as noted the Open Offer provides for a 12-year term.

[redacted] The Open Offer provides customers with protections relating to IP. For example, under the Open Offer, Illumina commits to give customers a right under Illumina's core intellectual property to use its sequencing instruments and core consumables. (PFF ¶ 1036; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.) Further, under the Open Offer, Illumina commits that it will not have the right to cease shipments of the products solely on the basis of a claim of infringement of Illumina's intellectual property rights. (PFF ¶ 1037; Berry (Illumina) Tr. 864; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.)

[redacted]

Finally, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4260. [redacted] (PX7055 (Otte (Freenome) IHT at 116-17) (*in camera*)).

Response to Finding No. 4260:

Respondents incorporate their responses to CCFF ¶ 4259 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4261. [redacted] (PX7055 (Otte (Freenome) IHT at 117-18) (*in camera*)).

Response to Finding No. 4261:

The proposed finding relates to irrelevant subject matter [redacted] Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4262. [redacted] (PX8375 (Freenome) at 003 (Email from G. Otte, Freenome, to M. Nolan et. al, Freenome, Oct. 9, 2020) (*in camera*)).

Response to Finding No. 4262:

Respondents incorporate their responses to CCFF ¶ 4259 herein.

4263. [redacted] (PX7055 (Otte (Freenome) IHT at 118-19) (*in camera*)).

Response to Finding No. 4263:

Respondents incorporate their responses to CCFF ¶ 4259 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4264. [redacted] (PX7055 (Otte (Freenome) IHT at 120-11) (*in camera*)).

Response to Finding No. 4264:

Respondents incorporate their responses to CCFF ¶ 4259 herein. [redacted] (PFF ¶ 1000; Berry (Illumina) Tr. 690–91, 861, 874–75; Conroy (Exact/Thrive) Tr. 1725; deSouza (Illumina) Tr. 2402; PX0064 (Illumina) at 5.) Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4265. [redacted]

(PX7094 (Nolan (Freenome) Dep. at 166) (*in camera*)).

Response to Finding No. 4265:

Respondents incorporate their responses to CCFF ¶¶ 4258–59 herein.

4266. [redacted]

[redacted] (PX7094 (Nolan (Freenome) Dep. at 165-67) (*in camera*)).

Response to Finding No. 4266:

Respondents incorporate their responses to CCFF ¶¶ 4258–59 herein.

4267. [redacted] (PX7055 (Otte (Freenome) IHT at 129-30) (*in camera*)).

Response to Finding No. 4267:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina worked to assuage customers' concerns about the merger and assure customers that their relationship with Illumina would not change post-acquisition. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4268. [redacted] (PX7055 (Otte (Freenome) IHT at 129) (*in camera*); PX8375 (Freenome) at 001 (Email from G. Otte, Freenome, to M. Nolan et. al, Freenome, Oct. 9, 2020) (*in camera*)).

Response to Finding No. 4268:

Respondents incorporate their responses to CCFF ¶ 4259 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4269. [redacted] (PX7055 (Otte (Freenome) IHT at 129-30) (*in camera*)).

Response to Finding No. 4269:

Respondents incorporate their responses to CCFF ¶ 4259 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4270. [redacted] (*in camera*)).

Response to Finding No. 4270:

Respondents incorporate their responses to CCFF ¶ 4259 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

c) Concerns Regarding Illumina's Acquisition of Grail Expressed by Illumina Customers

(1) [redacted]

4271. [redacted]

Response to Finding No. 4271:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶ 4259 herein.

4272. [redacted]

Response to Finding No. 4272:

Respondents incorporate their responses to CCFF ¶ 4271 herein.

4273. [redacted]

Response to Finding No. 4273:

Respondents incorporate their responses to CCFF ¶ 4271 herein.

4274. [redacted]

Response to Finding No. 4274:

Respondents incorporate their responses to CCFF ¶ 4271 herein. [redacted] (Berry (Illumina) Tr. 969), was created to allay those concerns and ensure that Illumina treats its customers fairly relative to GRAIL and to each other. (*See* PFF ¶¶ 997–1057.) Further, contrary to Mr. Nolan's testimony, Illumina is not the sole supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.)

4275. [redacted]

Response to Finding No. 4275:

Respondents have no specific response except to note that, [redacted] Further, the proposed finding relies on IH

testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4276. [redacted]

Response to Finding No. 4276:

The proposed finding is incomplete and misleading. At trial, Ms. Berry testified about [redacted]

[redacted]

(2) [redacted]

4277. [redacted]

Response to Finding No. 4277:

The proposed finding is incomplete and misleading. [redacted] But the Open Offer forbids Illumina (under the "no-obsolescence term") from discontinuing products that any oncology customer has purchased in the prior year. ([redacted]; Berry (Illumina) Tr. 883; PX0064 (Illumina) at 6; [redacted].) Thus, customers can ensure that they keep their current products. [redacted]

[redacted] But the Open Offer ensures that customers are treated equitable with respect to pricing relative to both GRAIL and to any other For-Profit Entity. (PFF ¶¶ 1013–19; Berry (Illumina) Tr. 889–90, 892–94, 902–03, 914; deSouza (Illumina) Tr. 2402–03; PX0064 (Illumina) at 7–8.) Further, the Open Offer prevents Illumina from raising prices for the entire 12-year term and even requires Illumina to lower certain prices by 2025 by at least 43%. PFF ¶¶ 1021–23; [redacted]; Berry (Illumina) Tr. 899–904 ; Conroy (Exact/Thrive) Tr. 1731–32; PX0064 (Illumina) at 7; [redacted].)

[redacted] However, the Open Offer requires Illumina to provide customers with a consistent source of supply of sequencing instruments and core consumables. (*See* PFF ¶¶ 1000, 1005, 1007, 1009, 1011, 1037; [redacted]; Berry (Illumina) Tr. 690–91, 861, 864, 874–75, 878–79, 883; Conroy (Exact/Thrive) 1725; deSouza (Illumina) Tr. 2402, 2434–35, 2437–38; PX0064 (Illumina) at 5–6, 9; RX3935 (Illumina) at 2; RX6002 (Guerin-Calvert Trial Dep. at 59–60, 77–79.) The Open Offer also requires Illumina to allocate supply in an equitable manner among its customers in the event of a supply shortage. (PFF ¶ 1012; Berry (Illumina) Tr. 885–86; PX0064 (Illumina) at 9.) The Open Offer's short-supply provision ensures that customers

with the greatest need—those whose lots are expiring the earliest—will receive allocations of short supply first, rather than Illumina favoring GRAIL. (PFF ¶ 1012.4; RX6002 (Guerin-Calvert Trial Dep. at 77).) Further, [redacted] the Open Offer requires Illumina to establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (PFF ¶ 1039; [redacted]; deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted].)

[redacted] But under the Open Offer, if Illumina created a new product or an improved version of an existing product, Illumina would be required to provide potential GRAIL rivals with access to it within 5 days of GRAIL or any other For-Profit Entity receiving access. (PFF ¶¶ 1005–1005.2; deSouza (Illumina) Tr. 2448; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) Further, the Open Offer requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶ 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.) This term not only prevents Illumina from disadvantaging GRAIL rivals, but also requires Illumina to act in a particular way to support rivals developing their own competitive products. (PFF ¶ 1010.9; RX6002 (Guerin-Calvert Trial Dep. at 68).)

Moreover, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4278. [redacted]

Response to Finding No. 4278:

Respondents incorporate their responses to CCFF ¶ 4277 herein.

4279. [redacted]

Response to Finding No. 4279:

Respondents incorporate their responses to CCFF ¶ 4277 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4280. [redacted]

Response to Finding No. 4280:

Respondents incorporate their responses to CCFF ¶ 4277 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4281. [redacted]

Response to Finding No. 4281:

Respondents incorporate their responses to CCFF ¶ 4277 herein.

4282. [redacted]

Response to Finding No. 4282:

Respondents incorporate their responses to CCFF ¶ 4277 herein.

4283. [redacted]

Response to Finding No. 4283:

Respondents incorporate their responses to CCFF ¶ 4277 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4284. [redacted]

Response to Finding No. 4284:

Respondents incorporate their responses to CCFF ¶ 4277 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4285. [redacted]

Response to Finding No. 4285:

Respondents incorporate their responses to CCFF ¶ 4277 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4286. [redacted]

Response to Finding No. 4286:

Respondents incorporate their responses to CCFF ¶ 4277 herein. Additionally, Illumina is not the sole supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.) Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4287. [redacted]

[redacted]

Response to Finding No. 4287:

The proposed finding is inaccurate, incomplete and misleading. [redacted] Specifically, the Open Offer forbids Illumina (under the "no-obsolescence term") from discontinuing products that any oncology customer has purchased in the prior year. ([redacted]; Berry (Illumina) Tr. 883; PX0064 (Illumina) at 6; [redacted].) Thus, customers can ensure that they keep their current products. [redacted]

Moreover, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4288. [redacted]

[redacted]

Response to Finding No. 4288:

The proposed finding is inaccurate, incomplete and misleading. Under the Open Offer, which Illumina offered to Exact/Thrive (Berry (Illumina) Tr. 980), Illumina commits to give customers a right under Illumina's core intellectual property to use its sequencing instruments and core consumables. (PFF ¶ 1036; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.) [redacted] Moreover, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4289. [redacted]

Response to Finding No. 4289:

Respondents incorporate their responses to CCFF ¶ 4288 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4290. [redacted]

[redacted]

Response to Finding No. 4290:

The proposed finding is inaccurate, incomplete and misleading. The Open Offer, [redacted] forbids Illumina (under the "no-obsolescence term") from discontinuing products that any oncology customer has purchased in the prior year. (PFF ¶ 1011; [redacted]; Berry (Illumina) Tr. 883; PX0064 (Illumina) at 6; [redacted].) Thus, customers can ensure that they keep their current products. [redacted]

Additionally, the Open Offer requires Illumina to provide to provide documentation to assist customers with FDA approval or marketing authorization to sell a for-profit, clinical test using Illumina's sequencing instruments and core consumables. (PFF ¶ 1027; PX0064 (Illumina) at 8; PX7093 (Young Dep. at 68).)

Finally, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4291. [redacted]

Response to Finding No. 4291:

The proposed finding is incomplete and misleading. The Open Offer, [redacted] requires Illumina to provide customers with a consistent source of supply of sequencing instruments and core consumables. (*See* PFF ¶¶ 1000, 1005, 1007, 1009, 1011, 1037; [redacted]; Berry (Illumina) Tr. 690–91, 861, 864, 874–75, 878–79, 883; Conroy (Exact/Thrive) 1725; deSouza (Illumina) Tr. 2402, 2434–35, 2437–38; PX0064 (Illumina) at 5–6, 9; RX3935 (Illumina) at 2; RX6002 (Guerin-Calvert Trial Dep. at 59–60, 77–79.) Moreover, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4292. [redacted]

Response to Finding No. 4292:

The proposed finding is incomplete and misleading. The Open Offer, [redacted] requires Illumina to provide customers, within 5 days, with the same information that GRAIL receives about final product specifications of any sequencing instruments or core consumables. (PFF ¶ 1006; RX3935 (Illumina) at 2.) Considering the length of time that it takes to develop a test on a sequencing platform, 5 days (or even 45 days) is "a very inconsequential amount of time" for a developer making a test. (*see* Aravanis (Illumina) Tr. 1930; *see also* Berry (Illumina) Tr. 702–03; [redacted]

[redacted] Moreover, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4293. [redacted]

Response to Finding No. 4293:

Respondents have no specific response except to note that there is no evidence that [redacted] (*See* PFF ¶¶ 418–43.) Moreover, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4294. [redacted]

Response to Finding No. 4294:

Respondents have no specific response.

4295. [redacted]

Response to Finding No. 4295:

Respondents have no specific response except to note that at trial, Mr. deSouza [redacted]

[redacted]

Further, there is no evidence that [redacted] (*See* PFF ¶¶ 418–43.) In fact, Mr. Conroy himself admitted that [redacted]

4296. [redacted]

Response to Finding No. 4296:

The proposed finding is incomplete and misleading to the extent that it suggests Illumina is the only supplier of NGS products. To the contrary, Illumina is not the sole supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.)

4297. [redacted]

Response to Finding No. 4297:

Respondents incorporate their responses to CCFF ¶ 4296 herein.

4298. [redacted]

Response to Finding No. 4298:

Respondents incorporate their responses to CCFF ¶¶ 4295–96 herein.

4299. [redacted]

Response to Finding No. 4299:

Respondents incorporate their responses to CCFF ¶¶ 4295–96 herein. Further, the Open Offer, [redacted] fully addresses any alleged incentives by Illumina to foreclose GRAIL rivals. (PFF ¶ 1082; RX6002 (Guerin-Calvert Trial Dep. at 20–21, 108–09).) The Open Offer's provisions in their totality also ensure that Illumina's incentives are to support GRAIL's rivals. (PFF ¶ 1082.2–1082.4; *see* RX6002 (Guerin-Calvert Trial Dep. at 20–22, 108–09; RX6000 (Carlton Trial Dep. at 84–85).)

4300. [redacted]

[redacted]

Response to Finding No. 4300:

Respondents have no specific response except to note that while Mr. Conroy testified

[redacted]

4301. [redacted]

Response to Finding No. 4301:

Respondents incorporate their responses to CCFF ¶ 4302 herein.

4302. [redacted]

[redacted] (*in camera*)).

Response to Finding No. 4302:

The proposed finding is incomplete and misleading. At the outset, Dr. Lengauer admitted that [redacted] Post-merger, Illumina cannot make changes that favor one test developer over another, because under the Open Offer, [redacted] if Illumina created a new product or an improved version of an existing product, Illumina would be required to provide potential GRAIL rivals with access to it within 5 days of GRAIL or any other For-Profit Entity receiving access. (PFF ¶¶ 1005–1005.2; deSouza (Illumina) Tr. 2448; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) Further, the Open Offer requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶ 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.)

Further, the Open Offer affirmatively requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize

interoperability with the customer's tests. (PFF ¶ 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.) This not only prevents Illumina from disadvantaging potential GRAIL rivals, but also requires Illumina to act in a particular way to support customers developing competing products. (PFF ¶ 1010.10; RX6002 (Guerin-Calvert Trial Dep. at 70–71).)

(3) Guardant's Concerns

4303. Illumina's acquisition of Grail "presents a challenge on multiple fronts to Guardant." (PX7040 (Getty (Guardant) IHT at 160)).

Response to Finding No. 4303:

Respondents incorporate their responses to CCFF ¶¶ 4304–05 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4304. Illumina's acquisition of Grail "challenges [Guardant's] ability to be successful as a company in the screening market. And interestingly enough, it also challenges [Guardant's] ability to be competitive in any other portion of the market, because if we see on portion of the business fail, it could have such a negative impact on the broader organization and the market cap of the organization because [Guardant is] not in that business that, you know, the fuel for even those smaller opportunities like therapy selection are irreparably harmed, and therefore, patients are as well because there's just not as many opportunities." (PX7040 (Getty (Guardant) IHT at 160)).

Response to Finding No. 4304:

The proposed finding is inaccurate, incomplete and misleading. Contrary to the testimony of Mr. Getty here, the acquisition does not challenge Guardant's ability to be successful as a company in the screening market. As Mr. deSouza testified, [redacted]

[redacted] Moreover, to the extent that customers have any concerns about the relationship between Illumina and its customers post-acquisition, the Open Offer was created to allay those concerns and ensure that Illumina treats its customers fairly relative to GRAIL and to each other. (*See* PFF ¶¶ 997–1057.) Because the acquisition does not harm Guardant in the screening market, there is also no basis to conclude that the acquisition would harm Guardant in other markets. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents also incorporate their responses to CCFF ¶ 4305 herein.

4305. Illumina could hinder Guardant's ability to compete in the screening market in at least three critical ways: first, Illumina could increase the pricing for Guardant's non-screening oncology product, for example, Guardant360, which can hamstring the dollars Guardant can push towards screening. (PX7040 (Getty (Guardant) IHT at 161). Second, Illumina could gain visibility into Guardant's business. Mr. Getty testified that Illumina "could very easily have an advantage to understand what it is [Guardant's] doing, what type of volume… and then target accordingly." (PX7040 (Getty (Guardant) IHT at 161-62). Third, in the downstream distribution of Guardant's screening test Illumina could hinder the distribution of a kitted Guardant product. (PX7040 (Getty (Guardant) IHT at 162)).

Response to Finding No. 4305:

The proposed finding is inaccurate, incomplete and misleading. [redacted]

[redacted]

Guardant attached the amended supply agreement to its 2020 10–K because the amended agreement represented a material and important contract for Guardant. (PFF ¶ 1075.4; Getty (Guardant) Tr. 2668–69; PX0060 (Guardant) at 151.) In its negotiations with Illumina, Guardant never indicated to Illumina that Guardant viewed its amended supply agreement as, in substance, unenforceable or worthless. (PFF ¶ 1075.5; Getty (Guardant) Tr. 2669.)

Moreover, the Open Offer [redacted] provides even greater protections. The Open Offer includes most-favored-nation pricing and confidentiality provisions [redacted]. (PFF ¶¶ 1017–18, 1038–39; [redacted]; Berry (Illumina) Tr. 893, 916–17; PX0064 (Illumina) at 7–10.) Further, the Open Offer also commits Illumina not to increase prices beyond inflation for the 12–year term of the agreement. (PFF ¶ 1021; [redacted]; Berry (Illumina) Tr. 899; Conroy (Exact/Thrive) Tr. 1731; PX0064 (Illumina) at 7; [redacted] Under the Open Offer,

Illumina also agrees that by 2025, it will continue its pre-merger approach to reducing sequencing pricing and reduce the pricing of sequencing by at least 43%, regardless of whether a customer is receiving Grandfathered Pricing or Universal Pricing. (PFF ¶ 1023; [redacted]; Berry (Illumina) Tr. 712–13, 897, 903–04; Conroy (Exact/Thrive) Tr. at 1731–32; deSouza (Illumina) Tr. 2403; PX0064 (Illumina) at 7; [redacted] Additionally, the Open Offer requires Illumina, on a customer's request, to enter into a separate agreement with the customer based on standardized terms to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33; [redacted]; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; [redacted].) These requirements in the Open Offer prevent Illumina from withholding support as MCED test developers seek FDA approval. (PFF ¶ 1035; RX6002 (Guerin-Calvert Trial Dep. at 74).)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4306. Guardant's Mr. Getty testified that he has concerns about Guardant's "reliance on Illumina, and the cost of that reliance is significant." (PX7040 (Getty (Guardant) IHT at 133-34, 162) ("Illumina controls Guardant as much as anything… because it's inescapable to move away from Illumina")).

Response to Finding No. 4306:

Respondents have no specific response except to note that, contrary to Mr. Getty's testimony, customers do not need to rely on Illumina's products to develop screening tests. Illumina is not the sole supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.) Further, the proposed finding relies on IH

testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4307. Mr. Getty is concerned that post-acquisition "Illumina will be acutely aware of [Guardant's] development exercises by simply knowing what [Guardant is] purchasing from them." (PX7040 (Getty (Guardant) IHT at 133-34)). Illumina could then "easily [] increase the cost" of its products "such that [Guardant] couldn't pursue that new development" and therefore would be "less competitive with [Guardant's] product." (PX7040 (Getty (Guardant) IHT at 133-34)).

Response to Finding No. 4307:

Respondents incorporate their responses to CCFF ¶ 4305 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4308. Mr. Getty is concerned that post-acquisition, Illumina would be able to interfere in Guardant's efforts to improve the sensitivity and innovation of its cancer tests. (PX7040 (Getty (Guardant) IHT at 136-38)).

Response to Finding No. 4308:

The proposed finding is incomplete and misleading. The Open Offer [redacted] not only prevents Illumina from interfering in Guardant's efforts, but affirmatively requires Illumina to support those efforts. Even though Illumina typically has not provided support in the development or commercialization of customers' products, to provide additional benefits to customers, the Open Offer requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶ 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.) This not only prevents Illumina from disadvantaging GRAIL rivals, but also requires Illumina to act in a particular way to support rivals developing their own competitive products. (PFF ¶ 1010.9; RX6002 (Guerin-Calvert Trial Dep. at 68).)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4309. Mr. Getty is further concerned with acquisition's "downstream impact" on patients because patients would "not have a product that was most sensitive, that could find the disease early and help treat those patients." (PX7040 (Getty (Guardant) IHT at 135)).

Response to Finding No. 4309:

Respondents incorporate their responses to CCFF ¶ 4308 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4310. Mr. Getty is also concerned with what he calls a more "nefarious potential" of Illumina's acquisition of Grail:

> [Where] you have a competitor who controls essentially your margins, and so, you know– and they– and internally Illumina obviously, you know, wants the most profitable product and can do things at a lower cost because they are the manufacturer of the reagent, and so not only could they copy what [Guardant is] doing, they could do it at a lower cost, maximize their own profitability, and slowly squeeze [Guardant] into a position of being completely uncompetitive or, you know, potentially not able to support the innovation that [Guardant] would need or the innovation [Guardant would] want to pursue.

(PX7040 (Getty (Guardant) IHT at 135)).

Response to Finding No. 4310:

The proposed finding is incomplete and misleading. The Open Offer [redacted] allows customers to receive most-favored-nations pricing protections relative to GRAIL. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 7–8.) The Open Offer also commits Illumina not to increase prices beyond inflation for the 12–year term of the agreement. (PFF ¶ 1021; [redacted]; Berry (Illumina) Tr. 899; Conroy (Exact/Thrive) Tr. 1731; PX0064 (Illumina) at 7; [redacted] And, under the Open Offer, Illumina also agrees that by 2025, it

will continue its pre-merger approach to reducing sequencing pricing and reduce the pricing of sequencing by at least 43%, regardless of whether a customer is receiving Grandfathered Pricing or Universal Pricing. [redacted]; Berry (Illumina) Tr. 712–13, 897, 903–04; Conroy (Exact/Thrive) Tr. at 1731–32; deSouza (Illumina) Tr. 2403; PX0064 (Illumina) at 7; [redacted]

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4311. As relating to Guardant's LUNAR-2 test Guardant has concerns because the cancer screening market is the "absolute golden goose" and "the underpinning of a lot of companies' valuations" including Guardant's. (PX7040 (Getty (Guardant) IHT at 158-9)).

Response to Finding No. 4311:

Respondents incorporate their responses to CCFF ¶¶ 4304–05, 4308 and 4310. Further, Respondents note that [redacted] (PFF ¶ 849.1; deSouza (Illumina) Tr. 2291.) Because Illumina's "core business is to sell sequencers and consumables", its "strong incentive is to continue to be successful selling sequencers and consumables into the market segments that we serve." (PFF ¶ 849.1; deSouza (Illumina) Tr. 2378.) Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4312. Mr. Getty testified that he had concerns that the proposed acquisition between Illumina and Grail would have an impact on the cancer screening market as a whole:

> [I]f you take aside Guardant Health, as a, you know, business, let's imagine for a moment that, you know, we never make it into the screening game. We decide for whatever reason we don't pursue it. The acquisition of Grail by Illumina

> impacts every other company out there pursuing these technologies in the same way it could potentially disenfranchise Guardant. But the impact of that is real. It's patients that are actually impacted. And so by creating this sort of vertically integrated diagnostic player, you've taken the incentives out of the market for all these other companies to pursue the technologies.

(PX7040 (Getty (Guardant) IHT at 179-81)).

Response to Finding No. 4312:

Respondents have no specific response except to note that the weight of the evidence shows that the benefits of the Transaction more than offset any alleged harm. (*See* PFF ¶¶ 1106–79.) Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4313. Mr. Getty testified that his concerns over the proposed acquisition are heightened because there is no replacement for Illumina and there will not be anytime soon, so "it means that, you know, the whole of patients will be negatively impacted." (PX7040 (Getty (Guardant) IHT at 181)).

Response to Finding No. 4313:

The proposed finding is inaccurate, incomplete and misleading. Illumina is not the sole supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.) Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4314. Mr. Getty has concerns about Illumina and Grails combined intellectual property portfolio post-acquisition. (PX7040 (Getty (Guardant) IHT at 192-93) (stating that "intellectual property is a very important component" and "it forms a moat for others to have– to have to penetrate in order to, you know, be a formidable competitor. And so, you know, the intersection of the IP associated with a company who owns all the underlying technology and then, you know, potentially layering on additional patents on top of that, you know, it creates a rather challenging dynamic for other companies to potentially develop competing modalities that leverage that underlying technology because there's an intersection there")).

Response to Finding No. 4314:

Respondents have no specific response except to note that the Open Offer [redacted] contains protections for customers relating to intellectual property. For example, under the Open Offer, Illumina commits to give customers a right under Illumina's core intellectual property to use its sequencing instruments and core consumables. (PFF ¶ 1036; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.)

Further, under the Open Offer, Illumina commits that it will not have the right to cease shipments of the products solely on the basis of a claim of infringement of Illumina's intellectual property rights. (PFF ¶ 1037; Berry (Illumina) Tr. 864; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.) This provision applies even if Illumina has a legitimate claim of infringement. (PFF ¶ 1037.2; RX6002 (Guerin-Calvert Trial Dep. at 78).) [redacted] This provision effectively addresses the foreclosure concern that Illumina could disrupt supply to GRAIL rivals. (PFF ¶ 1037.3; *see* RX6002 (Guerin-Calvert Trial Dep. at 77–79).)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4315. Mr. Getty testified that he anticipates that the Illumina-Grail intellectual property portfolio will impact Guardant's decisions on innovating going forward. (PX7040 (Getty (Guardant) IHT at 193) (adding that "in large part everyone is dependent on Illumina," and that if Illumina were to "suggest that there is some, you know, infringement ongoing," that "[i]t just may stop you in your track to say, Wow, we can't afford to fight with them")).

Response to Finding No. 4315:

Respondents incorporate their responses to CCFF ¶ 4314 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4316. Illumina asked Guardant to sign a disclosure saying that Guardant was not concerned about Illumina's proposed acquisition of Grail. (PX7040 (Getty (Guardant) IHT at 190)).

Response to Finding No. 4316:

The proposed finding is directed to irrelevant subject matter because Guardant's decision not to sign a disclosure in support of the acquisition is immaterial to Illumina's incentive or ability to foreclose Guardant or other potential GRAIL rivals. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4317. Illumina sent Guardant this disclosure at the beginning of 2021. (PX7040 (Getty (Guardant) IHT at 191)).

Response to Finding No. 4317:

Respondents incorporate their responses to CCFF ¶ 4316 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4318. Illumina's Mr. Welland drafted Illumina's disclosure that it sent to Guardant. (PX7040 (Getty (Guardant) IHT at 191)).

Response to Finding No. 4318:

Respondents incorporate their responses to CCFF ¶ 4316 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4319. Guardant did not sign Illumina's disclosure because they "have some major concerns with the acquisition of Grail." (PX7040 (Getty (Guardant) IHT at 192)).

Response to Finding No. 4319:

Respondents incorporate their responses to CCFF ¶¶ 4304–14 and 4316 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(4) [redacted]

4320. [redacted]

Response to Finding No. 4320:

The proposed finding is incomplete and misleading. [redacted] under the Open Offer, Illumina commits to give customers a right under Illumina's core intellectual property to use its sequencing instruments and core consumables. (PFF ¶ 1036; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.) Illumina also commits that commits that it will not have the right to cease shipments of the products solely on the basis of a claim of infringement of Illumina's intellectual property rights. (PFF ¶ 1037; Berry (Illumina) Tr. 864; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.) Further, the Open Offer requires Illumina to provide customers with a consistent source of supply of sequencing instruments and core consumables. (*See* PFF ¶¶ 1000, 1005, 1007, 1009, 1011, 1037; [redacted]; Berry (Illumina) Tr. 690–91,

861, 864, 874–75, 878–79, 883; Conroy (Exact/Thrive) 1725; deSouza (Illumina) Tr. 2402, 2434–35, 2437–38; PX0064 (Illumina) at 5–6, 9; RX3935 (Illumina) at 2; RX6002 (Guerin-Calvert Trial Dep. at 59–60, 77–79.) And, the Open Offer ensures that customers will continue to receive access to the same product and support services to which they had access before the Transaction. (*See* PFF ¶¶ 1004.1, 1004.9; [redacted]; Berry (Illumina) Tr. 865–66; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 58).) [redacted]

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4321. [redacted]

Response to Finding No. 4321:

The proposed finding is incomplete and misleading. *First*, the weight of the evidence shows that when Illumina acquired Verinata, it continued to support downstream rivals, Illumina helped grow the NIPT space, and innovation and competition flourished to the benefit of patients. (*See* PFF ¶¶ 950–963.)

Second, the Open Offer [redacted] requires Illumina to provide FDA support even though typically Illumina has a "very minimal

role" in the FDA approval process. (PFF ¶ 1414–15; Goswami (Illumina) Tr. 3187–88.) Specifically, the Open Offer requires Illumina to provide to provide documentation to assist customers with FDA approval or marketing authorization to sell a for-profit, clinical test using Illumina's sequencing instruments and core consumables. (PFF ¶ 1027; PX0064 (Illumina) at 8; [redacted].) It also requires Illumina, on a customer's request, to enter into a separate agreement with the customer based on standardized terms to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33; [redacted]; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; [redacted].) These requirements in the Open Offer prevent Illumina from withholding support as MCED test developers seek FDA approval. (PFF ¶ 1035; RX6002 (Guerin-Calvert Trial Dep. at 74).)

Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4322. [redacted]).

Response to Finding No. 4322:

Respondents have no specific response except to note that the Open Offer [redacted] requires Illumina, on a customer's request, to enter into a separate agreement with the customer based on standardized terms to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33; [redacted]; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; [redacted].) This requirement in the Open Offer prevents Illumina from withholding support as MCED test developers seek FDA approval. (PFF ¶ 1035; RX6002 (Guerin-Calvert Trial Dep. at 74).) Respondents also incorporate their responses to CCFF ¶ 4321 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(5) [redacted]

4323. [redacted]

Response to Finding No. 4323:

Respondents have no specific response except to note that Dr. Chahine's views on this acquisition or on antitrust law are not probative as to Illumina's actual incentives or abilities to foreclose potential GRAIL rivals.

4324. [redacted]

Response to Finding No. 4324:

Respondents incorporate their responses to CCFF ¶ 4323 herein.

4325. [redacted]

Response to Finding No. 4325:

Respondents have no specific response except to note that the weight of the evidence shows that the Open Offer [redacted] provides the economically necessary terms to prevent any alleged anticompetitive harms from the transaction in both the short term and the long term. (RX6002 (Guerin-Calvert Trial Dep. at 21–22).) The Open Offer also represents an improvement for customers over the pre-merger status quo. (RX6002 (Guerin-Calvert Trial Dep. at 37, 52–53, 57); *see also* RX6000 (Carlton Trial Dep. at 48).)

4326. [redacted]

Response to Finding No. 4326:

Respondents have no specific response except to note that the Open [redacted] expressly prohibits Illumina from sharing any customer confidential information with GRAIL or its subsidiaries or employees, or with Illumina employees who work with GRAIL, and requires Illumina to establish a firewall that prohibits the flow of customer confidential information between Illumina and GRAIL. (PFF ¶ 1038–39; [redacted]; Berry (Illumina) Tr. 916–17;

PX0064 (Illumina) at 9–10.) Moreover, Dr. Chahine agreed that implementing the firewall in the Open Offer would mitigate concerns about the potential for sharing sensitive information between Illumina and GRAIL. (PFF ¶ 1039.7; PX7077 (Chahine (Helio) Dep. at 123–24.)

4327. [redacted]

Response to Finding No. 4327:

The proposed finding is incomplete and misleading. In the portion of Dr. Chahine's testimony cited here, Dr. Chahine admitted that [redacted] Respondents further incorporate their responses to CCFF ¶ 4325.

4328. [redacted]

Response to Finding No. 4328:

Respondents incorporate their responses to CCFF ¶¶ 4325 and 4327 herein.

4329. [redacted]

Response to Finding No. 4329:

Respondents incorporate their responses to CCFF ¶¶ 4325 and 4327 herein.

4330. [redacted]

Response to Finding No. 4330:

Respondents incorporate their responses to CCFF ¶¶ 4325 and 4327 herein.

(6) [redacted]

4331. [redacted]

Response to Finding No. 4331:

The proposed finding is incomplete and misleading. [redacted] This provision was incorporated into the Open Offer (PFF 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.) [redacted]

4332. [redacted]

The proposed finding is incomplete and misleading. In the portion of Ms. Perettie's testimony cited here, Ms. Perettie provided context for this answer: [redacted]

[redacted]

4333. [redacted]

Response to Finding No. 4333:

The proposed finding is incomplete and misleading. [redacted]

[redacted] Illumina commits to give customers a right under Illumina's core intellectual property to use its sequencing instruments and core consumables. (PFF ¶ 1036; deSouza (Illumina) Tr.

2405; PX0064 (Illumina) at 9.) [redacted] Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4334. [redacted]

Response to Finding No. 4334:

Respondents incorporate their responses to CCFF ¶ 4333 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4335. [redacted]

Response to Finding No. 4335:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

does. For example, under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (PFF ¶ 1039; [redacted]; deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted].) Illumina is very familiar with how to set up and operate this kind of confidentiality provision because it already shields confidential information in other contexts. (PFF ¶ 1041.3; Goswami (Illumina) Tr. 3231.) [redacted]

The Open Offer's firewall provision will have the characteristics of an effective firewall,

specifically: monitoring and auditing, methods to report violations and consequences for violations. (PFF ¶¶ 1041.5, 1100; RX6002 (Guerin-Calvert Trial Dep. at 84–85).)

The Open Offer also requires Illumina to provide customers with a consistent source of supply of sequencing instruments and core consumables. (*See* PFF ¶¶ 1000, 1005, 1007, 1009, 1011, 1037; [redacted]; Berry (Illumina) Tr. 690–91, 861, 864, 874–75, 878–79, 883; Conroy (Exact/Thrive) 1725; deSouza (Illumina) Tr. 2402, 2434–35, 2437–38; PX0064 (Illumina) at 5–6, 9; RX3935 (Illumina) at 2; RX6002 (Guerin-Calvert Trial Dep. at 59–60, 77–79.) The provisions on access to products address the concern that products could be withheld so as to disadvantage potential GRAIL rivals because they require providing equivalent access within a very short time frame. (PFF ¶ 1009.1; RX6002 (Guerin-Calvert Trial Dep. at 60).)

Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4336. [redacted]

Response to Finding No. 4336:

The proposed finding is incomplete and misleading. [redacted]

[redacted] Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4337. [redacted]

Response to Finding No. 4337:

Respondents incorporate their responses to CCFF ¶ 4336 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

d) [redacted]

(1) [redacted]

4338. [redacted]

Response to Finding No. 4338:

Respondents have no specific response except to note that, [redacted] (Berry (Illumina) Tr. 975.) Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4339. [redacted]

Response to Finding No. 4339:

The proposed finding is incomplete and misleading because the term [redacted]

4340. [redacted]

Response to Finding No. 4340:

Respondents have no specific response except to note that, [redacted] (Berry (Illumina) Tr. 975.)

4341. [redacted]

Response to Finding No. 4341:

Respondents have no specific response.

4342. [redacted]

Response to Finding No. 4342:

Respondents have no specific response.

4343. [redacted]

Response to Finding No. 4343:

The proposed finding is inaccurate, incomplete and misleading. [redacted]

(Berry (Illumina) Tr. 975.)

4344. [redacted]

Response to Finding No. 4344:

Respondents have no specific response.

4345. [redacted]

Response to Finding No. 4345:

Respondents have no specific response except to note that [redacted]

4346. [redacted]

Response to Finding No. 4346:

Respondents have no specific response except to note that Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial

in this case, (CC Exhibit Index at 61), and therefore should not be entitled to rely on it to establish anything beyond the words on the page.

4347. [redacted]

Response to Finding No. 4347:

The proposed finding is incomplete and misleading because [redacted]

[redacted] Finally, Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 61), and therefore should not be entitled to rely on it to establish anything beyond the words on the page.

4348. [redacted]

Response to Finding No. 4348:

Respondents incorporate their responses to CCFF ¶ 4347 herein. Further, the Open Offer, [redacted] provides for most-favored nations pricing that ensures customers are treated no less favorably than GRAIL or any other For-Profit Entity in terms of pricing. (PFF ¶¶ 1017–19; Berry (Illumina) Tr. 893–94, 914; PX0064 (Illumina) at 7–8.)

4349. [redacted]

Response to Finding No. 4349:

Respondents incorporate their responses to CCFF ¶¶ 4347–48 herein.

4350. [redacted]

Response to Finding No. 4350:

Respondents incorporate their responses to CCFF ¶¶ 4347–48 herein.

4351. [redacted]

Response to Finding No. 4351:

Respondents incorporate their responses to CCFF ¶¶ 4347–48 herein. Further, the Open Offer, [redacted] requires Illumina to engage in a biannual audit to ensure compliance with the Open Offer. (PFF ¶ 1047; deSouza (Illumina) Tr. 2405, 2438; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.) If a customer has a good-faith basis for alleging that Illumina is in breach of the Open Offer, Illumina will engage an auditor to assess the customer's allegation separate from the biannual audits. (PFF ¶ 1047; PX0064 (Illumina) at 10.) Illumina is obligated to provide customers with a written report confirming compliance with the Open Offer's commitments. (PFF ¶ 1048; PX0064 (Illumina) at 10; PX7076 (Berry (Illumina) Dep. at 287).) Additionally, customers must be promptly notified,

within 10 days, of any potential noncompliance. (PFF ¶ 1048; deSouza (Illumina) Tr. 2478; RX3935 (Illumina) at 3.) Audits of the Open Offer provisions on pricing can ensure that Illumina's customers are not disadvantaged by enabling Illumina to improve its procedures to help prevent instances of noncompliance and by providing customers with information to help them decide whether arbitration is necessary. (PFF ¶ 1051.2; RX6003 (Rock Trial Dep. at 62–63, 66–67).)

4352. [redacted]

Response to Finding No. 4352:

Respondents incorporate their responses to CCFF ¶ 4347 herein.

4353. [redacted]

Response to Finding No. 4353:

The proposed finding is misleading and incomplete. [redacted]

[redacted]; Conroy (Exact/Thrive) Tr. 1730.)

4354. [redacted]

Response to Finding No. 4354:

Respondents incorporate their responses to CCFF ¶ 4355.

4355. [redacted]

Response to Finding No. 4355:

The proposed finding is incomplete and misleading. Specifically, Mr. Welland of Illumina stated that: [redacted] Further, the Open Offer, [redacted] provides for most-favored nations (MFN) pricing that ensures customers are treated no less favorably than

GRAIL or any other For-Profit Entity in terms of pricing. (PFF ¶¶ 1017–19; Berry (Illumina) Tr. 893–94, 914; PX0064 (Illumina) at 7–8.) The Open Offer's MFN provisions do not differentiate between sequencing instruments or core consumables; all Supplied Products are covered under the Open Offer's MFN provisions. (*See* PFF ¶¶ 1017–18; PX0064 (Illumina) at 7–8.)

4356. [redacted]

Response to Finding No. 4356:

Respondents have no specific response except to note that in the cited evidence, [redacted] Additionally, Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 61), and therefore should not be entitled to rely on it to establish anything beyond the words on the page.

4357. [redacted]

Response to Finding No. 4357:

Respondents have no specific response except to note that Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 61), and therefore should not be entitled to rely on it to establish anything beyond the words on the page.

4358. [redacted]

Response to Finding No. 4358:

Respondents have no specific response except to note that Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 61), and therefore should not be entitled to rely on it to establish anything beyond the words on the page.

4359. [redacted]

Response to Finding No. 4359:

Respondents incorporate their responses to CCFF ¶ 4361 herein. Further, Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 61), and therefore should not be entitled to rely on it to establish anything beyond the words on the page.

4360. [redacted]

Response to Finding No. 4360:

Respondents incorporate their responses to CCFF ¶ 4361 herein.

4361. [redacted]

Response to Finding No. 4361:

The proposed finding is incomplete and misleading. [redacted]

4362. [redacted]

Response to Finding No. 4362:

Respondents incorporate their responses to CCFF ¶ 4361 herein.

4363. [redacted]

Response to Finding No. 4363:

Respondents have no specific response except to note that [redacted]

[redacted] Moreover, to the extent that customers have any concerns about the relationship between Illumina and its customers post-acquisition, the Open Offer was created to allay those concerns and ensure that Illumina treats its customers fairly relative to GRAIL and to each other. (*See* PFF ¶¶ 997–1057.)

4364. [redacted]

Response to Finding No. 4364:

Respondents incorporate their responses to CCFF ¶ 4363 herein.

4365. [redacted]

Response to Finding No. 4365:

Respondents incorporate their responses to CCFF ¶ 4363 herein.

4366. [redacted]

Response to Finding No. 4366:

Respondents have no specific response except to note that [redacted]

4367. When the Illumina-Grail transaction was announced it was Mr. Conroy's expectation that Exact could reach a long-term supply agreement that would be in the mutual best interests of both Illumina and Exact. (Conroy (Exact) Tr. 1723-24).

Response to Finding No. 4367:

Respondents have no specific response except to note that [redacted]

4368. Mr. Conroy and Mr. deSouza had met on several different occasions and had several conversations. (Conroy (Exact) Tr. 1724).

Response to Finding No. 4368:

Respondents have no specific response.

4369. [redacted]

Response to Finding No. 4369:

Respondents incorporate their responses to CCFF ¶ 4361 herein.

4370. [redacted] (Conroy (Exact) Tr. 1602-03 (*in camera*)).

Response to Finding No. 4370:

Respondents incorporate their responses to CCFF ¶¶ 4361 and 4367 herein.

4371. [redacted]

Response to Finding No. 4371:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

4372. [redacted]

Response to Finding No. 4372:

Respondents have no specific response.

4373. [redacted]

Response to Finding No. 4373:

Respondents incorporate their responses to CCFF ¶ 4371 herein.

4374. [redacted]

[redacted]

Response to Finding No. 4374:

Respondents incorporate their responses to CCFF ¶ 4371 herein.

4375. [redacted]

Response to Finding No. 4375:

The proposed finding is inaccurate, incomplete and misleading. *First*, Illumina is not the sole supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.) [redacted]

4376. [redacted]

[redacted]

Response to Finding No. 4376:

Respondents incorporate their responses to CCFF ¶ 4371 herein. [redacted]

[redacted]

[redacted]

4377. [redacted]

Response to Finding No. 4377:

The proposed finding is based on hearsay and lacks support. In fact, [redacted]

4378. [redacted]

Response to Finding No. 4378:

The proposed finding is incomplete and misleading. [redacted]

4379. [redacted]

Response to Finding No. 4379:

Respondents have no specific response except to note that [redacted]

4380. [redacted]

Response to Finding No. 4380:

Respondents incorporate their responses to CCFF ¶ 4371 herein. Further, the proposed finding is incomplete and misleading. [redacted], Illumina has contractually committed that by 2025, it will continue its pre-merger approach to reducing sequencing pricing and reduce the pricing of sequencing by at least 43%. (PFF ¶ 1023; [redacted]; Berry (Illumina) Tr. 712–13, 897, 903–04; Conroy (Exact/Thrive) Tr. at 1731–32; deSouza (Illumina) Tr. 2403; PX0064 (Illumina) at 7**;** [redacted]**.)**

4381. [redacted]

[redacted]

Response to Finding No. 4381:

Respondents incorporate their responses to CCFF ¶¶ 4371 and 4380 herein.

4382. [redacted]

Response to Finding No. 4382:

Respondents incorporate their responses to CCFF ¶¶ 4371 and 4380 herein.

4383. [redacted]

Response to Finding No. 4383:

The proposed finding is incomplete and misleading. *First*, Illumina is not the sole supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.) *Second*, the weight of the evidence shows that the Open Offer, [redacted] effectively addresses any concern Illumina will have the incentive and ability to anticompetitively disadvantage GRAIL's rivals. (PFF ¶ 997; RX6002 (Guerin-Calvert Trial Dep. at 20–21).) *Third*, [redacted]

[redacted] the Open Offer expressly forbids Illumina from raising prices over the entire 12-year term and affirmatively requires Illumina to lower the price of sequencing by at least 43% by 2025. (PFF ¶ ¶ 1021–23; [redacted]; Berry (Illumina) Tr. 899, 901–04; Conroy (Exact/Thrive) Tr. 1731–32; deSouza (Illumina) Tr. 2403; PX0064 (Illumina) at 7; [redacted]

4384. [redacted]

Response to Finding No. 4384:

Respondents have no specific response except to note that [redacted]

4385. [redacted]

Response to Finding No. 4385:

Respondents have no specific response except to note that [redacted]

4386. [redacted]

Response to Finding No. 4386:

Respondents incorporate their responses to CCFF ¶ 4371 herein. Further, the proposed finding is incomplete and misleading, including because [redacted]

[redacted]

4387. [redacted]

Response to Finding No. 4387:

Respondents incorporate their responses to CCFF ¶ 4371 herein.

4388. [redacted]

Response to Finding No. 4388:

The proposed finding is incomplete and misleading. [redacted] Further, as Mr. Conroy admitted, prior to the merger, Exact/Thrive did not have any rights to the GRAIL IP or an IP license of any kind from GRAIL and has never had any expectation that it would be given access to GRAIL's IP as a mechanism to develop the CancerSEEK test. (PFF ¶ 1708; Conroy (Exact/Thrive) Tr. 1730.)

Moreover, Illumina has offered other IP-protections in the Open Offer, [redacted]: Under the Open Offer, Illumina commits

to give customers a right under Illumina's core intellectual property to use its sequencing instruments and core consumables. (PFF ¶ 1036; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.) Also, under the Open Offer, Illumina commits that it will not have the right to cease shipments of the products solely on the basis of a claim of infringement of Illumina's intellectual property rights. (PFF ¶ 1037; Berry (Illumina) Tr. 864; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.) Mr. Conroy, however, did not know the substance of the Open Offer's intellectual property provisions and had not even read the Open OFfer. (PFF ¶¶ 1073, 1073.4; Conroy (Exact/Thrive) Tr. 1728–29.) Thus, his testimony on this point should be given little weight.

4389. [redacted]

Response to Finding No. 4389:

Respondents incorporate their responses to CCFF ¶ 4388 herein.

4390. [redacted]

Response to Finding No. 4390:

Respondents incorporate their responses to CCFF ¶ 4388 herein.

4391. [redacted]

Response to Finding No. 4391:

Respondents have no specific response except to note that the Open Offer, [redacted] provides that, for 6 years after the closing of the Illumina-GRAIL transaction (*i.e.*, until August 18, 2027), customers may enter into one or more separate agreements with Illumina to develop IVD test kits for use on

Illumina's platforms. (PFF ¶ 1026; [redacted]; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; [redacted]

4392. [redacted] (Conroy (Exact) Tr. 1605 (*in camera*)).

Response to Finding No. 4392:

Respondents incorporate their responses to CCFF ¶ 4391 herein.

4393. [redacted]

Response to Finding No. 4393:

The proposed finding is incomplete and misleading. In the email cited here, [redacted] Further, Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 61), and therefore should not be entitled to rely on it to establish anything beyond the words on the page.

4394. [redacted]

Response to Finding No. 4394:

Respondents have no specific response.

4395. [redacted]

Response to Finding No. 4395:

The proposed finding is incomplete and misleading. At trial, Mr. deSouza explained that [redacted]

4396. [redacted]

Response to Finding No. 4396:

The proposed finding is incomplete and misleading. [redacted]

Respondents incorporate their responses to CCFF ¶ 4371 herein.

4397. [redacted]

Response to Finding No. 4397:

Respondents have no specific response except to note that [redacted]

4398. [redacted]

Response to Finding No. 4398:

Respondents incorporate their responses to CCFF ¶ 4397 herein.

4399. [redacted]

Response to Finding No. 4399:

The proposed finding is inaccurate, incomplete and misleading. [redacted] Illumina has a "very minimal role" in customers' FDA approval process. (PFF ¶ 1414–15; Goswami (Illumina) Tr. 3187–88.) Illumina's role is "mostly as a supplier". (PFF ¶ 1414; Goswami (Illumina) Tr. 3188.) Additionally, the Open Offer requires Illumina, on a customer's request, to enter into a separate agreement with the customer based on standardized terms to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33; [redacted]; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; [redacted].) These requirements in the Open Offer prevent Illumina from withholding support as MCED test developers seek FDA approval. (PFF ¶ 1035; RX6002 (Guerin-Calvert Trial Dep. at 74).)

[redacted] Under the Open Offer's IVD agreement provisions, customers

can choose from one of three standardized template agreements. (*See* PFF ¶ 1028; Goswami (Illumina) Tr. 3208; PX0064 (Illumina) at 28–40.) Thus, the process of contracting is simplified. And, given Illumina's minimal role in the FDA approval process, the IVD agreements are sufficient to address any necessary support from Illumina in the process. (PFF ¶ 1035; RX6002 (Guerin-Calvert Trial Dep. at 74).)

(2) [redacted]

4400. [redacted]

Response to Finding No. 4400:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina worked to assuage customers' concerns regarding the acquisition of GRAIL and to assure them that their relationship with Illumina would not change post-merger.

4401. [redacted]

Response to Finding No. 4401:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina worked to assuage customers' concerns regarding the acquisition of GRAIL and to assure them that their relationship with Illumina would not change post-merger.

4402. [redacted]

Response to Finding No. 4402:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina worked to assuage customers' concerns regarding the acquisition of GRAIL and to assure them that their relationship with Illumina would not change post-merger.

4403. [redacted]

Response to Finding No. 4403:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina worked to assuage customers' concerns regarding the acquisition of GRAIL and to assure them that their relationship with Illumina would not change post-merger.

4404. [redacted]

Response to Finding No. 4404:

Respondents have no specific response except to note that [redacted] is not relevant to Illumina's alleged ability or incentive to foreclose potential GRAIL rivals. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4405. [redacted]

Response to Finding No. 4405:

The proposed finding is inaccurate, incomplete and misleading. [redacted]

[redacted]

4406. [redacted]

Response to Finding No. 4406:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

Under the Open Offer, Illumina commits to give customers a right under Illumina's core intellectual property to use its sequencing instruments and core consumables. (PFF ¶ 1036; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.)

[redacted]

The Open Offer provides for most-favored-nation pricing relative to GRAIL, which ensures that customers can purchase Supplied Products at prices that are the same as or better than those available to GRAIL. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 7–8.) Further, customers can ensure that Illumina adheres to this provision because the Open Offer requires Illumina to publish the pricing grids under which GRAIL purchases Supplied Products and services. (PFF ¶ 1005.5; RX3935 (Illumina) at 2.)

[redacted]

[redacted]

Further, the Open Offer provides that Illumina cannot cease shipments of its products solely on the basis of a claim of infringement of Illumina's intellectual property rights. (PFF ¶ 1037; Berry (Illumina) Tr. 864; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.) This provision applies even if Illumina has a legitimate claim of infringement. (PFF ¶ 1037.2; RX6002 (Guerin-Calvert Trial Dep. at 78).) [redacted]

Finally, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4407. [redacted]

[redacted]

Response to Finding No. 4407:

The proposed finding is incomplete and misleading. The weight of the evidence shows that when Illumina acquired Verinata, it continued to support downstream rivals, Illumina helped grow the NIPT space, and innovation and competition flourished to the benefit of patients. (*See* PFF ¶¶ 950–963.) Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4408. [redacted]

Response to Finding No. 4408:

The proposed finding is incomplete and misleading. Ms. Berry provided context for this at trial: [redacted]

[redacted]

[redacted]

4409. [redacted]

Response to Finding No. 4409:

Respondents incorporate their responses to CCFF ¶ 4410 herein.

4410. [redacted]

Response to Finding No. 4410:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

[redacted] For example, through its most-favored-nations pricing provisions, the Open Offer allows customers to receive volume-based net pricing for each Supplied Product that is "no less favorable (i.e., the same or better) than" that received by GRAIL. (PFF 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 7–8.) The Open Offer also expressly forbids Illumina from raising prices over the entire 12-year term and affirmatively requires Illumina to lower the price of sequencing by at least 43% by 2025. (PFF ¶ ¶ 1021–23; [redacted]; Berry (Illumina) Tr. 899, 901–04; Conroy (Exact/Thrive) Tr. 1731–32; deSouza (Illumina) Tr. 2403; PX0064 (Illumina) at 7; [redacted] The Open Offer's pricing provisions, in their totality, provide guarantees to potential MCED test developers that they will receive fair pricing from Illumina in the short term, medium term and long term. (PFF ¶ 1025.1; RX6002 (Guerin-Calvert Trial Dep. at 53).)

Additionally, the Open Offer requires Illumina to give customers access to purchase any Pre-Release Sequencing Products to which GRAIL or any For-Profit Entity is offered access within 5 days of when GRAIL or such For-Profit Entity is offered access. (PFF ¶ 1008; [redacted]; Berry (Illumina) Tr. 702; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) This provision directly address the concern that new products could be withheld so as to disadvantage GRAIL rivals because the provision requires providing equivalent access to customers within a very short time frame. (PFF ¶ 1009.1; RX6002 (Guerin-Calvert Trial Dep. at 60).)

Finally, under the Open Offer, Illumina commits to give customers a right under Illumina's core intellectual property to use its sequencing instruments and core consumables. (PFF ¶ 1036; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.) Illumina also commits that

it will not have the right to cease shipments of the products solely on the basis of a claim of infringement of Illumina's intellectual property rights. (PFF ¶ 1037; Berry (Illumina) Tr. 864; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.) This provision effectively addresses the concern that Illumina could disrupt supply to potential GRAIL rivals based on a claim of IP infringement. (PFF ¶ 1037.3; *see* RX6002 (Guerin-Calvert Trial Dep. at 77–79).)

4411. [redacted]

Response to Finding No. 4411:

Respondents incorporate their responses to CCFF ¶ 4410 herein. Respondents also note that the proposed finding is based on speculation and should be given little weight.

4412. [redacted]

Response to Finding No. 4412:

The proposed finding is complete and misleading. [redacted] as explained in Responses to CCFF ¶¶ 4413 and 4414. Respondents incorporate their responses to CCFF ¶ ¶ 4413 and 4414 herein and also note that [redacted]

4413. [redacted]

Response to Finding No. 4413:

The proposed finding is incomplete and misleading. Under the Open Offer [redacted] Illumina cannot release a new version of a Supplied Product at a higher price than the previous version, unless the new version results in a material improvement in performance or capability. (PFF ¶ 1022; Berry (Illumina) Tr. 901–02.) Illumina's ability to raise prices based on material improvements is constrained because he price of any new version must take into account the value of the improvement. (RX3935 (Illumina) at 2–3.) "[I]n any arbitration in which the price of a new version of a Supplied Product or a new Supplied Product is disputed, *the arbitrator is empowered to determine the reasonableness of the price, including the value of the any improvement in performance or capability, and to require that Illumina charge a price that is commensurate with the improvement, as well as require any associated refunds to Customer*." (RX3935 (Illumina) at 2 (emphasis added); *see also* deSouza (Illumina) Tr. 2408.)

These provisions resolve any concern that Illumina would avoid its commitment not to increase pricing by redefining what counts as a materially improved product. Specifically, the new-product-pricing provision does not obligate customers to switch to a new product. (PFF ¶ 1022.3; RX6002 (Guerin-Calvert Trial Dep. at 47).) Thus, if a customer did not agree that there was a material improvement in performance or capability of a new version of a Supplied Product, they could stay with their existing product. (PFF ¶ 1022.3; RX6002 (Guerin-Calvert Trial Dep. at 48).) Alternatively, if a customer felt that there was a material improvement in performance or capability, but that this improvement did not justify a new price, the customer could take this issue directly to Illumina or to arbitration, where the arbitrator could determine

the reasonableness of the price in light of the improvement. (PFF ¶ 1022.3; RX6002 (Guerin-Calvert Trial Dep. at 48).)

4414. [redacted]

Response to Finding No. 4414:

The proposed finding is incomplete and misleading. The Open Offer [redacted] contains *two* most-favored-nations (MFN) provisions—one relative to Equivalent customers and one relative to GRAIL. For the GRAIL MFN, the Open Offer allows customers to receive volume-based net pricing for each Supplied Product that is "no less favorable (i.e., the same or better) than" that received by GRAIL. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 7–8.) Further, the Open Offer also expressly forbids Illumina from raising prices over the entire 12-year term and affirmatively requires Illumina to lower the price of sequencing by at least 43% by 2025. (PFF ¶ ¶ 1021–23; [redacted]; Berry (Illumina) Tr. 899, 901–04; Conroy (Exact/Thrive) Tr. 1731–32; deSouza (Illumina) Tr. 2403; PX0064 (Illumina) at 7; [redacted] The Open Offer's pricing provisions, in their totality, provide guarantees to potential MCED test developers that they will receive fair pricing from Illumina in the short term, medium term and long term. (PFF ¶ 1025.1; RX6002 (Guerin-Calvert Trial Dep. at 53).)

4415. [redacted]

Response to Finding No. 4415:

Respondents incorporate their responses to CCFF ¶¶ 4407, 4410 and 4413–14 herein. Respondents also note that the proposed finding is based on speculation and is thus entitled to no weight.

4416. [redacted]

Response to Finding No. 4416:

Respondents have no specific response except to note that the Open Offer's provisions in their totality ensure that Illumina's incentives are to support GRAIL's rivals. (PFF ¶ 1082.2–1082.4; *see* RX6002 (Guerin-Calvert Trial Dep. at 20–22, 108–09; RX6000 (Carlton Trial Dep. at 84–85).) Further, the most important issue with regard to the efficacy of the Open Offer is whether it sufficiently prevents Illumina from acting on any alleged incentive to foreclose GRAIL's potential rivals. (PFF ¶ 1082.1; RX6002 (Guerin-Calvert Trial Dep. at 20–21, 109).) It does. The Open Offer provides the economically necessary terms to prevent the alleged anticompetitive harms from the transaction in both the short term and the long term. (PFF ¶ 997.1; RX6002 (Guerin-Calvert Trial Dep. at 21–22).) Moreover, the enforcement terms of the Open Offer provide Illumina's clinical oncology customers with effective monitoring and enforcement mechanisms to ensure compliance with the Open Offer terms and to effectuate its purpose of ensuring that Illumina cannot materially disadvantage GRAIL rivals post-merger. (PFF ¶ 1044; RX6002 (Guerin-Calvert Trial Dep. at 22–23).) The very public aspect of the

Open Offer can also bolster compliance. (PFF ¶ 1044; *see* RX6002 (Guerin-Calvert Trial Dep. at 22–23).)

4417. [redacted]

Response to Finding No. 4417:

Dr. Rabinowitz's unsupported attacks on the Open Offer in the portion of Dr. Rabinowitz's testimony cited here ignore the Open Offer's terms, as explained in the responses to CCFF ¶¶ 4533–34, 4708, 4729, 4809, 4844–45 and 4933, which respondents incorporate herein.

4418. [redacted]

Response to Finding No. 4418:

Respondents have no specific response except to note that the amended supply agreement incorporated the provisions of the Open Offer and is evidence that Illumina worked to resolve customers' concerns about the transaction and to assure customers that their relationship with Illumina would remain unchanged post-merger.

(3) [redacted]

4419. [redacted]

Response to Finding No. 4419:

Respondents have no specific response except to note that [redacted]

[redacted]

4420. [redacted]

Response to Finding No. 4420:

Respondents have no specific response except to note that Ms. Berry testified that

[redacted]

4421. [redacted]

Response to Finding No. 4421:

Respondents incorporate their responses to CCFF ¶ 4420 herein.

4422. [redacted]

Response to Finding No. 4422:

Respondents incorporate their responses to CCFF ¶ 4420 herein.

4423. [redacted]

Response to Finding No. 4423:

The proposed finding is incomplete and misleading. Specifically, Ms. Berry testified that [redacted]

4424. [redacted]

Response to Finding No. 4424:

Respondents have no specific response.

4425. [redacted]

Response to Finding No. 4425:

The proposed finding is incomplete and misleading to the extent that it suggests that [redacted]

[redacted]

4426. [redacted]

Response to Finding No. 4426:

Respondents have no specific response except to note that Ms. Berry testified that [redacted]

4427. [redacted]

Response to Finding No. 4427:

Respondents have no specific response.

4428. [redacted]

Response to Finding No. 4428:

Respondents have no specific response except to note that [redacted]

[redacted]

4429. [redacted]

Response to Finding No. 4429:

Respondents incorporate their responses to CCFF ¶ 4428 herein.

4430. [redacted]

Response to Finding No. 4430:

Respondents incorporate their responses to CCFF ¶ 4428 herein.

4431. [redacted]

Response to Finding No. 4431:

Respondents incorporate their responses to CCFF ¶ 4428 herein.

4432. [redacted]

[redacted]

Response to Finding No. 4432:

The proposed finding is incomplete and misleading. [redacted]

4433. [redacted]

Response to Finding No. 4433:

Respondents have no specific response.

4434. [redacted]

Response to Finding No. 4434:

Respondents have no specific response except to note that [redacted]

[redacted]

4435. [redacted]

Response to Finding No. 4435:

Respondents incorporate their responses to CCFF ¶¶ 4432 and 4434 herein.

4436. [redacted]

Response to Finding No. 4436:

Respondents have no specific response.

4437. [redacted]

Response to Finding No. 4437:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

[redacted]

4438. [redacted]

Response to Finding No. 4438:

Respondents incorporate their responses to CCFF ¶ 4437 herein.

4439. [redacted]

Response to Finding No. 4439:

Respondents incorporate their responses to CCFF ¶ 4437 herein.

4440. [redacted]

Response to Finding No. 4440:

Respondents incorporate their responses to CCFF ¶ 4437 herein.

4441. [redacted]

Response to Finding No. 4441:

Respondents incorporate their responses to CCFF ¶ 4437 herein.

4442. [redacted]

Response to Finding No. 4442:

Respondents have no specific response except to note that [redacted]

4443. [redacted]

Response to Finding No. 4443:

Respondents have no specific response except to note that [redacted] The Open Offer is *12-year* supply agreement. (PFF ¶ 1000; Berry (Illumina) Tr. 690–91, 861, 874–75; Conroy (Exact/Thrive) Tr. 1725; deSouza (Illumina) Tr. 2402; PX0064 (Illumina) at 5.) The Open Offer provides MFN pricing relative to both GRAIL and any other For-Profit Entity. (PFF ¶¶ 1017–18; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 7–8.) And the Open Offer assures an uninterrupted supply of core consumables. (*See* PFF ¶¶ 1000, 1005, 1007, 1009, 1011, 1037; Rabinowitz (Natera) Tr. 421–22; Berry (Illumina) Tr. 690–91, 861, 864, 874–75, 878–79, 883; Conroy (Exact/Thrive) 1725; deSouza (Illumina) Tr. 2402, 2434–35, 2437–38; PX0064 (Illumina) at 5–6, 9; RX3935 (Illumina) at 2; RX6002 (Guerin-Calvert Trial Dep. at 59–60, 77–79.)

[redacted] The Open Offer provides

that customers can terminate the supply relationship with Illumina at any time and without specifying any reason. (PFF ¶ 1001; Berry (Illumina) Tr. 862–63; deSouza (Illumina) Tr. 2402; PX0064 (Illumina) at 10.). It also requires that "Illumina cannot terminate this Supply Agreement for convenience during the Term." (PFF ¶ 1002; PX0064 (Illumina) at 10; *see also* (Berry (Illumina) Tr. 863; deSouza (Illumina) Tr. 2402.) [redacted], but as noted the Open Offer provides for a 12-year term.

The Open Offer also provides customers with protections relating to IP. For example, under the Open Offer, Illumina commits to give customers a right under Illumina's core intellectual property to use its sequencing instruments and core consumables. (PFF ¶ 1036; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.) Further, under the Open Offer, Illumina commits that it will not have the right to cease shipments of the products solely on the basis of a claim of infringement of Illumina's intellectual property rights. (PFF ¶ 1037; Berry (Illumina) Tr. 864; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.)

4444. [redacted]

Response to Finding No. 4444:

Respondents incorporate their responses to CCFF ¶ 4443 herein.

4445. [redacted]

Response to Finding No. 4445:

Respondents incorporate their responses to CCFF ¶ 4443 herein.

4446. [redacted]

[redacted]

Response to Finding No. 4446:

Respondents incorporate their responses to CCFF ¶ 4443 herein. Further, the proposed finding is evidence that Illumina has worked to assuage customers' concerns surrounding the transaction and assure customers that their relationship with Illumina will remain unchanged post-merger.

4447. [redacted]

Response to Finding No. 4447:

Respondents incorporate their responses to CCFF ¶ 4443 herein.

4448. [redacted]

Response to Finding No. 4448:

Respondents incorporate their responses to CCFF ¶ 4443 herein.

4449. [redacted]

Response to Finding No. 4449:

Respondents incorporate their responses to CCFF ¶ 4443 herein.

4450. [redacted]

Response to Finding No. 4450:

Respondents incorporate their responses to CCFF ¶ 4443 herein.

4451. [redacted]

Response to Finding No. 4451:

Respondents incorporate their responses to CCFF ¶ 4443 herein.

(4) [redacted]

4452. Guardant had a supply agreement with Illumina prior to Illumina announcing its intent to acquire GRAIL. (PX7040 (Getty (Guardant) IHT at 176-77)).

Response to Finding No. 4452:

Respondents have no specific response.

4453. Guardant's pre-existing supply agreement covers Illumina sequencers, reagents, and service. (PX7040 (Getty (Guardant) IHT at 176)).

Response to Finding No. 4453:

Respondents have no specific response.

4454. [redacted] (Berry (Illumina) Tr. 762) (*in camera*)).

Response to Finding No. 4454:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina worked to resolve customers' concerns about the transaction and to assure customers that their relationship with Illumina would remain unchanged post-merger.

4455. [redacted] (PX2305 (Illumina) at 001 (Email from N. Berry, Illumina, to M. Kreitzinger, Illumina, Oct. 29, 2020) (*in camera*)).

Response to Finding No. 4455:

The proposed finding is incomplete and misleading to the extent that it suggests that [redacted]

[redacted]

4456. [redacted] (PX7040 (Getty (Guardant) IHT at 182); PX2306 (Illumina) at 008 [redacted] (*in camera*)).

Response to Finding No. 4456:

Respondents have no specific response except to note that [redacted] Guardant attached the amended supply agreement to its 2020 10–K because the amended agreement represented a material and important contract for Guardant. (PFF ¶ 1075.4; Getty (Guardant) Tr. 2668–69; PX0060 (Guardant) at 151.)

4457. Mr. Getty testified that Guardant did not actually engage in "true negotiation" with Illumina over the supply agreement. (PX7040 (Getty (Guardant) IHT at 182).

Response to Finding No. 4457:

Respondents incorporate their responses to CCFF ¶ 4455 herein. Further, Mr. Getty admitted at trial that [redacted] Additionally, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4458. Mr. Getty testified that Guardant's supply agreement with Illumina entered into in January 2021 does not have audit rights which makes enforceability of the contract a challenge. (PX7040 (Getty (Guardant) IHT at 184)).

Response to Finding No. 4458:

The proposed finding is incomplete and misleading. Specifically, the Open Offer [redacted] requires Illumina to engage in a biannual audit to ensure compliance with the Open Offer. (PFF ¶ 1047; deSouza (Illumina) Tr. 2405, 2438; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.) Additionally, if a

customer has a good-faith basis for alleging that Illumina is in breach of the Open Offer, Illumina will engage an auditor to assess the customer's allegation separate from the biannual audits. (PFF ¶ 1047; PX0064 (Illumina) at 10.) Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4459. [redacted]
(PX7105 (Getty (Guardant) Dep. at 77) (*in camera*)).

Response to Finding No. 4459:

The proposed finding is incomplete and misleading. *First*, Mr. Getty's statement is not credible. [redacted]
Guardant attached the amended supply agreement to its 2020 10–K because the amended agreement represented a material and important contract for Guardant. (PFF ¶ 1075.4; Getty (Guardant) Tr. 2668–69; PX0060 (Guardant) at 151.) In its negotiations with Illumina, Guardant never indicated to Illumina that Guardant viewed its amended supply agreement as, in substance, unenforceable or worthless. (PFF ¶ 1075.5; Getty (Guardant) Tr. 2669.)

Second, [redacted] The weight of the evidence shows that the Open Offer provides the economically

necessary terms to prevent the alleged anticompetitive harms from the transaction in both the short term and the long term. (RX6002 (Guerin-Calvert Trial Dep. at 21–22).)

4460. [redacted] (PX7105 (Getty (Guardant) Dep. at 77-78) (*in camera*) ([redacted])).

Response to Finding No. 4460:

The proposed finding is incomplete and misleading. [redacted] Illumina is not the sole supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.) Respondents also incorporate their responses to CCFF ¶¶ 4455 and 4459 herein.

(5) [redacted]

4461. [redacted] (Berry (Illumina) Tr. 761) (*in camera*)).

Response to Finding No. 4461:

Respondents have no specific response.

4462. [redacted] (PX8396 (Roche/FMI) [redacted] (*in camera*)).

Response to Finding No. 4462:

Respondents have no specific response except to note that Dr. Fiedler of FMI testified that [redacted]

[redacted]

4463. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 93) (*in camera*); *see* PX7118 (Fiedler (FMI) Dep. at 11)).

Response to Finding No. 4463:

Respondents have no specific response.

4464. Mr. Fiedler testified that it is important to secure supply for FMI's tests "[b]ecause [FMI] serve[s] several hundred thousand patients every year and it is important, and patients are waiting for the results because the results might determine the– how their treatment plan looks like, and therefore, every day counts." (PX7118 (Fiedler (FMI) Dep. at 12)).

Response to Finding No. 4464:

Respondents have no specific response except to note that, as Dr. Fiedler testified,

[redacted]

4465. FMI would have to shut down its business if it did not have a continued supply of Illumina products. (PX7118 (Fiedler (FMI) Dep. at 12-13)).

Response to Finding No. 4465:

Respondents incorporate their responses to CCFF ¶ 4464 herein.

e) [redacted]

4466. [redacted] (PX2306 (Illumina) at 008-021 [redacted] (*in camera*)).

Response to Finding No. 4466:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina worked to assuage customers' concerns about the merger and assure customers that their relationship with Illumina would not change post-acquisition.

4467. [redacted] (PX8396 (Roche/FMI) [redacted] (*in camera*)).

Response to Finding No. 4467:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina worked to assuage customers' concerns about the merger and assure customers that their relationship with Illumina would not change post-acquisition. Additionally, Dr. Fiedler of FMI testified that [redacted]

4468. Guardant's Mr. Getty testified that he has multiple concerns with the supply agreement, including lack of insight into Grail's prices (which are used as a ceiling for Guardant's prices), inability to monitor whether Guardant is getting new technology from Illumina at the same time as Grail, and lack of an enforceable firewall. (PX7040 (Getty (Guardant) IHT at 183-89)). Mr. Getty further testified that, although certain provisions of the supply agreement may be helpful to Guardant, "it doesn't change the underlying premise of our analysis that the combined company would have the opportunity and incentives to advantage Grail in a competitive environment." (Getty (Guardant) Tr. 2561).

Response to Finding No. 4468:

The proposed finding is incomplete and misleading. *First*, Mr. Getty's statements are not credible. [redacted]

[redacted]

Guardant attached the amended supply agreement to its 2020 10–K because the amended agreement represented a material and important contract for Guardant. (PFF ¶ 1075.4; Getty (Guardant) Tr. 2668–69; PX0060 (Guardant) at 151.) In its negotiations with Illumina, Guardant never indicated to Illumina that Guardant viewed its amended supply agreement as, in substance, unenforceable or worthless. (PFF ¶ 1075.5; Getty (Guardant) Tr. 2669.)

Second, [redacted] The Open Offer requires Illumina to give insight into GRAIL's prices because it requires Illumina to "publish, on the 'Oncology Contract Terms' website, (i) the Supplied Products, by SKU, that GRAIL is purchasing; (ii) the service plans, by SKU, that GRAIL is purchasing; and (iii) the pricing grid for both products and services under which GRAIL is purchasing Supplied Products and services. To the extent necessary, Illumina shall update this website within 5 days of entry of any purchase order for Supplied Products or any service contract relating to the Supplied Products by GRAIL." (RX3935 (Illumina) at 2; RX4003 (Illumina) at 1; RX3960 (Illumina).)

The Open Offer also allows customers to know whether customers receive new technology at the same time as GRAIL because the Open Offer requires Illumina to engage in a biannual audit to ensure compliance with the Open Offer. (PFF ¶ 1-47; deSouza (Illumina) Tr. 2405, 2438; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.) Further, if a customer has a

good-faith basis for alleging that Illumina is in breach of the Open Offer, Illumina will engage an auditor to assess the customer's allegation separate from the biannual audits. (PFF ¶ 1047; PX0064 (Illumina) at 10.) Illumina is obligated to provide customers with a written report confirming compliance with the Open Offer's commitments. (PFF ¶ 1048; PX0064 (Illumina) at 10; PX7076 (Berry (Illumina) Dep. at 287).) Additionally, customers must be promptly notified, within 10 days, of any potential noncompliance. (PFF ¶ 1048; deSouza (Illumina) Tr. 2478; RX3935 (Illumina) at 3.)

And, the Open Offer includes an enforceable firewall. Illumina is currently implementing the confidentiality provisions of the Open Offer by operating GRAIL as a completely separate and distinct organization and by thoroughly reviewing any interface points with GRAIL. (PFF ¶ 1100.1; Berry (Illumina) Tr. 917–18.) The firewall under the Open Offer will have all of the necessary characteristics of an effective firewall, including clear policies around confidentiality, a means to enforce the firewall and a means to disseminate confidentiality policies to relevant personnel. (PFF ¶ 1100.2; *see* RX6002 (Guerin-Calvert Trial Dep. at 84–85).) These types of firewalls have been implemented by the FTC (and other antitrust agencies or regulatory agencies) in vertical transactions with success since at least the 1970s. (RX6002 (Guerin-Calvert Trial Dep. at 81–82); *see also* RX3082 (*In re Broadcom Ltd.* Decision and Order) at 5–7; RX3192 (*In re Evanston Northwestern Healthcare Corp.* Final Order) at 5–7; RX3527 (*In re Northrop Grumman* Decision and Order) at 9–13; RX 3557 (*In re PepsiCo, Inc.* Decision and Order) at 6–9; RX3664 (*In re Sycamore Partners II* Analysis of Agreement Containing Consent Order) at 3–4.) [redacted]

[redacted]

Finally, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4469. [redacted] (PX7105 (Getty (Guardant) Dep. at 77) (*in camera*)).

Response to Finding No. 4469:

The proposed finding is incomplete and misleading. [redacted] The weight of the evidence shows that the Open Offer provides the economically necessary terms to prevent the alleged anticompetitive harms from the transaction in both the short term and the long term. (RX6002 (Guerin-Calvert Trial Dep. at 21–22).)

4470. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 117-18) (*in camera*)).

Response to Finding No. 4470:

The proposed finding is incomplete and misleading. [redacted] under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (PFF ¶ 1039; [redacted] deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted].) Illumina is very familiar with how to set up and operate this kind of confidentiality provision because it already shields confidential information in other contexts. (PFF ¶ 1041.3; Goswami (Illumina) Tr. 3231.) [redacted]

[redacted]

The Open Offer's firewall provision will have the characteristics of an effective firewall, specifically: monitoring and auditing, methods to report violations and consequences for violations. (PFF ¶¶ 1041.5, 1100; RX6002 (Guerin-Calvert Trial Dep. at 84–85).)

The Open Offer also requires Illumina to provide customers with a consistent source of supply of sequencing instruments and core consumables. (*See* PFF ¶¶ 1000, 1005, 1007, 1009, 1011, 1037; [redacted]; Berry (Illumina) Tr. 690–91, 861, 864, 874–75, 878–79, 883; Conroy (Exact/Thrive) 1725; deSouza (Illumina) Tr. 2402, 2434–35, 2437–38; PX0064 (Illumina) at 5–6, 9; RX3935 (Illumina) at 2; RX6002 (Guerin-Calvert Trial Dep. at 59–60, 77–79.) The provisions on access to products address the concern that products could be withheld so as to disadvantage potential GRAIL rivals because they require providing equivalent access within a very short time frame. (PFF ¶ 1009.1; RX6002 (Guerin-Calvert Trial Dep. at 60).)

Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4471. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 97-98; 101; 103-04; 110) (*in camera*)).

Response to Finding No. 4471:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

[redacted]

[redacted] Illumina commits to give customers a right under Illumina's core intellectual property to use its sequencing instruments and core consumables. (PFF ¶ 1036; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.) [redacted] Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4472. [redacted] (PX7111 (Fesko (Natera) Dep. at 98) (*in camera*)).

Response to Finding No. 4472:

Respondents incorporate their responses to CCFF ¶ 4416 herein.

4473. [redacted] (Rabinowitz (Natera) Tr. 368-72) (*in camera*)).

Response to Finding No. 4473:

Dr. Rabinowitz's unsupported attacks on the Open Offer in the portion of Dr. Rabinowitz's testimony cited here ignore the Open Offer's terms, as explained in the responses to CCFF ¶¶ 4533–34, 4708, 4729, 4809, 4844–45 and 4933, which respondents incorporate herein incorporate their responses.

(1) [redacted]

4474. [redacted] (PX8383 (Tempus) [redacted] (*in camera*)).

Response to Finding No. 4474:

Respondents have no specific response.

4475. Tempus is a precision medical company headquartered in Chicago, Illinois that currently offers diagnostic tests and data services, including its xF and xT therapy selection tests. (PX7080 (Silvis (Tempus) Dep. at 16-17, 26, 29-30).

Response to Finding No. 4475:

Respondents have no specific response.

4476. [redacted] (PX7080 (Silvis (Tempus) Dep. at 49-50, 65-66) (*in camera*)).

Response to Finding No. 4476:

Respondents have no specific response except to note that Tempus expressed its support for the Transaction in a letter to the Commission. (PX9207 (Tempus) at 1).)

4477. [redacted] (PX7080 (Silvis (Tempus) Dep. at 48-49, 51-52) (*in camera*)).

Response to Finding No. 4477:

Respondents have no specific response.

4478. [redacted] (PX8383 (Tempus) [redacted]

Response to Finding No. 4478:

Respondents have no specific response.

f) Illumina's March 2021 Open Offer Letter

4479. After engaging in supply agreement negotiations with customers and hearing concerns about the acquisition from oncology customers, Illumina made public a standardized twelve-year supply agreement referred to as an "Open Offer" on its website. (Berry (Illumina) Tr. 687-89; PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)).

Response to Finding No. 4479:

Respondents have no specific response except to note that the Open Offer was developed based on Illumina's interactions with customers during its customer outreach after the announcement of the transaction, as well as supply agreement negotiations with specific customers. (PFF ¶ 990; Berry (Illumina) Tr. 857, [redacted].) Respondents also note that although Illumina does not believe that the transaction will have any anticompetitive effect, it made the Open Offer available to address concerns raised by both Complaint Counsel and certain customers that the Illumina-GRAIL transaction would allow Illumina to foreclose GRAIL rivals. (PFF ¶ 992; *see* Berry (Illumina) Tr. 688–89, 709–10; deSouza (Illumina) Tr. 2338–39, 2401; Goswami (Illumina) Tr. 3207; PX0064 (Illumina) at 1; [redacted].)

4480. The Open Offer listed on Illumina's website is dated March 29th, 2021. (Berry (Illumina) Tr. 690; PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)).

Response to Finding No. 4480:

Respondents have no specific response.

4481. The Open Offer contains standardized 12-year supply agreement terms for Illumina's oncology customers. (Berry (Illumina) Tr. 688, 690).

Response to Finding No. 4481:

Respondents have no specific response.

4482. Ms. Berry is Illumina's signatory on the Open Offer. (Berry (Illumina) Tr. 690; PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)).

Response to Finding No. 4482:

Respondents have no specific response.

4483. On September 8, 2021, in the middle of trial, Illumina published a revised open offer letter (RX3935 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

Response to Finding No. 4483:

Respondents have no specific response except to note that the revisions were added because Illumina found ways it could make the Open Offer "even slightly better, and so [Illumina] wanted to share that with [its] customers right away". (deSouza (Illumina) Tr. 2406.)

3. Illumina's Open Offer Fails to Remedy Anticompetitive Harm from the Merger

4484. [redacted]

Response to Finding No. 4484:

Respondents have no specific response except to note that [redacted] (*see* PFF Section VI),

Illumina made the Open Offer available to address concerns raised by both Complaint Counsel and certain customers (including Natera) (PFF ¶ 992; *see* Berry (Illumina) Tr. 688–89, 709–10; deSouza (Illumina) Tr. 2338–39, 2401; Goswami (Illumina) Tr. 3207; PX0064 (Illumina) at 1; [redacted].).

4485. [redacted]

Response to Finding No. 4485:

Dr. Rabinowitz's unsupported attacks on the Open Offer in the portion of Dr. Rabinowitz's testimony cited here ignore the Open Offer's terms, as explained in the responses to CCFF ¶¶ 4533–34, 4708, 4729, 4809, 4844–45 and 4933, which respondents incorporate herein incorporate their responses.

4486. [redacted]

Response to Finding No. 4486:

The proposed finding is incomplete and misleading. Dr. Rabinowitz's unsupported attacks on the Open Offer in the portion of Dr. Rabinowitz's testimony cited here ignore the Open Offer's terms, as explained in the responses to CCFF ¶¶ 4533–34, 4708, 4729, 4809, 4844–45 and 4933, which respondents incorporate herein.

4487. [redacted]

Response to Finding No. 4487:

Respondents have no specific response except to note that Illumina is not the sole supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.)

4488. [redacted]).

Response to Finding No. 4488:

The proposed finding is incomplete and misleading. First, Illumina is not the sole supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.) Moreover, Illumina has offered its customers unprecedented support in the FDA approval process, should customers choose to use Illumina's products in developing MCED tests. For example, the Open Offer requires Illumina, on a customer's request, to enter into a separate agreement with the customer based on standardized terms to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33; [redacted]; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; [redacted].) This prevents Illumina from withholding support as MCED test developers seek FDA approval. (PFF ¶ 1035; RX6002 (Guerin-Calvert Trial Dep. at 74).) Alternatively, if a customer who has signed the Open Offer decides to switch to one of the other NGS providers, the Open Offer allows customers to terminate their supply relationship with Illumina for any reason and switch to that alternative supplier. (PFF ¶ 1001; Berry (Illumina) Tr. 862–63; PX0064 (Illumina) at 10.)

4489. Mr. Getty of Guardant testified that Guardant is "inextricably tied to Illumina in order to be successful or to run our lab," including through the supply of critical instruments and reagents, servicing of the technology, and optimization of the products to Guardant's tests. (PX7105 (Getty (Guardant) Dep. at 55-56)).

Response to Finding No. 4489:

Respondents have no specific response except to note that Illumina is not the sole supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.)

4490. Mr. Getty further testified, "the Illumina logo could be placed on the lab." (PX7105 (Getty (Guardant) Dep. at 56)).

Response to Finding No. 4490:

Respondents incorporate their responses to CCFF ¶ 4489 herein.

a) [redacted]

4491. [redacted]

Response to Finding No. 4491:

The proposed finding is incomplete and misleading. [redacted], that Illumina cannot cease shipments of the products solely on the basis of a claim of infringement of Illumina's intellectual property rights. (PFF ¶ 1037; Berry (Illumina) Tr. 864;

deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.) This provision applies even if Illumina has a legitimate claim of infringement. (RX6002 (Guerin-Calvert Trial Dep. at 78).)

4492.

Response to Finding No. 4492:

The proposed finding is incomplete and misleading.

Illumina has made a specific contractual commitment through the Open Offer to provide customers with the same access to services to which GRAIL or any other For-Profit Entity has access, or to which customers had access before the merger, and at the same prices. (PFF ¶ 1004; ; Berry (Illumina) Tr. 865–66; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.)

4493. [redacted]

Response to Finding No. 4493:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

4494. [redacted]

Response to Finding No. 4494:

The proposed finding is incomplete and misleading. Under the Open Offer, [redacted] Illumina cannot release a new version of a Supplied Product at a higher price than the previous version, unless the new version results in a material improvement in performance or capability. (PFF ¶ 1022; Berry (Illumina) Tr. 901–02.) Illumina's ability to raise prices based on material improvements is constrained because he price of any new version must take into account the value of the improvement. (RX3935 (Illumina) at 2–3.) "[I]n any arbitration in which the price of a new version of a Supplied Product or a new Supplied Product is disputed, *the arbitrator is empowered to determine the reasonableness of the price, including the value of the any improvement in performance or capability, and to require that Illumina charge a price that is commensurate with the improvement, as well as require any associated refunds to Customer*." (RX3935 (Illumina) at 2 (emphasis added); *see also* deSouza (Illumina) Tr. 2408.)

These provisions resolve any concern that Illumina would avoid its commitment not to increase pricing by redefining what counts as a materially improved product. Specifically, the new-product-pricing provision does not obligate customers to switch to a new product. (PFF ¶ 1022.3; RX6002 (Guerin-Calvert Trial Dep. at 47).) Thus, if a customer did not agree that there was a material improvement in performance or capability of a new version of a Supplied Product, they could stay with their existing product. (PFF ¶ 1022.3; RX6002 (Guerin-Calvert Trial Dep. at 48).) Alternatively, if a customer felt that there was a material improvement in

performance or capability, but that this improvement did not justify a new price, the customer could take this issue directly to Illumina or to arbitration, where the arbitrator could determine the reasonableness of the price in light of the improvement. (PFF ¶ 1022.3; RX6002 (Guerin-Calvert Trial Dep. at 48).)

b) Illumina's Commitment to Product Services Is Flawed

4495. The Open Offer states that a "[c]ustomer shall have access to the same product services and support services for purchase relating to the Supplied Products to which GRAIL or any For-Profit Entity has access, or which Customer had access before the Transaction." (PX0064 § 4.a. (Illumina, Open Offer Letter, Mar. 29, 2021)).

Response to Finding No. 4495:

Respondents have no specific response except to note that the proposed finding is evidence that the Open Offer fully addresses any alleged anticompetitive concerns from the merger.

4496. The Open Offer does not define "product services" or "support services." (PX0064 § 4.a. (Illumina, Open Offer Letter, Mar. 29, 2021)).

Response to Finding No. 4496:

The proposed finding is incomplete and misleading. Illumina keeps track of services that customers order using service contract SKUs. (PFF ¶ 1004.4; Berry (Illumina) Tr. 866–68.) When a customer purchases a service SKU, there is an agreement that describes aspects of the service relationship such as turnaround time and the number of preventative maintenances to which a customer is entitled. (PFF ¶ 1004.4; Berry (Illumina) Tr. 867.) As with products, there is a standard list of orderable service SKUs, each associated with a standard U.S. list price. (PFF ¶ 1004.4; Berry (Illumina) Tr. 868–69.) Thus, the product and support services provided by Illumina correspond to standardized, orderable SKUs.

4497. The Open Offer does not explain how such services could be measured to ensure consistency in treatment between Grail and its rivals. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)).

Response to Finding No. 4497:

The proposed finding is incomplete and misleading. In order to ensure that it satisfies its obligations when a customer orders a service SKU, Illumina measures its customer support using key performance indicators (KPIs). (PFF ¶ 1004.6; Berry (Illumina) Tr. 867–68.) These KPIs include metrics like instrument downtime or the length of time between when a case is opened to when it is closed. (PFF ¶ 1004.6; Berry (Illumina) Tr. 867–68.) These KPIs enable Illumina to compare how it performs in terms of service and support across individual customers or groups of customers. (PFF ¶ 1004.6; Berry (Illumina) Tr. 868.) As Ms. Berry testified, "[i]t's a very metrics-intensive part of our business, our service and support organization, so we have the ability to compare how we're performing by using these KPIs across individual customers or groups of customers quit eeasily." (Berry (Illumina) Tr, 868.)

In addition, Illumina has a long and sophisticated onboarding process when it hires new service technicians, which helps ensure that service quality among technicians is consistent. (PFF ¶ 1004.5; Berry (Illumina) Tr. 869–70.) It also ensures consistent service among technicians by tracking individual cases to determine whether there is any gap in performance between service engineers. (PFF ¶ 1004.5; Berry (Illumina) Tr. 870–71.)

4498. Nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)).

Response to Finding No. 4498:

The proposed finding is incomplete and misleading. As Ms. Berry testified: "We've retained Deloitte Consulting to help us operationalize the terms that are . . . described in the open offer such that we can be assured that we can administer those terms in a way that maximizes compliance and minimizes any time delays in terms of ensuring that Illumina is prompt in upholding our obligations under the agreement." (Berry (Illumina) Tr. 896.) Thus, to the extent

that the term "access" needs definition, Illumina has already taken actions to resolve the issue in a customer-friendly manner.

4499. Illumina's own executive and Open Offer signatory, Nicole Berry, testified that customers would not know how fast its competitors receive service and support from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)); *see also* PX7105 (Getty (Guardant) Dep. at 69-71) (testifying that Illumina could "say simple things like 'We can't get a technician out to your sequencers until next Friday' or 'the Friday after,' and that could create challenges around turnaround time and disappoint customers and therefore hurt us competitively.")).

Response to Finding No. 4499:

The proposed finding is incomplete and misleading. The relevant question for Illumina's ability and incentive to foreclose potential GRAIL rivals is whether Illumina's customers would know about potential advantages conferred on GRAIL. The Open Offer provides a mechanism for customers to learn about the services and support offered to GRAIL because Illumina is required to publish on the "Oncology Contract Terms" website the service plans that GRAIL purchases. (PFF ¶ 1086.4; RX3935 (Illumina) at 2; RX4003 (Illumina) at 1; RX3960 (Illumina).) Illumina is also required to update this website within 5 days of entry of any service contract by GRAIL. (PFF ¶ 1086.4; RX3935 (Illumina) at 2.)

The speed of services for other customers is immaterial. In fact, customers have repeatedly stressed their desire to keep information about their development activities confidential. Thus, if anything, the proposed finding is evidence that Illumina can keep information about customers' development activities confidential.

4500. [redacted].

Response to Finding No. 4500:

Respondents incorporate their responses to CCFF ¶ 4499 herein.

4501. [redacted]

Response to Finding No. 4501:

The proposed finding is incomplete and misleading. [redacted] the Open Offer provides a mechanism for customers to learn about the services and support offered to GRAIL because Illumina is required to publish on the "Oncology Contract Terms" website the service plans that GRAIL purchases. (PFF ¶ 1086.4; RX3935 (Illumina) at 2; RX4003 (Illumina) at 1; RX3960 (Illumina).) Illumina is also required to update this website within 5 days of entry of any service contract by GRAIL. (PFF ¶ 1086.4; RX3935 (Illumina) at 2.) As noted above, the level of service corresponds to a specific, orderable service contract SKU and is tracked for consistency using key performance indicators. (*See* Responses to CCFF ¶¶ 4496–97.)

4502. [redacted]

Response to Finding No. 4502:

Respondents incorporate their responses to CCFF ¶ 4501 herein. Further, [redacted]

The "Oncology Contract Terms" website must be updated within 5 days of GRAIL ordering any new service contract SKU. Considering the length of time that it takes to develop a test on a sequencing platform, 5 days (or even 45 days) is "a very inconsequential amount of time" for a developer making a test. (*See* Aravanis (Illumina) Tr. 1930; *see also* Berry (Illumina) Tr. 702–

03; [redacted]; PX7100 (Chudova (Guardant) Dep. at 75–79); [redacted]

4503. [redacted]

Response to Finding No. 4503:

The proposed finding is inaccurate, incomplete and misleading. [redacted] While Illumina is required to update the "Oncology Contract Terms" website when GRAIL orders new service contract SKUs (*see* Responses to CCFF ¶ 4499), customers can ensure that Illumina adheres to this rule through the Open Offer's bi-annual audits. Mr. Nolan himself testified that [redacted] Nonetheless, to provide customers with even greater security, the Open Offer provides for regular audits *twice* a year (as well as *additional* audits when customers have a good-faith basis for alleging breach). (RX3935 (Illumina) at 3.)

4504. [redacted]

Response to Finding No. 4504:

Respondents incorporate their responses to CCFF ¶¶ 4499–503 herein.

4505. Ms. Berry testified that under the Open Offer, a customer would not know in real-time how fast its competitors receive service and support from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)).

Response to Finding No. 4505:

Respondents incorporate their responses to CCFF ¶ 4499 herein.

4506. Mr. George, Invitae's CEO, testified that under Open Offer term 4(a) it is "not clear" how Invitae will know they are receiving access to the same product services and support services as GRAIL. (PX7081 (George (Invitae) Dep. at 93-94)).

Response to Finding No. 4506:

Respondents incorporate their responses to CCFF ¶¶ 4501–03 herein. Further, Respondents note that Invitae's CEO said in a sworn declaration that Invitae does not oppose the Transaction and believes Illumina would "continue to be a tremendous partner to Invitae". (RRFF ¶ 4506 (RX1100 (George (Invitae) Decl. ¶¶ 16–17).)

4507. Mr. Getty testified that Illumina's control over which MCED test developer receives better treatment makes it "very difficult" to audit how equitable Illumina's customer service is: "[T]he individual that was chosen to go to Guardant Health could simply have had a vacation scheduled so that seems like normal course of business. But the person who didn't have a vacation scheduled ended up at GRAIL. . . So even a third party auditor would be– it would be very difficult to gauge like for like in terms of services." (PX7105 (Getty (Guardant) Dep. at 85-86)).

Response to Finding No. 4507:

The proposed finding is incomplete and misleading. Illumina has established extensive procedures to ensure consistency of service across customers. In order to ensure that it satisfies its obligations when a customer orders a service SKU, Illumina measures its customer support using key performance indicators (KPIs). (PFF ¶ 1004.6; Berry (Illumina) Tr. 867–68.) These KPIs include metrics like instrument downtime or the length of time between when a case is opened to when it is closed. (PFF ¶ 1004.6; Berry (Illumina) Tr. 867–68.) These KPIs enable Illumina to compare how it performs in terms of service and support across individual customers or groups of customers. (PFF ¶ 1004.6; Berry (Illumina) Tr. 868.) As Ms. Berry testified, "[i]t's

a very metrics-intensive part of our business, our service and support organization, so we have the ability to compare how we're performing by using these KPIs across individual customers or groups of customers quit eeasily." (Berry (Illumina) Tr, 868.) In addition, Illumina has a long and sophisticated onboarding process when it hires new service technicians, which helps ensure that service quality among technicians is consistent. (PFF ¶ 1004.5; Berry (Illumina) Tr. 869–70.) It also ensures consistent service among technicians by tracking individual cases to determine whether there is any gap in performance between service engineers. (PFF ¶ 1004.5; Berry (Illumina) Tr. 870–71.)

And contrary to the opinion of Mr. Getty (who is not an audit expert), a third-party auditor would be able to audit Illumina's compliance with the Open Offer's service provisions. An independent auditor can audit the access to services provision by publishing a comprehensive catalog of services, issuing notices when the catalog is updated and having the auditor perform procedures to test whether the catalog is updated, accurate and timely. (PFF ¶ 1103.5; RX6003 (Rock Trial Dep. at 59–62); *see also* RX6002 (Guerin-Calvert Trial Dep. at 158–161); PX7076 (Berry (Illumina) Dep. at 294).) By using steps like these and reporting the auditor's findings, an audit of the service provisions "will assist both Illumina on one hand, to improve its procedures and processes to help prevent or eliminate events of noncompliance in the future and then secondly it will help the customers [by] provid[ing] them information such that they would then determine whether they feel there's any further action that needs to be taken". (RX6003 (Rock Trial Dep. at 62–63.) This process of auditing the service provisions and reporting findings to customers (as required under the Open Offer (PFF ¶ 1048; PX0064 (Illumina) at 10; PX7076 (Berry (Illumina) Dep. at 287))) would be "very effective". (RX6003 (Rock Trial Dep. at 63.)

4508. Respondents' Expert, Ms. Guerin-Calvert, testified that an Illumina customer would not know how fast its competitors received service and support from Illumina. (RX6002 (Guerin-Calvert Trial Dep. at 151)).

Response to Finding No. 4508:

Respondents incorporate their responses to CCFF ¶ 4499.

4509. Ms. Guerin-Calvert agreed that Illumina's customers have different service contracts and different service needs. (RX6002 (Guerin-Calvert Trial Dep. at 151-52)).

Response to Finding No. 4509:

Respondents have no specific response except to note that the Open Offer's access-to-services provision does not require customers to accept certain service contracts. The Open Offer requires that "Customer shall have access to the same product services and support services for purchase relating to the Supplied Products to which GRAIL or any For-Profit Entity has access, *or which Customer had access before the Transaction*." (PX0064 (Illumina) at 6 (emphasis added).) In other words, any given Open Offer customer has access to the service contracts purchased by GRAIL or any other For-Profit Entity, and they also have access to the service contracts that the customer purchased before the Transaction. Thus, regardless of the different needs of customers, customers can access the services they require.

4510. Ms. Guerin-Calvert agreed that an Illumina customer is not well positioned to compare the services it receives from Illumina with the services that its competitor receives. (RX6002 (Guerin-Calvert Trial Dep. at 152)).

Response to Finding No. 4510:

The proposed finding is incomplete and misleading. The proposed finding suggests that there is greater variability in services provided by Illumina than is actually the case. Illumina's service offerings are highly standardized. Illumina customers can purchase 3 different levels of service contracts—gold, silver or bronze. (PFF ¶ 1004.3; Berry (Illumina) Tr. 681–82.) The different levels of service contracts vary based on considerations like response times and the

number of instances that Illumina technicians will proactively service the customer's instruments. (PFF ¶ 1004.3; Berry (Illumina) Tr. 682.) Further, as with Illumina's products, there is a standard list of orderable service SKUs, each associated with a standard U.S. list price. (PFF ¶ 1004.4; Berry (Illumina) Tr. 868–69.) The Open Offer requires that Illumina "publish, on the 'Oncology Contract Terms' website, . . . the service plans, by SKU, that GRAIL is purchasing" as well as "the pricing grid for . . . services under which GRAIL" purchases the services. (RX3935 (Illumina) at 2; RX4003 (Illumina) at 1; RX3960 (Illumina).) Additionally, the Open Offer requires bi-annual audits and notification within 10 days of any potential noncompliance by Illumina. (deSouza (Illumina) Tr. 2478; PX7076 (Berry (Illumina) Dep. at 287; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.) Thus, Illumina's customers will know whether they have access to the same service plan contracts available to GRAIL or other customers, which is the essential consideration when determining whether Illumina is attempting to disadvantage potential GRAIL rivals. As Ms. Guerin-Calvert testified, "if a customer is getting [Illumina's product and support services], there's going to be nondiscriminatory treatment of them relative to GRAIL or any for-profit entity" and (RX6002 (Guerin-Calvert Trial Dep. at 56).)

(1) MCED Customers Rely on Illumina Product and Support Service

4511. [redacted]

Response to Finding No. 4511:

Respondents have no specific response except to note that the Open Offer's equal-services commitment ensures that customers will receive at least the same level of service that they did before the merger. (PFF ¶ 1004.9; RX6002 (Guerin-Calvert Trial Dep. at 58).)

4512. [redacted]

Response to Finding No. 4512:

Respondents have no specific response except to note that the Open Offer's equal-services commitment ensures that customers will receive at least the same level of service that they did before the merger and "very specifically addresses" and resolves the concern that Illumina could delay services to disadvantage MCED test developers. (PFF ¶¶ 1004.9–1004.10; RX6002 (Guerin-Calvert Trial Dep. at 58–59).)

4513. [redacted]

Response to Finding No. 4513:

Respondents incorporate their responses to CCFF ¶ 4512 herein.

4514. [redacted]

Response to Finding No. 4514:

Respondents incorporate their responses to CCFF ¶ 4512 herein.

4515. [redacted]

[redacted]

Response to Finding No. 4515:

Respondents incorporate their responses to CCFF ¶ 4512 herein.

4516. [redacted]

Response to Finding No. 4516:

Respondents incorporate their responses to CCFF ¶ 4512 herein.

4517. [redacted]

Response to Finding No. 4517:

Respondents incorporate their responses to CCFF ¶ 4512 herein and further note that the Open Offer ensures that there will be no [redacted] in the services provided to customers or the timing of such services because the Open Offer guarantees that customers "will be getting the same quality and type of services". (RX6002 (Guerin-Calvert Trial Dep. at 59).)

4518. [redacted]

Response to Finding No. 4518:

The proposed finding is incomplete and misleading because [redacted] (Berry (Illumina) Tr. 879 ("Q. Could Illumina decide to provide worse services or sequencing instruments or

consumables to a customer laboratory who did not also purchase Galleri? A. No. Q. And why not? A. We'd be in breach of the open offer if we were to provide disadvantaged products or services in quality to a customer that is in the area of, you know, oncology testing, an equivalent customer for GRAIL.").)

4519. [redacted]

Response to Finding No. 4519:

Respondents have no specific response except to note that Illumina's role in its interactions with customers is "mostly as a supplier". (PFF ¶ 1414; Goswami (Illumina) Tr. 3188.) Illumina's support services are limited to assistance with using Illumina's instruments. For example, Illumina typically does not provide support in the development or commercialization of customers' products. (PFF ¶¶ 1010.4–1010.7; Berry (Illumina) Tr. 844–47; [redacted].)

4520. [redacted]

Response to Finding No. 4520:

Respondents have no specific response except to note that [redacted] the Open Offer adequately resolves any concern that Illumina would use customer confidential information improperly. (*See* RX6002 (Guerin-Calvert Trial Dep. at 79–80); *see also* PFF ¶¶ 1038–42.)

4521. [redacted]

[redacted]

Response to Finding No. 4521:

Respondents incorporate their responses to CCFF ¶ 4512 herein.

4522. Guardant relies on Illumina in its development and the fine-tuning of Guardant's technology. (Getty (Guardant) Tr. 2509, 2514).

Response to Finding No. 4522:

The proposed finding is inaccurate, incomplete and misleading. Illumina has a "very minimal role" in customer product development. (PFF ¶ 1414–15; Goswami (Illumina) Tr. 3187–88.) Illumina's role is "mostly as a supplier". (PFF ¶ 1414; Goswami (Illumina) Tr. 3188.) Illumina typically does not provide support in the development or commercialization of customers' products. (PFF ¶¶ 1010.4–1010.7; Berry (Illumina) Tr. 844–47; [redacted].) For example, as Mr. Getty admitted, the LUNAR-2 assay is proprietary to Guardant, and Illumina did not help Guardant develop the LUNAR-2 assay, did not contribute to the scientific effort Guardant undertook in connection with the LUNAR-2 assay, and did not brainstorm with Guardant on how it could improve the LUNAR-2 assay. (Getty (Guardant) Tr. 2645–46.)

4523. Guardant relies upon Illumina to service its sequencers. (Getty (Guardant) Tr. 2509).

Response to Finding No. 4523:

Respondents incorporate their responses to CCFF ¶¶ 4511–12 herein.

4524. Illumina technicians come to Guardant's lab to work on sequencers on a regular basis, probably weekly. (Getty (Guardant) Tr. 2514).

Response to Finding No. 4524:

Respondents incorporate their responses to CCFF ¶¶ 4511–12 herein.

4525. Illumina's instruments are "highly tuned machines" so "in order for us to maximize the value of those, we certainly need to know from Illumina representatives how those might be best deployed." (Getty (Guardant) Tr. 2514).

Response to Finding No. 4525:

Respondents incorporate their responses to CCFF ¶¶ 4511–12 herein.

4526. Illumina updates its sequencers' software from time to time. (deSouza (Illumina) Tr. 2383).

Response to Finding No. 4526:

Respondents have no specific response.

c) Illumina's Commitment to Supplied Products Is Flawed

4527. The Open Offer states that a "[c]ustomer shall have access to the Supplied Products for purchase that GRAIL or any For-Profit Entity has access within 45 days of when GRAIL or such For-Profit Entity, as applicable, is offered such access (if not earlier) for purchase." (PX0064 at 006 (Illumina Open Offer Letter, Mar. 29, 2021)).

Response to Finding No. 4527:

Respondents have no specific response except to note that the proposed finding is evidence that the Open Offer fully addresses any alleged anticompetitive concerns from the merger.

4528. [redacted]

Response to Finding No. 4528:

The proposed finding is incomplete and misleading. Illumina cannot avoid its obligations under the Open Offer by defining what counts as a product or an improvement. (*See* PFF ¶ 1093.) For example, the Open Offer specifically prohibits price increases (other than those due to inflation or factors outside of Illumina's control) unless a new product or new version results in a material improvement. (PFF ¶ 1093.1; PX0064 (Illumina) at 7.) Illumina's ability to raise prices based on material improvements is constrained because the price of any new version must

take into account the value of the improvement. (PFF ¶ 1093.2; RX3935 (Illumina) at 2–3.) In any arbitration over pricing of new products or new version of products, the arbitrator "is empowered to determine the reasonableness of the price, including the value of the . . . improvement in performance or capability, and to require that Illumina charge a price that is commensurate with the improvement, as well as require any associated refunds to Customer." ((PFF ¶ 1093.3; RX3935 (Illumina) at 2–3.)

Similarly, Illumina cannot avoid its obligation to reduce the price of sequencing by at least 43% by 2025 by changing what it defines as a new product because Illumina's minimum obligation is to reduce the price of the NovaSeq S4 300 flow cell. (Berry (Illumina) Tr. 908–09 ("If there is no other new product that we're able to launch . . . that allows, you know, the technology innovation that then would, under normal circumstances, translate to a price reduction on our part, then we are absolutely committing to customers . . . [that] we will make available to the market a flow cell and a kit that is 43 percent lower across the volume-adjusted, volume-based net price grid than we do today. And if that highest throughput flow cell and highest throughput instrument is the current product that we're offering today, we will simply be obligated to reduce the price of that kit by 43 percent. So there's -- so, again, the customer is guaranteed to get the reduction essentially.").

4529. [redacted]

Response to Finding No. 4529:

Respondents incorporate their responses to CCFF ¶ 4528 herein.

4530. [redacted]

Response to Finding No. 4530:

Respondents incorporate their responses to CCFF ¶ 4528 herein.

4531. [redacted]

Response to Finding No. 4531:

Respondents incorporate their responses to CCFF ¶ 4528 herein.

4532. [redacted]

Response to Finding No. 4532:

The proposed finding is incomplete and misleading. The Open Offer expressly forbids Illumina from raising prices over the entire 12-year term and affirmatively requires Illumina to lower the price of sequencing by at least 43% by 2025. (PFF ¶ ¶ 1021–23; [redacted]; Berry (Illumina) Tr. 899, 901–04; Conroy (Exact/Thrive) Tr. 1731–32; deSouza (Illumina) Tr. 2403; PX0064 (Illumina) at 7; [redacted]

4533. [redacted]

Response to Finding No. 4533:

The proposed finding is incomplete and misleading. [redacted] "Q. Under [the product] access provisions, could Illumina supply lower-quality reagents to one of the customers under

the open offer? A. No. That's– we are not permitted to do that under the open offer. Q. What if Illumina deliberately delayed fulfilling a purchase order for a customer or somehow, you know, monkeyed with supply? Would that be permitted under the access provisions of the open offer? A. No. That would -- Illumina would be in breach of the agreement if we were found to be disadvantaging a customer under the open offer relative to GRAIL or another for-profit entity." (Berry (Illumina) Tr. 878–79.)

4534. [redacted]

Response to Finding No. 4534:

The proposed finding is incomplete and misleading. [redacted] the pricing in the Open Offer is not contingent on the customer purchasing any other products: any customer buying sequencing reagents for use with a cancer screening test will pay the Open Offer price, regardless of whether that customer is also buying the Galleri test. (PX0064 (Illumina) at 6–7, 12–27; Berry (Illumina) Tr. 864:16-865:6.) To the extent that Dr. Rabinowitz is suggesting that Illumina could sell the Galleri test at steeper discounts to its customers that are also purchasing sequencing reagents, Natera could provide the same discounts for its own purported MCED test in development. Further, the Open Offer requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶ 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.) This not only prevents Illumina from disadvantaging

GRAIL rivals, but also requires Illumina to act in a particular way to support rivals developing their own competitive products. (PFF ¶ 1010.10; RX6002 (Guerin-Calvert Trial Dep. at 68).)

4535. [redacted]

Response to Finding No. 4535:

The proposed finding is incomplete and misleading. In the portion of Ms. Berry's testimony cited here, Ms. Berry provided context for this answer: [redacted]

(1) Illumina Can Customize Its Consumables to Favor Grail

4536. [redacted]

[redacted] (*See* deSouza (Illumina) Tr. 2434 (testifying that Illumina can design products that "take into account modifications that will improve GRAIL's work flow"); [redacted]

Response to Finding No. 4536:

The proposed finding is not supported by the cited evidence and is incomplete and misleading. [redacted] When asked whether the Open Offer prevents Illumina from designing products to optimize GRAIL's tests, Mr. deSouza responded: "[W]e commit that any product we give GRAIL, everyone will have access to it, so it won't be a product specifically for GRAIL. It will be a product for everyone." (deSouza (Illumina) Tr. 2433.) He also testified: "We're not a consulting firm, so we don't design products for one customer. If we are going to embark on a substantial undertaking from an engineering team perspective, we want a product that can meet the needs more broadly of a customer. So we don't do -- we are not a consulting firm, so we don't do custom development for -- like that." (deSouza (Illumina) Tr. 2434.)

Judge Chappell also asked Mr. deSouza some clarifying questions about Illumina's obligations under the Open Offer: "Regarding that answer, the question was, 'Nothing in the open offer will prevent Illumina from designing a product tailored to GRAIL's specific work flow,' and then part of your answer, 'We are not allowed to make a product just available for GRAIL.' How is it you're not allowed? THE WITNESS: So in this offer letter we're saying that any product that's available for GRAIL will be available for everyone. So we're not

allowed to make a product only for GRAIL. JUDGE CHAPPELL: And you're referring to you're not allowed by this agreement? THE WITNESS: That's correct. JUDGE CHAPPELL: All right, thank you. And I think you told me earlier, do you make specific products with your sequencers today? Do you make specific products for your customers? THE WITNESS: No, we do not. We sell to everyone the same portfolio." (deSouza (Illumina) Tr. 2434–35.)

Additionally, even though Illumina typically has not provided support in the development or commercialization of customers' products, to provide additional benefits to customers, the Open Offer requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶ 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.) Thus, to the extent that customers are worried that Illumina will optimize its equipment for GRAIL, customers can also ask Illumina to optimize its equipment for their tests. As a result, customers are completely protected: They can access any product GRAIL has access to and they can specifically request customized products that improve interoperability with their own tests.

4537. [redacted]

Illumina has previously collaborated with Grail on "extraction methodology to improve library yields" as well as collaborated with Grail on the development of library prep and sequencing kits. Some of these kits were "built specifically for GRAIL". (PX2541 (Illumina) at 010, 017 (Interim Review K2-GRAIL, Feb. 2, 2017)).

Response to Finding No. 4537:

Respondents incorporate their responses to CCFF ¶ 4536 herein.

4538. [redacted]

Response to Finding No. 4538:

The proposed finding is incomplete and misleading. [redacted]

Respondents also incorporate their responses to CCFF ¶ 4536 herein.

4539. [redacted]

Response to Finding No. 4539:

Respondents also incorporate their responses to CCFF ¶¶ 4536 and 4538 herein.

4540. [redacted]

Response to Finding No. 4540:

Respondents incorporate their responses to CCFF ¶ 4536 herein. Respondents also note that, under the Open Offer, [redacted] customers have access to the same standardized, volume-based net prices that GRAIL receives under a universal pricing grid. (*See* PFF ¶¶ 1014, 1016; Berry (Illumina) Tr. 894; PX0064 (Illumina) at 7.) Customers also receive most-favored-nation (MFN) pricing protections

relative to GRAIL, meaning that they have access to prices that are "no less favorable (i.e., the same or better) than" the prices provided to GRAIL. PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 7–8.)

(2) Supply Shortage

4541. Ms. Guerin-Calvert agreed that Illumina's MCED customers may need different levels of supply of either sequencers or consumables. (RX6002 (Guerin-Calvert Trial Dep. at 154)).

Response to Finding No. 4541:

Respondents have no specific response except to note that the Open Offer's provision requiring Illumina to allocate short supply "in an equitable manner among its customers (including Affiliates) based on expiring lots, and which shall not favor Affiliates over other customers" (PX0064 (Illumina) at 9) ensures that customers with the greatest need—those whose lots are expiring the earliest—will receive allocations of short supply first (RX6002 (Guerin-Calvert Trial Dep. at 77)).

4542. Ms. Guerin-Calvert testified that she had not seen any documents or testimony that spells out how Illumina intends to allocate short supply among its customers. (RX6002 (Guerin-Calvert Trial Dep. at 154-55)).

Response to Finding No. 4542:

The proposed finding is incomplete and misleading. The Open Offer itself spells out how Illumina intends to allocate short supply among its customers: "based on expiring lots". (PX0064 (Illumina) at 9.) Ms. Guerin-Calvert testified that this ensures that customers with the greatest need will receive allocations of short supply first. (RX6002 (Guerin-Calvert Trial Dep. at 77).)

4543. [redacted] (PX7085 (Harada (Exact) Dep. at 277-78) (*in camera*)).

Response to Finding No. 4543:

Respondents have no specific response except to note that the Open Offer specifically addresses the concern about allocations of supply during a supply shortage. (RX6002 (Guerin-Calvert Trial Dep. at 76–77); *see also* PFF ¶ 1012; Responses to CCFF ¶¶ 4541–42.)

(3) Illumina's Open Offer Does Not Cover Library Preparation Kits—"The Secret Sauce" of MCED Tests

4544. Illumina's library prep kits "can be customized" and that helps customers select and enrich specific targets within genetic material for sequencing. (PX7076 (Berry (Illumina) Dep. at 164-65)).

Response to Finding No. 4544:

The proposed finding is incomplete and misleading. In the portion of Ms. Berry's deposition cited here, Ms. Berry provided context for this answer: "[W]e sell library prep kits that are used in the NGS workflow that can be customized, but *not our core consumables*. Our core consumables are all standard, general purpose reagents that are not customizable." (PX7076 (Berry (Illumina) Dep. at 165) (emphasis added).)

4545. [redacted] (PX7076 (Berry (Illumina) Dep. at 166-67) (*in camera*) [redacted]).

Response to Finding No. 4545:

Respondents incorporate their responses to CCFF ¶ 4544 herein.

4546. [redacted] (PX7076 (Berry (Illumina) Dep. at 166-67) (*in camera*); deSouza (Illumina) Tr. 2456).

Response to Finding No. 4546:

Respondents have no specific response.

4547. At trial, Ms. Berry described library preparation as "the very important differential piece of the work flow between" Galleri's test and Guardant's test. (Berry (Illumina) Tr. at 679).

Response to Finding No. 4547:

The proposed finding is incomplete and misleading. Ms. Berry provided context at trial when she explained Illumina's role in the steps in the sequencing workflow, which include the genetic material isolation step, the library preparation step, and the sequencing and analysis steps. (Berry (Illumina) Tr. 814–22.)

"Once the DNA is isolated, it would go into what we call a library preparation step. And this step is very important because it's very *specific to the type of sequencing analysis that the user is -- desires to perform on the sample*." (Berry (Illumina) Tr. 815 (emphasis added).) "This is v*ery unique and specific to the particular test provider's sort of approach or methodology* to how they actually look at the DNA or RNA and then derive information from it". (Berry (Illumina) Tr. 815 (emphasis added).) "[T]he library prep is where the IP resides basically for Galleri and/or for Guardant or Tempus or Natera, or pick your oncology testing provider. So that's– those customers generally don't– they *don't buy that stuff from Illumina at all*. They create their own. And that's, again, where the essence of the differentiation and much of the intellectual property sits, in that library preparation step." (Berry (Illumina) Tr. 679 (emphasis added).) Additionally, "there are hundreds and hundreds of library preparation methods and . . . potentially *hundreds of providers* of library preparation technology or kits, *many commercial players* are in the library preparation space [whose] whole business, their whole company is focused purely on, you know, unique methods for library preparation". (Berry (Illumina) Tr. 816 (emphases added).)

After library preparation, the sample is sequenced and analyzed. Ms. Berry explained: "The core sequencing steps is where really we move into the uniquely Illumina– for our users, the uniquely Illumina step of the workflow. And it's kind of a universal step of the

workflow . . . in that an Illumina sequencer . . . is essentially a really fancy fluorescence detection machine." (Berry (Illumina) Tr. 816.) Illumina sequencers "are designed to detect fluorescent molecules . . . [a]nd it's– it's that fluorescent signal that is then translated into the fundamental DNA code . . . . And then the process of translating that code into, again, related to the application, a format that can be understood and then from which an insight can be gleaned are the steps within data analysis." (Berry (Illumina) Tr. 816–17.)

Ms. Berry further clarified the data analysis steps: Primary analysis involves the basic translation of fluorescent signals into the bases of DNA. (Berry (Illumina) Tr. 819.) "Secondary analysis is a second sort of subcomponent of data analysis whereby the specific information that is -- that correlates to the library preparation method is able to be ascertained." (Berry (Illumina) Tr. 820.) "Finally, there's a step in data analysis called tertiary analysis whereby the presence or absence of the biomarker is then potentially translated into a biological insight or a clinical insight." (Berry (Illumina) Tr. 820.) While Illumina participates in primary analysis, "as you move further through the analysis steps, so secondary analysis and finally tertiary analysis, that tends to be the domain of other providers. And specifically, the tertiary analysis piece tends to correlate very closely with library preparation. And oftentimes the library preparation provider will also provide the data analysis piece because those two pieces of the workflow go hand in hand." (Berry (Illumina) Tr. 821.)

As Ms. Berry's testimony indicates, Illumina plays a role in only one step of the DNA analysis process—the step of translating detecting fluorescent signals and translating those to DNA bases. Illumina does not participate in the library preparation step, which is the work of "hundreds of providers" whose "whole company is focused purely on" library preparation.

(Berry (Illumina) Tr. 816.) In fact, "customers generally don't– they *don't buy that stuff from Illumina at all* ." (Berry (Illumina) Tr. 679.)

4548. Library preparation is "the secret sauce for each customer" and "where the IP resides" for Galleri, Guardant, Natera, or "pick your oncology testing provider." (Berry (Illumina) Tr. 679).

Response to Finding No. 4548:

Respondents have no specific response except to note that "customers generally don't– they *don't buy [library preparation materials] from Illumina at all.* They create their own." (Berry (Illumina) Tr. 679 (emphasis added).)

4549. Ms. Berry explained, "in the case of an oncology screening assay, the library preparation method would interrogate certain places in the genome that might be indicative of the presence of a potential cancer in that person." (Berry (Illumina) Tr. 820).

Response to Finding No. 4549:

Respondents have no specific response.

4550. Ms. Berry testified that there are many companies that provide library prep technology, but noted that "in order to run a library on an Illumina platform there are specific steps at the very tail end of that process that . . . make that sample compatible to be read on an Illumina sequencer." (Berry (Illumina) Tr. 816).

Response to Finding No. 4550:

The proposed finding is incomplete and misleading. Later in her testimony, Ms. Berry provided context for this answer: The few steps at the "very tail end" of the library preparation process involve adding adapters, which are "short pieces of DNA called oligonucleotides or oligos for short", to a customer's library preparation method. (Berry (Illumina) Tr. 845.) "[T]here are numerous providers of oligos in the market." (Berry (Illumina) Tr. 845.) Further, test developers "can engineer those adapters into their library prep method and [do] not have to rely on [Illumina] for that part of the workflow". (Berry (Illumina) Tr. 845–46.)

4551. Illumina's Open Offer refers to "Supplied Product(s)," "Pre-Release Sequencing Product," "NGS Consumables," and "Sequencing Consumables." (PX0064 at 004, 012 (Illumina Open Offer agreement, Mar. 29, 2021)).

Response to Finding No. 4551:

Respondents have no specific response.

4552. The definition of "Supplied Products" includes Illumina's NGS instruments, as well as Illumina's "Sequencing Consumables." The term "Sequencing Consumables" includes "core consumables," but it does not include library prep kits or library prep consumables." (PX0064 at 004-005 (Illumina Open Offer agreement, Mar. 29, 2021)). [redacted] (PX7076 (Berry (Illumina) Dep. at 74) (*in camera*)).

Response to Finding No. 4552:

Respondents have no specific response.

4553. The provisions in the Open Offer that relate to customer access to supplied products and customer pricing do not include access to or pricing of library prep consumables. (PX0064 at 005-008 (Illumina Open Offer agreement, Mar. 29, 2021)).

Response to Finding No. 4553:

Respondents incorporate their responses to CCFF ¶¶ 4544, 4547 and 4550 herein.

4554. [redacted] (PX8390 (Exact) at 010-11 (Email from S. Coward, Exact, to A. Welland et al., Illumina, Jan. 19, 2021) (*in camera*) [redacted]).

Response to Finding No. 4554:

The proposed finding is incomplete and misleading. In the email cited here, [redacted]

[redacted]

[redacted] Further, Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 61), and therefore should not be entitled to rely on it to establish anything beyond the words on the page. Finally, Respondents also incorporate their responses to CCFF ¶¶ 4544, 4547 and 4550 herein.

d) Illumina's Commitment to Pre-Released Sequencing Products Is Flawed

4555. The Open Offer states that a "[c]ustomer shall have access for purchase to any Pre-Release Sequencing Product to which GRAIL or any For-Profit Entity is offered access within 45 days of when GRAIL or such For-Profit Entity, as applicable, is offered such access (if not earlier), and for the same categories of uses, specifically: (i) feedback to Illumina for development of NGS products, including through alpha or beta testing; (ii) for clinical trials; (iii) for clinical validation; (iv) for pre-commercial test development not relating to clinical trials; or (v) for a commercialized product developed by Customer. Customer's purchase of any Pre-Release Sequencing Product is subject to the pricing terms in Section 5 in this Supply Agreement. This provision does not apply to Pre-Release Sequencing Products that are developed by Illumina for a specific For-Profit Entity pursuant to a development agreement under 4.d. with such For-Profit Entity." (PX0064 at 004 (Illumina Open Offer Letter, Mar. 29, 2021)).

Response to Finding No. 4555:

Respondents have no specific response except to note that the proposed finding is evidence that the Open Offer fully addresses any alleged anticompetitive concerns from the merger.

4556. [redacted]

Response to Finding No. 4556:

The proposed finding is incomplete and misleading. [redacted]

Under the Open Offer [redacted], Illumina must engage "an *independent third-party auditor* selected by Illumina from among the 'Big 4' accounting firms to audit Illumina's compliance" with the Open Offer (including its product access provisions) twice a year. (PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.) Additionally, "[t]o the extent Customer has a good faith basis for alleging that Illumina is in breach of a commitment contained herein, Illumina shall engage an auditor to assess Customer's allegation separate from and in addition to Illumina's [biannual] audit[s]." (PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.) Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4557. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 103) (*in camera*)).

Response to Finding No. 4557:

Respondents incorporate their responses to CCFF ¶ 4556 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4558. Ms. Berry testified that Illumina's customers would not know whether they have access to prerelease products at the same time as Grail "unless Illumina proactively communicated such." (Berry (Illumina) Tr. 701).

Response to Finding No. 4558:

The proposed finding is incomplete and misleading. In the portion of Ms. Berry's testimony cited here, Ms. Berry provided context for this answer: Ms. Berry testified that it "certainly is [Illumina's] intent [to proactively inform customers of relevant information] as described in other sections of this open offer". (Berry (Illumina) Tr. 701.) Further, Illumina is required to provide customers with access to Pre-Release Sequencing Products within *5 days* of GRAIL receiving access (PFF ¶ 1008.1), and this provision (like the rest of the Open Offer) is subject to bi-annual, independent audits (*see* PFF ¶¶ 1047, 1051.2). Thus, customers can know whether they receive access within 5 days of GRAIL to Pre-Release Sequencing Products without Illumina proactively communicating this information. Considering the length of time that it takes to develop a test on a sequencing platform, 5 days is "a very inconsequential amount of time" for a developer making a test. (*See* Aravanis (Illumina) Tr. 1930; *see also* Berry (Illumina) Tr. 702–03; [redacted]; PX7100 (Chudova (Guardant) Dep. at 75–79); [redacted]

4559. As Dr. Bert Vogelstein explained in his declaration, "advanced knowledge of future product developments and refinements . . . could alter the research and development of new or modified tests for the earlier detection of cancer. For example, if researchers become aware that a new sequencer or product improvements would enable the field to

> analyze many more genes in one test than it can do now, researchers could use that information to begin developing tests that would be more accurate and, perhaps less expensive, to perform." (PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶ 9)).

Response to Finding No. 4559:

Respondents have no specific response except to note that the Open Offer requires Illumina to provide customers, within 5 days, with the same information that GRAIL receives about final product specifications of any sequencing instruments or core consumables. (PFF ¶ 1006; RX3935 (Illumina) at 2.)

(1) Illumina Has Already Treated Grail Preferentially with Regard to Early Access to Products

4560. [redacted]

Response to Finding No. 4560:

Respondents incorporate their responses to CCFF ¶ 4561 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4561. [redacted]

Response to Finding No. 4561:

The proposed finding is incomplete and misleading. Under the Open Offer, [redacted] GRAIL receives pricing under a universal pricing grid. (PFF ¶ 1016.5; Berry (Illumina) Tr. 894.) Customers who sign the Open Offer can choose (for each product purchased) to use the pricing they had before the Transaction or to use pricing under the same universal grid that GRAIL uses. (PFF ¶ 1014; Berry (Illumina) Tr. 892;

PX0064 (Illumina) at 7.) Additionally, under this universal pricing grid, customers receive most-favored-nations (MFN) pricing protections, which ensure that the customer has access to volume-based prices "that are no less favorable (i.e., the same or better) than" those provided to GRAIL. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 7–8.) The option to use this universal pricing grid directly addresses the concern that Illumina could treat GRAIL more favorably in terms of pricing. (PFF ¶ 1016.7; RX6002 (Guerin-Calvert Trial Dep. at 37–38).) Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Respondents also incorporate their responses to CCFF ¶ 4562 herein.

4562. [redacted]

Response to Finding No. 4562:

The proposed finding is incomplete and misleading. Specifically, under the Open Offer, [redacted], Illumina is required to provide customers with the same access to purchase sequencing instruments and core consumables that GRAIL or any other For-Profit Entity has within 5 days of when GRAIL or such For-Profit Entity receives access. (PFF ¶ 1007; Berry (Illumina) Tr. 878–79; deSouza (Illumina) Tr. 2434–35, 2437–38; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) The Open Offer's access provisions specifically address the concern that Illumina could delay access to products because they level the playing field and prevent individual customers from lagging behind in terms of the products available to them. (PFF ¶ 1009.4; RX6002 (Guerin-Calvert Trial Dep. at 61–62).) Further, the proposed finding relies on IH testimony which is hearsay and which Respondents

had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4563. [redacted]

Response to Finding No. 4563:

The proposed finding is incomplete and misleading. Specifically, under the Open Offer, [redacted], Illumina is prohibited from discontinuing products that any oncology customer has purchased in the prior year. (PFF ¶ 1011; [redacted]; Berry (Illumina) Tr. 883; PX0064 (Illumina) at 6; [redacted].) This provision adequately addresses the concern that Illumina could advantage GRAIL by simply no longer providing a product and ensures that customers as "certainly no worse off than in the current world". (PFF ¶¶ 1011.7–.8; RX6002 (Guerin-Calvert Trial Dep. at 71–73).) Additionally, the Open Offer requires Illumina to provide customers, within 5 days, with the same information that GRAIL receives about final product specifications of any sequencing instruments or core consumables. (PFF ¶ 1006; RX3935 (Illumina) at 2.) Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4564. [redacted]

Response to Finding No. 4564:

Respondents incorporate their responses to CCFF ¶ 4563 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4565. [redacted]

Response to Finding No. 4565:

Respondents incorporate their responses to CCFF ¶ 4563 herein and further note that even though Illumina typically has not provided support in the development or commercialization of customers' products, to provide additional benefits to customers, the Open Offer requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶ 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.) This not only prevents Illumina from disadvantaging GRAIL rivals, but also requires Illumina to act in a particular way to support rivals developing their own competitive products. (PFF ¶ 1010.9; RX6002 (Guerin-Calvert Trial Dep. at 68).) Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(2) Illumina's Commitment to Providing Customers Access for Purchase to Any Pre-Release Sequencing Product Within 45 Days of When Illumina Offers the Same Pre-Release Sequencing Product to Grail Fails to Adequately Protect Customers

4566. Section 4(c) of the open offer provides that customers shall have access for purchase to any pre-release sequencing product within 45 days of when Illumina offers the same pre-release

sequencing product to Grail. (Berry (Illumina) Tr. 702). Illumina's revised Open Offer shortens this time period to five days. (RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021).

Response to Finding No. 4566:

Respondents have no specific response except to note that the proposed finding is evidence that the Open Offer fully addresses any alleged anticompetitive concerns from the merger.

4567. Illumina does not commit in the open offer to provide customers access for purchase to any pre-release sequencing products in less than the 45 days (or 5 days under the Revised Open Offer) of when Illumina offers the pre-release sequencing product to Grail. (Berry (Illumina) Tr. 703-04; RX3935 at 001 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

Response to Finding No. 4567:

The proposed finding is incomplete and misleading. To be clear, the Open Offer requires Illumina to provide customers access for purchase to any pre-release sequencing products within *5 days* (not 45 days). (PFF ¶ 1008; RX3935 (Illumina) at 2.) Considering the length of time that it takes to develop a test on a sequencing platform, 5 days (or even 45 days) is "a very inconsequential amount of time" for a developer making a test. (PFF ¶ 1008.6; *see* Aravanis (Illumina) Tr. 1930; *see also* Berry (Illumina) Tr. 702–03; [redacted]; PX7100 (Chudova (Guardant) Dep. at 75–79); [redacted] Further, in the portion of Ms. Berry's testimony cited here, Ms. Berry explained that Illumina "had to set a time for which– we had to quantitate that somehow" based on what was "operationally reasonable on Illumina's side and [would] not put a potential customer at a disadvantage relative to GRAIL . . . or relative to another for-profit entity". (Berry (Illumina) Tr. 703.) Thus, the time limit set in the Open Offer is the "absolute maximum". (Berry (Illumina) Tr. 703.)

4568. Illumina does not commit in the open offer to provide customers access for purchase to any pre-release sequencing products at the same time that Illumina offers the pre-release sequencing product to Grail. (Berry (Illumina) Tr. 705-06).

Response to Finding No. 4568:

Respondents incorporate their responses to CCFF ¶ 4567 herein.

4569. Illumina's "ability to provide equitable access [to its products] has practical . . . limitations." (Berry (Illumina) Tr. 704-05).

Response to Finding No. 4569:

Respondents incorporate their responses to CCFF ¶ 4567 herein.

4570. The open offer does not define the term "access" used in Section 4(c). (Berry (Illumina) Tr. 707).

Response to Finding No. 4570:

The proposed finding is incomplete and misleading. As Ms. Berry testified: "We've retained Deloitte Consulting to help us operationalize the terms that are . . . described in the open offer such that we can be assured that we can administer those terms in a way that maximizes compliance and minimizes any time delays in terms of ensuring that Illumina is prompt in upholding our obligations under the agreement." (Berry (Illumina) Tr. 896.) Thus, to the extent that the term "access" needs further definition, Illumina has already taken actions to refine the definition in a customer-friendly manner.

4571. Ms. Berry testified at trial that Section 4(c) of the open offer does not prevent GRAIL from having knowledge of Illumina's new technology before other companies developing oncology tests. (Berry (Illumina) Tr. 708).

Response to Finding No. 4571:

The proposed finding is incomplete and misleading. Specifically, while section 4(c) of the Open Offer does not provide customers with protections relating to access to information, section 4(f) does. Specifically, section 4(f) of the Open Offer requires Illumina to provide customers, within 5 days, with the same information that GRAIL receives about final product

specifications of any sequencing instruments or core consumables. (PFF ¶ 1006; RX3935 (Illumina) at 2.)

4572. Under the open offer, Grail can learn the specifications of new Illumina sequencers before its rival MCED test developers. (Berry (Illumina) Tr. 708).

Response to Finding No. 4572:

The proposed finding is incomplete and misleading. First, in the portion of Ms. Berry's testimony cited here, Ms. Berry provided context for this answer: She testified that it "clearly is not [Illumina's] intent" to provide specifications to GRAIL before potential GRAIL rivals and that Illumina's "intent with this offer is to, you know, create a level playing field" between customers. (Berry (Illumina) Tr. 708.) Moreover, the cited portion of Ms. Berry's testimony is from August 26, 2021, but the Open Offer was amended to provide additional protections on September 8, 2021. (*See* PFF ¶ 996; RX3935 (Illumina) at 1; deSouza (Illumina) Tr. at 2405–06.) These additional protections included section 4(f) of the Open Offer, which requires Illumina to provide customers, within 5 days, with the same information that GRAIL receives about final product specifications of any sequencing instruments or core consumables. (PFF ¶ 1006; RX3935 (Illumina) at 2.)

4573. Guardant's William Getty testified, Illumina could "provide favored status or development opportunities to their internal partners in GRAIL, which would convey potentially a lack of opportunity for us to advance our technology at a faster rate." (PX7105 (Getty (Guardant) Dep. at 69-71)).

Response to Finding No. 4573:

The proposed finding is incomplete and misleading. Contrary to Mr. Getty's testimony, under the Open Offer, [redacted], Illumina cannot favor GRAIL in developing new products. As Mr. deSouza testified: "[I]n this offer letter we're saying that any product that's available for GRAIL will be available for

everyone. So we're not allowed to make a product only for GRAIL. . . . JUDGE CHAPPELL: All right, thank you. And I think you told me earlier, do you make specific products with your sequencers today? Do you make specific products for your customers? THE WITNESS: No, we do not. We sell to everyone the same portfolio." (deSouza (Illumina) Tr. 2434–35.)

Further, even though Illumina typically has not provided support in the development or commercialization of customers' products, to provide additional benefits to customers, the Open Offer requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶ 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.) This not only prevents Illumina from disadvantaging GRAIL rivals, but also requires Illumina to act in a particular way to support rivals developing their own products. (PFF ¶ 1010.9; RX6002 (Guerin-Calvert Trial Dep. at 68).)

4574. Mr. Getty testified that under the Open Offer there is no way for Guardant to know when the 45-day clock begins in which Guardant should have access to the same products as Grail. (PX7105 (Getty (Guardant) Dep. at 87)).

Response to Finding No. 4574:

The proposed finding is incomplete and misleading. At the outset, there is no "45-day clock" because the Open Offer requires Illumina to provide customers with the equivalent access to products within *5 days* of when GRAIL or such For-Profit Entity receives access. (PFF ¶ 1007; RX3935 (Illumina) at 2.) Further, customers will be aware when the clock starts running for the access provisions because, under the Open Offer, customers must be notified when a product is made available. (PFF ¶ 1091.3; RX6002 (Guerin-Calvert Trial Dep. at 64).)

4575. Further, Mr. Getty testified that even if there was the ability to know when the 45-day clock begins, "it would be largely unimportant because ultimately" it would be too late. (PX7105 (Getty (Guardant) Dep. at 87-88) ("Q. Is there any way for Guardant to known when that– the 45-day clock begins in which Guardant should have access to the same products as

> GRAIL? A. No. And even if there was an ability to do so, it would be largely unimportant because ultimately, you know, if we go back to the example of a product being developed and, you know, the interaction of a test with that product, product being, say, a sequencer, imagine a scenario where the, you know, head of GRAIL's research and development speaks with the heads of Illumina's sequencer development, the head of Illumina's sequencer development says, you know, "Ultimately we will have this technology available on" such and such date. And GRAIL's R&D engine is able to ramp up quickly in order to take advantage of that technological advance much faster than the competitive set. So, you know, whether or not we have even an ability to see it, which we wouldn't, ultimately there's also additional impacts that would be negative to Guardant, relatively speaking, from the combined company.")).

Response to Finding No. 4575:

The proposed finding is incomplete and misleading. Specifically, contrary to Mr. Getty's testimony, considering the length of time that it takes to develop a test on a sequencing platform, 45 days is "a very inconsequential amount of time" for a developer making a test. (PFF ¶ 1008.6; *see* Aravanis (Illumina) Tr. 1930; *see also* Berry (Illumina) Tr. 702–03; [redacted]; PX7100 (Chudova (Guardant) Dep. at 75–79); [redacted] Thus, the Open Offer's *significantly shorter* time frame of *5 days* is even less consequential for test developers.

Further, the Open Offer addresses the concerns hinted at in Mr. Getty's testimony that GRAIL would have early access to information about new products or would be favored in Illumina's development of new products. Specifically, the Open Offer requires Illumina to provide customers, within 5 days, with the same information that GRAIL receives about final product specifications of any sequencing instruments or core consumables (PFF ¶ 1006; RX3935 (Illumina) at 2.), so other developers will also have access to the necessary information about new products to develop their tests. Further, to the extent that developers' tests have unique features that are less compatible with new products, the Open Offer requires Illumina to enter

into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶ 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.) This not only prevents Illumina from disadvantaging GRAIL rivals, but also requires Illumina to act in a particular way to support rivals developing their own products. (PFF ¶ 1010.9; RX6002 (Guerin-Calvert Trial Dep. at 68).)

4576. [redacted]

Response to Finding No. 4576:

Respondents incorporate their responses to CCFF ¶ 4571 herein.

4577. [redacted]

Response to Finding No. 4577:

The proposed finding is incomplete and misleading. Specifically, to the extent that developers' tests have unique features that are less compatible with new products, the Open Offer, [redacted], requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶ 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.) This not only prevents Illumina from disadvantaging GRAIL rivals, but also requires Illumina to act in a particular way to support rivals developing their own products. (PFF ¶ 1010.9; RX6002 (Guerin-Calvert Trial Dep. at 68).)

4578. [redacted]

[redacted]

Response to Finding No. 4578:

Specifically, the Open Offer, [redacted], requires Illumina to provide customers, within 5 days, with the same information that GRAIL receives about final product specifications of any sequencing instruments or core consumables (PFF ¶ 1006; RX3935 (Illumina) at 2.), so other developers will also have access to the necessary information about new products to develop their tests. It also requires Illumina to give customers access to purchase any Pre-Release Sequencing Products to which GRAIL or any For-Profit Entity is offered access within 5 days of when GRAIL or such For-Profit Entity is offered access. (PFF ¶ 1008; [redacted]; Berry (Illumina) Tr. 702; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.)

Further, to the extent that developers' tests have unique features that are less compatible with new products, the Open Offer requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶ 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.) This not only prevents Illumina from disadvantaging GRAIL rivals, but also requires Illumina to act in a particular way to support rivals developing their own products. (PFF ¶ 1010.9; RX6002 (Guerin-Calvert Trial Dep. at 68).)

4579. [redacted]

Response to Finding No. 4579:

The proposed finding is incomplete and misleading. At the outset, the Open Offer requires Illumina to provide customers with the equivalent access to products within *5 days* (not 45 days) of when GRAIL or such For-Profit Entity receives access. (PFF ¶ 1007; RX3935 (Illumina) at 2.) [redacted], Illumina must engage "an independent third-party auditor selected by Illumina from among the 'Big 4' accounting firms to audit Illumina's compliance" with the Open Offer (including its product access provisions) twice a year. (PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.) Additionally, "[t]o the extent Customer has a good faith basis for alleging that Illumina is in breach of a commitment contained herein, Illumina shall engage an auditor to assess Customer's allegation separate from and in addition to Illumina's [biannual] audit[s]." (PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.) As Mr. Nolan himself testified, Freenome [redacted] Nonetheless, to provide customers with even greater insight, the Open Offer provides for regular audits *twice* a year (as well as additional audits when customers have a good-faith basis for alleging breach). (RX3935 (Illumina) at 3.)

4580. [redacted]

[redacted]

Response to Finding No. 4580:

Respondents incorporate their responses to CCFF ¶ 4579 herein.

4581. [redacted]

Response to Finding No. 4581:

Respondents incorporate their responses to CCFF ¶ 4578 herein.

4582. [redacted]

Response to Finding No. 4582:

Respondents incorporate their responses to CCFF ¶ 4578 herein.

4583. [redacted]

Response to Finding No. 4583:

Respondents incorporate their responses to CCFF ¶ 4578 herein.

4584. [redacted]

Response to Finding No. 4584:

The proposed finding is incomplete and misleading. [redacted] the Open Offer requires Illumina to provide customers with the equivalent access to products within *5 days* of when GRAIL or such For-Profit Entity receives access. (PFF ¶ 1007; RX3935 (Illumina) at 2.) Further, customers will be aware when the clock starts running for the access provisions because, under the Open Offer, customers must be notified when a product is made available. (PFF ¶ 1091.3; RX6002 (Guerin-Calvert Trial Dep. at 64).)

4585. [redacted]

Response to Finding No. 4585:

Respondents incorporate their responses to CCFF ¶ 4584 herein.

4586. [redacted]

Response to Finding No. 4586:

The proposed finding is incomplete and misleading. [redacted]

[redacted] Audit provisions in general are common and can be effectively implemented. (PFF ¶ 1050; RX6003 (Rock Trial Dep. at 29–32, 35–36, 45–46).) And an independent auditor specifically can audit the access to products provisions by publishing a comprehensive catalog of products, issuing notices when the catalog is updated and performing procedures to test whether the catalog is updated, accurate and timely. (PFF ¶ 1103.5; RX6003 (Rock Trial Dep. at 59–62); *see also* RX6002 (Guerin-Calvert Trial Dep. at 158–161); PX7076 (Berry (Illumina) Dep. at 294).)

(a) Ms. Guerin-Calvert's Pre-Release Products Analysis Does Not Meet Her Own Report's Standards

4587. Ms. Guerin-Calvert's expert report does not analyze whether Grail can access information about Illumina's pre-release products before Grail's competitors. (RX6002 (Guerin-Calvert Trial Dep. at 147)).

Response to Finding No. 4587:

The proposed finding is incomplete and misleading. Ms. Guerin-Calvert's report is dated July 16, 2021. (RX3865 (Guerin-Calvert Rebuttal Report) at 1.) However, the Open Offer was amended on September 8, 2021 to provide additional benefits, including equivalent access to information about final product specifications for new products within 5 days of when GRAIL receives such information. (PFF ¶ 1006; RX3935 (Illumina) at 2.)

4588. Ms. Guerin-Calvert testified that if Illumina gave Grail a pre-release product without requiring that Grail purchase the product that such an arrangement would be equivalent to a zero-price transfer. (RX6002 (Guerin-Calvert Trial Dep. at 147-48)).

Response to Finding No. 4588:

Respondents have no specific response.

4589. Ms. Guerin-Calvert testified that a zero-price transfer could potentially trigger Section 5(f) of the Illumina open offer. (RX6002 (Guerin-Calvert Trial Dep. at 148)).

Response to Finding No. 4589:

Respondents have no specific response.

4590. Ms. Guerin-Calvert testified that she is not providing an opinion as to whether an arbitrator must find that giving GRAIL access to a pre-release sequencing product without purchasing it is a zero-price transfer. (RX6002 (Guerin-Calvert Trial Dep. at 148)).

Response to Finding No. 4590:

The proposed finding is incomplete and misleading. When asked whether she was providing an opinion as to whether an arbitrator *must* find that giving GRAIL access to a pre-released sequencing product without purchasing it is a zero price transfer, Ms. Guerin-Calvert responded: "That's right. I said that's something that is what a role of the arbiter to do, is to evaluate that." (RX6002 (Guerin-Calvert Trial Dep. at 178).) In other words, the arbitrator's role would be to determine whether Illumina complied with its obligations. Respondents further note that "[i]n resolving any dispute under the [Open Offer], the Arbitrator shall take into account, and the Arbitrator's decision shall reflect, that the purpose of the [Open Offer] is to allay any concerns relating to the Transaction, including that Illumina would disadvantage GRAIL's potential competitors after the Transaction by increasing their sequencing prices or by withholding access to Illumina's latest innovations in NGS." (RX3935 (Illumina) at 3.)

4591. Ms. Guerin-Calvert testified that she is not providing an opinion as to whether an arbitrator must find that such a transfer of a pre-release Illumina sequencing product triggers Section 5(f) of the open offer. (RX6002 (Guerin-Calvert Trial Dep. at 148)).

Response to Finding No. 4591:

Respondents incorporate their responses to CCFF ¶ 4590 herein.

4592. Ms. Guerin-Calvert did not evaluate any potential lost revenues an MCED test developer would suffer as a result of a delay in accessing a pre-release product from Illumina. (RX6002 (Guerin-Calvert Trial Dep. at 149-50)).

Response to Finding No. 4592:

Respondents have no specific response except to note that the Open Offer prevents any potential losses due to a delay in accessing a pre-release product because the Open Offer's access provisions prevent Illumina from delaying access to products in the first place and thus prevent individual customers from lagging behind in terms of the products available to them. (PFF ¶ 1009.4; RX6002 (Guerin-Calvert Trial Dep. at 61–62).) Additionally, in the event that Illumina breached this portion of the Open Offer, an arbitrator is empowered to "order any relief necessary to restore the status quo prior to Illumina's breach, including monetary and/or injunctive relief" and the arbitrator's decision is required to reflect the fact that the purpose of the Open Offer is to allay any concerns relating to the Illumina-GRAIL transaction. (PFF ¶¶ 1055–56; RX3935 (Illumina) at 3.)

4593. Ms. Guerin-Calvert did not evaluate any loss to an MCED test developer's gross profits as a result of a delay in accessing a pre-release product from Illumina. (RX6002 (Guerin-Calvert Trial Dep. at 150)).

Response to Finding No. 4593:

Respondents incorporate their responses to CCFF ¶ 4592 herein.

(3) Early Access to New Products

4594. [redacted] (*See* PX0064 (Illumina Open Offer agreement, Mar. 29, 2021); *see also* PX7068 (Perettie (FMI-Roche) IHT at 99-100) (*in camera*)).

Response to Finding No. 4594:

The cited evidence does not support the proposed finding. [redacted]

[redacted] And the Open Offer explicitly states that Illumina must provide access to its new products within 5 days of when GRAIL or any other For-Profit Entity receives access, [redacted]. (PFF ¶ 1007; RX3935 (Illumina) at 2.) Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4595. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 100) (*in camera*)).

Response to Finding No. 4595:

The proposed finding is incomplete and misleading. [redacted], Illumina is not the sole supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.) Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4596. The last clause in the Open Offer "Access to Pre-Release Sequencing Products" term states, "This provision does not apply to Pre-Release Sequencing Products that are developed by Illumina for a specific For-Profit Entity pursuant to a development agreement under 4.d. with such For-Profit Entity." (PX0064 at 007 (Illumina Open Offer agreement, Mar. 29, 2021)).

Response to Finding No. 4596:

Respondents have no specific response.

4597. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 100-01) (*in camera*)).

Response to Finding No. 4597:

The proposed finding is inaccurate, incomplete and misleading. [redacted] However, the Open Offer also includes section 2(f), which requires Illumina to provide customers, within 5 days, with the same information that GRAIL receives about final product specifications of any sequencing instruments or core consumables. (PFF ¶ 1006; RX3935 (Illumina) at 2.)

Second, under the Open Offer, [redacted] (Berry (Illumina) Tr. 949), Illumina cannot develop a product solely for GRAIL pursuant to a development agreement. The term in the Open Offer that allows customers to enter into agreements with Illumina to create customized versions of products applies to "Customers" as defined in the Open Offer: "Illumina shall enter into, upon Customer request, a separate development agreement with Customer on commercially reasonable terms, relating to the design or modification of any Supplied Product . . . ." (PX0064 (Illumina) at 6.) Customer is defined as "the For-Profit Entity that enters into [the Open Offer agreement] with Illumina". (PX0064 (Illumina) at 3.) And the definition of For-Profit Entity specifically excludes GRAIL: "For-Profit Entity excludes governments, government agencies, hospitals, research institutes, academic institutions,

nonprofits and Illumina Affiliates (including GRAIL)." (PX0064 (Illumina) at 3.) Thus, under the Open Offer Illumina could have an agreement with GRAIL that allows them to develop a product for GRAIL alone. To the contrary, Illumina cannot favor GRAIL in developing new products. As Mr. deSouza testified: "[I]n this offer letter we're saying that any product that's available for GRAIL will be available for everyone. So we're not allowed to make a product only for GRAIL." (deSouza (Illumina) Tr. 2434–35.)

Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4598. One of Mr. Getty's concerns about the Proposed Acquisition is that sharing information about a new sequencer in development could give Grail a "significant head start" on developing the next version of its assay. (Getty (Guardant) Tr. 2518-19).

Response to Finding No. 4598:

The proposed finding is incomplete and misleading. Specifically, the Open Offer addresses this concern. The Open Offer requires Illumina to provide customers, within 5 days, with the same information that GRAIL receives about final product specifications of any sequencing instruments or core consumables. (PFF ¶ 1006; RX3935 (Illumina) at 2.) Further, to the extent that customers remain concerned that GRAIL would somehow be favored in Illumina's development of new products, the Open Offer requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶ 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.) This not only prevents Illumina from disadvantaging GRAIL rivals, but also requires Illumina to act in a particular way to support rivals developing their own products. (PFF ¶ 1010.9; RX6002 (Guerin-Calvert Trial Dep. at 68).)

4599. [redacted]

Response to Finding No. 4599:

Respondents incorporate their responses to CCFF ¶ 4598 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4600. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 101) (*in camera*)).

Response to Finding No. 4600:

The proposed finding is incomplete and misleading. [redacted]

[redacted] Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4601. [redacted]

Response to Finding No. 4601:

The proposed finding is incomplete and misleading. Specifically, the Open Offer requires Illumina to provide customers with access to new products within 5 days of GRAIL receiving access. (PFF ¶ 1007; Berry (Illumina) Tr. 878–79; deSouza (Illumina) Tr. 2434–35, 2437–38; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) The Open Offer's access provisions specifically address the concern that Illumina could delay access to products because they level the playing field and prevent individual customers from lagging behind in terms of the products available to them. (PFF ¶ 1009.4; RX6002 (Guerin-Calvert Trial Dep. at 61–62).)

4602. [redacted]

Response to Finding No. 4602:

Respondents have no specific response.

4603. [redacted]

Response to Finding No. 4603:

Respondents incorporate their responses to CCFF ¶ 4598 herein.

4604. [redacted]

[redacted]

Response to Finding No. 4604:

Respondents incorporate their responses to CCFF ¶ 4597 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4605. [redacted]

Response to Finding No. 4605:

Respondents incorporate their responses to CCFF ¶ 4598 herein.

4606. [redacted]

Response to Finding No. 4606:

Respondents incorporate their responses to CCFF ¶ 4598 herein.

4607. Dr. Vogelstein testified that based on his "knowledge and experience as a cancer researcher" the "advanced knowledge of future product developments and refinements from Illumina's public announcements could alter the research and development of new or modified tests for the earlier detection of cancer." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 69-71)). As an example, Dr. Vogelstein testified that "if researchers become aware that a new sequencer or product improvements" have been made then this "would enable the field to analyze many more genes in one test than it can do now" and "researchers could use that information to begin developing tests that would be more accurate and perhaps less expensive to perform." (PX7101 (Vogelstein (JHU Johns Hopkins University Dep. at 70-71)).

Response to Finding No. 4607:

Respondents incorporate their responses to CCFF ¶ 4559 herein.

4608. Dr. Vogelstein testified that the "foreknowledge" about future product developments and refinements of Illumina's products "could substantially alter research and development in

the field and the nature of the test products that are eventually produced." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 70)).

Response to Finding No. 4608:

Respondents incorporate their responses to CCFF ¶ 4559 herein.

e) Illumina's Development Agreement Commitment Is Flawed

4609. The Open Offer states that a "Illumina shall enter into, upon Customer request, a separate development agreement with Customer on commercially reasonable terms, relating to the design or modification of any Supplied Product, in a manner that optimizes interoperability with Customer's tests, including, without limitation, capabilities, performance, speed, efficiency, cost, convenience, accuracy, specificity, precision, ease of use and user experience." (PX0064 at 006 (Illumina Open Offer agreement, Mar. 29, 2021)). Ms. Berry explained that "this provision provides the opportunity for Illumina and the customer to discuss and develop potentially a separate agreement that might relate to a customer's interest in modifying a supplied product specifically for that customer and to, you know, work optimally with that customer's part of the workflow or their tests." (Berry (Illumina) Tr. 881).

Response to Finding No. 4609:

Respondents have no specific response except to note that the proposed finding is evidence that the Open Offer fully addresses any alleged anticompetitive concerns from the merger.

4610. Ms. Berry testified that she is not aware of any development agreements Illumina has with any of its customers. (PX7076 (Berry (Illumina) Dep. at 280)).

Response to Finding No. 4610:

The proposed finding is incomplete and misleading. In the portion of Ms. Berry's deposition cited here, Ms. Berry testified that this question was "outside of [her] area of responsibility". (PX7076 (Berry (Illumina) Dep. at 280).)

4611. [redacted]

[redacted]

Response to Finding No. 4611:

The proposed finding is incomplete and misleading. [redacted]

The term in the Open Offer that allows customers to enter into development agreements with Illumina to create customized versions of products applies to "Customers" as defined in the Open Offer: "Illumina shall enter into, upon Customer request, a separate development agreement with Customer on commercially reasonable terms, relating to the design or modification of any Supplied Product . . . ." (PX0064 (Illumina) at 6.) Customer is defined as "the For-Profit Entity that enters into [the Open Offer agreement] with Illumina". (PX0064 (Illumina) at 3.) And the definition of For-Profit Entity specifically excludes GRAIL: "For-Profit Entity excludes governments, government agencies, hospitals, research institutes, academic institutions, nonprofits and Illumina Affiliates (including GRAIL)." (PX0064 (Illumina) at 3.) Thus, under the Open Offer Illumina could have an agreement with GRAIL that allows them to develop a product for GRAIL alone. To the contrary, Illumina cannot favor GRAIL in developing new products. As Mr. deSouza testified: "[I]n this offer letter we're saying that any product that's available for GRAIL will be available for everyone. So we're not allowed to make a product only for GRAIL." (deSouza (Illumina) Tr. 2434–35.) Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no

opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4612. [redacted]

Response to Finding No. 4612:

Respondents incorporate their responses to CCFF ¶ 4611 herein. Respondents further note that, contrary to the statement in the proposed finding, [redacted] Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4613. [redacted]

Response to Finding No. 4613:

The proposed finding is directed to irrelevant subject matter because [redacted]

[redacted]

4614. [redacted]

Response to Finding No. 4614:

The proposed finding is incomplete and misleading. [redacted]

4615. Dr. Scott Morton, testified that "[u]nder the status quo" meaning if Illumina and Grail remain separate "Illumina has an incentive to help its customers develop profitable

products so that it can sell sequencing. It will be helping those consumers in any way that makes sense that enables [Illumina] to increase its sales and without owning GRAIL, [Illumina] has that incentive for all MCED developers." (RX3852 (Scott Morton Dep. at 256)).

Response to Finding No. 4615:

The proposed finding is incomplete and misleading. Specifically, Illumina continues to be incentivized to help its customers develop profitable products because [redacted] Moreover, prior to the Open Offer, Illumina typically did not provide support in the development or commercialization of its customers' products. (Berry (Illumina) Tr. 846–47.) Instead, customers have typically purchased Illumina equipment and reagents "off the shelf" and have not been able to commission Illumina to make custom sequencing equipment. (Berry (Illumina) Tr. 845; [redacted] Thus, under the status quo, it would be extremely rare for a customer to enter such a development agreement with Illumina.

Additionally, regardless of Dr. Scott Morton's views on Illumina's incentives pre- and post-merger, the development agreement term still represents an improvement over the status quo because customers are *guaranteed* that Illumina will enter into development agreement on a customer's request.

4616. Ms. Scott Morton continued to explain that if Illumina and Grail remain separate, customers will not need a development agreement guarantee from Illumina because Illumina will have an incentive to work with the customer. "If there is no reason to enter into the development agreement because Illumina wouldn't make money, Illumina won't. But if [Illumina] will [make money], then they have an incentive to do it, and that protects those customers." (RX3852 (Scott Morton Dep. at 256)).

Response to Finding No. 4616:

Respondents incorporate their responses to CCFF ¶ 4615 herein.

4617. Prior to Illumina and Grail closing their transaction, customers did not have a commitment from Illumina to enter into a development agreement. However customers did not "need one because the competition protects them. Illumina doesn't own GRAIL and doesn't have an incentive to foreclose against them." (RX3852 (Scott Morton Dep. at 256-57)).

Response to Finding No. 4617:

Respondents incorporate their responses to CCFF ¶ 4615 herein.

f) Illumina's No Obsolescence Commitment Is Flawed

4618. The Open Offer states that "Illumina shall not discontinue any Supplied Product so long as Customer continues to purchase that Supplied Product. Illumina may discontinue a Supplied Product that Customer has not purchased in more than one year." (PX0064 at 006 (Illumina Open Offer agreement, Mar. 29, 2021)).

Response to Finding No. 4618:

Respondents have no specific response except to note that the proposed finding is evidence that the Open Offer fully addresses any alleged anticompetitive concerns from the merger.

4619. [redacted]

Response to Finding No. 4619:

Respondents have no specific response.

4620. [redacted]

Response to Finding No. 4620:

Respondents have no specific response.

4621. [redacted]

Response to Finding No. 4621:

The proposed finding is inaccurate, incomplete and misleading. [redacted]

[redacted]

The Open Offer's no-obsolescence term forbids Illumina from discontinuing products that any oncology customer has purchased in

the prior year. (PFF ¶ 1011; Berry (Illumina) Tr. 883; PX0064 (Illumina) at 6; [redacted].) The no-obsolescence term also interacts with the pricing terms of the Open Offer by ensuring that customers are "certainly no worse off than in the current world" and are actually better off because they are assured continued availability of products and no price increases. (RX6002 (Guerin-Calvert Trial Dep. at 72–73).) If a customer does want to switch to a new product, they are able to because Illumina must provide Open Offer customers with access to any new products within 5 days of GRAIL or any For-Profit Entity receiving access. (See PFF ¶¶ 1005, 1008; Berry (Illumina) Tr. 702, 878–79; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.

4622. [redacted]

Response to Finding No. 4622:

Respondents incorporate their responses to CCFF ¶ 4621 herein.

4623. [redacted]

Response to Finding No. 4623:

Respondents incorporate their responses to CCFF ¶ 4621 herein.

4624. [redacted]

[redacted]

Response to Finding No. 4624:

Respondents have no specific response except to note that the Open Offer's provisions on obsolescence ensure that customers are not required to migrate to a new instrument when it comes available. (*See* PFF ¶ 1011.) Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4625. [redacted]

Response to Finding No. 4625:

Respondents incorporate their responses to CCFF ¶ 4624 herein.

4626. [redacted]

Response to Finding No. 4626:

Respondents incorporate their responses to CCFF ¶ 4624 herein.

4627. [redacted]

Response to Finding No. 4627:

The proposed finding is incomplete and misleading. [redacted]

4628. [redacted]

Response to Finding No. 4628:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

4629. [redacted]

Response to Finding No. 4629:

Respondents have no specific response.

4630. [redacted]

Response to Finding No. 4630:

Respondents have no specific response.

g) Illumina's Pricing Commitments Are Flawed

4631. Mr. deSouza testified the Open Offer provides that a customer "will get access to the same prices" as Grail. (deSouza (Illumina) Tr. 2402).

Response to Finding No. 4631:

Respondents have no specific response except to note that the proposed finding is evidence that the Open Offer fully addresses any alleged anticompetitive concerns from the merger.

4632. Specifically, the Open Offer provides that Illumina will not increase prices, and that, by 2025, the volume-based price "per gigabase of sequencing using the highest throughput Illumina instrument then available . . . will be at least 43% lower" than the current price per gigabase of sequencing using the NovaSeq instrument. (PX0064 (Illumina) at 007 (Open Offer § 5d New Product Pricing, Mar. 29, 2021)).

Response to Finding No. 4632:

Respondents have no specific response except to note that the proposed finding is evidence that the Open Offer fully addresses any alleged anticompetitive concerns from the merger.

4633. [redacted]

Response to Finding No. 4633:

The proposed finding is incomplete and misleading. [redacted] Under the Open Offer, "Illumina shall publish, on the 'Oncology Contract Terms' website, (i) the Supplied Products, by SKU, that

GRAIL is purchasing; (ii) the service plans, by SKU, that GRAIL is purchasing; and (iii) the pricing grid for both products and services under which GRAIL is purchasing Supplied Products and services. To the extent necessary, Illumina shall update this website within 5 days of entry of any purchase order for Supplied Products or any service contract relating to the Supplied Products by GRAIL." (PFF ¶ 1005.5; RX3935 (Illumina) at 2; RX4003 (Illumina) at 1; RX3960 (Illumina).)

Further, the pricing provisions of the Open Offer are enforceable. *First*, the pricing provisions (like the rest of the Open Offer) are subject to bi-annual audits, as well as additional audits if customers have a good-faith basis for alleging breach. (PFF ¶ 1047; deSouza (Illumina) Tr. 2405, 2438; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.) An independent auditor can audit the pricing provisions by ensuring that the population of data audited is complete, ensuring accuracy of net prices and discount tiers and ensuring reporting and compliance with the no-price-increase commitment. (PFF ¶ 1103.6; RX6003 (Rock Trial Dep. at 63–65); *see also* RX6002 (Guerin-Calvert Trial Dep. at 159); PX7076 (Berry (Illumina) Dep. at 284, 290).)

Second, Illumina agrees to binding arbitration in the event that a dispute arises under the agreement. (PFF ¶ 1054; [redacted]; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 10–11; PX7076 (Berry (Illumina) Dep. at 282–83).) The arbitrator may order any relief necessary to restore the status quo prior to Illumina's breach, including monetary and/or injunctive relief, and must follow the Commercial Arbitration Rules of the American Arbitration Association. (PFF ¶ 1055; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3; deSouza (Illumina) Tr. 2451–52.)

Finally, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4634. Because the Open Offer states that a customer will get access to the same prices as Grail, this means that Illumina has to provide its products to Grail's rivals at cost—something that Respondents have never alleged, and that Carlton admits "is not my understanding." (RX6000 (Carlton Trial Dep. at 142)).

Response to Finding No. 4634:

The proposed finding is not supported by the cited evidence, and is incomplete and misleading. The Open Offer states that customers will have access to the same prices as GRAIL, but this does not mean that Illumina will provide its products to GRAIL's potential rivals at cost. Mr. deSouza testified: "GRAIL is a separate organization. . . . They will have their own budget, and they do, and then they will spend against that budget. And so if they purchase a [product from Illumina], it will be against that budget, and they would have to pay the other Illumina entity for those transactions." (deSouza (Illumina) Tr. 2468.) Thus, the Open Offer does not require Illumina to make its products available to GRAIL or GRAIL's potential rivals at cost. In the portion of Dr. Carlton's testimony cited, Complaint Counsel asked Dr. Carlton whether the Open Offer would require Illumina "to offer NGS sequencing to MCED developers at Illumina's marginal cost", and Dr. Carlton responded, "That is not my understanding." (RX6000 (Carlton Trial Dep. at 142).) Dr. Carlton's response makes sense because this is not what the Open Offer requires.

Nonetheless, the Open Offer's provisions fully address any anticompetitive concerns relating to pricing, and any suggestion that the failure to provide access to products at cost renders the pricing provisions ineffective is misplaced. There are at least four complementary components of the pricing provisions that work together to ensure that customers are not

disadvantaged post-merger. *First*, the Open Offer requires that customers can access the same volume-based prices that GRAIL or any other For-Profit Entity has access to, which ensures that Illumina cannot favor GRAIL or any other For-Profit Entity in terms of pricing. (*See* PFF ¶¶ 1016–19; RX6002 (Guerin-Calvert Trial Dep. at 37–38).) *Second*, to the extent that customers prefer to keep their existing, pre-merger pricing, customers may opt for Grandfathered Pricing, which ensures that customers can continue to receive their legacy pricing over the full 12-year term. (*See* PFF ¶ 1015; Berry (Illumina) Tr. 902–03; PX0064 (Illumina) at 6–7.) *Third*, the Open Offer expressly forbids Illumina from raising prices over the entire 12-year term. (*see* PFF ¶ 1021; [redacted] Berry (Illumina) Tr. 899; Conroy (Exact/Thrive) Tr. 1731; PX0064 (Illumina) at 7; [redacted].) *Fourth*, under the Open Offer, Illumina agrees that by 2025, it will reduce the pricing of sequencing by at least 43%, regardless of whether a customer is receiving Grandfathered Pricing or Universal Pricing. (*See* PFF ¶ 1023; [redacted]; Berry (Illumina) Tr. 712–13, 897, 903–04; Conroy (Exact/Thrive) Tr. at 1731–32; deSouza (Illumina) Tr. 2403; PX0064 (Illumina) at 7; [redacted].) All of these pricing provisions work together to provide guarantees to potential MCED test developers that they will receive fair pricing from Illumina in the short term, medium term and long term. (PFF ¶ 1025; RX6002 (Guerin-Calvert Trial Dep. at 53).)

4635. [redacted]

Response to Finding No. 4635:

The proposed finding is incomplete and misleading. Specifically, under the Open Offer, Illumina is forbidden from increasing prices beyond inflation for the entire 12-year term. (PFF ¶ 1021; [redacted]; Berry (Illumina) Tr. 899; Conroy (Exact/Thrive) Tr.

1731; PX0064 (Illumina) at 7; [redacted].) Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4636. [redacted]

Response to Finding No. 4636:

Respondents incorporate their responses to CCFF ¶ 4635 herein. Respondents further notes that [redacted] Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4637. [redacted]

Response to Finding No. 4637:

The proposed finding is incomplete and misleading. Under the Open Offer [redacted] customers must have access to

pricing that is "no less favorable (i.e., the same or better) than" that provided to GRAIL. (PFF ¶ 1018.1; PX0064 (Illumina) at 8.) Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4638. Helio's CEO, Mr. Chahine, testified that post acquisition "Illumina would be Grail, so I don't know what giving Grail a price actually means in this context." (PX7077 (Chahine (Helio) Dep. at 114-15)).

Response to Finding No. 4638:

The proposed finding is incomplete and misleading. As Mr. deSouza testified, "GRAIL is a separate organization. . . . They will have their own budget, and they do, and then they will spend against that budget. And so if they purchase a [product from Illumina], it will be against that budget, and they would have to pay the other Illumina entity for those transactions." (deSouza (Illumina) Tr. 2468.) Additionally, in the cited portion of Mr. Chahine's deposition, he stated that "[p]utting everyong in an equal playing field with respect to a competitive advantage that GRAIL would have with respect to pricing would certainly be– would certainly mitigate some of [Helio's] concern." (PX7077 (Chahine (Helio) Dep. at 115).)

(1) Pricing Terms Allow for Illumina Manipulation

4639. Illumina can offer customers discretionary discounts off of the public pricing discount grid for special projects or to upgrade sequencers. (deSouza (Illumina) Tr. 2440-43; *see* PX6056 (Illumina) at 022 (Narrative Response to Second Request, Mar. 1, 2021 ("Illumina from time to time negotiates customer-specific discounts" and "promotional discounts")).

Response to Finding No. 4639:

The proposed finding is incomplete and misleading. If GRAIL received a discretionary discount that was higher than the discounts in the Open Offer's universal pricing grid, "Illumina would be obliged to reduce the price that was offered" to GRAIL. (Berry (Illumina) Tr. 893–

94.) Illumina would also be obliged under the Open Offer to extend a discretionary discount that was offered to one customer to all other Equivalent customers. (Berry (Illumina) Tr. 893–94.)

4640. Illumina's does not publish other oncology customers' discretionary discounts. (deSouza (Illumina) Tr. 2440).

Response to Finding No. 4640:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina maintains the confidentiality of customers' competitively sensitive information.

4641. [redacted] (Berry (Illumina) Tr. 781 (*in camera*)).

Response to Finding No. 4641:

Respondents incorporate their responses to CCFF ¶ 4639 herein.

4642. Under the Open Offer, customers are only eligible to receive discretionary discounts for activities that are considered "short term projects" as defined in the Open Offer, meaning the activities fall outside of the normal course of business. (Berry (Illumina) Tr. 925; PX0064 at 008 (Illumina Open Offer agreement, dated March 30, 2021)).

Response to Finding No. 4642:

Respondents have no specific response.

4643. Ms. Berry testified that discretionary discounts determine the "ultimate[] price the customer pays." (PX7063 (Berry (Illumina) IHT at 17-18)).

Response to Finding No. 4643:

Respondents incorporate their responses to CCFF ¶ 4639 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4644. Some of Illumina's customers have negotiated lower pricing than what is contemplated in the Open Offer. (Berry (Illumina) Tr. 926).

Response to Finding No. 4644:

Respondents have no specific response except to note that, under the Open Offer, customers may select Grandfathered Pricing, which gives customers the option to keep their legacy price. (Berry (Illumina) Tr. 889–90.) This provision was included because some customers may have the view that their current (pre-merger) pricing was more favorable for a particular product than the price offered in the Open Offer. (Berry (Illumina) Tr. 889–90.)

[redacted] (RX6002 (Guerin-Calvert Trial Dep. at 41).)

4645. [redacted]

Response to Finding No. 4645:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina maintains the confidentiality of customers' competitively sensitive information.

4646. Transactions between Illumina and Grail are now between two Illumina entities. (deSouza (Illumina) Tr. 2462).

Response to Finding No. 4646:

The proposed finding is incomplete and misleading. As Mr. deSouza testified, "GRAIL is a separate organization. . . . They will have their own budget, and they do, and then they will spend against that budget. And so if they purchase a [product from Illumina], it will be against that budget, and they would have to pay the other Illumina entity for those transactions." (deSouza (Illumina) Tr. 2468.)

4647. Illumina will be responsible for publishing any prices on Grail's website. (deSouza (Illumina) Tr. 2466).

Response to Finding No. 4647:

Respondents have no specific response except to note that this requirement, as with the other requirements of the Open Offer, is subject to bi-annual audits to report any instances of non-compliance by Illumina. (*See* PFF ¶¶ 1047–52.)

4648. The price at which Grail purchases products from Illumina represents the price at which one Illumina entity purchases from another. (deSouza (Illumina) Tr. 2465).

Response to Finding No. 4648:

Respondents incorporate their responses to CCFF ¶ 4646 herein.

4649. The price Illumina charges to its Grail subsidiary for consumables will have no net impact on the combined entity's net P&L. (deSouza (Illumina) Tr. 2467-68).

Response to Finding No. 4649:

Respondents incorporate their responses to CCFF ¶ 4646 herein.

4650. The price Illumina charges to its Grail subsidiary for sequencers will have no net impact on the combined entity's net P&L. (deSouza (Illumina) Tr. 2469-70).

Response to Finding No. 4650:

Respondents incorporate their responses to CCFF ¶ 4646 herein.

4651. Grail's own Vice President of Finance, Aaron Freidin, testified that while he does not know how Illumina will account for Grail's purchases of Illumina products, he does know "that it's all eliminates and you end up with a true cost at the end when you report your financials as a public company." (Freidin (Grail) Tr. 3153).

Response to Finding No. 4651:

Respondents incorporate their responses to CCFF ¶ 4646 herein.

4652. Respondents' economic expert, Dr. Carlton, likewise testified that "GRAIL doesn't technically pay a price. If you want to make up a scenario in which you force GRAIL to 'pay some price,' and you call that a transfer price . . . I'm happy to make that assumption." (RX6000 (Carlton Trial Dep. at 141-42)).

Response to Finding No. 4652:

The proposed finding is incomplete and misleading. In the portion of Dr. Carlton's testimony cited here, Dr. Carlton was discussing the relevant economic considerations for the estimations about EDM made in Table 1 of his report. (*See* RX6000 (Carlton Trial Dep. at 139–42).) Dr. Carlton explained: The question as to whether "the GRAIL rivals are paying a price other than a price paid by GRAIL isn't the particularly meaningful economic question. There can be a different question, which is could [Illumina] set a transfer price that provides some additional protection to GRAIL rivals? That's a separate question entirely, but from my point of view, if you're asking me how do I know that a rival to GRAIL won't have to fear that its costs go up from GRAIL, that's what the open offer protects, and, in particular, the part of the open offer that says I'm not going to raise price, and, moreover, I'm going to lower price by 43 percent by 2025. That's their protection. There's an additional clause -- and this is perhaps what you're referring to on, I believe, transfer pricing -- but from my point of view as an economist, I don't really need that, but if someone is worried about that as providing additional protection or someone wants that to provide additional protection, that additional protection will depend entirely on what are the mechanics for how that transfer price is set." (RX6000 (Carlton Trial Dep. at 140–41.)

That is, from an economic standpoint, the transfer price is irrelevant to the question of whether Illumina can raise potential GRAIL rivals' costs. As Dr. Carlton testified, the Open Offer "specifically prevents [Illumina] from raising [customers'] costs" and, in fact, includes "a 43 percent price decrease guarantee by 2025". (RX6000 (Carlton Trial Dep. at 202).) While the transfer price is not relevant to that question, the universal pricing provisions provide additional

protection for customers by ensuring that customers have access to the transfer price set for GRAIL. (*See* PFF ¶¶ 1016, 1018.)

4653. Section 5(d) of the Open Offer provides that the price per giga base of sequencing on Illumina's then-available highest throughput instrument will be 43 percent lower than the price per giga base of sequencing using the NovaSeq sequencer. (Berry (Illumina) Tr. 710-11).

Response to Finding No. 4653:

Respondents have no specific response.

4654. The Open Offer only provides for a 43 percent price decrease on Illumina's highest throughput instrument. (Berry (Illumina) Tr. 712; PX0064 at 005 (Illumina Open Offer, Mar. 29, 2021)).

Response to Finding No. 4654:

The proposed finding is incomplete and misleading. In the portion of Ms. Berry's testimony cited here, she provided context for this answer: "Well, what we're doing essentially in this paragraph is committing and obligating ourselves to a significant price reduction, and the only way to really define that is on an apples-to-apples basis. . . . [W]e have to pick something to create an apples-to-apples comparison, because we have a broad portfolio of flow cells, and so the stake that we're putting in the ground is we will guarantee a price reduction for a flow cell that relative to its position in our current portfolio, you know, similar to the NovaSeq S4, will be 43 percent less." (Berry (Illumina) Tr. 711–12.)

4655. Under Section 5(d) of the Open Offer, if Illumina introduces a higher throughput instrument than the NovaSeq by 2025, the 43 percent price decrease commitment would only apply to that new, higher throughput sequencer. (Berry (Illumina) Tr. 712).

Response to Finding No. 4655:

Respondents incorporate their responses to CCFF ¶ 4654 herein.

4656. Ms. Berry testified at trial that customers that are currently developing multicancer early detection tests on the NovaSeq would have to switch to the new higher throughput instrument in order to benefit from the pricing decrease. (Berry (Illumina) Tr. 713).

Response to Finding No. 4656:

The proposed finding is incomplete and misleading. In the portion of Ms. Berry's testimony cited here, Ms. Berry provided context for this answer: Switching to a new instrument to benefit from a price decrease is "absolutely consistent with how we have conducted our, you know, new product introduction practices. So certainly our acquisition of GRAIL doesn't disadvantage a customer relative to our legacy, you know, strategies as they relate to pricing and new product introductions. And, in fact, I would say that this is– the terms introduced in this paragraph actually are better for a customer because they absolutely commit and obligate Illumina to reducing price, where, absent this agreement, there was no such commitment." (Berry (Illumina) Tr. 713.)

4657. The Open Offer provides no guarantee that Illumina will reduce the price of its sequencers before 2025. (Berry (Illumina) Tr. 714-15).

Response to Finding No. 4657:

The proposed finding is incomplete and misleading. In the portion of her testimony cited here, Ms. Berry provided context for this answer: "[I]f you look at Illumina' track record in terms of our innovation and new product introduction process, we consistently have sought to drive down pricing through the introduction of new instrument platforms, through new chemistries within instrument platforms, on a very regular basis." (Berry (Illumina) Tr. 714.)

4658. The Open Offer provides Illumina's MCED test developing customers with no guarantee that Illumina will reduce the price of its sequencers by more than 43 percent by 2025. (Berry (Illumina) Tr. 715).

Response to Finding No. 4658:

The proposed finding is incomplete and misleading. In the portion of Ms. Berry's testimony cited here, Ms. Berry provided context for this answer: "[W]e had to put a stake in the ground against which customers could be assured and we could specifically hold ourselves

compliant to an absolute specification or threshold, and 43 percent is the threshold we chose, which is a very significant reduction relative to where the NovaSeq S4 300 is today." (Berry (Illumina) Tr. 715.) Further, the 43-percent number was chosen "because that's the price we assumed in our business model that GRAIL" would pay in 2025. (deSouza (Illumina) Tr. 2338.)

4659. It costs approximately $600 to sequence one person's genome today. (Berry (Illumina) Tr. 716).

Response to Finding No. 4659:

Respondents have no specific response.

4660. Illumina has publicly announced its intent to drive sequencing costs down to $100 per genome. (Berry (Illumina) Tr. 715).

Response to Finding No. 4660:

Respondents have no specific response except to note that the proposed finding is evidence of Illumina's efforts to expand access to NGS.

4661. Illumina anticipates that sequencing costs will fall significantly over time. (PX7104 (Aravanis (Illumina) Dep. at 219-220)).

Response to Finding No. 4661:

The proposed finding is incomplete and misleading. In the portion of Dr. Aravanis's deposition cited here, Dr. Aravanis was asked: "How much lower is the price of sequencing going to get in the next five years?" (PX7104 (Aravanis (Illumina) Dep. at 219).) Dr. Aravanis responded: "Well, we've committed openly to at least a– I believe a 43 percent reduction. We're going to work hard to achieve that. That's what is in our open letter. We have capabilities in development that over time should reduce the cost of sequencing even more. I can't predict exactly when those will be available, but eventually they should be." (PX7104 (Aravanis (Illumina) Dep. at 219–20).)

4662. Ms. Berry testified at trial that a sequencing cost decrease from $600 to $100 is more than the 43 percent price decrease in Illumina's open offer. (Berry (Illumina) Tr. 715 (a decrease from $600 to $100 per genome would be a 83 percent decrease)).

Response to Finding No. 4662:

The proposed finding is incomplete and misleading. While Illumina aspires and aims to lower the price of sequencing a human genome to $100, the Open Offer provides an enforceable contractual guarantee that lllumina will lower the price of sequencing by 2025. As Ms. Berry explained, "the terms introduced in this paragraph actually are better for a customer [than the status quo, in which Illumina aimed, but was not required, to reduce sequencing prices] because they absolutely commit and obligate Illumina to reducing price[s]". (Berry (Illumina) Tr. 713.)

4663. Ms. Berry testified that a $100 genome is a stated goal of Illumina's. (Berry (Illumina) Tr. 715).

Response to Finding No. 4663:

Respondents have no specific response except to note that the proposed finding is evidence of Illumina's efforts to expand access to NGS.

4664. Ms. Berry confirmed that the Open Offer does not guarantee a reduce in Illumina's pricing more than 43 percent. (Berry (Illumina) Tr. 715).

Response to Finding No. 4664:

Respondents incorporate their responses to CCFF ¶ 4658 herein.

4665. Ms. Berry testified that Illumina's sequencing cost for one genome on the NovaSeq 6000 is about $600. (Berry (Illumina) Tr. 716).

Response to Finding No. 4665:

Respondents have no specific response except to note that the proposed finding is evidence of Illumina's efforts to expand access to NGS.

4666. Ms. Berry testified that a price decrease from $600 to $100 is much more than a 43 percent price decrease. (Berry (Illumina) Tr. 716).

Response to Finding No. 4666:

Respondents incorporate their responses to CCFF ¶ 4462 herein.

4667. Illumina's CEO, Mr. deSouza testified that today Illumina is already at a $600 genome and Illumina has "publicly said we are going to take it down by another 80 percent, [to] $100 a genome." (deSouza (Illumina) Tr. 2398).

Response to Finding No. 4667:

Respondents have no specific response.

4668. [redacted]

Response to Finding No. 4668:

Respondents have no specific response.

4669. [redacted] (PX2558 (Illumina) at 012 (Email from E. Milsovic, Illumina, to F. deSouza, Illumina, attaching February 2021 Board of Directors Executive Session Presentation, Feb. 9, 2021) (*in camera*)).

Response to Finding No. 4669:

Respondents have no specific response.

4670. [redacted]

Response to Finding No. 4670:

The proposed finding is incomplete and misleading. The term Moore's law describes a reduction in price over time in the computer industry, and "Flatley's law" was "coined to describe the dramatic reduction in price in genomics . . . that was achieved during Jay Flatley's leadership at Illumina." (Berry (Illumina) Tr. 811.) Although Flatley's law continues today and "it still remains an absolute relentless goal that [Illumina's] research and technology

development groups are pursuing", "the curve is flattening out" in terms of the price reduction that Illumina can achieve with each innovation. (Berry (Illumina) Tr. 811–12.) Moreover, Illumina anticipates that the current "competitive environment [in genomics] will . . . only become more intensive over time." (Berry (Illumina) Tr. 813.)

Additionally, the 43-percent number in the Open Offer was chosen "because that's the price [Illumina] assumed in [its] business model that GRAIL" would pay in 2025. (deSouza (Illumina) Tr. 2338.) The 43-percent decrease "very directly" addresses the concern that Illumina could foreclose GRAIL rivals because it "commits Illumina by a date-certain, 2025, for its highest throughput product to deliver to customers a 43 percent reduction in price of that product." (RX6002 (Guerin-Calvert Trial Dep. at 49).) As Ms. Berry explained, the price-decrease provision is "better for a customer [than the status quo, in which Illumina aimed, but was not required, to reduce sequencing prices] because [the provision] absolutely commit[s] and obligate[s] Illumina to reducing price[s]". (Berry (Illumina) Tr. 713.)

4671. [redacted]

Response to Finding No. 4671:

The proposed finding is incomplete and misleading. In the portion of Dr. Chahine's deposition cited here, Dr. Chahine testified that [redacted]

4672. [redacted]

Response to Finding No. 4672:

The proposed finding is incomplete and misleading. As Mr. deSouza testified, "GRAIL is a separate organization. . . . They will have their own budget, and they do, and then they will spend against that budget. And so if they purchase a [product from Illumina], it will be against that budget, and they would have to pay the other Illumina entity for those transactions." (deSouza (Illumina) Tr. 2468.)

4673. [redacted] (PX7138 (Scott Morton Trial Dep. at 76) (*in camera*)).

Response to Finding No. 4673:

The proposed finding is incomplete and misleading. In concluding that [redacted] [redacted] Dr. Scott Morton improperly assumed that, in the world without the merger (1) Illumina would have succeed in sufficiently lowering its costs by 2025, (2) Illumina would have passed all of those reductions on to its customers and (3) Illumina would have provided any reductions to all customers equally. (RX6002 (Guerin-Calvert Trial Dep. at 50–52).) [redacted], the 43-percent decrease "very directly" addresses the concern that Illumina could foreclose GRAIL rivals because it "commits Illumina by a date-certain, 2025, for its highest throughput product to deliver to customers a 43 percent reduction in price of that product." (RX6002 (Guerin-Calvert Trial Dep. at 49).)

4674. [redacted] (PX7138 (Scott Morton Trial Dep. at 76-77) (*in camera*)).

Response to Finding No. 4674:

[redacted], the Open Offer does afford MCED test developers pricing protections because it prohibits Illumina from raising prices over the entire 12-year term and commits them to a guaranteed price decrease by 2025. (PFF ¶¶ 1021–23.) As Dr. Carlton explained, "from my point of view, if you're asking me how do I know that a rival to GRAIL won't have to fear that its costs go up from GRAIL, that's what the open offer protects, and, in particular, the part of the open offer that says I'm not going to raise price, and, moreover, I'm going to lower price by 43 percent by 2025. That's their protection." (RX6000 (Carlton Trial Dep. at 140.)

(2) Illumina's 43% Per Gigabase of Sequencing Price Reduction on Sequencing Products by 2025 Compared to Moore's Law

4675. Section 5(d) of the Open Offer only commits to a 43 [] percent price decrease for price per giga base of the then-available highest throughput instrument. (Berry (Illumina) Tr. 923; PX0064 at 007 (Illumina Open Offer, Mar. 29, 2021)).

Response to Finding No. 4675:

Respondents incorporate their responses to CCFF ¶ 4654 herein.

4676. The 43 percent price decrease only relates to the price per gigabase of the sequencing rather than the price per read. (PX0064 at 007 (Illumina Open Offer, Mar. 29, 2021); Berry (Illumina) Tr. 923)).

Response to Finding No. 4676:

The proposed finding is incomplete and misleading. Specifically, DNA sequencing involves analyzing the nucleotides, or bases, of DNA or RNA in a sample. (*See* Berry (Illumina) Tr. 818–20; PX8399 (Henry (PacBio) Decl.) at 1.) A gigabase is one million DNA or RNA bases. (PX7076 (Berry (Illumina) Dep. at 265).) Sequencing flow cells are described in terms of the number of gigabases of DNA or RNA that can be sequenced. (Berry (Illumina) Tr. 904–05.) Thus, describing the price reduction using a price per gigabase nomenclature allows for normalizing different capacity flow cells and comparing different kits' pricing on an "apples-to-apples basis". (Berry (Illumina) Tr. 905; *see also* RX6002 (Guerin-Calvert Trial Dep. at 43).)

While the number of gigabases refers to a number of DNA or RNA bases, a "read" refers to the processing of a fragment of DNA or RNA. (*See* Berry (Illumina) Tr. 818–20; PX8399 (Henry (PacBio) Decl.) at 1–2.) The number of reads in an S4 300 flow cell kit is constant. (Berry (Illumina) Tr. 923.) Thus, if Illumina reduced price *per gigabase* of the S4 300 flow cell by 43%, it would *also* reduce the price *per read* by 43% because the given number of reads in that S4 300 flow cell kit is constant. (Berry (Illumina) Tr. 923.) Further, by reducing price per gigabase, Illumina will also reduce a customer's price per sample on an absolute linear basis,

presuming that the customer's assay does not change in terms of the amount of sequencing required for that sample. (Berry (Illumina) Tr. 905–06.)

4677. The Open Offer indicates that customers will receive a 43% decrease in sequencing costs per giga base by 2025, enabled by the anticipated improvements in Illumina's sequencing technology. (PX0064 at 007 (Illumina Open Offer, Mar. 29, 2021)).

Response to Finding No. 4677:

Respondents have no specific response except to note that the proposed finding is evidence that the Open Offer fully addresses any alleged anticompetitive concerns from the merger.

4678. Illumina's Open Offer commits to a 43 percent reduction in the cost per giga base for the then-available highest throughput instrument that Illumina sells. (Berry (Illumina) Tr. 923).

Response to Finding No. 4678:

Respondents have no specific response except to note that the proposed finding is evidence that the Open Offer fully addresses any alleged anticompetitive concerns from the merger.

4679. Ms. Berry explained that "per giga base of sequencing" was used because "sequencing flow cells are described in terms of capacity in a number of gig abases able to be sequenced. So if we describe pricing in a price-per-gigabase nomenclature, it allows us essentially to normalize the different capacity flow cells and compare different kits' pricing on sort of an apples-to-apples basis. So it would be analogous to, say, price per gallon if you're looking at, you know, say, milk purchased in a gallon container versus in a tractor-trailer truckload. So it's simply a way for us to conveniently refer to a normalized price that allows us to easily understand whether or not, relative to or irrespective of quantity or capacity in this case of a flow cell, whether or not the price is actually higher or lower." (Berry (Illumina) Tr. 904-05).

Response to Finding No. 4679:

Respondents have no specific response.

4680. [redacted]

Response to Finding No. 4680:

Respondents incorporate their responses to CCFF ¶ 4676 herein.

4681. [redacted]

Response to Finding No. 4681:

Respondents have no specific response.

4682. [redacted]

Response to Finding No. 4682:

Respondents incorporate their responses to CCFF ¶ 4676 herein.

4683. [redacted]

Response to Finding No. 4683:

Respondents incorporate their responses to CCFF ¶ 4673 herein.

4684. [redacted]

Response to Finding No. 4684:

Respondents have no specific response.

4685. [redacted]

Response to Finding No. 4685:

Respondents incorporate their responses to CCFF ¶ 4670 herein.

4686. [redacted]

Response to Finding No. 4686:

Respondents incorporate their responses to CCFF ¶ 4670 herein.

4687. [redacted]

Response to Finding No. 4687:

Respondents incorporate their responses to CCFF ¶ 4670 herein.

4688. [redacted]

Response to Finding No. 4688:

Respondents incorporate their responses to CCFF ¶ 4670 herein.

4689. [redacted]

Response to Finding No. 4689:

Respondents incorporate their responses to CCFF ¶ 4670 herein.

4690. [redacted]

Response to Finding No. 4690:

Respondents incorporate their responses to CCFF ¶ 4670 herein.

4691. [redacted]

Response to Finding No. 4691:

Respondents have no specific response.

4692. [redacted]

Response to Finding No. 4692:

Respondents incorporate their responses to CCFF ¶ 4670 herein.

4693. [redacted]

[redacted]

Response to Finding No. 4693:

Respondents incorporate their responses to CCFF ¶ 4670 herein.

4694. [redacted]

Response to Finding No. 4694:

Respondents have no specific response.

4695. [redacted]

Response to Finding No. 4695:

Respondents have no specific response.

4696. Ms. Berry testified that if Illumina does introduce an instrument with a higher throughput than the NovaSeq, currently Illumina's highest throughput instrument, then the 43 percent price decrease would only apply to that new, higher throughput sequencer. (Berry (Illumina) Tr. 712).

Response to Finding No. 4696:

Respondents incorporate their responses to CCFF ¶ 4654 herein.

4697. If Illumina introduced an instrument with throughput higher than the NovaSeq, Ms. Berry confirmed that customers that are currently developing multicancer early detection tests on the NovaSeq would have to switch to the new higher throughput instrument in order to benefit from the pricing decrease. (Berry (Illumina) Tr. 713).

Response to Finding No. 4697:

Respondents incorporate their responses to CCFF ¶ 4656 herein.

4698. Section 5(d) of the Open Offer provides a 43 percent pricing decrease by 2025, however, it is not specified in the Open Offer whether that is January 1, 2025 or December 31, 2025. (PX0064 at 007 (Illumina Open Offer, Mar. 29, 2021); Berry (Illumina) Tr. 713-14).

Response to Finding No. 4698:

The proposed finding is incomplete and misleading. In the portion of Ms. Berry's testimony cited here, Ms. Berry stated that "'by 2025' means the first date that 2025 is part of that date" (*i.e.*, January 1, 2025).

4699. Flatley's law, named after Illumina's prior CEO Jay Flatley, is the comparison between sequencing pricing and Moore's law. (Berry (Illumina) Tr. 811).

Response to Finding No. 4699:

Respondents have no specific response.

4700. Ms. Berry testified that "'Flatley's law' was a term coined by an author– a writer in Forbes magazine when he wrote an article comparing the reduction in the price of sequencing to Moore's law, which describes the reduction in the price of like silicon wafers or something in the computer industry, and specifically under Jay Flatley, our former CEO's leadership, and it was during, you know, his leadership where we really drove significant, significant reductions in the price of sequencing, you know, down towards the level that they are today. And you know, "Moore's law" was the– was the term that describes the reduction in price in the silicon wafer, and "Flatley's law" then was coined to describe the dramatic reduction in price in genomics that has– that was achieved during Jay Flatley's leadership of Illumina." (Berry (Illumina) Tr. 811).

Response to Finding No. 4700:

Respondents have no specific response.

4701. Dr. Aravanis testified that Illumina has "longer-term goals" to bring down the cost of sequencing more than the 43 percent stated in the Open Offer. (Aravanis (Illumina) Tr. 1868).

Response to Finding No. 4701:

Respondents have no specific response.

4702. Dr. Vogelstein testified that Illumina's NGS sequencing costs have "gone down considerably" over time and "they call it analogous to computers." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 62)).

Response to Finding No. 4702:

Respondents have no specific response.

4703. [redacted]

Response to Finding No. 4703:

Respondents incorporate their responses to CCFF ¶ 4703 herein.

(a) Ms. Guerin-Calvert's Price Per Gigabase and Equivalent Pricing Analysis Does Not Meet Her Own Report's Standards

4704. When analyzing Illumina's grandfathered versus universal pricing, Respondent's Expert, Ms. Guerin-Calvert used price per gigabase as a comparator because "[p]rice per gigabase is a standard metric that is used that makes for -- the possibility for comparing across various products. It's a standard way of doing it, and that was my basis for using it." (RX6002 (Guerin-Calvert Trial Dep. at 43)).

Response to Finding No. 4704:

Respondents have no specific response.

4705. Ms. Guerin-Calvert testified that an MCED test developer would have to rely on Illumina's assurances that the customer received equivalent pricing as Grail. (RX6002 (Guerin-Calvert Trial Dep. at 144).

Response to Finding No. 4705:

The proposed finding is incomplete and misleading. In the portion of her trial deposition cited here, Ms. Guerin-Calvert noted that Illumina would need to comply with the provisions of the Open Offer, "any breach would be [detected] under the audit or under a special audit if the customer had a reason to believe that their pricing was different". (RX6002 (Guerin-Calvert Trial Dep. at 144).) Thus, she did not testify that a customer "would have to rely on Illumina's assurances"; to the contrary, they would have the benefit of the Open Offer's audit protections.

4706. [redacted] (RX6002 (Guerin-Calvert Trial Dep. at 144-45).

Response to Finding No. 4706:

The proposed finding is incomplete and misleading. Specifically, Ms. Guerin-Calvert testified that [redacted] (RX6002 (Guerin-Calvert Trial Dep. at 144–45) (emphasis added).) And when asked whether the dispute mechanism could take up to 120 days, she responded, "As a *separate question*, the answer to that is yes." (RX6002 (Guerin-Calvert Trial Dep. at 145) (emphasis added.) That is, under the Open Offer, a customer is not obligated to go through the complete arbitration process because, as Ms. Guerin-Calvert testified, the Open Offer also provides a mechanism for resolving disputes without arbitration. Prior to submitting any matter to arbitration, Illumina must attempt, in good faith, to resolve any Open Offer dispute "in a final and binding fashion" by meeting with representatives of the complaining customer "for a period of thirty (30) days (or such other period of time as Illumina and the Customer shall mutually agree)". (PX0064 (Illumina) at 10.) Only if this brief resolution process is unsuccessful would the parties need to engage in arbitration. If arbitration *is* required, it will not be excessively costly or time-consuming. Illumina aims "to get through arbitration as fast as possible and use as accelerated a process as available" because doing so is in Illumina's own best interests. (deSouza (Illumina) Tr. 2460; PFF 1105.2–3.)

h) Illumina's FDA Commitments Are Flawed

4707. The Open Offer states that "Customer may enter into, at any time from today, effective as of the closing of the Transaction, until the sixth anniversary of the closing of the Transaction, an agreement with Illumina under which Customer may develop and commercialize in-vitro diagnostic ("IVD") test kits for use on Illumina's diagnostic ("Dx") sequencing platforms. Illumina will provide standard terms for Customer to enter into a standalone agreement to enable Customer to develop and commercialize IVD test kits on one or all of Illumina's Dx sequencing platforms. Illumina shall provide any documentation or information reasonably required for Customer to seek FDA approval or FDA marketing

authorization to sell a for-profit, clinical test using the Supplied Products." (PX0064 (Illumina) at 006-7 (Illumina Open Offer, Mar. 29, 2021)).

Response to Finding No. 4707:

Respondents have no specific response except to note that the proposed finding is evidence that the Open Offer fully addresses any alleged anticompetitive concerns from the merger.

4708. [redacted] (Rabinowitz (Natera) Tr. 372-73 (*in camera*)).

Response to Finding No. 4708:

The proposed finding is incomplete and misleading. [redacted] Illumina has a "very minimal role" in a customers' FDA approval process. (Goswami (Illumina) Tr. 3187–88.) For an LDT or single-site PMA test, Illumina "provides [its] instruments and reagents to [the customer] as [Illumina] provides them to all [its] customers". (Goswami (Illumina) Tr. 3187–88.) "[T]he lab developer then has the sole responsibility of developing the test, designing it and, you know, at the end of the day qualifying the test and being responsible for ongoing quality management" for FDA approval purposes. (Goswami (Illumina) 3188.) For a kitted IVD test that uses one of Illumina's Dx platforms, Illumina's responsibility "focuses on the Dx platform that [the] developer uses". (Goswami (Illumina) Tr. 3188 .) "But the developer then takes responsibility for all the clinical trial that they have to run to– to validate the test, to submit the clinical trial results, both analytical and clinical validation to the FDA, and then they take on the burden of then making sure that they are manufacturing the distributable kit according to FDA guidelines and maintaining the quality of that kit going forward." (Goswami (Illumina) Tr. 3188–89.)

[redacted] Therefore, the IVD agreement and FDA provision of the Open Offer specifically guarantees that Illumina will provide equal or greater assistance to MCED test developers with respect to FDA approval than it did pre-merger. (PFF ¶ 1035.3; RX6002 (Guerin-Calvert Trial Dep. at 75).)

4709. [redacted]

Response to Finding No. 4709:

Respondents incorporate their responses to CCFF ¶ 4708. Respondents also note that the Open Offer includes a right of reference to any relevant Illumina regulatory documentation for Illumina's IVD partners. (Leite (Illumina/InterVenn) Tr. 2156; PX0064 (Illumina) at 39; [redacted] Under this right, a partner developing on Illumina systems may reference Illumina's files in their regulatory submission. (PX0064 (Illumina) at 39; [redacted]

4710. [redacted]

Response to Finding No. 4710:

The proposed finding is inaccurate, incomplete and misleading. [redacted] (Rabinowitz (Natera) Tr. 372.) This

is simply wrong. The FDA provision of the Open Offer provides that a "[c]ustomer *may enter into*, at any time . . . until the sixth anniversary of the closing of the Transaction," an IVD agreement with Illumina based on one of three standardized templates. (PX0064 (Illumina) at 8.) The standardized templates have term lengths of 10 or 15 years. (*See* PFF ¶ 1031; Goswami (Illumina) Tr. 3210; PX0064 (Illumina) at 29.) Thus, while customers can enter into agreements within 6 years of the closing of the Transaction, Illumina is committed to providing any FDA support for at least 10 years.

4711. [redacted]

Response to Finding No. 4711:

Respondents incorporate their responses to CCFF ¶ 4710 herein.

(1) Illumina's IVD Agreement Requires Technology Access Fees, Milestone Payments, and Royalty Fees for Customers to Have an FDA Cleared Distributed Test Product

4712. [redacted] (PX7120 (Young (Illumina) Dep. at 8) (*in camera*)).

Response to Finding No. 4712:

The proposed finding is incomplete and misleading. The statement [redacted] (PX7120 (Young (Illumina) Dep. at 8).) Further, the financial terms of the template IVD agreements are consistent across customers and are standard in the industry. (PFF ¶ 1032.1–6; Goswami (Illumina) Tr. 3212; [redacted]; PX7097 (Felton (Thermo Fisher) Dep. at 127–29).)

4713. [redacted] (PX7120 (Young (Illumina) Dep. at 9-10) (*in camera*)).

Response to Finding No. 4713:

Respondents have no specific response except to note that the financial terms of the template IVD agreements in the Open Offer are consistent across customers and are standard in the industry. (PFF ¶ 1032.1–6; Goswami (Illumina) Tr. 3212; [redacted]; PX7097 (Felton (Thermo Fisher) Dep. at 127–29).)

4714. Illumina's Open Offer includes revenue sharing that requires its customers to pay 6% of net IVD sales to Illumina. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)).

Response to Finding No. 4714:

Respondents have no specific response except to note that the financial terms of the template IVD agreements in the Open Offer are consistent across customers and are standard in the industry. (PFF ¶ 1032.1–6; Goswami (Illumina) Tr. 3212; [redacted]; PX7097 (Felton (Thermo Fisher) Dep. at 127–29).)

4715. If a customer wanted a different revenue share percentage with Illumina than 6%, the customer would need to negotiate with Illumina. (Goswami (Illumina) Tr. 3269).

Response to Finding No. 4715:

Respondents have no specific response except to note that in the portion of Dr. Goswami's testimony cited here, he also testified that "[u]nder the open offer, . . . the terms are the same for all customers." (Goswami (Illumina) Tr. 3269.)

i) Illumina's Intellectual Property Commitments Are Flawed

4716. The Open Offer's IP provisions at section 9 address two categories of IP: "Core IP Rights" and "IP Infringement." (PX0064 at 009 (Illumina Open Offer agreement, Mar. 29, 2021)).

Response to Finding No. 4716:

Respondents have no specific response.

4717. The Open Offer's Core IP Rights provision states: "Customer's purchase of Supplied Products under this Supply Agreement confers upon Customer the non-exclusive, non-transferable, personal, non-sublicensable right solely under Illumina's Core IP to use the Supplied Products, only with Illumina hardware and software, and only in Customer facilities. Except as expressly stated in this Section 9 with respect to Core IP, no right or license under any Illumina Intellectual Property Rights is granted, expressly, by implication, or by estoppel, to Customer under this Supply Agreement." (PX0064 at 009 (Illumina Open Offer agreement, Mar. 29, 2021)).

Response to Finding No. 4717:

Respondents have no specific response except to note that the proposed finding is evidence that the Open Offer fully addresses any alleged anticompetitive concerns from the merger.

4718. The Open Offer's IP Infringement provision states: "In no event will Illumina have the right to cease shipping of the Supplied Product solely on the basis of any alleged claim of infringement of any intellectual property rights of Illumina." (PX0064 at 009 (Illumina Open Offer agreement, Mar. 29, 2021)).

Response to Finding No. 4718:

Respondents have no specific response except to note that the proposed finding is evidence that the Open Offer fully addresses any alleged anticompetitive concerns from the merger.

4719. Illumina's Open Offer provides no prohibition against Illumina suing the customer for IP infringement and does not provide for a customer to license any application specific IP. (*See* PX0064 at 003-004, 009, 039 (Illumina Open Offer agreement, Mar. 29, 2021)).

Response to Finding No. 4719:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

4720. [redacted]

Response to Finding No. 4720:

The proposed finding is incomplete and misleading. [redacted] Illumina's management of intellectual property has, in fact, helped develop emerging markets.

When Illumina sued Natera for infringement, Illumina was obligated to sue because Illumina is the custodian of a patent pool with multiple patentholders. (PFF ¶ 1099.2; deSouza (Illumina) Tr. 2470–71.) Illumina's efforts in creating this patent pool helped prevent the non-competitive use of intellectual property rights in the market for non-invasive prenatal tests (NIPT.) (PFF ¶ 1099.3; *see* PX7089 (Naclerio (Illumina) Dep. at 49–50, 57–58, 150).) In the nascent NIPT market that existed before Illumina acquired Verinata, several companies, such as Verinata, Sequenom and Ariosa, were engaged in ongoing intellectual property litigation. (PFF ¶ 1099.4; PX7089 (Naclerio (Illumina) Dep. at 49).) These disputes led to exceedingly high prices for NIPT tests for patients. (PFF ¶ 1099.4; PX7089 (Naclerio (Illumina) Dep. at 49–50).) Illumina recognized that these disputes held back the NIPT market. (PFF ¶ 1099.4; PX7089 (Naclerio (Illumina) Dep. at 49–50).)

Illumina chose to acquire Verinata in part to accelerate adoption of NIPT by settling this intellectual property litigation. (PFF ¶ 1099.5; PX7089 (Naclerio (Illumina) Dep. at 57–58).) Illumina recognized that it could accomplish this because Illumina could help bring the

companies in disputes to the negotiating table. (PFF ¶ 1099.5; PX7089 (Naclerio (Illumina) Dep. at 57–59).) Illumina's strategy in this acquisition was to settle the intellectual property litigation promptly and then make NIPT technology available to other labs around the world to grow the market and lower prices. (PFF ¶ 1099.6; PX7089 (Naclerio (Illumina) Dep. at 58–59).)

[redacted] (PFF ¶ 1099.7; *see* PX7089 (Naclerio (Illumina) Dep. at 64–65, 150).)

4721. [redacted]

Response to Finding No. 4721:

Respondents incorporate their responses to CCFF ¶ 4720 herein. Further, Respondents note that, under the Open Offer, [redacted] Illumina commits to give customers a right under Illumina's core intellectual property to use its sequencing instruments and core consumables. (PFF ¶ 1036; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.)

4722. [redacted]

Response to Finding No. 4722:

The proposed finding is incomplete and misleading. Under the Open Offer, Illumina commits that it will not have the right to cease shipments of the products solely on the basis of a claim of infringement of Illumina's intellectual property rights. (PFF ¶ 1037; Berry (Illumina) Tr. 864; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.) This is true even if Illumina has

a legitimate claim of infringement. (PFF ¶ 1037.2; RX6002 (Guerin-Calvert Trial Dep. at 78).)

[redacted]

4723. [redacted]

Response to Finding No. 4723:

Respondents incorporate their responses to CCFF ¶¶ 4721–22 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

j) Illumina's Commitments to Confidentiality Are Flawed

4724. [redacted]

Response to Finding No. 4724:

The proposed finding is incomplete and misleading. *First*, Illumina takes extensive precautions to protect the confidentiality of information it receives from developers including: (1) setting up confidentiality agreements with partners, (2) training staff and requiring them to sign confidentiality agreements, (3) separating teams who might work on similar products, (4) using document control processes and (5) providing legal guidance if individuals request access to protected documents. (PFF ¶¶ 1040–1040.5; Goswami (Illumina) Tr. 3227–30.) These practices are standard in the industry and generally accepted by companies that serve multiple clients in the same industry. (PFF ¶ 1040.8; Goswami (Illumina) Tr. 3228–29.)

Second, under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL.

(PFF ¶ 1039; [redacted]; deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted].) Illumina is very familiar with how to set up and operate these types of confidentiality provisions because it already shields confidential information in other contexts. (PFF ¶ 1041.3; Goswami (Illumina) Tr. 3231.) [redacted] (PFF ¶ 1041; RX6002 (Guerin-Calvert Trial Dep. at 80–85); [redacted].) The Open Offer's firewall provision will have the characteristics of an effective firewall, specifically: monitoring and auditing, methods to report violations and consequences for violations. (PFF ¶¶ 1041.5, 1100; RX6002 (Guerin-Calvert Trial Dep. at 84–85).)

4725. [redacted]

Response to Finding No. 4725:

Respondents incorporate their responses to CCFF ¶ 4724 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4726. [redacted]

Response to Finding No. 4726:

Respondents incorporate their responses to CCFF ¶ 4724 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4727. [redacted]

Response to Finding No. 4727:

Respondents incorporate their responses to CCFF ¶ 4724 herein.

(1) The Open Offer's Firewall Provision Is Insufficient to Prevent Sharing of Competitively Sensitive Information Between Grail and Illumina

4728. The Open Offer provides that "Illumina shall establish a firewall designed to prevent any GRAIL personnel (and any Illumina personnel carrying out activities with respect to the GRAIL business or products) from accessing any Confidential Information obtained by or made available to Illumina relating to Customer or its business or products, whether pursuant to this Supply Agreement or otherwise." (PX0064 at 009-010 (Illumina Open Offer agreement, Mar. 29, 2021)).

Response to Finding No. 4728:

Respondents have no specific response except to note that the proposed finding is evidence that the Open Offer fully addresses any alleged anticompetitive concerns from the merger.

4729. [redacted]

Response to Finding No. 4729:

The proposed finding is incomplete and misleading. The evidence shows that the GRAIL firewall can be effectively implemented and provides adequate protection for customers' confidential information. (PFF ¶ 1100; RX6002 (Guerin-Calvert Trial Dep. at 84–85).) The

firewall under the Open Offer will have all of the necessary characteristics of an effective firewall, including clear policies around confidentiality, a means to enforce the firewall and a means to disseminate confidentiality policies to relevant personnel. (PFF ¶ 1100.2; *see* RX6002 (Guerin-Calvert Trial Dep. at 84–85).) [redacted] (PFF ¶ 1100.5; Fiedler (FMI) Tr. 4487–88.)

4730. [redacted]

Response to Finding No. 4730:

The proposed finding is incomplete and misleading. Customers do not need to rely on Illumina's assurances that it is maintaining a firewall with GRAIL because this provision, like the entirety of the Open Offer, is subject to bi-annual audits of Illumina's compliance. (PFF ¶ 1047; deSouza (Illumina) Tr. 2405, 2438; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.) Specifically, an independent auditor can successfully audit the confidentiality provisions by obtaining a list of Illumina employees working with GRAIL and ensuring the list is complete and accurate, obtaining a list of all Illumina and GRAIL employees who are authorized to receive confidential information, executing employee compliance certifications regularly, examining reports of violations, performing keyword email searches, creating and testing electronic barriers, testing for noncompliance with respect to hard-copy information and interviewing select personnel. (RX6003 (Rock Trial Dep. at 67–71).)

4731. [redacted]

[redacted]

Response to Finding No. 4731:

Respondents incorporate their responses to CCFF ¶ 4729–30 herein. Respondents further note that the most important issue with regard to the efficacy of the Open Offer is whether it sufficiently prevents Illumina from acting on any alleged incentive to foreclose GRAIL's potential rivals. (PFF ¶ 1082.1; RX6002 (Guerin-Calvert Trial Dep. at 20–21, 109).) The Open Offer fully addresses any alleged incentives by Illumina to foreclose GRAIL rivals. (PFF ¶ 1082; RX6002 (Guerin-Calvert Trial Dep. at 20–21, 108–09).) Further, the Open Offer's provisions in their totality also ensure that Illumina's incentives are to support GRAIL's rivals. (PFF ¶ 1082.2–1082.4; *see* RX6002 (Guerin-Calvert Trial Dep. at 20–22, 108–09; RX6000 (Carlton Trial Dep. at 84–85).) For example, [redacted] Similarly, the Open Offer, as a private contract, creates an incentive for Illumina customers to take advantage of it and enforce it. (PFF ¶ 1082.4; RX6000 (Carlton Trial Dep. at 84).)

4732. Guardant's Mr. Getty testified that Illumina's firewall provision does "not at all" alleviate Guardant's concerns about the sharing of competitively sensitive information with Illumina. (PX7040 (Getty (Guardant) IHT at 188)).

Response to Finding No. 4732:

Respondents have no specific response except to note that, contrary to Mr. Getty's testimony, there is no reason to think that the Open Offer's firewall provision would be ineffective in resolving concerns about information sharing. Further, the proposed finding relies

on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4733. Mr. Getty testified that "individuals on [Illumina's] executive team have traded back and forth already. . . . There are individuals– you know, Illumina was an early investor in Grail, and there are individuals who are on the executive team at Illumina who hold large stakes in Grail." (PX7040 (Getty (Guardant) IHT at 188-89)).

Response to Finding No. 4733:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4734. Mr. Getty of Guardant testified that it is difficult for Guardant to know whether someone from Illumina's sequencing business has spoken with someone in Grail's business. (PX7105 (Getty (Guardant) Dep. at 79-80)).

Response to Finding No. 4734:

The proposed finding is incomplete and misleading. In the portion of Mr. Getty's deposition cited here, Mr. Getty does not even mention Illumina sharing its customers' confidential information with GRAIL. (*See* PX7105 (Getty (Guardant) Dep. at 79-80).) He also states that "[a]s a for instance, we don't have the ability to audit". (PX7105 (Getty (Guardant) Dep. at 80).) But the Open Offer does guarantee at least bi-annual audits of Illumina's compliance. (PFF ¶ 1047; deSouza (Illumina) Tr. 2405, 2438; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.)

4735. Mr. Getty testified with respect to Guardant's concerns about its confidential information being shared between Illumina and Grail, "Illumina has an incentive to share that information with GRAIL." (PX7105 (Getty (Guardant) Dep. at 100)).

Response to Finding No. 4735:

Respondents incorporate their responses to CCFF ¶ 4731 herein.

4736. Mr. Getty testified, "presumably a combined company, the head of GRAIL and the head of Illumina, you know, at all different levels, head of, you know, R&D, head of

commercial, head of, you know, operations, what have you, all those individuals would be shareholders in a combined company. And so certainly they all play– have a financial and perhaps even other incentives to share information and create the most competitive GRAIL that can possibly exist in order to win the 60-billion-dollar market." (PX7105 (Getty (Guardant) Dep. at 100-01)).

Response to Finding No. 4736:

Respondents incorporate their responses to CCFF ¶¶ 4731 and 4733 herein.

4737. When asked what specifically was flawed about Illumina's firewall provision, Mr. Getty testified: "There's no enforceability of it. And with– if it was breached, how would [Guardant] know, right." (PX7040 (Getty (Guardant) IHT at 189)).

Response to Finding No. 4737:

The proposed finding is incomplete and misleading. The Open Offer's firewall provision will have the characteristics of an effective firewall, specifically: monitoring and auditing, methods to report violations and consequences for violations. (PFF ¶¶ 1041.5, 1100; RX6002 (Guerin-Calvert Trial Dep. at 84–85).) Illumina is very familiar with how to set up and operate these types of confidentiality provisions because it already shields confidential information in other contexts. (PFF ¶ 1041.3; Goswami (Illumina) Tr. 3231.) [redacted] (PFF ¶ 1041; RX6002 (Guerin-Calvert Trial Dep. at 80–85); PX7138 (Scott Morton Trial Dep. at 294).)

Further, the firewall provision, like the entirety of the Open Offer, is subject to bi-annual audits of Illumina's compliance. (PFF ¶ 1047; deSouza (Illumina) Tr. 2405, 2438; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.) Specifically, an independent auditor can successfully audit the confidentiality provisions by obtaining a list of Illumina employees working with GRAIL and ensuring the list is complete and accurate, obtaining a list of all Illumina and GRAIL employees who are authorized to receive confidential information, executing employee

compliance certifications regularly, examining reports of violations, performing keyword email searches, creating and testing electronic barriers, testing for noncompliance with respect to hard-copy information and interviewing select personnel. (RX6003 (Rock Trial Dep. at 67–71).) Moreover, in addition to the bi-annual audits, "if [Illumina] become[s] aware of a breach of confidentiality of any kind, we are obligated to promptly notify the other party of such breach". (Goswami (Illumina) Tr. 3233.)

Finally, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4738. Mr. Getty testified that with a combined Illumina-Grail, "you have now a circumstance where incentives are in-lined to share information to create a more competitive GRAIL organization. And so ultimately what you will see persist, of course, is exactly that, the sharing of that information." (PX7105 (Getty (Guardant) Dep. at 101)).

Response to Finding No. 4738:

Respondents incorporate their responses to CCFF ¶ 4731 herein.

4739. Mr. Getty testified that pre-acquisition, "while Illumina [had] all that information, there [was] less of an incentive to share that with [Guardant's] competitors, right, because ultimately [Illumina] would– they would be doing something that really wouldn't convey benefit for anybody and maybe create a negative environment." (PX7105 (Getty (Guardant) Dep. at 101)).

Response to Finding No. 4739:

Respondents incorporate their responses to CCFF ¶ 4731 herein.

4740. When asked whether the firewall provision in the Open Offer alleviates concerns about sharing of competitively sensitive information, Mr. Getty testified, "No, it does not. I– you know, I think the notion of a firewall invokes something that is impossible to enforce." (PX7105 (Getty (Guardant) Dep. at 102)).

Response to Finding No. 4740:

Respondents incorporate their responses to CCFF ¶ 4737 herein.

4741. Mr. Getty testified that "there are many examples, particularly in the banking industry, where firewalls have proven to be nothing of the sort. And, you know, it's also nearly impossible to actually enforce, relatively speaking, if, you know, you're not– yeah. It's just– it's not enforceable." (PX7105 (Getty (Guardant) Dep. 102)).

Response to Finding No. 4741:

Respondents incorporate their responses to CCFF ¶ 4737 herein. Further, the proposed finding is incomplete and misleading. In the portion of Mr. Getty's deposition cited here, Mr. Getty testified: "*I think* there are many examples" of unsuccessful firewalls in the banking industry, but he provided *no actual examples*. (PX7105 (Getty (Guardant) Dep. 102).). Similarly, at trial, Mr. Getty testified: [redacted] Respondents provided specific examples of firewalls implemented by the FTC and other antitrust agencies in vertical transactions. (PFF ¶ 1041.1; RX6002 (Guerin-Calvert Trial Dep. at 81–82); *see also* RX3082 (*In re Broadcom Ltd.* Decision and Order) at 5–7; RX3192 (*In re Evanston Northwestern Healthcare Corp.* Final Order) at 6; RX3527 (*In re Northrop Grumman* Decision and Order) at 9–13; RX 3557 (*In re PepsiCo, Inc.* Decision and Order) at 6–9; RX3664 (*In re Sycamore Partners II* Analysis of Agreement Containing Consent Order) at 3–4.)

4742. [redacted]

Response to Finding No. 4742:

The proposed finding is incomplete and misleading. As Ms. Guerin-Calvert testified, the Open Offer's firewall "provides for ways of reporting violations and consequences". (RX6002 (Guerin-Calvert Trial Dep. at 85).) Similarly, Dr. Goswami testified that if the firewall is breached, "[t]here are codified disciplinary actions that are in place . . . up to termination of the employee". (Goswami (Illumina) Tr. 3233.)

4743. [redacted]

Response to Finding No. 4743:

Respondents incorporate their responses to CCFF ¶ 4737 herein.

4744. [redacted]

Response to Finding No. 4744:

Respondents incorporate their responses to CCFF ¶ 4731 herein.

4745. [redacted]

Response to Finding No. 4745:

The proposed finding is incomplete and misleading. The firewall between Illumina and GRAIL fully addresses any concern involving employees who move from Illumina to GRAIL because employees are required to sign a confidentiality agreement and undergo confidentiality training when they join Illumina. (Goswami (Illumina) Tr. 3228.) As Dr. Goswami testified, "in the training on confidential information we clearly outline what is confidential and what the employee's obligations are under that confidentiality agreement". (Goswami (Illumina) Tr.

3232.) This is a "very standard process in the industry and [Illumina] know[s] how to do this." (Goswami (Illumina) Tr. 3232.)

4746. [redacted]

Response to Finding No. 4746:

The proposed finding is incomplete and misleading. [redacted]

4747. [redacted]

Response to Finding No. 4747:

Respondents incorporate their responses to CCFF ¶ 4737 herein.

4748. Ms. Berry testified at trial that the Open Offer does not define what constitutes "Confidential Information." (Berry (Illumina) Tr. 716-18).

Response to Finding No. 4748:

The proposed finding is incomplete and misleading. In the portion of Ms. Berry's testimony cited here, Ms. Berry provided context for this answer. Specifically, Ms. Berry testified that the customers contemplating executing the Open Offer "have a good understanding of what confidential information is, specifically related to their experience executing supply agreements with Illumina" and that the definition is "pretty standardized and well understood". (Berry (Illumina) Tr. 717–18.) Similarly, Dr. Goswami testified, "in the [required] training [for Illumina employees] on confidential information we clearly outline what is confidential and what the employee's obligations are under that confidentiality agreement". (Goswami (Illumina) Tr. 3232.) This is a "very standard process in the industry and [Illumina] know[s] how to do this." (Goswami (Illumina) Tr. 3232.)

4749. [redacted]

Response to Finding No. 4749:

Respondents incorporate their responses to CCFF ¶ 4748 herein.

4750. [redacted]

Response to Finding No. 4750:

The proposed finding is incomplete and misleading. Specifically, under the Open Offer, the firewall provision would be subject to bi-annual audits of Illumina's compliance. (PFF ¶ 1047; deSouza (Illumina) Tr. 2405, 2438; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.)

An independent auditor can successfully audit the confidentiality provisions by obtaining a list of Illumina employees working with GRAIL and ensuring the list is complete and accurate, obtaining a list of all Illumina and GRAIL employees who are authorized to receive confidential information, executing employee compliance certifications regularly, examining reports of violations, performing keyword email searches, creating and testing electronic barriers, testing for noncompliance with respect to hard-copy information and interviewing select personnel. (RX6003 (Rock Trial Dep. at 67–71).) Open Offer customers would then receive a report of the audit. (PX0064 (Illumina) at 10; PX7076 (Berry (Illumina) Dep. at 287).) Additionally, customers must be promptly notified, within 10 days, of any potential noncompliance. (deSouza (Illumina) Tr. 2478; RX3935 (Illumina) at 3.) Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4751. [redacted]

Response to Finding No. 4751:

The proposed finding is incomplete and misleading. [redacted]

[redacted] Further, the proposed finding relies on IH testimony which is hearsay and which

Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4752. [redacted]

Response to Finding No. 4752:

Respondents incorporate their responses to CCFF ¶ 4751 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4753. [redacted]

Response to Finding No. 4753:

Respondents incorporate their responses to CCFF ¶ 4750 herein. Further, [redacted] Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4754. [redacted]

[redacted] **Finding No. 4754:**

Respondents incorporate their responses to CCFF ¶ 4730 herein.

4755. [redacted]

Response to Finding No. 4755:

Respondents have no specific response except to note that the firewall provision in the Open Offer completely resolves any reasonable concern regarding sharing confidential information. (*See, e.g.*, Responses to CCFF ¶¶ 4731, 4737, 4742, 4745; PFF ¶¶ 1039–42.)

4756. After Illumina closed its acquisition of Grail, Illumina added a new account manager, Linda Ray, to handle the Grail account. (Berry (Illumina) Tr. 931).

Response to Finding No. 4756:

Respondents have no specific response.

4757. Linda Ray reports to Ms. Abernathy, who reports to Curtis Fideler, who reports to Ms. Berry. (Berry (Illumina) Tr. 931-32).

Response to Finding No. 4757:

Respondents have no specific response.

4758. [redacted]
(PX7076 (Berry (Illumina) Dep. at 78-81) (*in camera*) [redacted]).

Response to Finding No. 4758:

Respondents have no specific response except to note that, [redacted] employees are required to sign a confidentiality agreement and undergo confidentiality training when they join Illumina. (Goswami (Illumina) Tr. 3228.) If an Illumina employee violates these confidentiality rules, "[t]here are codified disciplinary actions that are in place . . . up to termination of the employee". (Goswami (Illumina) Tr. 3233.)

4759. [redacted] (Ofman (Grail) Tr. 3405 (*in camera*)).

Response to Finding No. 4759:

The proposed finding is incomplete and misleading. [redacted]

4760. [redacted]
(Ofman (Grail) Tr. 3406 (*in camera*)).

Response to Finding No. 4760:

Respondents incorporate their responses to CCFF ¶ 4759 herein. [redacted]

[redacted] experts have noted that the Open Offer's firewall will have the characteristics of an effective firewall, specifically: monitoring and auditing, methods to report violations and consequences for violations. (PFF ¶¶ 1041.5, 1100; RX6002 (Guerin-Calvert Trial Dep. at 84–85).)

4761. Illumina SVP of Corporate Development and Strategic Planning, Joydeep Goswami, testified that he oversees all of Illumina's customer contracts. (Goswami (Illumina) Tr. 3229).

Response to Finding No. 4761:

Respondents have no specific response.

4762. Mr. Goswami testified, "There's generally a set of [customer-related] things that I need to know and I can get that." (Goswami (Illumina) Tr. 3229).

Response to Finding No. 4762:

The proposed finding is incomplete and misleading. In the portion of Dr. Goswami's testimony cited here, Dr. Goswami was asked whether he gets access to "all of the confidential information" of his department since he oversees the whole department. Dr. Goswami responded: "No. We don't. . . . I don't need to make– get detailed information on any one of the customers or what they're doing, right. There's generally a set of things that I need to know and I can get that. But there are two other checks and balances". (Goswami (Illumina) Tr. 3229.) For the first, Dr. Goswami testified that Illumina has "document control processes, so I don't have access to all the documents that, you know, are– may be considered confidential or are considered confidential for any particular client, right. If I need access to them, I have to ask somebody for that information." (Goswami (Illumina) Tr. 3229.) For the second, Dr. Goswami explained that if he (or another executive) did ask for the information, then the person responsible for the information would "check with the legal person" to get legal guidance about whether they could provide the information to Dr. Goswami. (Goswami (Illumina) Tr. 3229.)

4763. [redacted]

Response to Finding No. 4763:

The proposed finding is incomplete and misleading. [redacted]

4764. [redacted]

Response to Finding No. 4764:

Respondents incorporate their responses to CCFF ¶ 4763 herein.

4765. [redacted]

Response to Finding No. 4765:

Respondents incorporate their responses to CCFF ¶ 4763 herein.

4766. [redacted]

Response to Finding No. 4766:

Respondents incorporate their responses to CCFF ¶ 4763 herein.

4767. [redacted]

Response to Finding No. 4767:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

4768. [redacted]

Response to Finding No. 4768:

Respondents have no specific response.

4769. [redacted]

Response to Finding No. 4769:

Respondents incorporate their responses to CCFF ¶ 4767 herein.

4770. [redacted]

Response to Finding No. 4770:

Respondents incorporate their responses to CCFF ¶ 4767 herein.

4771. [redacted]

[redacted]

Response to Finding No. 4771:

Respondents incorporate their responses to CCFF ¶ 4767 herein.

4772. [redacted]

Response to Finding No. 4772:

Respondents incorporate their responses to CCFF ¶ 4767 herein.

4773. [redacted]

Response to Finding No. 4773:

Respondents incorporate their responses to CCFF ¶ 4767 herein. Respondents further note that the relevant question is whether the Open Offer protects customers' confidential information, regardless of the level of detail. It does. Dr. Goswami's testimony on this point is informative. When asked whether he has access to the confidential information of his department since he oversees the department, Dr. Goswami responded: "No. We don't. . . . I don't need to make– get detailed information on any one of the customers or what they're doing". (Goswami (Illumina) Tr. 3229.)

He then explained that for *less* detailed information, there are still two significant access controls. *First*, Dr. Goswami testified that Illumina has "document control processes, so I don't have access to all the documents that, you know, are– may be considered confidential or are considered confidential for any particular client, right. If I need access to them, I have to ask

somebody for that information." (Goswami (Illumina) Tr. 3229.) *Second*, Dr. Goswami explained that if he (or another executive) did ask for the information, then the person responsible for the information would have to get legal guidance about whether they could provide the information to Dr. Goswami. (Goswami (Illumina) Tr. 3229.) Thus, there are thorough protections for even high-level confidential information.

4774. [redacted]

Response to Finding No. 4774:

Respondents incorporate their responses to CCFF ¶ 4767 herein.

4775. [redacted]

[redacted]

Response to Finding No. 4775:

Respondents incorporate their responses to CCFF ¶ 4767 herein.

4776. [redacted]

Response to Finding No. 4776:

Respondents incorporate their responses to CCFF ¶ 4767 herein.

(2) [redacted]

4777. [redacted]

Response to Finding No. 4777:

Respondents incorporate their responses to CCFF ¶ 4767 herein.

4778. [redacted]

Response to Finding No. 4778:

Respondents incorporate their responses to CCFF ¶ 4767 herein.

4779. [redacted]

Response to Finding No. 4779:

Respondents incorporate their responses to CCFF ¶ 4767 herein.

4780. [redacted]

Response to Finding No. 4780:

Respondents incorporate their responses to CCFF ¶ 4767 herein.

4781. [redacted]

[redacted]

Response to Finding No. 4781:

Respondents incorporate their responses to CCFF ¶ 4767 herein.

4782. [redacted]

Response to Finding No. 4782:

Respondents incorporate their responses to CCFF ¶ 4737 herein.

(3) Respondents' Expert Ms. Guerin-Calvert's Firewall Analysis Does Not Meet Her Own Report's Standards

4783. Respondent's Expert, Ms. Guerin-Calvert's Expert Report identifies certain characteristics of an effective and enforceable firewall. (RX6002 (Guerin-Calvert Trial Dep. at 118); RX3865 (Guerin-Calvert Rebuttal Report) ¶ 97).

Response to Finding No. 4783:

Respondents have no specific response.

4784. Ms. Guerin-Calvert's first criteria for an effective and enforceable firewall in Ms. Guerin-Calvert's Expert Report is "[c]onfidentiality policies, procedures and protocols that describe the specific persons and positions that can have access to competitively sensitive information." (RX3865 (Guerin-Calvert Rebuttal Report) ¶ 97).

Response to Finding No. 4784:

Respondents have no specific response.

4785. Ms. Guerin-Calvert testified that she had not investigated which specific persons at Illumina would have access to competitively sensitive information. (RX6002 (Guerin-Calvert Trial Dep. at 118-19)).

Response to Finding No. 4785:

The proposed finding is incomplete and misleading. In the portion of Ms. Guerin-Calvert's trial deposition cited here, Ms. Guerin-Calvert was answering a question about what she knew *at the time of her discovery deposition*. However, at the time of Ms. Guerin-Calvert's discovery deposition, the Illumina/GRAIL transaction had not even closed. (RX6002 (Guerin-Calvert Trial Dep. at 156).) Ms. Guerin-Calvert explained that she knew that "Illumina had engaged a consulting firm to be working with them to develop the various implementation plans for the open offer". (RX6002 (Guerin-Calvert Trial Dep. at 157).) She also testified that she "knew that Illumina already had a framework in place with regard to how it handled its current arrangements on confidential information with third parties and with firewalls". (RX6002 (Guerin-Calvert Trial Dep. at 157).)

4786. Ms. Guerin-Calvert testified that she did not know what process Illumina was using to identify individuals who would have access to competitively sensitive information. (RX6002 (Guerin-Calvert Trial Dep. at 119)).

Response to Finding No. 4786:

Respondents incorporate their responses to CCFF ¶ 4785 herein.

4787. Ms. Guerin-Calvert's second criteria for an effective and enforceable firewall in Ms. Guerin-Calvert's Expert Report is "[c]lear definitions of what constitutes competitively sensitive information and thoroughly describes and captures the information that needs to be protected from dissemination." (RX3865 (Guerin-Calvert Rebuttal Report) ¶ 97).

Response to Finding No. 4787:

Respondents have no specific response.

4788. Ms. Guerin-Calvert testified that she did not know at what stage Illumina was in terms of developing its implementation plan for the audit program and the firewall. (Guerin-RX6002 (Guerin-Calvert Trial Dep. at 119-20)).

Response to Finding No. 4788:

Respondents incorporate their responses to CCFF ¶ 4785 herein.

4789. Ms. Guerin-Calvert testified that she did not know what specific competitively sensitive information was to be protected through the firewall. (RX6002 (Guerin-Calvert Trial Dep. at 120)).

Response to Finding No. 4789:

Respondents incorporate their responses to CCFF ¶ 4785 herein. Respondents further note that Dr. Goswami testified, "in the training on confidential information we clearly outline what is confidential and what the employee's obligations are under that confidentiality agreement". (Goswami (Illumina) Tr. 3232.) This is a "very standard process in the industry and [Illumina] know[s] how to do this." (Goswami (Illumina) Tr. 3232.)

4790. Ms. Guerin-Calvert testified that she did not know who at Illumina was in charge of identifying the specific competitively sensitive pieces of information that would be protected by the firewall. (RX6002 (Guerin-Calvert Trial Dep. at 120-21)).

Response to Finding No. 4790:

Respondents incorporate their responses to CCFF ¶¶ 4785 and 4789 herein.

4791. Ms. Guerin-Calvert testified that she had not seen any specific implementation plans that documented how Illumina would prevent its employees with access to third-party competitively sensitive information from sharing it with Grail. (RX6002 (Guerin-Calvert Trial Dep. at 122-23)).

Response to Finding No. 4791:

Respondents incorporate their responses to CCFF ¶ 4785 herein.

4792. Ms. Guerin-Calvert's fourth criteria for an effective and enforceable firewall in Ms. Guerin-Calvert's Expert Report is "[e]stablished policies and procedures for reporting of violations." (RX3865 (Guerin-Calvert Rebuttal Report) ¶ 97).

Response to Finding No. 4792:

Respondents have no specific response.

4793. Ms. Guerin-Calvert testified that she did not know who at Illumina had been designated to receive any complaints of firewall violations related to Grail. (RX6002 (Guerin-Calvert Trial Dep. at 123)).

Response to Finding No. 4793:

Respondents incorporate their responses to CCFF ¶ 4785 herein.

4794. Ms. Guerin-Calvert had not seen any documents laying out the policies and procedures for reporting a violation of a firewall that might be implemented in the context of the Illumina/Grail transaction. (RX6002 (Guerin-Calvert Trial Dep. at 123)).

Response to Finding No. 4794:

Respondents incorporate their responses to CCFF ¶ 4785 herein.

4795. Ms. Guerin-Calvert testified that she did not recall any specific information about Illumina's policies and procedures for reporting a violation of a firewall. (RX6002 (Guerin-Calvert Trial Dep. at 123-24)).

Response to Finding No. 4795:

Respondents incorporate their responses to CCFF ¶ 4785 herein.

4796. Ms. Guerin-Calvert's fifth criteria for an effective and enforceable firewall in Ms. Guerin-Calvert's Expert Report is "[m]eaningful consequences for violation." (RX3865 (Guerin-Calvert Rebuttal Report) ¶ 97).

Response to Finding No. 4796:

Respondents have no specific response.

4797. Ms. Guerin-Calvert testified that she was neither aware of information regarding, nor could she identify specific instances, where Illumina administered a punishment or some other consequence as a result of an employee violating a confidentiality agreement. (RX6002 (Guerin-Calvert Trial Dep. at 124)).

Response to Finding No. 4797:

Respondents incorporate their responses to CCFF ¶ 4785 herein. Respondents further note that Dr. Goswami testified that if the firewall is breached, "[t]here are codified disciplinary actions that are in place . . . up to termination of the employee". (Goswami (Illumina) Tr. 3233.)

4798. Respondent's Expert, Ms. Guerin-Calvert has never served as a compliance monitor for the antitrust agencies. (RX6002 (Guerin-Calvert Trial Dep. at 125-26)).

Response to Finding No. 4798:

The proposed finding is directed to irrelevant subject matter because the fact that Ms. Guerin-Calvert has not served as a compliance monitor does not suggest that she cannot assess the adequacy of firewall provisions.

4799. Ms. Guerin-Calvert's Expert Report cites to six consent decrees that used firewalls. (RX3865 (Guerin-Calvert Rebuttal Report) ¶ 99). But Ms. Guerin-Calvert did not work on any of the six matters cited to in her report. (RX6002 (Guerin-Calvert Trial Dep. at 125)).

Response to Finding No. 4799:

The proposed finding is directed to irrelevant subject matter because the fact that Ms. Guerin-Calvert did not personally work on certain firewall provisions does not suggest that she cannot assess the adequacy of the Open Offer's firewall provision.

4800. In preparing her report, Ms. Guerin-Calvert did not review any of the compliance reports filed in the six consent decrees that used firewalls. (RX6002 (Guerin-Calvert Trial Dep. at 126-27).

Response to Finding No. 4800:

The proposed finding is incomplete and misleading. The portion of Ms. Guerin-Calvert's report that discusses the six firewalls mentions the firewalls as evidence that "FTC and USDOJ, and other regulatory agencies *use* consent decrees with firewall provisions", suggesting that "vertically-integrated firms can develop and implement appropriate safeguards to protect competitively sensitive materials". (RX3835 (Guerin-Calvert Rebuttal Report) ¶ 99 (emphasis

added).) That is, the fact that FTC, DOJ and other agencies *continue to use* firewalls in vertical mergers is evidence that firewalls are effective constraints.

4801. Ms. Guerin-Calvert did not interview any of the monitors in the six consent decrees that used firewalls. (RX6002 (Guerin-Calvert Trial Dep. at 127).

Response to Finding No. 4801:

Respondents incorporate their responses to CCFF ¶ 4800 herein.

4802. Ms. Guerin-Calvert testified that she does not know if there was a firewall violation in any of the six consent decrees that used firewalls. (RX6002 (Guerin-Calvert Trial Dep. at 127-28).

Response to Finding No. 4802:

Respondents incorporate their responses to CCFF ¶ 4800 herein.

4803. Ms. Guerin-Calvert testified that she does not know if there were changes to the list of individuals who could receive confidential information over the life span of any the six consent decrees that used firewalls. (RX6002 (Guerin-Calvert Trial Dep. at 127-28)

Response to Finding No. 4803:

Respondents incorporate their responses to CCFF ¶ 4800 herein.

k) The Open Offer Is Difficult to Monitor and Enforce

4804. Mr. Getty testified further that "a contract is only as good as it is enforceable. And ultimately, you know, our ability– our ability, being Guardant's ability . . . to investigate adherence to the term of that contract is nearly impossible." (PX7105 (Getty (Guardant) Dep. at 79-80)).

Response to Finding No. 4804:

The proposed finding is incomplete and misleading. The Open Offer adequately addresses this concern. The Open Offer requires Illumina to engage in a biannual audit to ensure compliance with the Open Offer. (deSouza (Illumina) Tr. 2405, 2438; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.) Further, if a customer has a good-faith basis for alleging that Illumina is in breach of the Open Offer, Illumina will engage an auditor to assess the customer's allegation separate from the biannual audits. (PX0064 (Illumina) at 10.) As part of these audits,

Illumina is obligated to provide customers with a written report confirming compliance with the Open Offer's commitments. (PFF ¶ 1048; PX0064 (Illumina) at 10; PX7076 (Berry (Illumina) Dep. at 287).) Additionally, customers must be promptly notified, within 10 days, of any potential noncompliance. (PFF ¶ 1048; deSouza (Illumina) Tr. 2478; RX3935 (Illumina) at 3.) Audit expert Robert Rock testified that the Open Offer's audit provision allows for effective audits of Illumina's compliance with the Open Offer's requirements. (PFF ¶ 1051; *see* RX6003 (Rock Trial Dep. at 31, 35, 44–45, 50–72).)

Additionally, to further allay any concerns with the transaction, Illumina presented Complaint Counsel with a Proposed Consent Order to incorporate the terms of the Open Offer and its addendum. (PFF ¶ 1070; RX4002 (Illumina) at 1.) The Proposed Consent Order includes a monitor provision that allows the FTC to appoint a monitor to assure that Illumina complies with the obligations of the Order. (PFF ¶ 1072; RX4002 (Illumina) at 14–15.) Thus, through the Open Offer (and the Proposed Consent Order), customers are assured that any non-compliance by Illumina will be detected.

Finally, the Open Offer was based in part on [redacted] In its negotiations with Illumina, Guardant never indicated to Illumina that Guardant viewed its amended supply agreement as, in substance, unenforceable or worthless. (PFF ¶ 1075.5; Getty (Guardant) Tr. 2669.)

4805. Mr. Getty testified that Guardant "[doesn't] have the ability to audit. We also -- you know, in a different context, we also don't have the ability to know what goes on on a day-to-day

basis at Illumina. You know, did the head of sequencing have a conversation with the head of GRAIL and say, 'Hey, look, if you go this direction or that direction, you know, by the way that's going to convey a benefit'?" (PX7105 (Getty (Guardant) Dep. at 79-80)).

Response to Finding No. 4805:

Respondents incorporate their responses to CCFF ¶ 4804 herein.

4806. Mr. Getty testified that "ultimately we just have no ability to understand or actually enforce the terms of the contract, and such that, you know, they could continue to operate as they see fit, and ultimately over time, as we talked about, you know, change terms, change pricing, you know, send a technician a few months after they could have. Those things are unknowable and ultimately could be very debilitating to our business." (PX7105 (Getty (Guardant) Dep. at 79-80)).

Response to Finding No. 4806:

Respondents incorporate their responses to CCFF ¶ 4804 herein.

4807. Mr. Getty explained the "nearly impossible" enforcement of a contract with Illumina: "A contract is only as good as it is enforceable. And ultimately, [Guardant's ability] to investigate adherence to the terms of that contract is nearly impossible." (PX7105 (Getty (Guardant) Dep. at 79-80)).

Response to Finding No. 4807:

Respondents incorporate their responses to CCFF ¶ 4804 herein.

4808. Mr. Getty testified that Illumina's control over which MCED test developer receives better treatment makes it "very difficult" to audit how equitable Illumina's customer service is: "[T]he [Illumina] individual that was chosen to go to Guardant Health could simply have had a vacation scheduled so that seems like normal course of business. But the person who didn't have a vacation scheduled ended up at GRAIL . . . So even a third party auditor would be– it would be very difficult to gauge like-for-like in terms of services." (PX7105 (Getty (Guardant) Dep. at 85-86)).

Response to Finding No. 4808:

Respondents incorporate their responses to CCFF ¶ 4804 herein. Further, contrary to the testimony of Mr. Getty, audit expert Robert Rock explained that the Open Offer's provisions on access to services can be successfully audited. An independent auditor can audit the access to services provision by publishing a comprehensive catalog of services, issuing notices when the catalog is updated and having the auditor perform procedures to test whether the catalog is

updated, accurate and timely. (PFF ¶ 1103.6; RX6003 (Rock Trial Dep. at 59–62); *see also* RX6002 (Guerin-Calvert Trial Dep. at 158–161); PX7076 (Berry (Illumina) Dep. at 294).)

4809. [redacted]

Response to Finding No. 4809:

The proposed finding is incomplete and misleading. [redacted] Illumina cannot [redacted] with support because if Illumina delayed or refused to service an instrument that belonged to a customer who had signed the Open Offer, Illumina would be in breach of the agreement. (PFF ¶ 1004.7; Berry (Illumina) Tr. 871.) Illumina would also be in breach if it provided worse services to a customer laboratory who did not also purchase Galleri. (PFF ¶ 1004.7; Berry (Illumina) Tr. 879.) Moreover, refusing to service instruments would hurt Illumina's overall business because customers would stop buying kits from Illumina. (PFF ¶ 1004.7; Berry (Illumina) Tr. 871–72.) The services provision thus ensures that customers will receive at least the same level of service that they did before the merger. (PFF ¶ 1004.9; RX6002 (Guerin-Calvert Trial Dep. at 58).)

Respondents further incorporate their responses to CCFF ¶ 4808 herein.

4810. [redacted]

Response to Finding No. 4810:

The proposed finding is incomplete and misleading without additional support. [redacted]

[redacted]

Respondents also incorporate their responses to CCFF ¶ 4804 herein.

4811. A customer that suspects Illumina is in breach of its commitments in the open offer would not know whether it has access to prerelease products at the same time as Grail unless Illumina chose to disclose this information to the customer. (Berry (Illumina) Tr. 7009-01).

Response to Finding No. 4811:

The proposed finding is incomplete and misleading. The relevant question is whether a customer would know if Illumina has breached the Open Offer. They would. The Open Offer requires that customers must be promptly notified, within 10 days, of any potential noncompliance. (PFF ¶ 1048; deSouza (Illumina) Tr. 2478; RX3935 (Illumina) at 3.)

4812. A customer that suspects Illumina is in breach of its commitments in the open offer would not know how quickly Illumina repairs Grail or its competitors' equipment. (Berry (Illumina) Tr.700).

Response to Finding No. 4812:

Respondents incorporate their responses to CCFF ¶ 4811 herein.

4813. A customer that suspects Illumina is in breach of its commitments in the open offer would not know how fast Grail or its competitors receive service and support from Illumina. (Berry (Illumina) Tr. 700).

Response to Finding No. 4813:

Respondents incorporate their responses to CCFF ¶ 4811 herein.

4814. Under the terms of the open offer, it may take 120 days for a customer to resolve a dispute with Illumina if the customer proceeds with arbitration. (Berry (Illumina) Tr. 721-23).

Response to Finding No. 4814:

The proposed finding is incomplete misleading. As Mr. deSouza explained at trial, Illumina aims to get through any arbitration as fast as possible and to use the most accelerated process available. (PFF ¶ 1105.2; deSouza (Illumina) Tr. 2460–61.) Illumina is open to soliciting feedback and improving the arbitration process to make it more expeditious if possible.

(PFF ¶ 1105.2; deSouza (Illumina) Tr. 2460–61.) Prior to any binding arbitration, the Open Offer also provides for an immediate dispute resolution process, which helps address any concern about the time and expense of arbitration. (PFF ¶ 1105.3; PX0064 (Illumina) at 10; RX6002 (Guerin-Calvert Trial Dep. at 89–91).)

4815. Under the terms of the open offer, Grail is not subject to the dispute resolution terms of the open offer. (Berry (Illumina) Tr. 724).

Response to Finding No. 4815:

Respondents have no specific response.

4816. Under Section 12(a) of the open offer, Illumina agrees to an annual audit of its compliance with commitments in the open offer. (Berry (Illumina) Tr. 697-99).

Response to Finding No. 4816:

The proposed finding is incomplete and misleading. At the time of Ms. Berry's testimony (August 26, 2021), the then-current version of the Open Offer provided for annual audits. However, on September 8, 2021, Illumina amended the Open Offer because Illumina found ways it could make the Open Offer "even slightly better". (deSouza (Illumina) Tr. 2406.) As part of these amendments, Illumina changed the annual audit to a biannual audit. (*See* RX3935 (Illumina) at 3.) [redacted] Nonetheless, to provide customers with even greater security, the Open Offer now provides for regular audits *twice* a year (as well as *additional* audits when customers have a good-faith basis for alleging breach). (RX3935 (Illumina) at 3.)

4817. Separate from the annual audit, Illumina's compliance with its commitments in the open offer may be audited if a customer has a "good faith basis" for alleging that Illumina is in breach of a commitment in the open offer. (Berry (Illumina) Tr. 699).

Response to Finding No. 4817:

Respondents incorporate their responses to CCFF ¶ 4816 herein.

4818. Illumina decides if the customer's suspicion of a breach rises to a good faith basis. (Berry (Illumina) Tr. 699-700).

Response to Finding No. 4818:

Respondents have no specific response except to note that, under the Open Offer, customers must be notified of even a *potential* noncompliance with Illumina's obligations within 10 days. (RX3935 (Illumina) at 2–3.)

4819. Illumina considers "customer-specific information related to sales, order history, service and support to be all confidential information." (Berry (Illumina) Tr. 647). For example, Ms. Berry testified at trial that Illumina considers the products that a customer purchases and the prices that a customer pays to be confidential information. (Berry (Illumina) Tr. 647-48).

Response to Finding No. 4819:

Respondents have no specific response.

4820. A customer that suspects Illumina is in breach of its commitments in the open offer would not know what prices its competitors are paying for Illumina's products. (Berry (Illumina) Tr. 700).

Response to Finding No. 4820:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina keeps sensitive customer information confidential.

4821. A customer that suspects Illumina is in breach of its commitments in the open offer would not know what products its competitors are purchasing from Illumina. (Berry (Illumina) Tr. 700).

Response to Finding No. 4821:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina keeps sensitive customer information confidential.

4822. Outside of the annual audit process, a customer that suspects Illumina is in breach of its commitments in the open offer would not know whether they have access to the same products as Grail. (Berry (Illumina) Tr. 701).

Response to Finding No. 4822:

Respondents incorporate their responses to CCFF ¶ 4816 herein.

4823. [redacted]

Response to Finding No. 4823:

Respondents have no specific response.

4824. [redacted]

Response to Finding No. 4824:

The proposed finding is incomplete and misleading. [redacted] The Open Offer, by contrast, provides for binding arbitration. (*See* deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 10–11.) [redacted] the Open Offer does not need to be enforced through a lawsuit in court and can instead be enforced through arbitration. (*See* deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 10–11.) Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no

opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

(1) MCED Test Developers Will Not Know What Products Grail Has Access To, What Services Grail Received From Illumina, or What Prices Grail Pays Illumina

4825. Ms. Berry testified that certain information, such as a customer's order information and service reports, is confidential and one customer would not have access to another customer's information). (PX7076 (Berry (Illumina) Dep. at 81; 291)).

Response to Finding No. 4825:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina maintains the confidentiality of customers' competitively sensitive information.

4826. Ms. Berry testified that under the Open Offer, customers would not be able to know in real-time what prices its competitors are paying for Illumina products. (PX7076 (Berry (Illumina) Dep. at 291-92)).

Response to Finding No. 4826:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina maintains the confidentiality of customers' competitively sensitive information.

4827. Ms. Berry testified that under the Open Offer, a customer would not know in real-time what products its competitors are purchasing from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)).

Response to Finding No. 4827:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina maintains the confidentiality of customers' competitively sensitive information.

4828. Ms. Berry testified that under the Open Offer, a customer would not know in real-time how quickly Illumina repairs its competitors' equipment. (PX7076 (Berry (Illumina) Dep. at 292)).

Response to Finding No. 4828:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina maintains the confidentiality of customers' competitively sensitive information.

4829. Mr. Getty testified that under the Open Offer there is no way for Guardant to know what products GRAIL has access to. (PX7105 (Getty (Guardant) Dep. at 87-88) ("Q. Is there any way for Guardant to known when that– the 45-day clock begins in which Guardant should have access to the same products as GRAIL? A. No. And even if there was an ability to do so, it would be largely unimportant because ultimately, you know, if we go back to the example of a product being developed and, you know, the interaction of a test with that product, product being, say, a sequencer, imagine a scenario where the, you know, head of GRAIL's research and development speaks with the heads of Illumina's sequencer development, the head of Illumina's sequencer development says, you know, "Ultimately we will have this technology available on" such and such date. And GRAIL's R&D engine is able to ramp up quickly in order to take advantage of that technological advance much faster than the competitive set. So, you know, whether or not we have even an ability to see it, which we wouldn't, ultimately there's also additional impacts that would be negative to Guardant, relatively speaking, from the combined company.")).

Response to Finding No. 4829:

Respondents incorporate their responses to CCFF ¶¶ 4574–75 herein. Further, contrary to the statement in the proposed finding, Guardant could know the products that GRAIL has access to because, under the Open Offer [redacted] "Illumina shall publish, on the "Oncology Contract Terms" website, (i) the Supplied Products, by SKU, that GRAIL is purchasing; (ii) the service plans, by SKU, that GRAIL is purchasing; and (iii) the pricing grid for both products and services under which GRAIL is purchasing Supplied Products and services. To the extent necessary, Illumina shall update this website within 5 days of entry of any purchase order for Supplied Products or any service contract relating to the Supplied Products by GRAIL." (RX3935 (Illumina) at 2; RX4003 (Illumina) at 1; RX3960 (Illumina).)

4830. [redacted]

Response to Finding No. 4830:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina maintains the confidentiality of customers' competitively sensitive information.

4831. [redacted]

Response to Finding No. 4831:

The proposed finding is inaccurate, incomplete and misleading. Under the Open Offer [redacted] Illumina is not allowed to share customers' confidential information with GRAIL. (PFF ¶ 1039; [redacted]; deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted].) Further, "Illumina shall publish, on the 'Oncology Contract Terms' website, (i) the Supplied Products, by SKU, that GRAIL is purchasing; (ii) the service plans, by SKU, that GRAIL is purchasing; and (iii) the pricing grid for both products and services under which GRAIL is purchasing Supplied Products and services. To the extent necessary, Illumina shall update this website within 5 days of entry of any purchase order for Supplied Products or any service contract relating to the Supplied Products by GRAIL." (RX3935 (Illumina) at 2; RX4003 (Illumina) at 1; RX3960 (Illumina).)

4832. [redacted]

Response to Finding No. 4832:

Respondents incorporate their responses to CCFF ¶¶ 4574–75 herein.

4833. [redacted] (Getty (Guardant) Tr. 2551 (*in camera*)). [redacted]

Response to Finding No. 4833:

Respondents incorporate their responses to CCFF ¶¶ 4574–75 herein.

4834. [redacted]

Response to Finding No. 4834:

Respondents incorporate their responses to CCFF ¶¶ 4574–75 and 4579 herein.

4835. [redacted]

Response to Finding No. 4835:

The proposed finding is incomplete and misleading. Specifically, Mr. Nolan testified that [redacted] Nonetheless, to provide customers with even greater security, the Open Offer provides for regular audits *twice* a year (as well as *additional* audits when customers have a good-faith basis for alleging breach). (RX3935 (Illumina) at 3.)

4836. [redacted]

Response to Finding No. 4836:

Respondents incorporate their responses to CCFF ¶ 4502 herein.

4837. Mr. Getty testified that there is no way for Guardant to know what level of service Grail is receiving from Illumina. (PX7105 (Getty (Guardant) Dep. 84)).

Response to Finding No. 4837:

The proposed finding is incomplete and misleading. Contrary to Mr. Getty's testimony, customers can know the level of service that GRAIL receives. Illumina's service contracts come in one of three levels gold, silver or bronze. (PFF ¶ 1004.3; Berry (Illumina) Tr. 681–82.) The different levels of service contracts vary based on considerations like response times and the number of instances that Illumina technicians will proactively service the customer's instruments. (PFF ¶ 1004.3; Berry (Illumina) Tr. 682.) As with products, there is a standard list of orderable service SKUs, each associated with a standard U.S. list price. (PFF ¶ 1004.4; Berry (Illumina) Tr. 868–69.) When a customer purchases a service SKU, there is an agreement that describes aspects of the service relationship such as turnaround time and the number of preventative maintenances to which a customer is entitled. ((PFF ¶ 1004.4; Berry (Illumina) Tr. 867.) Under the Open Offer [redacted] Illumina must publish the service contract SKUs on the "Oncology Contract Terms" website within 5 days of GRAIL purchasing a SKU. (PFF ¶ 1005.5; RX3935 (Illumina) at 2; RX4003 (Illumina) at 1; RX3960 (Illumina).)

Further, Illumina has established extensive procedures to ensure consistency of service across customers ordering a specific SKY. In order to ensure that it satisfies its obligations when a customer orders a service SKU, Illumina measures its customer support using key performance indicators (KPIs). (PFF ¶ 1004.6; Berry (Illumina) Tr. 867–68.) These KPIs include metrics like instrument downtime or the length of time between when a case is opened to when it is closed.

(PFF ¶ 1004.6; Berry (Illumina) Tr. 867–68.) These KPIs enable Illumina to compare how it performs in terms of service and support across individual customers or groups of customers. (PFF ¶ 1004.6; Berry (Illumina) Tr. 868.) As Ms. Berry testified, "[i]t's a very metrics-intensive part of our business, our service and support organization, so we have the ability to compare how we're performing by using these KPIs across individual customers or groups of customers quit eeasily." (Berry (Illumina) Tr, 868.) In addition, Illumina has a long and sophisticated onboarding process when it hires new service technicians, which helps ensure that service quality among technicians is consistent. (PFF ¶ 1004.5; Berry (Illumina) Tr. 869–70.) It also ensures consistent service among technicians by tracking individual cases to determine whether there is any gap in performance between service engineers. (PFF ¶ 1004.5; Berry (Illumina) Tr. 870–71.)

Finally, contrary to the opinion of Mr. Getty (who is not an audit expert), a third-party auditor would be able to audit Illumina's compliance with the Open Offer's service provisions. An independent auditor can audit the access to services provision by publishing a comprehensive catalog of services, issuing notices when the catalog is updated and having the auditor perform procedures to test whether the catalog is updated, accurate and timely. (PFF ¶ 1103.5; RX6003 (Rock Trial Dep. at 59–62); *see also* RX6002 (Guerin-Calvert Trial Dep. at 158–161); PX7076 (Berry (Illumina) Dep. at 294).) By using steps like these and reporting the auditor's findings, an audit of the service provisions "will assist both Illumina on one hand, to improve its procedures and prcesses to help prevent or eliminate events of noncompliance in the future and then secondly it will help the customers [by] provid[ing] them information such that they would then determine whether they feel there's any further action that needs to be taken". (RX6003 (Rock Trial Dep. at 62–63.) This process of auditing the service provisions and reporting findings to

customers would be "very effective". (RX6003 (Rock Trial Dep. at 63.) Thus, customers can know the level of service GRAIL receives.

4838. Mr. Getty testified that "there's absolutely no way to even gauge the value of that service. And so when I read things like 'service,' put it in quotes, it's a rather broad terminology. They could provide a service with a technician who, you know, just joined Illumina yesterday and has zero years of experience, and GRAIL could end up with the individual who has 25 years of experience and has been at GRAIL and worked with them ostensibly all the time. And so in short, we wouldn't know that differential, No. 1. And No. 2, if that differential exists, it conveys a very different value of service. So a term like ['Access to Service'] is largely– you know it's– it does not convey any benefit or frankly any value to Guardant Health." (PX7105 (Getty (Guardant) Dep. 84-85)).

Response to Finding No. 4838:

Respondents incorporate their responses to CCFF ¶ 4837 herein.

4839. [redacted] (Getty (Guardant) Tr. 2544 (*in camera*)).

Response to Finding No. 4839:

Respondents have no specific response except to note that the proposed finding is evidence that Illumina maintains the confidentiality of customers' competitively sensitive information.

4840. [redacted] (Getty (Guardant) Tr. 2547 (*in camera*)).

Response to Finding No. 4840:

Respondents incorporate their responses to CCFF ¶ 4831 herein.

4841. [redacted] (Getty (Guardant) Tr. 2561 (*in camera*)).

Response to Finding No. 4841:

The proposed finding is inaccurate, incomplete, misleading and not supported by the cited evidence. In the portion of Mr. Getty's testimony cited here, [redacted]

[redacted] Robert Rock, an audit expert, testified that an independent auditor can successfully audit each of the core provisions of the Open Offer. (See PFF ¶¶ 1103.4–7.) Further, Illumina is contractually committed to cooperating in any audits under the Open Offer, which enhances the efficacy of the audit. (PFF ¶ 1103.3; PX0064 (Illumina) at 10; RX6002 (Guerin-Calvert Trial Dep. at 86–87).)

4842. [redacted] (Getty (Guardant) Tr. 2562 (*in camera*)).

Response to Finding No. 4842:

The proposed finding is incomplete and misleading. Under the Open Offer, Illumina is required to notify customers of any potential non-compliance within 10 days. (RX3935 (Illumina) at 2–3.) Thus, customers would know of a potential breach by Illumina, which could serve as the grounds for an additional audit request under the "good faith basis" clause in the Open Offer. Further, Illumina must comply with this obligation to notify customers promptly of potential non-compliance because failure to do so could be detected in one of the bi-annual audits and could subject Illumina to an enforcement action later on. (*See* PFF ¶¶ 1045, 1047–51, 1054–56.)

(2) Illumina's Audit Provision Is Flawed

4843. The Open Offer Enforcement term provides an Audit subterm which states "Illumina agrees to conduct an annual audit by an independent third-party auditor selected by Illumina from among the "Big 4" accounting firms to audit Illumina's compliance with the commitments set forth herein. Illumina will provide Customers with a written report (with reasonable redactions) confirming compliance with the commitments set forth herein. Illumina shall provide cooperation, including access to necessary books and records, in support of any audit conduct. To the extent Customer has a good faith basis for alleging that Illumina is in breach of a commitment contained herein, Illumina shall engage an auditor to assess Customer's allegation separate from and in addition to Illumina's annual audit." (PX0064 § 12.a. (Illumina Open Offer Agreement, Mar. 29, 2021)).

Response to Finding No. 4843:

The proposed finding is incomplete and misleading. On September 8, 2021, Illumina amended the Open Offer because Illumina found ways it could make the Open Offer "even slightly better". (deSouza (Illumina) Tr. 2406.) As part of these amendments, Illumina revised the audit provision to provide for biannual rather than annual audits (in addition to further audits if a customer has a good-faith basis for alleging breach). (RX3935 (Illumina) at 3.)

4844. [redacted]

Response to Finding No. 4844:

The proposed finding is inaccurate, incomplete and misleading. The Open Offer fully resolves any concern that the auditor would be biased in favor of Illumina because the auditor is an independent auditor, chosen from among the "Big 4" accounting firms. (PFF ¶ 1102; PX0064 (Illumina) at 10.)

4845. [redacted]

[redacted]

[redacted]

Response to Finding No. 4845:

The proposed finding is inaccurate, incomplete and misleading. [redacted]

[redacted]

Under the Open Offer, Illumina "agrees to" conduct biannual audits, "will" provide customers with a written report ensuring compliance and "shall" cooperate with any audit. (PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.) Therefore, Illumina does not have the choice whether to conduct regular audits. Additionally, "[t]o the extent Customer has a good faith basis for alleging that Illumina is in breach of a commitment contained [in the Open Offer], Illumina *shall* engage an auditor" separate from and in addition to the biannual audits. (PX0064 (Illumina) at 10 (emphasis added).) Thus, Illumina again has no discretion whether to engage an auditor if a customer has a good faith basis for alleging breach. Further, if Illumina failed to engage an auditor in response to a customer's good faith request, the customer could pursue binding arbitration, in which "the Arbitrator shall take into account, and the Arbitrator's decision shall reflect, that the purpose of the [Open Offer] is to allay any concerns relating to the Transaction". (RX3935 (Illumina) at 3.) Therefore, Illumina is required to engage an auditor if a customer has a good faith basis for requesting that Illumina do so, and if Illumina failed to adhere to this responsibility, an arbitrator (whose decision is required to take into account customers' concerns) could order the good-faith-basis audit.

4846. [redacted]

Response to Finding No. 4846:

The proposed finding is incomplete and misleading. Specifically, customers must be promptly notified, within 10 days, of any potential noncompliance by Illumina. (PFF ¶ deSouza (Illumina) Tr. 2478; RX3935 (Illumina) at 3.) Further, the Open Offer requires the Open Offer requires Illumina to undergo binding arbitration for any dispute arising under the Open Offer. (*See* PFF 1048; ¶¶ 1054–57.) In such arbitration, "[i]f the Arbitrator determines that Illumina has breached any provision of the Supply Agreement, the Arbitrator may order any relief necessary to restore the status quo prior to Illumina's breach, including monetary and/or injunctive relief." (PFF ¶ 1055; RX3935 (Illumina) at 3.) Thus, to the extent that there were any delay between a breach by Illumina and notification to a customer, the customer could pursue arbitration and receive any relief necessary to restore the status quo prior to the breach.

4847. Mr. Getty testified that if "Illumina willfully breaches their commitment on day one of a year and the report is delivered on day 365, and over that period of time Illumina was able to take that breach and turn it into a significant competitive advantage for GRAIL by advancing their technology ahead of Guardant's" then "that would be extremely, extremely problematic and perhaps even pushing us to the nonexistence, if you will, over the course of a year." (PX7105 (Getty (Guardant) Dep. at 90-91)).

Response to Finding No. 4847:

The proposed finding is incomplete and misleading. The Open Offer allows for biannual audits. (RX3935 (Illumina) at 3.) Further, Respondents incorporate their responses to CCFF ¶ 4846 herein.

4848. [redacted] (Getty (Guardant) Tr. 2555 (*in camera*)).

Response to Finding No. 4848:

Respondents have no specific response except to note that Illumina takes extensive precautions to protect the confidentiality of information it receives from developers including:

(1) setting up confidentiality agreements with partners, (2) training staff and requiring them to sign confidentiality agreements, (3) separating teams who might work on similar products, (4) using document control processes and (5) providing legal guidance if individuals request access to protected documents. (PFF ¶¶ 1040–1040.5; Goswami (Illumina) Tr. 3227–30.) These practices are standard in the industry and generally accepted by companies that serve multiple clients in the same industry. (PFF ¶ 1040.8; Goswami (Illumina) Tr. 3228–29.) Further, the Open Offer requires that to the extent that Illumina has access to customer confidential information, Illumina shall not share such information with GRAIL, any GRAIL subsidiary or any employee who works within GRAIL. (PFF ¶ 1038; [redacted]; Berry (Illumina) Tr. 916–17; PX0064 (Illumina) at 9.) Further, under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (PFF ¶ 1039; [redacted]; deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; [redacted].)

4849. [redacted] (Getty (Guardant) Tr. 2557 (*in camera*)).

Response to Finding No. 4849:

The proposed finding is incomplete and misleading. [redacted], the weight of the evidence shows that the Open Offer's confidentiality protections can be effectively implemented. [redacted] (PFF ¶ 1041; RX6002 (Guerin-Calvert Trial Dep. at 80–85); PX7138 (Scott Morton Trial Dep. at 294).) The Open Offer's firewall provision will have the characteristics of an effective firewall,

specifically: monitoring and auditing, methods to report violations and consequences for violations. (PFF ¶¶ 1041.5, 1100; RX6002 (Guerin-Calvert Trial Dep. at 84–85).)

4850. Mr. Getty testified that under Section 12.a. of Illumina's Open Offer, Guardant would only receive a report of Illumina's compliance once a year. (PX7105 (Getty (Guardant) Dep. at 89-90)).

Response to Finding No. 4850:

The propose finding is incomplete and misleading. *First*, the Open Offer provides for *biannual* audits, and Illumina is required to provide customers with a written report confirming Illumina's compliance. (deSouza (Illumina) Tr. 2405, 2438; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.) *Second*, "[i]n addition to providing the written report, in the event of any finding of potential noncompliance with Illumina's performance under the [Open Offer], Customer shall be notified within 10 days of identifying such a finding of potential noncompliance." (RX3935 (Illumina) at 3.) Thus, Mr. Getty's testimony is mistaken.

4851. Mr**.** Getty testified that the impact on Guardant from only learning that Illumina breached its commitments one year after the breach would be "very significant." (PX7105 (Getty (Guardant) Dep. at 89-91)).

Response to Finding No. 4851:

Respondents incorporate their responses to CCFF ¶ 4850 herein.

4852. [redacted]

Response to Finding No. 4852:

Respondents incorporate their responses to CCFF ¶ 4850 herein.

4853. [redacted]

[redacted]

Response to Finding No. 4853:

Respondents have no specific response except to note that in the portion of Mr. Conroy's testimony cited here, Mr. Conroy admitted that [redacted] In fact, Mr. Conroy testified at trial that he had not read the Open Offer and, beyond what counsel had described to him, did not know what the Open Offer actually required Illumina to do. (PFF ¶ 1073; Conroy (Exact/Thrive) Tr. 1725–27.) Therefore, his testimony on the efficacy of the Open Offer's audit provision should be given no weight.

4854. [redacted]

Response to Finding No. 4854:

Respondents incorporate their responses to CCFF ¶ 4846 herein.

4855. [redacted]

Response to Finding No. 4855:

Respondents have no specific response except to note that the weight of the evidence shows that the provisions of the Open Offer requiring equivalent treatment with respect to

products can be effectively audited. (*See* PFF ¶ 1103.5; RX6003 (Rock Trial Dep. at 59–62); *see also* RX6002 (Guerin-Calvert Trial Dep. at 158–161).)

4856. [redacted]

Response to Finding No. 4856:

Respondents incorporate their responses to CCFF ¶ 4846 herein.

4857. [redacted]

Response to Finding No. 4857:

The proposed finding is incomplete and misleading. Mr. Conroy admitted that [redacted] In fact, Mr. Conroy testified at trial that he had not read the Open Offer and, beyond what counsel had described to him, did not know what the Open Offer actually required Illumina to do. (PFF ¶ 1073; Conroy (Exact/Thrive) Tr. 1725–27.) Therefore, his testimony on the efficacy of the Open Offer's audit provision should be given no weight. Further, the Open Offer requires the Open Offer requires Illumina to undergo binding arbitration for any dispute arising under the Open Offer. (*See* PFF 1048; ¶¶ 1054–57.) In such arbitration, "[i]f the Arbitrator determines that Illumina has breached any provision of the Supply Agreement, the Arbitrator may order any relief necessary to restore the status quo prior to Illumina's breach, including

monetary and/or injunctive relief." (PFF ¶ 1055; RX3935 (Illumina) at 3.) Thus, to the extent that there were any delay between a breach by Illumina and notification to a customer, the customer could pursue arbitration and receive any relief necessary to restore the status quo prior to the breach.

4858. Illumina had not engaged an auditor when Respondents' expert, Mr. Rock, prepared his expert report. (RX6003 (Rock Trial Dep. at 82)).

Response to Finding No. 4858:

The proposed finding is incomplete and misleading. Specifically, Mr. Rock's expert report is dated July 16, 2021. (RX3870 (Rock Rebuttal Report) at 12.) At that time, the Illumina/GRAIL transaction had not even closed.

4859. Neither Illumina nor anyone else had determined the specific procedures that would be employed by an auditor when Mr. Rock prepared his expert report. (RX6003 (Rock Trial Dep. at 82)).

Response to Finding No. 4859:

Respondents incorporate their responses to CCFF ¶ 4858 herein.

4860. The specific procedures that would be employed by an auditor had not been established when Mr. Rock prepared his expert report. (RX6003 (Rock Trial Dep. at 82)).

Response to Finding No. 4860:

Respondents incorporate their responses to CCFF ¶ 4858 herein.

4861. The specific procedures that would be employed by an auditor had not been established at the time of Mr. Rock's deposition. (RX6003 (Rock Trial Dep. at 83)).

Response to Finding No. 4861:

The proposed finding is incomplete and misleading. Mr. rock was deposed on August 3, 2021. (RX6003 (Rock Trial Dep at 75).) At that time, the Illumina/GRAIL transaction had not even closed.

4862. [redacted]

Response to Finding No. 4862:

Respondents have no specific response except to note that the proposed finding is evidence that Ms. Harada does not have a meaningful understanding of how audits work. As a result, her testimony with respect to the Open Offer's audit provision should be give no weight.

4863. Ms. Berry testified that she did not know whether other customers would have access to a report regarding a specific customer's complaint. (PX7076 (Berry (Illumina) Dep. at 287)).

Response to Finding No. 4863:

Respondents have no specific response.

4864. Ms. Berry testified that the auditor may potentially have access to Illumina's service reports, but she could not confirm. (PX7076 (Berry (Illumina) Dep. at 288-89)).

Response to Finding No. 4864:

The proposed finding is incomplete and misleading. Ms. Berry is the senior vice president and general manager of the Americas commercial team at Illumina. She is not tasked with operationalizing the Open Offer's audits and, in fact, the Open Offer's audits will be conducted by an independent auditor. (PFF ¶ 1047; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.) Further, Illumina is required to provide the third-party auditor with "access to necessary books and records, in support of any audit conducted." (PX0064 (Illumina) at 10.) To the extent that the phrase "necessary books and records" needs further definition, Illumina is working to operationalize the definition in a customer-friendly manner. As Ms. Berry testified: "We've retained Deloitte Consulting to help us operationalize the terms that are . . . described in the open offer such that we can be assured that we can administer those terms in a way that maximizes compliance and minimizes any time delays in terms of ensuring that Illumina is prompt in upholding our obligations under the agreement." (Berry (Illumina) Tr. 896.)

4865. Ms. Berry testified that she did not believe that notes related to customer negotiations constitute "books and records" for purposes of the open offer, but she could not confirm. (PX7076 (Berry (Illumina) Dep. at 289)).

Response to Finding No. 4865:

Respondents incorporate their responses to CCFF ¶ 4865 herein.

4866. Ms. Berry testified that she did not know whether a customer would have to give approval before the auditor has access to their confidential information. (PX7076 (Berry (Illumina) Dep. at 290-91)).

Response to Finding No. 4866:

The proposed finding is incomplete and misleading. Ms. Berry is the senior vice president and general manager of the Americas commercial team at Illumina. She is not tasked with operationalizing the Open Offer's audits and, in fact, the Open Offer's audits will be conducted by an independent auditor. (PFF ¶ 1047; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.)

(a) It Is Unclear When a Customer's Allegation Rises to a "Good Faith Basis"

4867. Ms. Berry testified that she did not know specifically who makes the determination of whether a customer's allegation rises to a good faith basis. (PX7076 (Berry (Illumina) Dep. at 284-85)).

Response to Finding No. 4867:

The proposed finding is incomplete and misleading. Regardless of who makes the initial determination of what rises to a good faith basis, if Illumina failed to engage an auditor in response to a customer's good faith request, the customer could pursue binding arbitration, in which "the Arbitrator shall take into account, and the Arbitrator's decision shall reflect, that the purpose of the [Open Offer] is to allay any concerns relating to the Transaction". (RX3935 (Illumina) at 3.) Therefore, the final determination of a good faith basis may be made by an

arbitrator whose decision is required to take into account customers' concerns and who is empowered to order any relief necessary to restore the status quo. (RX3935 (Illumina) at 3.)

4868. Ms. Berry testified that she did not know whether Illumina has to agree that a customer has a good faith basis for alleging Illumina is in breach of a commitment. (PX7076 (Berry (Illumina) Dep. at 285)).

Response to Finding No. 4868:

Respondents incorporate their responses to CCFF ¶¶ 4866–67 herein.

4869. Ms. Berry testified that Illumina's open offer letter does not state whether a customer's suspicion that the agreement has been violated constitutes a good faith basis for an audit. (PX7076 (Berry (Illumina) Dep. at 296-97) ("Can I point to the language that specifically describes that? Not specifically.")).

Response to Finding No. 4869:

Respondents have no specific response.

4870. Customers have to rely on Illumina's "intent" and "spirit" under the open offer to determine what constitutes a good faith basis for bringing an audit. (*See* PX7076 (Berry (Illumina) Dep. at 296-97)).

Response to Finding No. 4870:

Respondents incorporate their responses to CCFF ¶ 4867 herein.

4871. Ms. Berry testified that she was not aware of how customers would know what Illumina's "spirit" is under the open offer. (PX7076 (Berry (Illumina) Dep. at 297) ("Q. And how would customers be aware of the spirit? A. I'm not sure that there's a basis for them to be aware of the spirit")).

Response to Finding No. 4871:

Respondents incorporate their responses to CCFF ¶ 4867 herein. Further, Respondents note that the spirit and intent of the Open Offer are evident from the Open Offer's introductory letter and the Open Offer's contractual language. For example, the introductory letter states that the Offer is intended "to allay any concerns relating to the Transaction, including that Illumina would disadvantage GRAIL's potential competitors after the Transaction by increasing their sequencing prices or by withholding access to Illumina's latest innovations in Next-Generation

Sequencing ('NGS')." (PX0064 (Illumina) at 1.) The arbitration provision similarly explains that "[i]n resolving any dispute under the [Open Offer], the Arbitrator shall take into account, and the Arbitrator's decision shall reflect, that the purpose of the [Open Offer] is to allay any concerns relating to the Transaction, including that Illumina would disadvantage GRAIL's potential competitors after the Transaction by increasing their sequencing prices or by withholding access to Illumina's latest innovations in NGS." (RX3935 (Illumina) at 3.)

4872. [redacted]

Response to Finding No. 4872:

Respondents incorporate their responses to CCFF ¶ 4867 herein. Further, respondents note that, regardless of any separate requests for audits based on customers' allegations of breach by Illumina, Illumina is still required to cooperate with biannual audits by an independent auditor. (PFF ¶ 1047; deSouza (Illumina) Tr. 2405, 2438; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.)

4873. Mr. Getty testified that he did not know who would decide whether Guardant had a good faith basis under Section 12.a. of the Open Offer. (PX7105 (Getty (Guardant) Dep. at 92)).

Response to Finding No. 4873:

Respondents incorporate their responses to CCFF ¶ 4867 herein.

(b) Customers Do Not Know What Constitutes a "Good Faith Basis"

4874. [redacted]

Response to Finding No. 4874:

The proposed finding is incomplete and misleading. Under the Open Offer, Illumina is required to notify customers of any potential non-compliance within 10 days. (RX3935

(Illumina) at 2–3.) Thus, customers would know of a potential breach by Illumina, which could serve as the grounds for an additional audit request under the "good faith basis" clause in the Open Offer. Further, Illumina must comply with this obligation to notify customers promptly of potential non-compliance because failure to do so could be detected in one of the bi-annual audits and could subject Illumina to an enforcement action later on. (*See* PFF ¶¶ 1045, 1047–51, 1054–56.)

4875. [redacted]

Response to Finding No. 4875:

The proposed finding is incomplete and misleading. In the portion of her deposition cited here, Ms. Harada [redacted]

See Response to CCFF ¶ 4862. Respondents further incorporate their responses to CCFF ¶¶ 4867 and 4874 herein.

4876. [redacted]

Response to Finding No. 4876:

Respondents incorporate their responses to CCFF ¶¶ 4867 and 4874 herein.

4877. Additionally, Mr. Getty testified that Guardant's "lack of visibility to . . . things makes it almost impossible to determine when a potential breach has happened." (PX7105 (Getty (Guardant) Dep. at 91)).

Response to Finding No. 4877:

Respondents further incorporate their responses to CCFF ¶ 4874 herein.

4878. Mr. Getty further pointed out that "even in the context that you get over the hurdle defining what good faith means, you then get over the hurdle of being in good enough standing apparently to render that complaint and then, you know, you get over the hurdle of having someone look into that Complaint, you've lost the thing you can't get back, which is time, and potentially cementing of a significant competitive advantage that can't be undone. So ultimately the ability to [bring a good faith basis] doesn't really convey much value to Guardant Health." (PX7105 (Getty (Guardant) Dep. at 92)).

Response to Finding No. 4878:

The proposed finding is incomplete and misleading. The Open Offer requires the Open Offer requires Illumina to undergo binding arbitration for any dispute arising under the Open Offer. (*See* PFF 1048; ¶¶ 1054–57.) In such arbitration, "[i]f the Arbitrator determines that Illumina has breached any provision of the [Open Offer], the Arbitrator may order any relief necessary to restore the status quo prior to Illumina's breach, including monetary and/or injunctive relief." (PFF ¶ 1055; RX3935 (Illumina) at 3.) Thus, to the extent that there were any delay between a breach by Illumina and notification to a customer, the customer could pursue arbitration and receive any relief necessary to restore the status quo prior to the breach.

(c) Ms. Guerin-Calvert's Audit Analysis Does Not Meet Her Own Report's Standards

4879. At the time of her report, Respondent's Expert, Ms. Guerin-Calvert, wrote that, with respect to the audit plan, "the description and commitments codified in the Open Offer are not detailed." (RX3865 (Guerin-Calvert Rebuttal Report) ¶ 105; RX6002 (Guerin-Calvert Trial Dep. at 129)).

Response to Finding No. 4879:

The proposed finding is incomplete and misleading. In the portion of Ms. Guerin-Calvert's report cited here, Ms. Guerin-Calvert explained that: "Although the description and commitments [regarding regular audits] codified in the Open Offer are no detailed, . . . Illumina has engaged an outside firm to assist it in establishing a more detailed audit plan and supporting infrastructure." (RX3865 (Guerin-Calvert Rebuttal Report) ¶ 105).) Illumina has a contract with Deloitte Consulting to help them operationalize the terms of the Open Offer. [redacted]

[redacted] 896.) This engagement will help Illumina improve its systems to allow for maximally effective audits. (PX7135 (Rock Dep. at 90).)

4880. Ms. Guerin-Calvert agreed that an auditor of Illumina's compliance with its commitments pursuant to the Open Offer does not determine whether Illumina violated those commitments. (RX6002 (Guerin-Calvert Trial Dep. at 132)).

Response to Finding No. 4880:

The proposed finding is incomplete and misleading. Specifically, in the portion of Ms. Guerin-Calvert's deposition cited here, Ms. Guerin-Calvert testified that "[i]f by– by 'determination,' [] you mean like a legal opinion", she would agree that an auditor would not determine whether Illumina violated the Open Offer. (RX6002 (Guerin-Calvert Trial Dep. at 132).) She also explained that the audit "provides data and information of a breach, so that may not fit your word 'determination' [(*i.e.*, a legal opinion)], but it provides information or evidence of a violation." (RX6002 (Guerin-Calvert Trial Dep. at 132).)

4881. Ms. Guerin-Calvert testified that the auditing process is not "100 percent certain" and breaches of the firewall "may not end up falling to [the auditor] in a form that [is] detectable." (RX6002 (Guerin-Calvert Trial Dep. at 133)).

Response to Finding No. 4881:

The proposed finding is incomplete and misleading. Specifically, Ms. Guerin-Calvert testified that while "no process is 100 percent certain", "the auditor can go a long way to identifying breaches and violations of the firewall". (RX6002 (Guerin-Calvert Trial Dep. at 133).)

4882. Ms. Guerin-Calvert confirmed that Illumina has not committed to post the results of its audits on its website. (RX6002 (Guerin-Calvert Trial Dep. at 140)).

Response to Finding No. 4882:

The proposed finding is incomplete and misleading. Whether the results would be posted on Illumina's website is irrelevant. Illumina is obligated to provide customers with a written

report confirming compliance with the Open Offer's commitments. (PX0064 (Illumina) at 10; PX7076 (Berry (Illumina) Dep. at 287).) Additionally, customers must be promptly notified, within 10 days, of any potential noncompliance. (deSouza (Illumina) Tr. 2478; RX3935 (Illumina) at 3.)

4883. Ms. Guerin-Calvert testified that she was not aware of whether the audit provided to customers would be the same as a potential compliance report offered to the FTC. (RX6002 (Guerin-Calvert Trial Dep. at 140)).

Response to Finding No. 4883:

Respondents have no specific response.

4884. Ms. Guerin-Calvert testified that if a customer has "a [good faith] basis for believing that Illumina is in breach of a commitment, then Illumina would engage an auditor to assess the allegation . . . ." (RX6002 (Guerin-Calvert Trial Dep. at 87); RX3865 (Guerin-Calvert Rebuttal Report) ¶¶ 38, 105).

Response to Finding No. 4884:

Respondents have no specific response.

4885. Ms. Guerin-Calvert testified that her Expert Report does not state a particular economic test for assessing an Illumina customer's "good faith basis" alleging that Illumina has breached a commitment in the Open Offer. (RX6002 (Guerin-Calvert Trial Dep. at 130)).

Response to Finding No. 4885:

Respondents incorporate their responses to CCFF ¶¶ 4867 and 4874 herein.

4886. Ms. Guerin-Calvert testified that she is not offering a legal opinion on the definition of "good faith." (RX6002 (Guerin-Calvert Trial Dep. at 130)).

Response to Finding No. 4886:

Respondents have no specific response.

4887. Ms. Guerin-Calvert agreed that Illumina's Open Offer does not address who decides if a customer's allegation of a breach has a good faith basis. (RX6002 (Guerin-Calvert Trial Dep. at 130-31)).

Response to Finding No. 4887:

Respondents incorporate their responses to CCFF ¶¶ 4867 and 4874 herein.

4888. Ms. Guerin-Calvert testified that the Open Offer does not specify the criteria for determining or how to decide whether a customer's allegation of a breach has a good faith basis. (RX6002 (Guerin-Calvert Trial Dep. at 131)).

Response to Finding No. 4888:

Respondents incorporate their responses to CCFF ¶¶ 4867 and 4874 herein.

4889. Ms. Guerin-Calvert agreed that the Open Offer does not provide a time frame or a limit to how long a decisionmaker has to determine whether a customer's allegation of a breach has a good faith basis. (RX6002 (Guerin-Calvert Trial Dep. at 131)).

Response to Finding No. 4889:

Respondents have no specific response.

(d) Mr. Rock's Report Describes an "Illustrative" Set of Agreed-Upon Procedures That Illumina Has Not Actually Undertaken

4890. [redacted] (PX7135 (Rock Dep. at 59 (*in camera*))).

Response to Finding No. 4890:

Respondents have no specific response.

4891. In his report, Mr. Rock drafted an "illustrative list of potential agreed-upon procedures" to be used by Illumina's auditor. (RX6003 (Rock Trial Dep. at 88); RX3870 (Rock Rebuttal Report) ¶ 27). Mr. Rock conceded that his "illustrative" list is not a list of the procedures that the auditor and Illumina have agreed will be employed. (RX6003 (Rock Trial Dep. at 88)).

Response to Finding No. 4891:

Respondents have no specific response except to note that at the time of Mr. Rock's report, the Illumina/GRAIL transaction had not even closed yet. *See* Response to CCFF ¶ 4858.

4892. Mr. Rock does not know how the actual procedures employed by Illumina in connection with its Open Offer would compare with the "illustrative" procedures he lists in his report: "I don't know. Since I don't know what will be performed, I can't answer that." (RX6003 (Rock Trial Dep. at 88)).

Response to Finding No. 4892:

Respondents incorporate their responses to CCFF ¶ 4891 herein.

4893. Mr. Rock testified that he does not know whether an auditor engaged by Illumina would issue an agreed-upon procedures report. (RX6003 (Rock Trial Dep. at 77)).

Response to Finding No. 4893:

The proposed finding is incomplete and misleading. Mr. Rock testified: "It's not my opinion that [the auditor] will [issue an an agreed-upon procedures report]. It's my opinion that it's likely they will. . . . [T]hey may decide to issue an examination report, perform an examination and issue an examination report. But I have opined that I believe it's likely they will perform an agreed-upon procedures report." (RX6003 (Rock Trial Dep. at 77).) Further, Respondents note that at the time of Mr. Rock's report and discovery deposition, the Illumina/GRAIL transaction had not even closed yet. *See* Responses to CCFF ¶¶ 4858 and 4861.

4894. Mr. Rock testified that he believes an auditor's report, if issued, would likely be prepared consistent with Public Company Accounting Oversight Board (PCAOB) standards for agreed-upon procedures. (RX6003 (Rock Trial Dep. at 89)).

Response to Finding No. 4894:

Respondents have no specific response.

4895. Mr. Rock's illustrative list of agreed-upon procedures includes the word "test" to describe several procedures. (RX6003 (Rock Trial Dep. at 91)). Every time the word "test" appears in Mr. Rock's report, it could refer to four or ten or to thirty actual procedures, which are not identified in Mr. Rock's report. (RX6003 (Rock Trial Dep. at 92)).

Response to Finding No. 4895:

The proposed finding is incomplete and misleading. Mr. Rock testified that the report uses the word "test" to describe procedures "[b]ecause those [discussions of procedures refer to] *categories* of procedures". ((RX6003 (Rock Trial Dep. at 91–92) (emphasis added).) That is, Mr. Rock's report never attempted to lay out the specific procedures that would be used in the Open Offer audits because Mr. Rock is not the independent auditor of Illumina for Open Offer purposes. Rather, he is an expert witness engaged to opine on whether the Open Offer allows for effective audits. The auditor engaged by Illumina to audit Illumina's compliance with the Open

Offer would determine the precise procedures used to audit Illumina's compliance with various provisions. And, as Mr. Rock opined, the Open Offer's provisions can be effectively audited. (See, e.g., RX6003 (Rock Trial Dep. at 29–21, 50–56, 59–62.)

4896. Mr. Rock cites AT Section 201 of the PCAOB's standards for agreed-upon procedures in his report. (RX6003 (Rock Trial Dep. at 90; RX3870 (Rock Rebuttal Report) ¶ 19 n.6). Section 201.16 states, "Terms of uncertain meaning (such as general review, limited review, check, or test) should not be used in describing the procedures unless such terms are defined within the agreed-upon procedures." (RX6003 (Rock Trial Dep. at 90); PX0347 (Public Company Accounting Oversight Board AT Section 201.16 (Agreed-Upon Procedures Engagements), https://pcaobus.org/oversight/standards/attestation-standards/details/AT201)).

Response to Finding No. 4896:

Respondents incorporate their responses to CCFF ¶ 4895 herein.

4897. Mr. Rock's report does not identify any illustrative agreed-upon procedures at all for Section 4.d (Development Agreement) of the Open Offer. (RX6003 (Rock Trial Dep. at 92)).

Response to Finding No. 4897:

Respondents have no specific response except to note that Mr. Rock's report outlines "an illustrative list" of potential agreed-upon procedures for the Open Offer and does not purport to define an exhaustive list of specific procedures for each provision. (*See* RX3870 (Rock Rebuttal Report) ¶ 27.) "[T]he specific Agreed-Upon Procedures will be developed by Illumina and the [Independent Compliance Auditor], which is standard practice in developing Agreed-Upon Procedures." (RX3870 (Rock Rebuttal Report) ¶ 27.) Further, Mr. Rock testified that he did not believe there was any provision or commitment in the Open Offer that could not be subject to an effective audit. (RX6003 (Rock Trial Dep. at 72–73).)

4898. Mr. Rock's report does not state how compliance with section 5.h (Short Term Projects) of the Open Offer could be tested, and Mr. Rock did not attempt to offer an opinion on what procedures would be sufficient to test compliance with section 5.h (Short Term Projects) of the Open Offer. (RX6003 (Rock Trial Dep. at 91-92)).

Response to Finding No. 4898:

Respondents incorporate their responses to CCFF ¶ 4897 herein.

4899. Mr. Rock's report does not identify any illustrative agreed-upon procedures at all relating to Section 6 (FDA) of the Open Offer. (RX6003 (Rock Trial Dep. at 92-93)).

Response to Finding No. 4899:

Respondents incorporate their responses to CCFF ¶ 4897 herein.

4900. Mr. Rock's report does not identify any illustrative agreed-upon procedures at all relating to Section 8 (Short Supply) of the Open Offer. (RX6003 (Rock Trial Dep. at 93)).

Response to Finding No. 4900:

Respondents incorporate their responses to CCFF ¶ 4897 herein.

4901. Mr. Rock's report does not identify any illustrative agreed-upon procedures for testing compliance with Section 10.a (Confidentiality) of the Open Offer. (RX6003 (Rock Trial Dep. at 96)).

Response to Finding No. 4901:

Respondents incorporate their responses to CCFF ¶ 4897 herein.

(e) Mr. Rock's Report Describes Compliance Attestation Procedures That Illumina Has Not Actually Undertaken

4902. Mr. Rock claimed in his expert report that "[t]o establish effective compliance attestation procedures, Illumina will need to undertake" ten listed items. (RX3870 (Rock Rebuttal Report) ¶ 26).

Response to Finding No. 4902:

Respondents have no specific response.

4903. In his trial deposition, Mr. Rock claimed that "[n]ot all of these [items] are necessarily required" and that Illumina would "need [only] to undertake the vast majority of" the items as part of its offer audit process. (RX6003 (Rock Trial Dep. at 52, 84-85)). Mr. Rock admitted that this trial testimony was "slightly different" from what he wrote in his expert report. (RX6003 (Rock Trial Dep. at 84-85)).

Response to Finding No. 4903:

The proposed finding is incomplete and misleading. In the portion of Mr. Rock's testimony cited here, he explained that his list of ten items is "a good roadmap for the types of things that Illumina should be doing to prepare itself for the audit and to have the audit conducted." (RX6003 (Rock Trial Dep. at 52).) He also testified that he "believe[d] that [Illumina] need[s] to– will need to undertake the vast majority of these, but whether they don't do an item or two, I don't believe that would impact the effectiveness." (RX6003 (Rock Trial Dep. at 85).) This makes sense given that Mr. Rock's list of ten items is intended as a "roadmap" of steps Illumina will need to take, but not a list of ten indispensable prerequisites.

4904. Mr. Rock's report makes no claim that Illumina has actually undertaken any of the necessary ten compliance attestation procedures he lists in Paragraph 26 of his report. (RX6003 (Rock Trial Dep. at 85-86); RX3870 (Rock Rebuttal Report) ¶ 26).

Response to Finding No. 4904:

The proposed finding is incomplete and misleading. At the time of Mr. Rock's report, the Illumina/GRAIL transaction had not even closed yet. *See* Response to CCFF ¶ 4858.

4905. Mr. Rock's report does not state that Illumina has established evaluation criteria for each Open Offer contract obligation. (RX6003 (Rock Trial Dep. at 86)).

Response to Finding No. 4905:

Respondents incorporate their responses to CCFF ¶ 4904.

4906. Mr. Rock's report does not state that Illumina has developed and documented systems, policies, and procedures that would allow for the efficient and accurate tracking and reporting of the evaluation criteria, data, and calculations. (RX6003 (Rock Trial Dep. at 86)).

Response to Finding No. 4906:

Respondents incorporate their responses to CCFF ¶ 4904.

4907. Mr. Rock's report does not state that Illumina has developed a reporting framework to evaluate compliance with the Open Offer. (RX6003 (Rock Trial Dep. at 86)).

Response to Finding No. 4907:

Respondents incorporate their responses to CCFF ¶ 4904.

4908. Mr. Rock's report does not state that Illumina has developed an internal audit program to monitor and test compliance with the Open Offer. (RX6003 (Rock Trial Dep. at 87)).

Response to Finding No. 4908:

Respondents incorporate their responses to CCFF ¶ 4904.

4909. Mr. Rock's report does not state that Illumina has engaged an independent compliance auditor. (RX6003 (Rock Trial Dep. at 87)).

Response to Finding No. 4909:

Respondents incorporate their responses to CCFF ¶ 4904.

4910. Mr. Rock's report does not state that Illumina has established data room content and access procedures. (RX6003 (Rock Trial Dep. at 87)).

Response to Finding No. 4910:

Respondents incorporate their responses to CCFF ¶ 4904.

4911. Mr. Rock's report does not state that Illumina has established an Open Offer compliance hotline. (RX6003 (Rock Trial Dep. at 87)).

Response to Finding No. 4911:

Respondents incorporate their responses to CCFF ¶ 4904.

4912. Mr. Rock's report does not state that Illumina has developed agreed-upon procedures that address concerns that have been raised. (RX6003 (Rock Trial Dep. at 87)).

Response to Finding No. 4912:

Respondents incorporate their responses to CCFF ¶ 4904.

4913. In preparing his report, Mr. Rock did not go through the Open Offer's terms and analyze what kind of evidence would be available to test compliance with each term. (RX6003 (Rock Trial Dep. at 94)).

Response to Finding No. 4913:

Respondents incorporate their responses to CCFF ¶ 4904. Further, Respondents note that Mr. Rock is not the independent auditor of Illumina's compliance with the Open Offer. Rather, he is an expert witness engaged to opine on whether the Open Offer allows for effective audits. The auditor engaged by Illumina to audit Illumina's compliance with the Open Offer would determine the precise procedures used to audit Illumina's compliance with various provisions. And, as Mr. Rock opined, the Open Offer's provisions can be effectively audited. (See, e.g., RX6003 (Rock Trial Dep. at 29–21, 50–56, 59–62.)

4914. In preparing his report, Mr. Rock did not perform any procedures to check compliance or verify the records of Illumina. (RX6003 (Rock Trial Dep. at 93)).

Response to Finding No. 4914:

Respondents incorporate their responses to CCFF ¶ 4913 herein.

(f) An Auditor Would Not Certify Compliance with the Open Offer

4915. Mr. Rock agreed that "the objective of the [Independent Compliance Auditor's] agreed-upon procedures is to present specific findings to assist customers in evaluating an entity's compliance with specified requirements or the effectiveness of an entity's internal control over compliance based upon procedures agreed upon by the customers." (RX6003 (Rock Trial Dep. at 78)).

Response to Finding No. 4915:

Respondents have no specific response.

4916. Mr. Rock testified that the auditor "would not offer an affirmative opinion of compliance" and "is not going to issue a conclusion that the open offer has been complied with." (RX6003 (Rock Trial Dep. at 77-79)).

Response to Finding No. 4916:

Respondents have no specific response.

4917. Mr. Rock stated that "the auditor is not going to want to try to opine on compliance specifically since that would likely be a legal opinion, and most auditors or auditors aren't generally practicing law or issuing legal opinions." (RX6003 (Rock Trial Dep. at 31)).

Response to Finding No. 4917:

Respondents have no specific response.

4918. Mr. Rock further testified that an auditor would not be able to say affirmatively that there had been no breaches of confidentiality. (RX6003 (Rock Trial Dep. at 96)).

Response to Finding No. 4918:

Respondents have no specific response except to note that Mr. Rock testified that an audit of the Open Offer's confidentiality provisions would be "very effective in addressing the customers' concerns". (RX6003 (Rock Trial Dep. at 71–72).)

(g) Mr. Rock Testified That Gaps Could Exist in the Open Offer and That Auditing Would Not Necessarily Address All Customer Concerns

4919. Mr. Rock identified "illustrative categories" of procedures that might be employed by Illumina in connection with a Grail firewall. (RX6003 (Rock Trial Dep. at 67)).

Response to Finding No. 4919:

Respondents have no specific response.

4920. Mr. Rock testified that the "illustrative categories" of procedures that might be employed by Illumina in connection with a Grail firewall would not necessarily address all customer concerns. (RX6003 (Rock Trial Dep. at 71)).

Response to Finding No. 4920:

The proposed finding is incomplete and misleading. In the portion of Mr. Rock's testimony cited here, Mr. Rock discussed the agreed-upon procedures for the Open Offer's confidentiality provisions, specifically, not the procedures for auditing every provision in the Open Offer. (*See* RX6003 (Rock Trial Dep. at 71).) He also noted that the illustrative agreed-upon procedures for the confidentiality provisions would be "very effective in addressing the customers' concerns". (RX6003 (Rock Trial Dep. at 71–72).)

4921. Mr. Rock testified that "the auditor can help and the company will improve their procedures I believe [with respect to firewall confidentiality], the agreed-upon procedures over time,

and the company will try to eliminate gaps, [and] try to improve compliance over time." (RX6003 (Rock Trial Dep. at 72)).

Response to Finding No. 4921:

Respondents have no specific response.

4922. Mr. Rock testified that even with effective audit procedures, "[t]here might be degrees of gradation on whether, you know, you can close all the holes in" supply contracts. (RX6003 (Rock Trial Dep. at 42-43)).

Response to Finding No. 4922:

The proposed finding is incomplete and misleading. In the portion of Mr. Rock's testimony cited here, Mr. Rock was asked whether he knew of any literatures that suggests that contract provisions on issues like pricing, quality, rebates, discounts, incentives, confidentiality, adequacy of inventory and financial health cannot be effectively audited. (RX6003 (Rock Trial Dep. at 39–43).) He responded: "I'm not aware of any accounting or auditing literature that says they cannot be. There might be degrees of gradation on whether, you know, you can close all the holes in that, but I think that effective audit procedures can be performed, and I'm not aware of any literature that would suggest they can't." (RX6003 (Rock Trial Dep. at 43).)

4923. Mr. Rock testified that it is not necessary for an audit to discover all events of noncompliance for him to consider the audit "very effective." (RX6003 (Rock Trial Dep. at 46)).

Response to Finding No. 4923:

Respondents have no specific response except to note that Mr. Rock has extensive experience in directing audits for both public and private companies. (*See* RX3870 (Rock Rebuttal Report) ¶¶ 1–4, Ex. A.)

4924. Mr. Rock conceded that "it's possible that [the auditor] may not be able to catch" every instance of inappropriate disclosure of confidential information within Illumina: "[I]t's my opinion that they would not have certainty that they've caught all of those potential breaches that you describe, on the phone, in the bathroom, at a restaurant." (RX6003 (Rock Trial Dep. at 96-97)).

Response to Finding No. 4924:

Respondents incorporate their responses to CCFF ¶¶ 4920 and 4923 herein.

4925. Mr. Rock stated that "sometimes one– one item, one supply item, can interrupt the production of everything" for a customer. (RX6003 (Rock Trial Dep. at 41)).

Response to Finding No. 4925:

The proposed finding is incomplete and misleading. In the portion of Mr. Rock's testimony cited here, Mr. Rock specifically gave the example products of "an airplane" or "an automobile". (RX6003 (Rock Trial Dep. at 41).) Further, to the extent this concern applies to Illumina's customers, the Open Offer provides customers with a continuous source of supply of sequencing instruments and core consumables over the entire 12-year term. (*See* PFF ¶¶ 1000, 1005, 1007, 1009, 1011, 1037; [redacted]; Berry (Illumina) Tr. 690–91, 864, 878–79, 883; Conroy (Exact/Thrive) 1725; deSouza (Illumina) Tr. 2402, 2434–35, 2437–38; PX0064 (Illumina) at 5–6, 9; RX3935 (Illumina) at 2; RX6002 (Guerin-Calvert Trial Dep. at 59–60, 77–79.)

4926. Mr. Rock did not consider any monitor appointments from any FTC or DOJ antitrust cases in forming his opinions. (RX6003 (Rock Trial Dep. at 99)).

Response to Finding No. 4926:

Respondents have no specific response.

4927. Mr. Rock's report cites an FTC blog about a matter involving Coke and Pepsi, but Mr. Rock testified that he did not review any documents relating to the matter beyond the blog post in drafting his report and did not talk to the FTC-appointed monitor in the matter. (RX6003 (Rock Trial Dep. at 99-101)). Mr. Rock testified that he did not know whether Coke or Pepsi breached any firewall provisions or whether the monitor was able to resolve any problems that may have arisen in that matter, or if so, how much time it took to resolve any problems: "I have no idea if the monitor performed their procedures, what their findings were or what any resolution was. I do not know the– any of those." (RX6003 (Rock Trial Dep. at 101-102)).

Response to Finding No. 4927:

The proposed finding is incomplete and misleading. Mr. Rock's report cites to the FTC blog referenced here for the proposition that: "[T]he FTC has found that monitors can be helpful to ensuring that the order or consent decree is effective in preventing any loss of competition from [a] merger." (RX3870 (Rock Rebuttal Report) ¶ 15.) that is, Mr. Rock did not opine on the efficacy of the Coke/Pepsi monitor. This is irrelevant to the fact that the FTC has used monitors in previous mergers.

(3) Any Breach of the Open Offer Would Be Difficult for MCED Test Developers to Resolve

(a) A Dispute Related to the Open Offer Would Place MCED Test Developers in the Difficult Position of Negotiating, or Perhaps Even Litigating, Against the Sole Supplier of a Critical Input for MCED Tests

4928. [redacted]

Response to Finding No. 4928:

The proposed finding is incomplete and misleading. To the extent that Complaint Counsel attempts to suggest that [redacted] customers alleging that Illumina breached its obligations would not need to sue Illumina court or spend [redacted] litigating a case. To the contrary, the Open Offer provides for two dispute resolution mechanisms: a fast-track informal (but binding) process or binding arbitration

that would take no more than 120 days. (PFF ¶ 1054; [redacted]; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 10–11; PX7076 (Berry (Illumina) Dep. at 282–83).) Illumina aims to get through any arbitration as fast as possible and to use the most accelerated process available. (deSouza (Illumina) Tr. 2460–61.) Illumina is open to soliciting feedback and improving the arbitration process to make it more expeditious if possible. (deSouza (Illumina) Tr. 2460–61.)

4929. [redacted]

Response to Finding No. 4929:

The proposed finding is incomplete and misleading. *First*, under the Open Offer, Illumina is required to notify customers of any potential non-compliance within 10 days. (RX3935 (Illumina) at 2–3.) Second, in any arbitration, the arbitrator is expressly required to take into account, and the Arbitrator's decision shall reflect, that the purpose of the [Open Offer] is to allay any concerns relating to the Transaction". (RX3935 (Illumina) at 3.) Thus, the Open Offer aims to tilt the scales of the arbitration process to customers' benefit.

4930. [redacted]

Response to Finding No. 4930:

The proposed finding is incomplete and misleading. In the portion of Mr. Conroy's testimony cited here, [redacted] The Open Offer provides for two dispute resolution mechanisms: a fast-track informal (but binding) process or

binding arbitration that would take no more than 120 days. (PFF ¶ 1054; [redacted]; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 10–11; PX7076 (Berry (Illumina) Dep. at 282–83).) Illumina aims to get through any arbitration as fast as possible and to use the most accelerated process available. (deSouza (Illumina) Tr. 2460–61.) Illumina is open to soliciting feedback and improving the arbitration process to make it more expeditious if possible. (deSouza (Illumina) Tr. 2460–61.) Therefore, there is no basis to suggest that customers would need to spend years to ensure that the Open Offer was properly enforced. This makes sense given that Mr. Conroy has almost no knowledge of the Open Offer. Mr. Conroy testified at trial that he had not read the Open Offer and, beyond what counsel had described to him, did not know what the Open Offer actually required Illumina to do. (PFF ¶ 1073; Conroy (Exact/Thrive) Tr. 1725–27.) Therefore, his testimony on this point should be given no weight.

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4931. Singlera's Dr. Gao acknowledged the difference in resources in any battle with Illumina, stating, "We are the small ants. We cannot fight a war. We're hoping the giants will fight the war." (PX7042 (Gao (Singlera) IHT at 89)).

Response to Finding No. 4931:

The proposed finding is incomplete and misleading. In the portion of Dr. Gao's testimony cited here, Dr. Gao was not discussing enforcing the Open Offer. In fact, Dr. Gao knows next to nothing about the Open Offer. (PFF ¶ 1895; Gao (Singlera) Tr. 2952 ("Q. And are you aware that that open offer was amended as of just last week to make certain improvements to it? A. Sir, to be frank, I am not even aware of the first open -- open offer until my lawyer told me, and I am not even aware of the one if you don't tell me a week ago.").)

Instead, Dr. Gao was responding to a question about "Singlera's options going forward" if Singlera could not secure a supply agreement with Illumina. (PX7042 (Gao (Singlera) IHT at 89).) Dr. Gao stated that he hoped one of "the giants" like "Thrive, Natera, [or] Roche" would "force Illumina to abandon such an approach" of not offering supply agreements to customers like Singlera. (PX7042 (Gao (Singlera) IHT at 89).) But Dr. Gao admitted in the same portion of his testimony that Illumina *did* offer a supply agreement to Singlera, which Illumina "expect[ed] us [Singlera] to negotiate I'm sure, but we never went back" to negotiate with Illumina. (PX7042 (Gao (Singlera) IHT at 87).) Later, when asked whether the lack of a supply agreement has affected the development of the PanSeer test, Dr. Gao testified: "So far it's not, because we are still far away from the FDA approval, FDA clinical trial." PX7042 (Gao (Singlera) IHT at 90).)

Therefore, all that the cited (which testimony shows is that (1) Illumina offered a supply agreement to Singlera, which Singlera did not engage with, (2) Singlera thinks that other companies like Thrive, Natera and Roche have the resources to resolve their disputes with Illumina and (3) Singlera's PanSeer test is "still [so] far away from the FDA approval" that Singlera's decision not to engage with Illumina's supply agreement offer did not affect the development of PanSeer.

Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4932. [redacted]

Response to Finding No. 4932:

The proposed finding is incomplete and misleading. In the portion of Dr. Rabinowitz's testimony cited here, [redacted] under the Open Offer [redacted] Illumina commits that it will not have the right to withhold supply solely on the basis of a claim of infringement of Illumina's intellectual property rights. (PFF ¶ 1037; Berry (Illumina) Tr. 864; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.) This provision applies even if Illumina has a legitimate claim of infringement. (RX6002 (Guerin-Calvert Trial Dep. at 78).) [redacted]

4933. [redacted]

Response to Finding No. 4933:

The proposed finding is incomplete and misleading. [redacted] the Open Offer provides for two dispute resolution mechanisms: a fast-track informal (but binding) process or binding arbitration that would take no more than 120 days. (PFF ¶ 1054; [redacted]; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 10–11; PX7076 (Berry (Illumina) Dep. at 282–83).) [redacted], under the Open Offer, customers would be notified of any potential noncompliance within 10 days and since the arbitration in any arbitration is required to take into account customers' concerns about the merger. *See* Response to CCFF ¶ 4929.

(4) Illumina's Arbitration Provision Is Flawed

4934. The Open offer Arbitration term states in part: "If any dispute arises from or relates to this Supply Agreement, including as a result of a dispute over terms in a separate agreement that incorporates the terms herein (the "Dispute"), other than claims involving infringement, validity, or enforceability of Intellectual Property Rights (whether Illumina's or Customer's), or about the scope of Intellectual Property Rights in an agreement, Illumina and Customer (each a "party" and together the "parties") shall submit the matter to confidential binding arbitration to determine final terms and conditions of the supply agreement, or to settle the dispute as to the terms of a supply agreement." (PX0064 at 010 (Illumina Open Offer agreement, Mar. 29, 2021)).

Response to Finding No. 4934:

The proposed finding is incomplete and misleading. On September 8, 2021, Illumina amended the Open Offer because Illumina found ways it could make the Open Offer "even slightly better". (deSouza (Illumina) Tr. 2406.) As part of these amendments, Illumina added

the following language to the arbitration provision: "If the Arbitrator determines that Illumina has breached any provision of the Supply Agreement, the Arbitrator may order any relief necessary to restore the status quo prior to Illumina's breach, including monetary and/or injunctive relief. In resolving any dispute under the Supply Agreement, the Arbitrator shall take into account, and the Arbitrator's decision shall reflect, that the purpose of the Supply Agreement is to allay any concerns relating to the Transaction, including that Illumina would disadvantage GRAIL's potential competitors after the Transaction by increasing their sequencing prices or by withholding access to Illumina's latest innovations in NGS." (RX3935 (Illumina) at 3.)

4935. Ms. Berry testified that if a customer disputes the auditor's findings, they would engage in an arbitration with Illumina. (PX7076 (Berry (Illumina) Dep. at 286)).

Response to Finding No. 4935:

Respondents have no specific response.

4936. Arbitration takes time and involves costs. (deSouza (Illumina) Tr. 2456; PX7076 (Berry (Illumina) Dep. at 298-99); PX7105 (Getty (Guardant) Dep. at 93)).

Response to Finding No. 4936:

Respondents have no specific response except to note that the Open Offer addresses any concerns about the time and cost of arbitration. Specifically, the Open Offer provides two dispute resolution mechanisms: a fast-track informal (but binding) process or binding arbitration that would take no more than 120 days. (PFF ¶ 1054; [redacted]; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 10–11; PX7076 (Berry (Illumina) Dep. at 282–83).) The immediate dispute resolution process helps resolve any concerns about the time and expense of arbitration. (PFF ¶ 1105.3; RX6002 (Guerin-Calvert Trial Dep. at 89–91).) If a customer chooses to engage in arbitration, Illumina aims to get through any arbitration as fast as possible

and to use the most accelerated process available. (PFF ¶ 1105.2; deSouza (Illumina) Tr. 2460–61.) Illumina is open to soliciting feedback and improving the arbitration process to make it more expeditious if possible. (PFF ¶ 1105.2; deSouza (Illumina) Tr. 2460–61.)

4937. Mr. Getty testified that the impact enforcing a breach of contract would have on Guardant is extensive. Specifically, he testified "the cost of individual's time within the organization, and the bandwidth necessary to spend with those proceedings, to ensure that, you know, we put our best foot forward" would be one such impact. (PX7105 (Getty (Guardant) Dep. at 93-94)).

Response to Finding No. 4937:

Respondents incorporate their responses to CCFF ¶ 4936 herein. Further, Respondents note that the Open Offer requires that "[i]f the Arbitrator determines that Illumina has breached any provision of the Supply Agreement, the Arbitrator may order any relief necessary to restore the status quo prior to Illumina's breach, including monetary and/or injunctive relief." (RX3935 (Illumina) at 3.) That is, to the extent that the arbitration process itself caused any injury to a customer, the arbitrator is empowered to order relief to address such injury to restore the status quo prior to Illumina's breach.

4938. The cost of arbitration "while not defined in dollar amounts, ties up [Guardant's] time and energy and resources that could be deployed against development of tests for the future state. It could tie up their time for development of tests in the current state across all of the different areas that we exist in today[.]" (PX7105 (Getty (Guardant) Dep. at 93-94)).

Response to Finding No. 4938:

Respondents incorporate their responses to CCFF ¶¶ 4936–37 herein.

4939. Mr. Getty also testified that arbitration with Illumina would slow down Guardant's innovation and have a very significant impact on patient care "because ultimately [Guardant would be] tied up dealing with the arbitration around a matter that we have very limited visibility into." (PX7105 (Getty (Guardant) Dep. at 95)).

Response to Finding No. 4939:

Respondents incorporate their responses to CCFF ¶¶ 4936–37 herein.

4940. Mr. Getty testified that "if you were to spend a year in arbitration trying to figure out whether GRAIL had a competitive advantage that eventually, you know, sort of played out in terms of a differentiated test offering, and physicians start adopting, you know, whether or not Guardant is successful a year and a half later with an arbitration case may be frankly rendered useless because ultimately by that time, they've cemented such a position in the marketplace that they've been able to accelerate their market share well beyond what we could ever catch up to." (PX7105 (Getty (Guardant) Dep. at 95-96)).

Response to Finding No. 4940:

Respondents incorporate their responses to CCFF ¶¶ 4936–37 herein. Further, Respondents note that Mr. Getty's testimony about the consequences of spending "a year" in arbitration is irrelevant. Even assuming that arbitration under the Open Offer lasted as long as possible (which is the opposite of Illumina's intention and would be against Illumina's own self-interest (*see* deSouza (Illumina) Tr. 2460–61), the arbitration would still last only 120 days.

4941. Mr. Getty testified that there is a risk to getting into a contractual dispute with their sole supplier, Illumina. Specifically, he testified, "[y]ou know, there are significant externalities there. And, you know, as individuals and negotiating partners and partners just in general, as we've all experienced with personal relationships, you know, if you have a negative interaction, it certainly will create dynamics in the future state that may not be positive for that relationship. So, you know, for lack of a better metaphor, poking the bear is not exactly a good idea." (PX7105 (Getty (Guardant) Dep. at 96)).

Response to Finding No. 4941:

The proposed finding is incomplete and misleading. Mr. Getty's testimony about the potential impacts on relationships that might occur if a hypothetical enforcement action took place is pure speculation. Additionally, even assuming that the relationship between Illumina and a customer was damaged after an enforcement action based on the Open Offer, Illumina would still be bound by the Open Offer for the entre 12-year term. Therefore, the customer would still be protected against any foreclosure actions by Illumina.

4942. Mr. Fiedler testified that if FMI were to be in litigation with Illumina it would be a "very unfortunate situation" because "during litigation the business retreats to really focusing on contractual terms and not kind of going the extra mile when it's required." (PX7118 (Fiedler (FMI) Dep. at 84-85)).

Response to Finding No. 4942:

The proposed finding is incomplete and misleading. In the portion of Dr. Fiedler's testimony cited here, Dr. Fiedler testified that he "expect[s] Illumina to stick to the agreement and to the terms committed to" and that FMI was "in a good, trusting relationship" with Illumina. (PX7118 (Fiedler (FMI) Dep. at 84).) Moreover, at trial, Dr. Fiedler testified that [redacted]

4943. Mr. Fiedler testified that being in a contractual dispute with an essential supplier for FMI, such as Illumina, would be a "very grave concern if this would impact deliveries." (PX7118 (Fiedler (FMI) Dep. at 85-86) ("Q. Do you see any issues with being in a contractual dispute with an essential supplier for FMI? [Objections] A. I think the main concern is that as long as the delivery continues during that dispute, then as I said, it's the extra service of the extra flexibility that might be missing. It would be of very grave concern if this would impact deliveries.")).

Response to Finding No. 4943:

Respondents incorporate their responses to CCFF ¶ 4942 herein.

4944. To complete the entire arbitration process could take up to 120 days. (*See* Berry (Illumina) Tr. 721-23)).

Response to Finding No. 4944:

The proposed finding is incomplete and misleading. Specifically, the Open Offer provides two dispute resolution mechanisms: a fast-track informal (but binding) process or binding arbitration that would take no more than 120 days. (PFF ¶ 1054; Rabinowitz (Natera) Tr. 444; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 10–11; PX7076 (Berry (Illumina) Dep. at 282–83).) The immediate dispute resolution process helps resolve any concerns about the time of arbitration. (PFF ¶ 1105.3; RX6002 (Guerin-Calvert Trial Dep. at 89–91).) If a

customer chooses to engage in arbitration, Illumina aims to get through any arbitration as fast as possible and to use the most accelerated process available. (PFF ¶ 1105.2; deSouza (Illumina) Tr. 2460–61.) Illumina is open to soliciting feedback and improving the arbitration process to make it more expeditious if possible. (PFF ¶ 1105.2; deSouza (Illumina) Tr. 2460–61.)

4945. Ms. Berry does not know whether Grail, as an affiliate of Illumina, would have to go through the same 120-day arbitration process. (Berry (Illumina) Tr. 723-24).

Response to Finding No. 4945:

Respondents have no specific response.

4946. Grail, as an affiliate of Illumina now, is not subject to the Open Offer letter. (Berry (Illumina) Tr. 724).

Response to Finding No. 4946:

Respondents have no specific response.

(a) Ms. Guerin-Calvert's Arbitration Analysis Does Not Meet Her Own Report's Standards

4947. Ms. Guerin-Calvert agreed that if there was a dispute between Illumina's CEO and any of Illumina's customers, they would work through Section 12 of the open offer that details the dispute mechanism process. (RX6002 (Guerin-Calvert Trial Dep. at 137-38)).

Response to Finding No. 4947:

Respondents have no specific response.

4948. Ms. Guerin-Calvert testified that it could take up to 120 days for Illumina's customers to resolve a dispute through the dispute mechanism process. (RX6002 (Guerin-Calvert Trial Dep. at 133-34)).

Response to Finding No. 4948:

Respondents incorporate their responses to CCFF ¶ 4944 herein.

4949. Ms. Guerin-Calvert testified that Illumina's customers have to bear their own costs of arbitration with Illumina. (RX6002 (Guerin-Calvert Trial Dep. at 138)).

Response to Finding No. 4949:

The proposed finding is incomplete and misleading. Ms. Guerin-Calvert provided context for this answer: "[F]irms facing arbitration or considering arbitration are always doing a cost-benefit analysis. So I would expect that, as an economist looking at [the arbitration provision], . . . for circumstances where it is cost-effective– in other words, the benefit to be gained from resolving a dispute is significant– people would be willing to undertake those costs." (RX6002 (Guerin-Calvert Trial Dep. at 90–91).) She continue: "[T]hen also having the immediate dispute resolution mechanism helps potentially minimize those costs or at least lower them by saying if we can go this outside of the context of an actual arbitration, that may, again make it– the overall cost less." (RX6002 (Guerin-Calvert Trial Dep. at 91).)

4950. By contrast, if there's a dispute between Illumina's CEO and GRAIL, ultimately, Illumina's CEO is responsible for GRAIL's operations. (RX6002 (Guerin-Calvert Trial Dep. at 138)).

Response to Finding No. 4950:

Respondents have no specific response.

l) The Open Offer Cannot Account for Every Way Illumina Can Harm Grail's Rivals Over a 12-Year Term

4951. [redacted]

Response to Finding No. 4951:

The proposed finding is incomplete and misleading. As Ms. Berry testified at trial, the twelve-year term was chosen because "we wanted to provide eligible customers with assurances that . . . we are absolutely interested in, invested in, and our goal is to maintain longstanding, positive relationships as technology providers to these customers". (Berry (Illumina) Tr. 862.) She testified: "[O]ur goal with the open offer was to try to accommodate, you know, in an as

customer friendly way as possible the categories of requests that we might be likely to get over a twelve-year time horizon." (Berry (Illumina) Tr. 882.) Thus, Illumina included terms like the provision requiring Illumina to enter into development agreements with customers even though Illumina did not normally undertake these activities pre-merger. (Berry (Illumina) Tr. 81–82.)

Further, the weight of the evidence shows that the Open Offer fully addresses the competitive concerns that would likely arise over a 12-year term. (PFF ¶ 1083; RX6002 (Guerin-Calvert Trial Dep. at 103–04).) The Open Offer accomplishes this by using flexible terms that can respond to changes over time. For example, rather than prescribing specific types of assistance, the FDA provision requires Illumina to provide *whatever documentation is needed* for FDA approval. (PFF ¶ 1083.2; RX6002 (Guerin-Calvert Trial Dep. at 103–04).) This allows the provision to be effective even if FDA requirements change over time. (PFF ¶ 1083.3; *see* RX6002 (Guerin-Calvert Trial Dep. at 104).)

Moreover, customers have acknowledged that no contract is perfect and no contract can address all potential issues that might eventualize over the long term. (*See, e.g.*, [redacted]; Conroy (Exact/Thrive) Tr. 1723; [redacted] Nonetheless, these customers enter into contracts all the time. [redacted] Conroy (Exact/Thrive) Tr. 1723; [redacted]

4952. [redacted] (PX2385 (Illumina) at 001 (Text message from N. Berry, Illumina, to K. Peterson, Illumina, Nov. 19, 2020) (*in camera*))).

Response to Finding No. 4952:

The proposed finding is incomplete and misleading. Specifically, in the text exchange cited here, Ms. Berry stated that [redacted] These provisions in Guardant's agreement inspired similar provisions in the Open Offer. (*See* Berry (Illumina) Tr. 941–43; PFF ¶ 1008.) Thus, the evidence cited for the proposed finding shows that, while Illumina wanted to make sure it was prepared to extend these novel provisions to customers for a 12-year term, it ultimately decided to do so, to the benefit of Guardant and other customers.

4953. [redacted] (PX7076 (Berry (Illumina) Dep. at 221) (*in camera*)).

Response to Finding No. 4953:

The proposed finding is incomplete and misleading. Ms. Berry provided context for this answer at trial: Ms. Berry testified that the twelve-year term was chosen because "we wanted to provide eligible customers with assurances that . . . we are absolutely interested in, invested in, and our goal is to maintain longstanding, positive relationships as technology providers to these

customers". (Berry (Illumina) Tr. 862.) Further, Ms. Guerin-Calvert explained that the 12–year term is an improvement on the status quo, in which many customers do not have supply agreements and those that do have supply agreements have shorter term agreements. (PFF ¶ 1000.4; RX6002 (Guerin-Calvert Trial Dep. at 29).) Additionally, the 12-year term allows customers to plan for the long term more effectively. (PFF ¶ 1000.6; [redacted]; RX6002 (Guerin-Calvert Trial Dep. at 28–29).) Finally, a 12–year term is consistent with what is normally provided in consent decrees that the FTC and the DOJ have approved historically. (PFF ¶ 1000.3; RX6002 (Guerin-Calvert Trial Dep. at 28); *see, e.g.*, RX3082 (*In re Broadcom Ltd.* Decision and Order) at 11; RX3664 (*In re Sycamore Partners II* Analysis of Agreement Containing Consent Order) at 4).)

4954. Ms. Berry testified that its "fair to assume" that it's difficult to know every situation that may take place over the course of a 12-year supply agreement because "there's a lot of dynamic things that are happening amongst [Illumina's] customers." (Berry (Illumina) Tr. 694).

Response to Finding No. 4954:

Respondents incorporate their responses to CCFF ¶¶ 4951 and 4953 herein.

4955. [redacted]

Response to Finding No. 4955:

Respondents incorporate their responses to CCFF ¶¶ 4951 and 4953 herein. Further, Mr. Conroy of Exact/Thrive admitted that Exact relies on contracts to run its business, despite the fact that no contract is perfect and no contract can address all potential issues that might eventualize over a long term. (Conroy (Exact/Thrive) Tr. 1723.)

4956. [redacted]

[redacted]

Response to Finding No. 4956:

Respondents incorporate their responses to CCFF ¶¶ 4951, 4953 and 4955 herein.

4957. [redacted]

Response to Finding No. 4957:

Respondents incorporate their responses to CCFF ¶¶ 4951, 4953 and 4955 herein.

4958. [redacted]

Response to Finding No. 4958:

Respondents incorporate their responses to CCFF ¶¶ 4951, 4953 and 4955 herein.

4959. [redacted]

Response to Finding No. 4959:

Respondents incorporate their responses to CCFF ¶¶ 4951, 4953 and 4955 herein.

4960. Mr. Getty testified that he is unaware of all of the circumstances in which Guardant may need Illumina's assistance over the next 12 years. (PX7105 (Getty (Guardant) Dep. 82)).

Response to Finding No. 4960:

Respondents incorporate their responses to CCFF ¶¶ 4951 and 4953. Further, Mr. Getty admitted that [redacted]

[redacted]

4961. Mr. Getty further testified that he is unaware of all the issues that Guardant may face with Illumina as its supplier over the next 12 years because Guardant is "in a rapidly-evolving space that, you know, has remained stagnant very infrequently. And so ultimately just by virtue of the nature of 12 years on, it's challenging to see, but even in the sort of short term, it's difficult to even predict what's going to happen next month." (PX7105 (Getty (Guardant) Dep. 82)).

Response to Finding No. 4961:

Respondents incorporate their responses to CCFF ¶¶ 4951, 4953 and 4960 herein.

4962. Guardant's SVP of Commercial, Cancer Screening Core, William Getty, testified that "it's difficult to even predict what's going to happen next month[,]" and that "the risk premium goes up pretty significantly" further out in the contractual term. (PX7105 (Getty (Guardant) Dep. at 82-83)).

Response to Finding No. 4962:

Respondents incorporate their responses to CCFF ¶¶ 4951, 4953 and 4960 herein.

4963. Mr. Getty testified that "it's nearly impossible to determine" every contractual term that Guardant would need to ensure that it doesn't have any harm from Illumina's acquisition of Grail. (PX7105 (Getty (Guardant) Dep. 82-83)).

Response to Finding No. 4963:

Respondents incorporate their responses to CCFF ¶¶ 4951, 4953 and 4960 herein.

4964. Mr. Getty testified, with regard to identifying every contractual term Guardant would need from Illumina, that "the risk premium goes up pretty significantly relatively speaking when we start talking about terms that are, you know, 12 years on. So it's– it's impossible." (PX7105 (Getty (Guardant) Dep. 82-83)).

Response to Finding No. 4964:

Respondents incorporate their responses to CCFF ¶¶ 4951, 4953 and 4960 herein.

4965. Nitin Sood, former Senior Vice President of Products at Guardant, testified "I cannot imagine every way in which the Illumina acquisition of GRAIL could hurt GRAIL's competitors." (PX7090 (Sood (Guardant) Dep. at 146-47)).

Response to Finding No. 4965:

Respondents incorporate their responses to CCFF ¶¶ 4951, 4953 and 4960 herein.

4966. [redacted]

Response to Finding No. 4966:

Respondents incorporate their responses to CCFF ¶¶ 4951 and 4953 herein. Further, [redacted]. (PFF ¶ 1000.6; Fiedler (FMI) Tr. 4485.) Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4967. [redacted]

Response to Finding No. 4967:

Respondents incorporate their responses to CCFF ¶¶ 4951, 4953 and 4966 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4968. [redacted]

Response to Finding No. 4968:

Respondents incorporate their responses to CCFF ¶¶ 4951, 4953 and 4966 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4969. [redacted]

Response to Finding No. 4969:

Respondents have no specific response except to note that [redacted] (PFF ¶ 1000.6; Fiedler (FMI) Tr. 4485.)

4970. [redacted]

Response to Finding No. 4970:

Respondents incorporate their responses to CCFF ¶ 4969 herein.

4971. [redacted]

Response to Finding No. 4971:

Respondents incorporate their responses to CCFF ¶¶ 4951, 4953 and 4969 herein. Further, Dr. Fiedler testified that [redacted]

[redacted]

4972. [redacted]

Response to Finding No. 4972:

Respondents incorporate their responses to CCFF ¶¶ 4951, 4953, 4969 and 4971 herein.

4973. [redacted] (PX6090 (Scott Morton Report) ¶ 313 (*in camera*)).

Response to Finding No. 4973:

The proposed finding is incomplete and misleading. Contracts can be written to take away Illumina's ability to disadvantage GRAIL rivals. (PFF ¶ 1078.1; RX6002 (Guerin-Calvert Trial Dep. at 104–05).) Indeed, behavioral remedies like the Open Offer have been used by the FTC and DOJ since the 1970s in a wide variety of industries and cases. (PFF ¶ 1078.1; RX6002 (Guerin-Calvert Trial Dep. at 105).) Dr. Scott Morton's opinion that the Open Offer is inadequate because it cannot anticipate every contingency that could arise ignores the fact that this is true of all contracts. (PFF ¶ 1078.2; RX6000 (Carlton Trial Dep. at 49–50).) In fact, Dr. Scott Morton assumes that, absent the merger, sophisticated contracts could be written that would enable the efficiencies of the merger but places no confidence in the Open Offer's ability to protect GRAIL rivals, even though the Open Offer is a private contract that is privately enforceable. (PFF ¶ 1078.2; RX6000 (Carlton Trial Dep. at 49–50).) Economists have evaluated the Open Offer and concluded that it is a comprehensive contract that sufficiently addresses and

anticipates issues that are likely to arise over time. (PFF ¶ 1078.3; RX6002 (Guerin-Calvert Trial Dep. at 21–22, 103–04); RX6000 (Carlton Trial Dep. at 84–85).)

m) Potential Reputational Damage Will Not Prevent Illumina from Violating Its Contractual Commitments to MCED Customers

4974. As provided above in Section V. (Illumina NGS Is a Necessary Input to MCED Tests), MCED test developers testified unanimously that they have no alternative NGS options for their MCED tests.

Response to Finding No. 4974:

Respondents have no specific response. To the extent Complaint Counsel incorporates its Proposed Findings in Section V, Respondents incorporate their responses to those Proposed Findings herein.

4975. After Illumina closed its acquisition of Grail despite the European Commission's standstill order, Illumina told investors in an SEC filing that consummating the transaction when it did could lead to "other adverse consequences to, among other things, its reputation . . . ." (PX0378 at 004-05 (Illumina Form 8-K, Aug. 18, 2021)).

Response to Finding No. 4975:

Respondents have no specific response.

4976. Illumina's CEO Mr. deSouza acknowledged at trial that Illumina decided to close the transaction despite the potential risk to its reputation. (deSouza (Illumina) Tr. 2236-37).

Response to Finding No. 4976:

The proposed finding is incomplete and misleading. In the portion of Mr. deSouza's testimony cited here, Mr. deSouza provided context for this answer: Mr. deSouza testified that Illumina believes that "there won't be damage to Illumina's reputation, but there is a risk to it." (deSouza (Illumina) Tr. 2237.) In other words, Illumina closed the transaction despite a slight reputational risk because Illumina believed that its reputation would not ultimately be harmed. This differs from the reputational risk of violating the Open Offer. While closing the transaction is ultimately good for Illumina's reputation because it will generate efficiencies that could not be

achieved without the transaction (*see* PFF ¶¶ 1106–179), violating the Open Offer would only incur reputational damage. Thus, compliance with the Open Offer is in Illumina's own best interest. [redacted].)

4977. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 99 (*in camera*)).

Response to Finding No. 4977:

The proposed finding is incomplete and misleading. [redacted] the Open Offer requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶ 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.) Thus, if Illumina failed to optimize its reagents for other MCED tests, Illumina would violate the Open Offer. Similarly, the Open Offer requires Illumina, on a customer's request, to enter into a separate agreement with the customer based on standardized terms to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33; [redacted]; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; [redacted].) It also requires

Illumina to provide to provide documentation to assist customers with FDA approval or marketing authorization to sell a for-profit, clinical test using Illumina's sequencing instruments and core consumables. (PFF ¶ 1027; PX0064 (Illumina) at 8; [redacted].) These requirements in the Open Offer prevent Illumina from withholding support as MCED test developers seek FDA approval. (PFF ¶ 1035; RX6002 (Guerin-Calvert Trial Dep. at 74).) Therefore, Illumina could not disfavor one customer in the FDA approval process.

4978. As provided in Sections VII.A. (Illumina Has the Ability to Harm Grail's Rivals) and VII.B. (Illumina Has the Incentive to Lessen Competition in the U.S. MCED Test Market by Disadvantaging Grail's Rivals), Illumina has the ability to use its position as the sole NGS supplier to MCED test developers to hinder, alter, foreclose, or delay the progress of MCED test developers to the benefit of Grail.

Response to Finding No. 4978:

Respondents have no specific response. To the extent Complaint Counsel incorporates its Proposed Findings in Sections VII.A and VII.B, Respondents incorporate their responses to those Proposed Findings herein.

4979. [redacted]

Response to Finding No. 4979:

Respondents incorporate their responses to CCFF ¶ 4978 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4980. [redacted]

Response to Finding No. 4980:

The proposed finding is incomplete and misleading. Specifically, the Open Offer requires Illumina to provide customers, within 5 days, with the same information that GRAIL receives about final product specifications of any sequencing instruments or core consumables. (PFF ¶ 1006; RX3935 (Illumina) at 2.) Further, even though Illumina typically has not provided support in the development or commercialization of customers' products, to provide additional benefits to customers, the Open Offer requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶ 1010; Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.) This not only prevents Illumina from disadvantaging GRAIL rivals, but also requires Illumina to act in a particular way to support rivals developing their own products. (PFF ¶ 1010.9; RX6002 (Guerin-Calvert Trial Dep. at 68).) Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4981. [redacted]

Response to Finding No. 4981:

Respondents incorporate their responses to CCFF ¶ 4980 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4982. [redacted]

Response to Finding No. 4982:

The proposed finding is incomplete and misleading. Under the Open Offer, Illumina is prohibited from discontinuing products that any oncology customer has purchased in the prior year. (PFF ¶ 1011; [redacted]; Berry (Illumina) Tr. 883; PX0064 (Illumina) at 6; [redacted].) This provision adequately addresses the concern that Illumina could advantage GRAIL by simply no longer providing a product and ensures that customers as "certainly no worse off than in the current world". (PFF ¶¶ 1011.7–.8; RX6002 (Guerin-Calvert Trial Dep. at 71–73).) Further, as noted above, the Open Offer also requires Illumina to enter into a separate agreement on a customer's request to optimize Illumina's products to enable greater interoperability with the customer's test. (*See* Response to CCFF ¶ 4980.)

4983. [redacted]

Response to Finding No. 4983:

Respondents incorporate their responses to CCFF ¶ 4982 herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4984. [redacted]

Response to Finding No. 4984:

Respondents incorporate their responses to CCFF ¶ 4977 herein.

4985. [redacted]

Response to Finding No. 4985:

The proposed finding is incomplete and misleading. *First*, Complaint Counsel's citations here to Dr. Rabinowitz and Mr. Song are misplaced. Dr. Rabinowitz is not an unbiased witness. At trial, Dr. Rabinowitz [redacted] Therefore, his testimony about [redacted] should not be credited. The citation to Mr. Song is from Mr. Song's IH. This testimony is hearsay and Respondents had no opportunity to

cross examine Mr. Song during this IH, so this testimony should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

Second, in the same deposition of Mr. Daly cited here, Mr. Daly [redacted] Therefore, regardless of his personal views on Illumina's views of its customers, Mr. Daly's testimony about Illumina's *actions* suggests Illumina would have a positive reputation.

This strong reputation borne out by the testimony of other customers. For example, Dr. Fielder testified that, since FMI entered into a supply agreement with Illumina in 2013: Illumina has acted in good faith with respect to its obligations, FMI is a satisfied customer, Illumina has never "monkeyed" with supply, Illumina has never interrupted supply because it claimed FMI had infringed Illumina's intellectual property and Illumina has never reneged on a commitment made to FMI. (Fiedler (FMI) Tr. 4471–72.) He also testified that, based on his prior experiences with Illumina, he trusts Illumina to abide by its commitments. (Fielder (FMI) Tr. 4472.)

Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4986. Ken Song of Omniome previously worked at Ariosa, an NIPT competitor of Illumina. Mr. Song testified on the ways Illumina would act in the past when it was vertically integrated against Ariosa and how because of their position as the "only solution" in the NGS market, they could get away with it:

> So I'll speak based on my prior experience at Ariosa Diagnostics, where we were in situations where we were trying to sell our system, which ended up being a nonsequencing-based option, where Illumina would go to our customers or our prospective customers and tell them, well, you know -- you know, that's -- that either doesn't have adequate patent protection or if you do that, you know, not only is the company infringing, but you're potentially liable for infringing as well.
>
> So, you know, they're not saying that they're going to sue their customer, but they're definitely insinuating that that's a possibility, and I think they also use that to perhaps threaten the customer– the customer might still need to use Illumina's sequencing products for other applications, right, not just specific to -- in my case of Ariosa, on behalf of Ariosa, in the case of NIPT, that was just one application.
>
> But if a customer needs Illumina for, like, 80 percent of their other tests, you know, I think Illumina indirectly sort of said, well, you know, if you need to be reliant upon us for that other stuff, you should really use us for everything.
>
> So, look, I mean, they have been around. They're super smart. They're super successful. I think they have an army of lawyers there. So they know kind of -- I would anticipate they kind of know what they might be able to get away with, but it's -- but I would -- I would say it's sort of a -- you know, they're kind of the big bully, and I remember I thought of this back in my Ariosa days, that they literally do -- I believe they literally use their IP as a weapon to try and control the marketplace, and people are scared of them because of that, because they're really the only solution that's out there in a pretty large and expanding NGS market."

(PX7071 (Song (Omniome) IHT at 43-44)).

Response to Finding No. 4986:

The proposed finding is incomplete and misleading. *First*, contrary to Mr. Song's testimony, the weight of the evidence shows that Illumina does not "use their IP as a weapon to try to control the marketplace". (*See* PFF ¶ 1099.) When Illumina has sued entities based on Illumina's intellectual property, it has done so because those entities infringed Illumina's intellectual property. (PFF ¶ 1099.1; deSouza (Illumina) Tr. 2470.) For example, when Illumina

sued Natera for infringement, Illumina was obligated to sue because Illumina is the custodian of a patent pool with multiple patentholders. (PFF ¶ 1099.2; deSouza (Illumina) Tr. 2470–71.) Illumina's efforts in creating this patent pool helped prevent the non-competitive use of intellectual property rights in the market for non-invasive prenatal tests (NIPT). (PFF ¶ 1099.3; *see* PX7089 (Naclerio (Illumina) Dep. at 49–50, 57–58, 150).)

In the nascent NIPT market that existed before Illumina acquired Verinata, several companies, such as Verinata, Sequenom and Ariosa, were engaged in ongoing intellectual property litigation. (PFF ¶ 1099.4; PX7089 (Naclerio (Illumina) Dep. at 49).) These disputes led to exceedingly high prices for NIPT tests for patients. (PFF ¶ 1099.4; PX7089 (Naclerio (Illumina) Dep. at 49–50).) Illumina recognized that these disputes held back the NIPT market. (PFF ¶ 1099.4; PX7089 (Naclerio (Illumina) Dep. at 49–50).)

Illumina chose to acquire Verinata in part to accelerate adoption of NIPT by settling this intellectual property litigation. (PFF ¶ 1099.5; PX7089 (Naclerio (Illumina) Dep. at 57–58).) Illumina recognized that it could accomplish this because Illumina could help bring the companies in disputes to the negotiating table. (PFF ¶ 1099.5; PX7089 (Naclerio (Illumina) Dep. at 57–59).) Illumina's strategy in this acquisition was to settle the intellectual property litigation promptly and then make NIPT technology available to other labs around the world to grow the market and lower prices. (PFF ¶ 1099.6; PX7089 (Naclerio (Illumina) Dep. at 58–59).) Illumina ultimately succeeded in this strategy when, after acquiring Verinata, it negotiated a set of cross-licensing agreements to create a patent pool among six different entities. (PFF ¶ 1099.6; [redacted], 150).)

Second, any concern that Illumina could use intellectual property litigation or even the threat of such litigation as a reason to withhold supply is baseless given the Open Offer's

protections. The Open Offer specifically ensures that Illumina is not allowed to cease shipments of the products solely on the basis of a claim of infringement of Illumina's intellectual property rights. (PFF ¶ 1037; Berry (Illumina) Tr. 864; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.) This provision applies even if Illumina has a legitimate claim of infringement. (PFF ¶ 1037.2; RX6002 (Guerin-Calvert Trial Dep. at 78).) [redacted]

Finally, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4987. [redacted] (PX7071 (Song (Omniome) IHT at 44) (*in camera*)).

Response to Finding No. 4987:

Respondents incorporate their responses to CCFF ¶ 4986 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4988. [redacted] (PX7071 (Song (Omniome) IHT at 45) (*in camera*)).

Response to Finding No. 4988:

Respondents incorporate their responses to CCFF ¶ 4986 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

n) Illumina Does Not Need to Commit a Blatant Violation of the Open Offer to Materially Affect the Competitiveness of MCED Test Developers

(1) Rather Than Refusing to Sell MCED Test Developer Reagents Outright, Illumina Can Gradually Optimize Its Reagents to Work Best on Galleri Without Optimizing Its Reagents for Other MCED Tests

4989. [redacted]

Response to Finding No. 4989:

Respondents incorporate their responses to CCFF ¶ 4980 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4990. [redacted]

Response to Finding No. 4990:

Respondents incorporate their responses to CCFF ¶ 4980 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4991. [redacted]

Response to Finding No. 4991:

Respondents incorporate their responses to CCFF ¶ 4980 herein. Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4992. [redacted]

Response to Finding No. 4992:

The proposed finding is incomplete and misleading. Specifically, in the same deposition cited here, Mr. Daly [redacted]

o) Customers Do Not Believe Open Offer Will Resolve Concerns

(1) [redacted]

4993. Mr. Getty, Guardant's SVP of Commercial, Cancer Screening Core, testified, "the [open] offer that is put forward is nothing more than a paper tiger. It's very difficult to understand how that would alleviate our concerns about a combined GRAIL and Illumina organization," adding that "[u]ltimately, . . . we don't have an option." (PX7105 (Getty (Guardant) Dep. at 78-79)).

Response to Finding No. 4993:

The proposed finding is incomplete and misleading. [redacted] In its negotiations with Illumina, Guardant never indicated to Illumina that Guardant viewed its amended supply agreement as, in substance, unenforceable or worthless. (PFF ¶ 1075.5; Getty (Guardant) Tr. 2669.)

4994. [redacted]

Response to Finding No. 4994:

The proposed finding is incomplete and misleading. [redacted] Specifically, the Open Offer prevents Illumina from materially delaying support services. (PFF ¶¶ 1084.1–1084.2; Berry (Illumina) Tr. 871, 878–79; RX6002 (Guerin-Calvert Trial Dep. at 65, 67).) Further, the Open Offer expressly forbids Illumina from raising prices over the entire 12-year term and affirmatively requires Illumina to lower the price of sequencing by at least 43% by 2025. (PFF ¶ ¶ 1021–23; [redacted]; Berry (Illumina) Tr. 899, 901–04; Conroy (Exact/Thrive) Tr. 1731–32; deSouza (Illumina) Tr. 2403; PX0064 (Illumina) at 7; [redacted] Finally, the Open Offer requires Illumina to provide

customers with the same access to purchase sequencing instruments and core consumables that GRAIL or any other For-Profit Entity has within 5 days of when GRAIL or such For-Profit Entity receives access. (PFF ¶ 1007; Berry (Illumina) Tr. 878–79; deSouza (Illumina) Tr. 2434–35, 2437–38; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.)

4995. [redacted]

Response to Finding No. 4995:

The proposed finding is incomplete and misleading. Specifically, Illumina enters all of its supply agreements with the intent to follow them and has never entered a supply agreement planning to not follow it. (Berry (Illumina) Tr. 843.) Further, even if Illumina failed to adhere to its commitments in the Open Offer, the Open Offer provides effective monitoring and enforcement provisions. The Open Offer requires Illumina to engage in a biannual audit to ensure compliance with the Open Offer. (deSouza (Illumina) Tr. 2405, 2438; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.) Further, if a customer has a good-faith basis for alleging that Illumina is in breach of the Open Offer, Illumina will engage an auditor to assess the customer's allegation separate from the biannual audits. (PX0064 (Illumina) at 10.) Illumina is obligated to provide customers with a written report confirming compliance with the Open Offer's commitments. (PX0064 (Illumina) at 10; PX7076 (Berry (Illumina) Dep. at 287).) And, customers must be promptly notified, within 10 days, of any potential noncompliance. (deSouza (Illumina) Tr. 2478; RX3935 (Illumina) at 3.)

In addition to the audit provision, the Open Offer provides effective dispute resolution mechanisms. Illumina agrees to binding arbitration in the event that a dispute arises under the agreement. [redacted]; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 10–11; PX7076 (Berry (Illumina) Dep. at 282–83).) The arbitrator may order any relief necessary to restore the status quo prior to Illumina's breach and the arbitrator's decision is required to reflect the fact that the purpose of the Open Offer is to allay any concerns relating to the Illumina-GRAIL transaction. (deSouza (Illumina) Tr. 2451–52; RX3935 (Illumina) at 3.) The enforcement terms of the Open Offer provide Illumina's clinical oncology customers with effective monitoring and enforcement mechanisms to ensure compliance with the Open Offer terms and to effectuate its purpose of ensuring that Illumina cannot materially disadvantage GRAIL rivals post-merger. (RX6002 (Guerin-Calvert Trial Dep. at 22–23).)

Finally, Mr. Nolan's testimony should be given no weight. Although Mr. Nolan testified here that [redacted]

4996. [redacted]

Response to Finding No. 4996:

The proposed finding is incomplete and misleading. [redacted] Illumina is not the sole supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.)

4997. [redacted]

Response to Finding No. 4997:

The proposed finding is incomplete and misleading. [redacted] Illumina is not the sole supplier of NGS equipment and faces stiff competition from current and future NGS providers. (*See* PFF ¶¶ 578–674.) Further, the weight of the evidence shows that the Open Offer [redacted] provides the economically necessary terms to prevent the alleged anticompetitive harms from the transaction in both the short term and the long term. (RX6002 (Guerin-Calvert Trial Dep. at 21–22).)

4998. [redacted]

Response to Finding No. 4998:

The proposed finding is incomplete and misleading. Under the Open Offer [redacted] Illumina cannot monkey with supply. As Ms. Berry testified, Illumina would be in breach of the agreement if we were found to be disadvantaging a customer under the open offer relative to GRAIL or another for-profit entity" in terms of supply. (Berry (Illumina) Tr. 878–79.)

4999. [redacted]

Response to Finding No. 4999:

Under the Open Offer [redacted] Illumina cannot monkey with support. As Ms. Berry testified, Illumina "be in breach of the open offer if we were to provide disadvantaged . . . services in quality to a customer that is in the area of, you know, oncology testing, an equivalent customer for GRAIL." (Berry (Illumina) Tr. 879.)

5000. [redacted]

Response to Finding No. 5000:

Respondents incorporate their responses to CCFF ¶¶ 4708–10 herein.

5001. [redacted]

Response to Finding No. 5001:

The proposed finding is inaccurate and not supported by any evidence. Respondents did present to the Court that FMI has no concerns about the transaction in light of the agreement, but Complaint Counsel has simply no evidence that this is "incorrect". Indeed, both Ms. Perettie and Dr. Fiedler confirmed that FMI had no concerns about the transaction at this point. [redacted] And a trial, Dr. Fiedler testified that [redacted]

[redacted]

5002. [redacted]

Response to Finding No. 5002:

Respondents incorporate their responses to CCFF ¶ 5001 herein. [redacted]

[redacted]

Further, the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5003. [redacted]

Response to Finding No. 5003:

The proposed finding is incomplete and misleading. In the portion of Mr. Daly's testimony cited here, Mr. Daly [redacted] The weight of the evidence shows that the Open Offer does resolve pricing, supply and information-sharing concerns. (*See, e.g.*, PFF ¶¶ 1000–03, 1013–25, 1038–42.)

5004. [redacted]

Response to Finding No. 5004:

The proposed finding is incomplete and misleading. [redacted]

(2) [redacted]

5005. [redacted]

Response to Finding No. 5005:

The proposed finding is incomplete and misleading. [redacted] However, the Open Offer [redacted] resolves each of these concerns.

First, the weight of the evidence shows that the Open Offer fully addresses the competitive concerns that would be likely to arise over a 12–year term. (PFF ¶ 1083; RX6002 (Guerin-Calvert Trial Dep. at 103–04).)

Second, under the Open Offer, if Illumina created a new product or an improved version of an existing product, Illumina would be required to provide potential GRAIL rivals with access to it within 5 days of GRAIL or any other For-Profit Entity receiving access. (PFF ¶¶ 1005–1005.2; deSouza (Illumina) Tr. 2448; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) The Open Offer also requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests, which not only prevents Illumina from disadvantaging GRAIL rivals, but also requires Illumina to act in a particular way to support rivals developing their own products. (PFF ¶ 1010;

Berry (Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6; RX6002 (Guerin-Calvert Trial Dep. at 68).)

Third, under this universal pricing grid, customers receive most-favored-nations (MFN) pricing protections, which ensure that the customer has access to volume-based net prices "that are no less favorable (i.e., the same or better) than" those provided to GRAIL or an Equivalent customer. (PFF ¶ 1018; Berry (Illumina) Tr. 893; PX0064 (Illumina) at 7–8.) Therefore, if Illumina offered GRAIL or an Equivalent customer a discretionary discount, then Illumina would be obliged to reduce the price for other Open Offer customers at the same volume levels to match the prices under such discretionary discount. (PFF ¶ 1018.3; Berry (Illumina) Tr. 893–94; RX6002 (Guerin-Calvert Trial Dep. at 38–39).)

Finally, Mr. Conroy of Exact admitted that Exact relies on contracts to run its business, despite the fact that no contract is perfect and no contract can address all potential issues that might eventualize over a long term. (Conroy (Exact/Thrive) Tr. 1723.)

5006. [redacted]

Response to Finding No. 5006:

Respondents incorporate their responses to CCFF ¶ 4995 herein.

5007. [redacted]

Response to Finding No. 5007:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

[redacted] Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5008. [redacted]

Response to Finding No. 5008:

The proposed finding is incomplete and misleading. [redacted]

[redacted] Further, a supply agreement with Illumina, as a private contract, creates an incentive for Illumina customers to take advantage of it and enforce it. (*See* PFF ¶ 1082.4; RX6000 (Carlton Trial Dep. at 84).) [redacted]

[redacted] Finally, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5009. [redacted]

[redacted]

Response to Finding No. 5009:

Respondents incorporate their responses to CCFF ¶ 5008 herein.

5010. [redacted]

Response to Finding No. 5010:

The proposed finding is incomplete and misleading. At trial, Mr. Conroy admitted that Exact relies on contracts to run its business, despite the fact that no contract is perfect and no contract can address all potential issues that might eventualize over a long term. (Conroy (Exact/Thrive) Tr. 1723.)

Further, the Open Offer [redacted] addresses any concern about customizing products for GRAIL. Specifically, under the Open Offer, if Illumina created a new product or an improved version of an existing product, Illumina would be required to provide potential GRAIL rivals with access to it within 5 days of GRAIL or any other For-Profit Entity receiving access. (PFF ¶¶ 1005–1005.2; deSouza (Illumina) Tr. 2448; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.) Moreover, even though Illumina typically has not provided support in the development or commercialization of customers' products, to provide additional benefits to customers, the Open Offer requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (PFF ¶ 1010; Berry

(Illumina) Tr. 844–47, 881; PX0064 (Illumina) at 6.) This not only prevents Illumina from disadvantaging GRAIL rivals, but also requires Illumina to act in a particular way to support rivals developing their own products. (PFF ¶ 1010.9; RX6002 (Guerin-Calvert Trial Dep. at 68).)

Finally, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5011. [redacted]

Response to Finding No. 5011:

The proposed finding is incomplete and misleading. At trial, Mr. Conroy admitted that Exact relies on contracts to run its business, despite the fact that no contract is perfect and no contract can address all potential issues that might eventualize over a long term. (Conroy (Exact/Thrive) Tr. 1723.)

Further, the Open Offer [redacted] addresses any concern about FDA support. [redacted] Illumina has a "very minimal role" in customers' FDA approval process. (PFF ¶ 1414–15; Goswami (Illumina) Tr. 3187–88.) Illumina's role is "mostly as a supplier". (PFF ¶ 1414; Goswami (Illumina) Tr. 3188.) Additionally, the Open Offer requires Illumina, on a customer's request, to enter into a separate agreement with the customer based on standardized terms to develop IVD test kits for use on Illumina's platforms. (PFF ¶¶ 1026–33; [redacted]; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; [redacted].) These requirements in the Open Offer

prevent Illumina from withholding support as MCED test developers seek FDA approval. (PFF ¶ 1035; RX6002 (Guerin-Calvert Trial Dep. at 74).)

[redacted] Under the Open Offer's IVD agreement provisions, customers can choose from one of three standardized template agreements. (*See* PFF ¶ 1028; Goswami (Illumina) Tr. 3208; PX0064 (Illumina) at 28–40.) Thus, the process of contracting is simplified. And, given Illumina's minimal role in the FDA approval process, the IVD agreements are sufficient to address any necessary support from Illumina in the process. (PFF ¶ 1035; RX6002 (Guerin-Calvert Trial Dep. at 74).)

5012. [redacted]

Response to Finding No. 5012:

Respondents incorporate their responses to CCFF ¶ 4302 herein.

B. SUFFICIENT AND TIMELY ENTRY OF A NEW SHORT-READ NGS PLATFORM SUITABLE FOR MCED TEST DEVELOPERS IS UNLIKELY

5013. As discussed in Section V.G. above, even if a new company develops an NGS platform, significant barriers to entry exist, no NGS platform that may enter appears to be a viable option for MCED tests, and Illumina's product pipeline will improve upon its existing market leading and best-in-class NGS option for MCED tests.

Response to Finding No. 5013:

Respondents have no specific response. To the extent Complaint Counsel relies on its proposed findings in CCFF ¶¶ 1501–1767, Respondents incorporate their responses to those proposed findings herein.

C. THE PARTIES' CLAIMED EFFICIENCIES CANNOT JUSTIFY THE LIKELY HARM TO COMPETITION IN THE MCED MARKET

5014. Dr. Rothman testified that, according to the Horizontal Merger Guidelines, "it is incumbent upon the merging parties to substantiate their claimed efficiencies such that the following could be verified: the likelihood and magnitude of each claimed efficiency; how and when each claimed efficiency would be achieved, including the costs of achieving each claimed efficiency; how each claimed efficiency would enhance the merged firm's ability and incentive to compete; and why each claimed efficiency would be merger-specific." (PX7140 (Rothman Trial Dep. at 15-16)).

Response to Finding No. 5014:

The proposed finding is irrelevant and relies on improper expert witness testimony. *First*, Dr. Rothman's opinion regarding the Horizontal Merger Guideline's standard for substantiating efficiencies "invades the province of the court" by purporting to tell the factfinder "what result to reach" and to "define legal terms" or rules, *Berry v. City of Detroit*, 25 F.3d 1342, 1353 (6th Cir. 1994), or to "apply[] those legal rules to facts". *Neal v. Second Sole of Youngstown*, 2018 WL 1740140, at *4 (N.D. Ohio Apr. 11, 2018); *In re Initial Pub. Offering Sec. Litig.*, 174 F. Supp. 2d 61, 64 (S.D.N.Y. 2001) ("[E]very circuit has explicitly held that experts may not invade the court's province by testifying on issues of law.").

Second, Dr. Rothman's application of the guidelines are irrelevant because the Horizontal Merger Guidelines "are not binding" on any court, "are not intended to describe how the Agencies will conduct the litigation of cases," and "neither dictate nor exhaust the range of evidence the Agencies may introduce in litigation." *FTC v. Thomas Jefferson Univ.*, 505 F. Supp. 3d 522, 539 n.7 (E.D. Pa. 2020).

Third, Dr. Rothman's discussion of the Horizontal Merger Guidelines are irrelevant because they do not apply to this merger. It is undisputed that this merger is a vertical, not a horizontal case. In the case of a vertical merger it is incumbent on the government to prove that the merger is anticompetitive in light of the efficiencies. Accordingly, citations to the Horizonal Merger Guidelines are irrelevant and misguided.

Respondents further note that, to the extent Respondents are required to meet the requirements of the Horizontal Merger Guidelines in this case, they have done so. (PFOF § VIII.)

5015. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 42 (*in camera*); PX0338 at 029-031, (*Horizontal Merger Guidelines* § 10, Aug. 19, 2010)).

Response to Finding No. 5015:

The proposed finding is irrelevant and relies on improper expert witness testimony for the reasons explained in Respondents' responses to CCFF ¶ 5014, which Respondents' incorporate herein.

5016. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 42 (*in camera*); PX0338 at 029-031, (*Horizontal Merger Guidelines* § 10, Aug. 19, 2010)).

Response to Finding No. 5016:

The proposed finding is irrelevant and relies on improper expert witness testimony for the reasons explained in Respondents' responses to CCFF ¶ 5014, which Respondents' incorporate herein.

5017. [redacted]

[redacted] (PX6092 (Rothman Rebuttal Report) ¶ 42 (*in camera*); PX0338 at 029-031, (*Horizontal Merger Guidelines* § 10, Aug. 19, 2010)).

Response to Finding No. 5017:

The proposed finding is irrelevant and relies on improper expert witness testimony for the reasons explained in Respondents' responses to CCFF ¶ 5014, which Respondents' incorporate herein.

5018. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 42 (*in camera*); PX0338 at 029-031, (*Horizontal Merger Guidelines* § 10, Aug. 19, 2010)).

Response to Finding No. 5018:

The proposed finding is irrelevant and relies on improper expert witness testimony for the reasons explained in Respondents' responses to CCFF ¶ 5014, which Respondents' incorporate herein.

5019. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 43 (*in camera*); PX0338 at 029-031, (*Horizontal Merger Guidelines* § 10, Aug. 19, 2010)).

Response to Finding No. 5019:

The proposed finding is irrelevant and relies on improper expert witness testimony for the reasons explained in Respondents' responses to CCFF ¶ 5014, which Respondents' incorporate herein.

5020. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 43 (*in camera*); PX0338 at 029-031 (*Horizontal Merger Guidelines* § 10, Aug. 19, 2010)).

Response to Finding No. 5020:

The proposed finding is irrelevant and relies on improper expert witness testimony for the reasons explained in Respondents' responses to CCFF ¶ 5014, which Respondents' incorporate herein. Respondents further note that the efficiencies that will result from the transaction have been substantiated by every fact witness that testified about them and that the Complaint Counsel has not offered any countervailing fact witness testimony. (PFOF § VIII.)

5021. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 43 (*in camera*); PX0338 at 029-031 (*Horizontal Merger Guidelines* § 10, Aug. 19, 2010)).

Response to Finding No. 5021:

The proposed finding is irrelevant and relies on improper expert witness testimony for the reasons explained in Respondents' responses to CCFF ¶¶ 5014 and 5020, which Respondents' incorporate herein. Respondents further note that there is past analogous experience of the claimed efficiencies. In particular, Illumina's past acquisition of Verinata lead to substantial efficiencies, including the discoveries that lead to the formation of GRAIL. (PFOF ¶ 1145, 1248, 1251, 1321, 1392, 1647, 1946.)

5022. At trial, Mr. Strom, a managing director of Morgan Stanley's healthcare investment banking group who advised Grail, testified that companies can fail to realize synergies from mergers and acquisitions. (Strom (Morgan Stanley) Tr. 3586-88).

Response to Finding No. 5022:

The proposed findings is irrelevant and incomplete and misleading. The proposed finding does not provide any information about the transaction at issue. In fact, Mr. Strom testified that [redacted]

[redacted] (Strom (Morgan Stanley) Tr. 3536–39.)

5023. At trial, Mr. Strom testified that mergers and acquisitions have execution risks. (Strom (Morgan Stanley) Tr. 3586-88).

Response to Finding No. 5023:

The proposed findings is irrelevant and incomplete and misleading. The proposed finding does not provide any information about the transaction at issue. In fact, Mr. Strom testified that [redacted] (Strom (Morgan Stanley) Tr. 3536–39.)

5024. At trial, Mr. Strom testified that corporate cultures can fail to mesh post-acquisition. (Strom (Morgan Stanley) Tr. 3587).

Response to Finding No. 5024:

The proposed findings is irrelevant and incomplete and misleading. Mr. Strom did not testify that under the facts of this case there was any risk that Illumina and GRAIL's corporate cultures would not mesh. In fact, there was significant fact witness testimony that reunion of Illumina and GRAIL would lead to significant efficiencies, including operations synergies and R&D efficiencies. (PFF ¶¶ 1136–45; 1157–67.)

5025. At trial, Mr. Strom testified that key employees can decide to leave because of a merger. (Strom (Morgan Stanley) Tr. 3587).

Response to Finding No. 5025:

The proposed findings is incomplete and misleading. Mr. Strom did not testify that the exit of key employees would have any effect on a merger's ability to lead to efficiencies.

5026. When Illumina first considered setting up Grail as a separate company, in 2015, it noted that success "will require that the company is the place with the best people in the world of cancer screening who we could not recruit to Illumina." (PX2006 (Illumina) at 001 (Email from Rick Klausner, Illumina, to Marc Stapley, Illumina, et al., Jul. 14, 2015)).

Response to Finding No. 5026:

The proposed findings is incomplete and misleading. The statements quoted in the proposed finding are explicitly the personal views of Dr. Klausner and not meant as an expression of Illumina's opinion regarding the Transaction. (PX2006 (Illumina) at 001 (Email from Rick Klausner, Illumina, to Marc Stapley, Illumina, et al., Jul. 14, 2015) ("*I think* that there are a variety of very strong reasons that this should be an independent start-up with a unique relationship to Illumina").) Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (See Resps.' Post-Trial Br. at 275–76.) Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 4) and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Further, at his investigatory hearing, Dr. Klausner testified that this document represented his views at the early stages of GRAIL and that these views no longer apply: "And so where are we now? I mean, so the difference between knowing -- asking whether or not something is possible and then demonstrating after five years that it's doable, that you can solve this problem, and you can check all those parameters that we set out at the beginning that we needed to try to do, that you're now in a world world. This is a new -- GRAIL no longer needs to be that out of the dark discovery company. GRAIL is at this inflection point where it has to become a totally different type of company. It still needs to advance its research, but that's to improve things, not to discover yes or no is something possible or impossible. When we started this, I didn't know if it was possible. And no one did. And that's what the last five years has been. Now, we're ready to scale, commercialize, et cetera, all those

other things that lots of companies know how to do well". (PX7048 (Klausner (GRAIL) IHT 81:1–17.))

5027. At trial, Mr. Strom agreed that, post-merger, Illumina could have a harder time attracting the type of talent that is drawn to a start-up like Grail. (Strom (Morgan Stanley) Tr. 3587).

Response to Finding No. 5027:

Respondents have no specific response except to note that Mr. Strom did not state that he believed it was likely that Illumina would have difficulty attracting the type of talent that is drawn to a start-up like GRAIL.

5028. When Illumina first considered setting up Grail as a separate company in 2015, Rick Klausner, Illumina's Chief Medical Officer at the time, stated that "Illumina has no IP, no special data or expertise or idea to put into this company." (PX2006 (Illumina) at 001 (Email from Rick Klausner, Illumina, to Marc Stapley, Illumina, et al., Jul. 14, 2015)).

Response to Finding No. 5028:

The proposed findings is incomplete and misleading. When the quoted sentence is read in full, it states: "This is not a spin out in that Illumina has no IP, no special data or expertise or idea to put into this company, ***yet without Illumina technology and cost considerations, this will not succeed***." (PX2006 (Illumina) at 001 (Email from Rick Klausner, Illumina, to Marc Stapley, Illumina, et al., Jul. 14, 2015)). Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Respondents further note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 4) and did not elicit any testimony regarding the specific bullet it relies upon with Dr. Klausner who was shown this document in his IH (*see* PX7048 (Klausner (GRAIL) IHT at 77–85)), and therefore the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

Respondents further note that the relevant document is from 2015 and does not relate to the conditions of Illumina or GRAIL at the time of the Transaction. In fact, Dr. Klausner testified that GRAIL is no longer in the position that it was at the time of this email. (PX7048 (Klausner (GRAIL) IHT 81:1–17.))

1. Acceleration of Galleri

a) FDA Acceleration

(1) Background on FDA Approval

5029. The FDA classifies MCED tests as Class III medical devices. (*See, e.g.*, PX7099 (Febbo (Illumina) Dep. at 83-84)).

Response to Finding No. 5029:

Respondents have no specific response.

5030. Medical devices categorized as Class III devices are considered to be the highest-risk category of medical devices. (PX7056 (Silvis (Tempus) IHT at 37)).

Response to Finding No. 5030:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5031. The FDA typically requires a developer of a Class III medical device to submit an application for PMA approval in order to determine the safety and efficacy. (PX7056 (Silvis (Tempus) IHT at 37)).

Response to Finding No. 5031:

The proposed finding is inaccurate, incomplete and misleading to the extent it implies that a test developer that wants to commercialize a Class III medical device is required by the FDA to submit a PMA application prior to commercialization of its test. While a PMA is required for FDA approval, test developers can choose to commercialize tests by other means, including as an LDT. (PFF ¶ 187.) The PMA for a class III device must contain sufficient valid

scientific evidence to assure that the device is safe and effective for its intended use(s). (PFF ¶ 188.) Such premarket approval (PMA) is the "most stringent type of device application required by FDA." (RX3585 (FDA Approval) at 10.) It often requires significant preparation and voluminous amounts of data, including in-depth review of the technical features of a device and extensive data from clinical trials to demonstrate the efficacy and safety of the device. (PFF ¶ 191.) PMA submissions not only take significant time, investment and resources to prepare, but they also take time for the FDA to review. (PFF ¶ 192.) PMA submission requires a rigorous evidence review. (PFF ¶ 192.)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

5032. A PMA requires submitting a lengthy application involving clinical and analytical validation data collected during clinical trials using the device. (PX4082 (Grail) at 135 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 5032:

Respondents have no specific response except to note that Illumina's regulatory team has extensive experience obtaining FDA clearances and approvals for diagnostic tests. Illumina has successfully obtained 510(k) clearance for a cystic fibrosis test and a PMA in cancer treatment selection for an extended RAS panel called Praxis. (Febbo (Illumina) Tr. 4338–43; 4113.)

[redacted]

(Febbo (Illumina) Tr. 4381–92.) Illumina also has experience bringing its next-generation sequencing products through FDA clearance. (Febbo (Illumina) Tr. 4338–39.) Illumina frequently interacts with the FDA, including through an educational program to teach the FDA about next-generation sequencing. (Febbo (Illumina) Tr. 4341.) Dr. Febbo testified that "both through my personal interactions and discussions with the FDA and FDA leaders, I have

compliments that we have helped them understand next-generation sequencing, and I've seen -- you know, I have seen evolution and improvements in their approach to next-generation sequencing." (Febbo (Illumina) Tr. 4342–43.) Illumina is therefore well-placed to help GRAIL traverse this admittedly challenging landscape.

Further, GRAIL's multi-cancer detection tests are a new approach to cancer screening, which present a number of novel and complex issues for FDA review. Because FDA has never cleared or approved a multi-cancer detection test, it is difficult to predict what information GRAIL will need to submit to obtain pre-market approval (PMA) from FDA for a proposed intended use, or if GRAIL will be able to obtain such approval on a timely basis or at all. (PFF ¶ 69.5.)

(2) The Claimed FDA Acceleration Efficiency Is Not Verifiable Because It Is Unlikely That Illumina Can Accelerate FDA Approval Compared to Grail on Its Own

5033. Dr. Rothman concluded that Respondents' experts' claimed acceleration efficiency is not a cognizable efficiency. (PX7140 (Rothman Trial Dep. at 17).

Response to Finding No. 5033:

The proposed finding is irrelevant, inaccurate and relies on improper expert witness testimony for the reasons explained in Respondents' responses to CCFF ¶ 5014, which Respondents' incorporate herein. By his own admission, Dr. Rothman lacks the expertise to opine on efficiencies related to the acceleration of Galleri's FDA approval and payor reimbursement and any of his opinions on these topics should also be given no weight. (PFF ¶¶ 2194–94.7.) This is not the first time Dr. Rothman has offered opinions for which he lacks the requisite expertise, which has led other courts, including this Court, to find his economic analysis to be flawed. *See, e.g.*, *In re Altria Grp., Inc.* No. 9393 at 91 (F.T.C. Feb. 15, 2022) ("Dr. Rothman's post-Transaction HHI calculations are not economically sound"); *Aya Healthcare*

Servs., Inc. v. AMN Healthcare, Inc., 2020 WL 3414662, at *4 (S.D. Cal. June 22, 2020) ("Dr. Rothman's study allegedly showing supracompetitive prices is seriously flawed," based on a "bare assertion," and devoid of any "economic analysis"); *Aya Healthcare Sers., Inc. v. AMN Healthcare, Inc.*, 2020 WL 2553181, at *18 (S.D. Cal. May 20, 2020) (his analysis is "unreliable under the *Daubert* standard and of marginal relevance"), *aff'd* 9 F.4th 1102 (9th Cir. 2021); *Evonik*, 436 F. Supp. 3d at 319 & n.33 (Dr. Rothman's product and geographic markets are "ill-conceived" and his calculation of a GUPPI is "unreliable" and inapplicable to the industry at issue).

Further, it is absolutely clear that the reunion of Illumina and GRAIL will accelerate market access to Galleri, a cognizable efficiency of the merger. Numerous fact witnesses testified to Illumina's ability to accelerate FDA approval for Galleri. (PFF ¶¶ 1127–32) [redacted] (PFF ¶ 2203; PFF ¶ 1144.5 ("Q. GRAIL and Illumina's witnesses have not yet offered their direct testimony at trial, have they? We can agree on that? A. Yes. Q. Okay. You don't know what those witnesses are going to say under direct examination, by definition, right? A. That's correct."); PX7140 (Rothman Trial Dep. at 51–52) ("by definition, at the time of your report, you had not considered any trial testimony from any witness, including respondents' witnesses in their affirmative case; correct? A. Yes. Q. And you've not submitted or requested to submit any sort of supplemental report at any time after your July 26, 2021 rebuttal report, have you? A. I have not."). That by itself renders his opinions unworthy of weight.

5034. [redacted]

(PX6092 (Rothman Rebuttal Report) ¶ 28 (*in camera*)).

Response to Finding No. 5034:

The proposed finding is irrelevant, inaccurate and relies on improper expert witness testimony for the reasons explained in Respondents' responses to CCFF ¶ 5014, which Respondents' incorporate herein. Dr. Rothman is not an expert in any aspect of market coverage, including FDA approval and payor coverage, as he admitted in his deposition. (PX7140 (Rothman Trial Dep. at 43–46.)

Further, there is extensive factual testimony supporting Respondents' experts description of the differences between Illumina and GRAIL's current capabilities relating to FDA and payor approval. All GRAIL witnesses confirmed Dr. Deverka's conclusion that GRAIL is a new company with no expertise or experience in achieving regulatory approval and payor coverage for an NGS test. (PFF ¶ 1130.) Moreover, Complaint Counsel's economic expert, Dr. Scott Morton agreed with this assessment. (PFF ¶¶ 1127.3, 1130–30.6.) In contrast, Illumina and GRAIL fact witnesses all testified that Illumina has unique experience and capabilities that will enable the acceleration of market access for Galleri. (PFF ¶¶ 1131–32.)

Respondents also note that the only "evaluation" Dr. Rothman did to assess these efficiencies was to read the documentary evidence that Respondents' experts cited and declare it inadequate. (PX6092 (Rothman Expert Report) ¶¶ 85–93.) Dr. Rothman testified that, in assessing the efficiencies, he did not conduct a study of record evidence, analyze all of the evidence considered in Respondents' expert reports or account for any of the direct testimony from fact witnesses. (PFF ¶ 2203; PFF ¶ 1144.5 ("Q. GRAIL and Illumina's witnesses have not yet offered their direct testimony at trial, have they? We can agree on that? A. Yes. Q. Okay.

You don't know what those witnesses are going to say under direct examination, by definition, right? A. That's correct."); PX7140 (Rothman Trial Dep. at 51–52) ("by definition, at the time of your report, you had not considered any trial testimony from any witness, including respondents' witnesses in their affirmative case; correct? A. Yes. Q. And you've not submitted or requested to submit any sort of supplemental report at any time after your July 26, 2021 rebuttal report, have you? A. I have not."). That by itself renders his opinions unworthy of weight.

5035. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 51 (*in camera*)).

Response to Finding No. 5035:

The proposed finding is irrelevant, inaccurate and relies on improper expert witness testimony for the reasons explained in Respondents' responses to CCFF ¶¶ 5014, 5033–34, which Respondents' incorporate herein. Respondents further note that numerous Illumina and GRAIL witnesses testified that the reunion of Illumina and GRAIL will accelerate Galleri's path to FDA approval and CMS and private payor coverage.

5036. Dr. Aravanis testified that the "regulatory aspects" of Illumina's potential assistance to Grail are "modest," and that "it's unlikely that there's any company out there that would feel that the regulatory aspects related to site-specific PMA are that meaningful." (PX7065 (Aravanis (Illumina) IHT at 229-31)).

Response to Finding No. 5036:

The proposed finding is also incomplete and misleading without further context. During the IH cited in the proposed finding Dr. Aravanis also testified that while his "expertise in this aspect of the regulatory process is limited" he believed "Illumina would apply its significant regulatory expertise to helping GRAIL be successful" and but for the Transaction "it will take years [for GRAIL] to be at the scale that Illumina has [regulatory] capabilities". (PX7065

(Aravanis (Illumina) IHT at 227–28.) Dr. Aravanis clarified that his statement related to the fact that without a merger other companies would not consider using Illumina's considerable expertise. (*See* PX7065 (Aravanis (Illumina) IHT at 232) ("even though I think it's appreciated that Illumina has considerable expertise here that it applies to its own products, it's never been an issue where customers have requested that").)

Respondents further note that numerous Illumina and GRAIL witnesses testified that Illumina's capabilities would accelerate Galleri's regulatory approvals. (PFF ¶ 1131–33.) The proposed finding also relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5037. Dr. Aravanis testified that "in terms of achieving a site-specific PMA which probably represents for cancer screening . . . all that will be achieved in the next five, maybe ten years, the regulatory aspect in the United States is probably pretty minimal and may or may not be a significant determinant of company success." (PX7065 (Aravanis (Illumina) IHT at 228)).

Response to Finding No. 5037:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5036, which Respondents incorporate herein. Respondents also note that Dr. Aravanis testified that his "expertise in this aspect of the regulatory process is limited" but that single-site PMA approval "can help with the brand of the product that it has received approval" and "might help in getting reimbursement or coverage, you know, or coverage decisions by payers or by public payers". (*See* PX7065 (Aravanis (Illumina) IHT at 171, 174.) Respondents also note that numerous fact witnesses, including third party witnesses testified that obtaining PMA approval for a cancer screening test is critical to the long-term commercial success of that test. (PFF ¶ 1129.)

5038. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 52 (*in camera*)).

Response to Finding No. 5038:

The proposed finding is irrelevant, inaccurate and relies on improper expert witness testimony for the reasons explained in Respondents' responses to CCFF ¶¶ 5014, 5033–34, which Respondents' incorporate herein.

5039. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 28 (*in camera*); PX7140 (Rothman Trial Dep. at 20) (*in camera*)).

Response to Finding No. 5039:

The proposed finding is irrelevant, inaccurate and relies on improper expert witness testimony for the reasons explained in Respondents' responses to CCFF ¶¶ 5014, 5033–34, which Respondents' incorporate herein.

(a) [redacted]

5040. In a September 2020 Illumina FAQ document relating to Illumina's acquisition of Grail, an "Employee FAQ" section stated: "We do not expect material synergies to the transaction." (PX2575 (Illumina) at 013 (E-mail from T. Friedman, Illumina, to J. Cunningham, Illumina, Sept. 29, 2020)).

Response to Finding No. 5040:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 215 which are incorporated herein. Respondents further note that the question being responded to related to specific cost savings that would result from the reunion of the two companies, not efficiencies generally. The next bullet in the same response states: "[i]t is worth noting that we believe Illumina will help GRAIL accelerate global commercialization timelines, increase accessibility and drive down test costs over time. We do

expect there will be opportunities for us to leverage GRAIL's machine learning and clinical trial expertise into other areas of the business." (PX2575 (Illumina) at 013 (E-mail from T. Friedman, Illumina, to J. Cunningham, Illumina, Sept. 29, 2020).) Question 33 in the same document makes clear that Illumina did expect synergies to arise from the transaction and that it was continuing to evaluate additional synergies: "Q33. Are there synergies we should be thinking about? We believe Illumina will help GRAIL accelerate global commercialization timelines and drive down test costs over time (allowing more patients access to early screening). Similarly, there will be opportunities for us to leverage GRAIL's machine learning and clinical trial expertise into other areas of the business. The expect modest COGS and Opex synergies and we will continue to evaluate synergy opportunities between sign and close". (PX2575 (Illumina) at 012 (E-mail from T. Friedman, Illumina, to J. Cunningham, Illumina, Sept. 29, 2020).)

Further, Respondents note that Complaint Counsel did not elicit any testimony regarding the specific language it relies upon in the source cited when it showed PX2575 to Mr. deSouza at trial (deSouza (Illumina) Tr. 2217–23) and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

5041. [redacted] (PX5042 (Illumina) [redacted] (*in camera*); Freidin (Grail) Tr. 3138; *see also* PX6092 (Rothman Rebuttal Report) ¶ 46 (*in camera*)).

Response to Finding No. 5041:

Respondents have no specific response.

5042. [redacted] (PX2163 (Illumina) at 025 [redacted] (*in camera*); *see* PX6092 (Rothman Rebuttal Report) ¶ 46 (*in camera*)).

Response to Finding No. 5042:

Respondents have no specific response.

5043. Illumina's claimed FDA acceleration efficiency is not reflected in the base case of Illumina's financial model for its acquisition of Grail. (Febbo (Illumina) Tr. 4361).

Response to Finding No. 5043:

The proposed finding is incomplete and misleading. Dr. Febbo explained this non-inclusion as follows: "[w]ell, as we looked at GRAIL and developed a model to get to an acquisition price of GRAIL, we looked at GRAIL as a stand-alone opportunity, the value of GRAIL as a company in and of itself. So we did not take into account all the value that we could bring to GRAIL because that's not the acquisition price. The acquisition price is given GRAIL, given its operations, given its teams' experience that they had already developed, of what was our best assessment of the current value, and so that model did not include the efficiencies we've discussed." (Febbo (Illumina) Tr. 4361.) He also testified that Illumina considered the effects of a one year acceleration of regulatory approval for Galleri in evaluating the transaction: "[w]ell, during the transaction, what we did do is we looked at, you know, any -- a lot of the variables that were important to the model in the valuation of GRAIL, and we did what I would call sensitivity training where we looked at what would happen if, you know, things were accelerated by a year. What would it impact? So we did model acceleration, for example, of regulatory approval by a year and saw the impact that could have on testing and on the value of GRAIL." (Febbo (Illumina) Tr. 4361–62.)

Further, Dr. Febbo confirmed his confidence in Illumina's ability to accelerate access to Galleri by at least one year. (Febbo (Illumina) Tr. 4362.) The acceleration efficiency's non-inclusion in Illumina's financial model in no way diminishes it, or proves that Illumina did not consider it.

5044. [redacted] (Qadan (Illumina) Tr. 4228 (*in camera*)).

Response to Finding No. 5044:

Respondents have no specific response.

5045. [redacted] (Qadan (Illumina) Tr. 4228 (*in camera*)).

Response to Finding No. 5045:

Respondents have no specific response.

5046. [redacted] (Qadan (Illumina) Tr. 4228 (*in camera*)).

Response to Finding No. 5046:

Respondents have no specific response.

5047. [redacted] (Qadan (Illumina) Tr. 4229 (*in camera*)).

Response to Finding No. 5047:

The proposed finding is incomplete. Mr. Qadan testified [redacted] (Qadan (Illumina) Tr. 4229.)

5048. [redacted] (Qadan (Illumina) Tr. 4229 (*in camera*)).

Response to Finding No. 5048:

Respondents have no specific response.

5049. [redacted] (PX5042 (Illumina) [redacted] (*in camera*); *see* PX6092 (Rothman Rebuttal Report) ¶ 47 (*in camera*)).

Response to Finding No. 5049:

Respondents have no specific response except to provide further context regarding the standalone model. [redacted]

[redacted] Dr. Febbo testified that the deal model was created to determine the acquisition price for GRAIL, and did not reflect the value that Illumina believed it could bring to GRAIL. (Febbo (Illumina) Tr. 4361.) Respondents also incorporate PFF ¶ 1379 herein.

5050. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 47 (*in camera*); *see* PX5042 (Illumina) [redacted] (*in camera*)).

Response to Finding No. 5050:

Respondents have no specific response except refer to Respondents' responses to CCFF ¶ 5049, which Respondents incorporate herein.

5051. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 47 nn. 79-80 (*in camera*); PX5042 (Illumina) [redacted] (*in camera*)).

Response to Finding No. 5051:

Respondents have no specific response except refer to Respondents' responses to CCFF ¶ 5049, which Respondents incorporate herein.

5052. [redacted] (Qadan (Illumina) Tr. 4229-30 (*in camera*)).

Response to Finding No. 5052:

Respondents have no specific response.

5053. [redacted] (Qadan (Illumina) Tr. 4230-31 (*in camera*)).

Response to Finding No. 5053:

The proposed response is incomplete and misleading. Mr. Qadan explained [redacted] (Qadan (Illumina) Tr. 4230.) [redacted] (Qadan (Illumina) Tr. 4230.)

5054. [redacted] (Qadan (Illumina) Tr. 4231 (*in camera*)).

Response to Finding No. 5054:

Respondents have no specific response.

5055. [redacted] (Febbo (Illumina) Tr. 4431 (*in camera*)).

Response to Finding No. 5055:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5033–34, which Respondents incorporate herein.

5056. [redacted] (PX6092 (Rothman Rebuttal Report) ¶¶ 46-49 (*in camera*); PX7140 (Rothman Trial Dep. at 25) (*in camera*)).

Response to Finding No. 5056:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5033–34, which Respondents incorporate herein.

5057. [redacted]

[redacted] (PX6092 (Rothman Rebuttal Report) ¶ 49 (*in camera*); PX7140 (Rothman Trial Dep. at 27) (*in camera*)).

Response to Finding No. 5057:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5033–34, 5043, which Respondents incorporate herein.

5058. [redacted] (PX7140 (Rothman Trial Dep. at 26) (*in camera*); *see also* PX6092 (Rothman Rebuttal Report) ¶ 49 (*in camera*)).

Response to Finding No. 5058:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5043, which Respondents incorporate herein. Further, the cited testimony of Dr. Rothman is improper expert testimony because, by his own admission, Dr. Rothman is not an expert in market access and his testimony should be given no weight. (PFF ¶ 1134.4.)

5059. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 47 (*in camera*); PX5042 (Illumina) [redacted] (*in camera*)).

Response to Finding No. 5059:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5043, which Respondents incorporate herein. Further, the cited testimony of Dr. Rothman is improper expert testimony because, by his own admission, Dr. Rothman is not an expert in market access and his testimony should be given no weight. (PFF ¶ 1134.4.)

5060. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 49 (*in camera*)).

Response to Finding No. 5060:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5043, which Respondents incorporate herein. Respondents note that Dr. Febbo testified that acceleration was not included in the model because the purpose of the model was to estimate the value of GRAIL as a standalone company. However, he also testified that Illumina considered the effects of a one year acceleration of regulatory approval for Galleri in evaluating the Transaction: "[w]ell, during the transaction, what we did do is we looked at, you know, any -- a lot of the variables that were important to the model in the valuation of GRAIL, and we did what I would call sensitivity training where we looked at what would happen if, you know, things were accelerated by a year. What would it impact? So we did model acceleration, for example, of regulatory approval by a year and saw the impact that could have on testing and on the value of GRAIL." (Febbo (Illumina) Tr. 4361–62.)

5061. [redacted] (*See, e.g.*, PX5030 (Illumina) at 016 [redacted] (*in camera*)).

Response to Finding No. 5061:

The proposed response is inaccurate, incomplete and misleading. *First*, Complaint Counsel misreads references to acceleration of international regulatory approval and market access to exclude acceleration in the U.S. but cites to no witness testimony that supports that view. *Second*, Complaint Counsel ignores the fact that ordinary course documents mention Illumina's ability to increase access to Galleri generally. The document cited in the proposed

finding mentions that Illumina "Can accelerate pharma partnership given ILMN experience and credibility", a benefit which clearly relates to market access for GRAIL's technology in the U.S. Other documents also mention Illumina's ability to increase accessibility generally. (*See* PX2575 (GRAIL) at 13 ("It is worth noting that we believe Illumina will help GRAIL accelerate global commercialization timelines, *increase accessibility* and drive down test costs over time.") (emphasis added).) *Third*, Complaint Counsel ignores witness testimony that Illumina began thinking about how to accelerate market access for Galleri in the U.S. as early as the due diligence phase of the transaction. (Qadan (Illumina) Tr. 4160–61 ("Q. When did Illumina develop that plan? A. So two parts. The first is, when we did the due diligence for the test, we have seen the challenges around clinical and economic utility, and so we had initially to think about what needs to be done to manage that, because, if there was no plan or there was no way to manage that, why would Illumina, you know, buy GRAIL. So that's one thing. The second thing is, as we started some of our discussions with -- for -- around certain groundbreaking partnerships especially in the U.S., Galleri test was front and center initially of those discussions as a way to accelerate the availability of Galleri in the U.S. marketplace."); Febbo (Illumina) Tr. 4362 ("Well, during the transaction, what we did do is we looked at, you know, any -- a lot of the variables that were important to the model in the valuation of GRAIL, and we did what I would call sensitivity training where we looked at what would happen if, you know, things were accelerated by a year. What would it impact? So we did model acceleration for example, of regulatory approval by a year and saw the impact that could have on testing and on the value of GRAIL".) *Fourth*, acceleration of regulatory approval and market access outside the U.S. will also accelerate approval in the U.S. (*See e.g.*, Aravanis (Illumina) Tr. 1966–67 ("With offering that test in many countries in the world, that will generate a significant amount of testing data.

We know that that testing data will be useful in payer discussions around the questions they'll have around clinical utility. We also know that that data will be useful in creating future versions of the Galleri test. We also know that that data will be useful in discussions with the FDA around FDA approval."). Finally, Complaint Counsel provides no reason to ignore the significant evidence presented at trial that the Transaction will result in U.S. regulatory and reimbursement acceleration. (*See* PFF ¶ 1133.)

5062. [redacted] (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 19 (RFA No. 24) (*in camera*)).

Response to Finding No. 5062:

The proposed finding is misleading. Respondents have put forward evidence that the Transaction is estimated to accelerate regulatory approvals and reimbursement and therefore accelerate the adoption of Galleri by at least one year. (PFF ¶¶ 1122–22.2.)

5063. [redacted] (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 22 (RFA No. 29) (*in camera*)).

Response to Finding No. 5063:

The proposed finding is misleading. Respondents have put forward evidence that the Transaction is estimated to accelerate regulatory approvals and reimbursement and therefore accelerate the adoption of Galleri by at least one year. (PFF ¶¶ 1122–22.2.)

5064. Illumina has not provided Grail with an estimate of how much earlier Illumina expects Galleri to receive FDA approval as a result of the transaction. (Freidin (Grail) Tr. 3145).

Response to Finding No. 5064:

The proposed finding is incomplete and misleading. The fact that Illumina did not provide GRAIL with a specific estimate does not mean that GRAIL did not believe Illumina would accelerate FDA approval. On the same page of the transcript Mr. Freidin testified that GRAIL determined that if Illumina accelerated Galleri "based off of their experience, that it would create more value sooner". (Freidin (GRAIL) Tr. 3145.) It is clear from Mr. Freidin's testimony that at the time of the Transaction GRAIL took into consideration the fact that Illumina would accelerate Galleri:

- Explaining that publicly available data on Illumina's regulatory experience "substantiated, you know, what Francis shared with us in that board meeting and shows that, you know, that Illumina has successfully had tests approved through the FDA. And when I compare that to think about what we have as our FDA resources we don't have anything approved through the FDA." (Freidin (GRAIL) Tr. 2985.)

- "Q. So then how did the prospect of accelerating FDA approval affect your consideration of whether to recommend acceptance of Illumina's offer for GRAIL? A. It -- it made that we should recommend -- that I would recommend that we should be acquired." (Freidin (GRAIL) Tr. 2986.)

- When asked why GRAIL didn't formally model the acceleration benefits, Mr. Freidin testified that "they were just obvious to us . . .they have got FDA successes, again things that GRAIL does not have. So it was just obvious". (Freidin (GRAIL) Tr. 3167.)

5065. Mr. Aaron Freidin leads Grail's financial projections and analysis team ("FP&A"). (Freidin (Grail) Tr. 3144).

Response to Finding No. 5065:

Respondents have no specific response.

5066. Mr. Freidin testified at trial that Grail did not prepare its own deal model. (Freidin (Grail) Tr. 3140).

Response to Finding No. 5066:

The proposed response is incomplete and misleading. Mr. Freidin testified that GRAIL did not formally model the acceleration benefits of the Transaction because "[he] didn't feel it was necessary to model out beyond just knowing that if [the acquisition] moves, we ramp faster, that there's lots of value there. There's lots of efficiency." (Freidin (GRAIL) Tr. 3141–42.) "As I was saying, they were just obvious to us. You know, a royalty goes away, access increases, price can come down. You know Illumina is a multinational billion dollar, multiproduct company. They have got international operations. They have got commercial experience. Also, they have got FDA successes, again, things that GRAIL does not have. So it was just obvious." (Freidin (GRAIL) Tr. 3167–68.) When asked whether he has identified any dissynergies from the Transaction, Mr. Freidin testified "No. I can't think of any or couldn't think of any". (Freidin (GRAIL) Tr. 3168.) Respondents also note that GRAIL did have a long-range planning model. (PFF ¶ 1169.)

5067. At trial, Mr. Freidin testified that Grail "hadn't done any modeling as if Grail was acquired by Illumina." (Freidin (Grail) Tr. 3141).

Response to Finding No. 5067:

The proposed response is incomplete and misleading. Mr. Freidin testified that GRAIL did not formally model the acceleration benefits of the Transaction because "[he] didn't feel it was necessary to model out beyond just knowing that if [the acquisition] moves, we ramp faster, that there's lots of value there. There's lots of efficiency." (Freidin (GRAIL) Tr. 3141–42.) "As I was saying, they were just obvious to us. You know, a royalty goes away, access increases, price can come down. You know Illumina is a multinational billion dollar, multiproduct company. They have got international operations. They have got commercial experience. Also, they have got FDA successes, again, things that GRAIL does not have. So it was just obvious."

(Freidin (GRAIL) Tr. 3167–68.) When asked whether he has identified any dissynergies from the Transaction, Mr. Freidin testified "No. I can't think of any or couldn't think of any". (Freidin (GRAIL) Tr. 3168.)

5068. Grail has not performed any analysis of any potential synergies from the Illumina transaction. (Freidin (Grail) Tr. 3151-52).

Response to Finding No. 5068:

The proposed response is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5067, which Respondents incorporate herein.

5069. When Grail agreed to combine with Illumina in September 2020, Grail had not quantified the efficiencies that could result from the combination. (Freidin (Grail) Tr. 3141).

Response to Finding No. 5069:

The proposed response is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5067, which Respondents incorporate herein.

5070. Grail's FP&A team, which Mr. Freidin leads, did not conduct an analysis of the extent of any acceleration to FDA approval that might occur if Grail were acquired by Illumina. (Freidin (Grail) Tr. 3145).

Response to Finding No. 5070:

The proposed response is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5067, which Respondents incorporate herein.

5071. Grail's Medical Affairs and Regulatory teams did not conduct an analysis of the extent of any acceleration to FDA approval that might occur if Grail were acquired by Illumina. (Freidin (Grail) Tr. 3145).

Response to Finding No. 5071:

The proposed response is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5067, which Respondents incorporate herein.

5072. [redacted] (Ofman (Grail) Tr. 3379 (*in camera*)).

Response to Finding No. 5072:

The proposed response is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5067, which Respondents incorporate herein. Respondents also note that Dr. Ofman testified [redacted] (Ofman (GRAIL) Tr. 3352.) Respondents also note that they have presented unrebutted evidence that the Transaction is estimated to accelerate the adoption of Galleri by at least one year. (PFF ¶¶ 1122–22.2.)

5073. [redacted] (Ofman (Grail) Tr. 3379-80 (*in camera*)).

Response to Finding No. 5073:

The proposed response is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5067 and 5072, which Respondents incorporate herein. Respondents further note that Dr. Ofman testified [redacted] While Respondents have not completed integration planning, that is only because they are not legally

permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5074. Grail's former CEO, Hans Bishop, could not quantify at trial how much sooner he expected Grail to receive PMA approval with assistance from Illumina versus without. (Bishop (Grail) Tr. 1426); PX7083 (Bishop (Grail) Dep. at 83-85)).

Response to Finding No. 5074:

The proposed response is incomplete and misleading. In response to the question during trial, Mr. Bishop testified "All I can share with you is my earnest judgment that it will help, and there is a good probability that it will speed things up, but to your question, can I give you a precise quantification, I think that would be overly accurate. Yes, that's right". (Bishop (GRAIL) Tr. 1426.) During his deposition, Mr. Bishop stated: "As a board member I think in good standing with my colleagues, a deep conviction that all those things we talked about, resources, existence, systems, stability of business will create the opportunity around the world, not just in the U.S., to accelerate true approval and de-risk the probability of not getting one, or not getting them. . . As I mentioned, Steve, I don't know if a date has been communicated. What I do know from discussions with my colleagues on the board is what I said earlier. There are substantial synergy opportunities to make this go faster and the reasons and areas we talked about and substantial de-risking opportunities associated with the merger." (PX7083 (Bishop (GRAIL) Dep. at 86–87.) Respondents also note that they have presented unrebutted evidence that the Transaction is estimated to accelerate the adoption of Galleri by at least one year. (PFF ¶¶ 1122–22.2.)

5075. Respondents' expert, Dr. Carlton, testified that he is "not the source" for the opinion that Illumina can accelerate the process for Galleri to achieve FDA approval. (RX6000 (Carlton Trial Dep. at 96-97); PX7134 (Carlton Dep. at 191)).

Response to Finding No. 5075:

The proposed finding is incomplete and misleading. Dr. Carlton testified that while he relied on other witnesses and documents, he came to his own independent conclusion based on the evidence that the reunion of Illumina and GRAIL will generate substantial efficiencies and that he is the source for the opinions expressed in his report and in his direct examination. (RX6000 (Carlton Tr. 196–97.) Respondents also note that they have presented unrebutted evidence that the Transaction is estimated to accelerate the adoption of Galleri by at least one year. (PFF ¶¶ 1122–22.2.)

5076. Dr. Carlton did not offer any testimony as an expert on the FDA's regulatory process. (RX6000 (Carlton Trial Dep. at 97); PX7134 (Carlton Dep. at 14)).

Response to Finding No. 5076:

Respondents have no specific response.

5077. Dr. Carlton relied on Illumina's estimates for FDA acceleration of Galleri. (PX7134 (Carlton Dep. at 191)).

Response to Finding No. 5077:

The proposed response is incomplete and misleading. Dr. Carlton testified that while he relied on other witnesses and documents, he came to his own independent conclusion based on the evidence that the reunion of Illumina and GRAIL will generate substantial efficiencies and that he is the source for the opinions expressed in his report and in his direct examination. (RX6000 (Carlton Tr. 196–97.) He also testified that the estimates put forward by Illumina sounded plausible from an economic point of view. (RX6000 (Carlton Tr. 97; RX3864 (Carlton Dep. at 191).) Respondents also note that they have presented evidence that the Transaction is estimated to accelerate the adoption of Galleri by at least one year. (PFF ¶¶ 1122–22.2.)

5078. Dr. Carlton did not perform a detailed analysis of what specific capabilities Illumina thinks it can contribute to accelerate FDA approval for Galleri. (RX6000 (Carlton Trial Dep. at 97)).

Response to Finding No. 5078:

The proposed response is incomplete and misleading. Dr. Carlton testified that while he relied on other witnesses and documents, he came to his own independent conclusion based on the evidence that the reunion of Illumina and GRAIL will generate substantial efficiencies and that he is the source for the opinions expressed in his report and in his direct examination. (RX6000 (Carlton Tr. 196–97.) He also testified that the estimates put forward by Illumina sounded plausible from an economic point of view. (RX6000 (Carlton Tr. 97; RX3856 (Carlton Dep. at 191).) Respondents also note that they have presented unrebutted evidence that the Transaction is estimated to accelerate the adoption of Galleri by at least one year. (PFF ¶¶ 1122–22.2.)

5079. [redacted] (PX7134 (Carlton Dep. at 197-198) (*in camera*)).

Response to Finding No. 5079:

The proposed response is incomplete and misleading. Dr. Carlton testified that he used the deal model only as a source for the number of tests Galleri would sell in a given year, not as a source for FDA acceleration projections. (RX3856 (Carlton Dep. 198–99).) [redacted] (RX6000 (Carlton Tr. 103.) The use of the deal model is conservative as it does not assume any increase in the number of tests that will be sold in a given year. (RX3856 (Carlton Dep. 198–99).) Respondents also note that they have presented unrebutted evidence that the Transaction is estimated to accelerate the adoption of Galleri by at least one year. (PFF ¶¶ 1122–22.2.)

5080. [redacted] PX7134 (Carlton Dep. at 198) (*in camera*)).

Response to Finding No. 5080:

Respondents have no specific response except to note that acceleration of one year is based on unrefuted evidence that the Transaction is estimated to accelerate the adoption of Galleri by at least one year. (PFF ¶¶ 1122–22.2.)

(b) Illumina and Grail Have Not Identified Specific Steps Toward FDA Approval That Illumina Might Accelerate

5081. [redacted] (PX6056 (Illumina) at 094 (Illumina, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 5081:

Respondents have no specific response.

5082. [redacted] (PX6056 (Illumina) at 094 (Illumina, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 5082:

Respondents have no specific response except to note that several documents relating to integration had been created by this point, including a GRAIL slide deck (RX0688) and an Illumina slide deck (PX4096).

5083. [redacted] (Febbo (Illumina) Tr. 4430 (*in camera*)).

Response to Finding No. 5083:

Respondents have no specific response except to note that Dr. Febbo stated that [redacted]

[redacted] (Febbo (Illumina) Tr. 4429–30.)

5084. [redacted] (Febbo (Illumina) Tr. 4429-30 (*in camera*)).

Response to Finding No. 5084:

Respondents have no specific response.

5085. [redacted] (Febbo (Illumina) Tr. 4429-30 (*in camera*); (Qadan (Illumina) Tr. 4239 (*in camera*)).

Response to Finding No. 5085:

Respondents have no specific response.

5086. [redacted] (Febbo (Illumina) Tr. 4429-30 (*in camera*)).

Response to Finding No. 5086:

Respondents have no specific response.

5087. [redacted] (Qadan (Illumina) Tr. 4239 (*in camera*)).

Response to Finding No. 5087:

Respondents have no specific response.

5088. [redacted] (Febbo (Illumina) Tr. 4430 (*in camera*)).

Response to Finding No. 5088:

The proposed finding is incomplete and misleading because it fails to explain that Illumina and GRAIL could not engage in further discussions due to the pending investigation by the FTC. While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5089. Illumina's CEO, Francis deSouza made a presentation to Grail's board on September 14, 2020. (Freidin (Grail) Tr. 3146-47).

Response to Finding No. 5089:

Respondents have no specific response.

5090. Grail did not learn from Mr. deSouza's presentation what Illumina's plans were for how to help GRAIL with FDA approvals. (Freidin (Grail) Tr. 3147).

Response to Finding No. 5090:

The proposed finding is incomplete and misleading. Mr. Freidin testified that "as part of the acquisition process and the discussions with Illumina, Francis deSouza in a board presentation talked to us about their FDA capabilities, the team, the employees that they have, some of their successes" and that the prospect of accelerating FDA approval "made that we should recommend -- that I would recommend that we should be acquired". (Freidin (GRAIL) Tr. 2982, 2986.) Illumina and GRAIL "didn't go into detailed plans. . . . [but] understood that [Illumina had] had FDA successes, and [GRAIL] had not, and at that level, it made sense that [Illumina] would make [GRAIL] more likely to be successful." (Freidin (GRAIL) Tr. 3147.) He also testified that "moving FDA approval, getting FDA approval earlier or later than what we're talking about, if you look at our LRP, it has billions of dollars of value of impact. So I didn't feel it was necessary to model out beyond just knowing that if that moves, we amp faster, that there's lots of value there. There's lots of efficiency." (Freidin (GRAIL) Tr. 3142.)

5091. [redacted] (Ofman (Grail) Tr. 3381 (*in camera*)).

Response to Finding No. 5091:

The proposed finding is incomplete and misleading. Dr. Ofman testified [redacted]

[redacted] (Ofman (GRAIL) Tr. 3380.) While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5092. [redacted] (Ofman (Grail) Tr. 3382 (*in camera*)).

Response to Finding No. 5092:

The proposed finding is incomplete and misleading. Dr. Ofman testified [redacted] (Ofman (GRAIL) Tr. 3380.) While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5093. [redacted] (Qadan (Illumina) Tr. 4240-41 (*in camera*)).

Response to Finding No. 5093:

The proposed finding is incomplete and misleading. During his deposition Dr. Qadan said [redacted] (Qadan (Illumina) Tr. 4240.) But he did note that Illumina has "been successful in the past in getting FDA approval. So I don't know how would that be different" and that acceleration of regulatory approval is a core element of Illumina's plan to accelerate Galleri. (Qadan (Illumina) Tr. 4162

and 4240.) Respondents also note that there is ample evidence from Illumina and GRAIL witnesses with knowledge of regulatory issues that GRAIL is a new company with no expertise or experience in achieving regulatory approval and payor coverage for an NGS test. In fact, Complaint Counsel's economic expert, Dr. Scott Morton agreed with this assessment. (PFF ¶¶ 1127.3, 1130–30.6.) There is also evidence that Illumina, in contrast, has unique experience and capabilities that will enable the acceleration of market access for Galleri. Its regulatory team has extensive expertise obtaining FDA clearances and approvals for diagnostic tests. (PFF ¶¶ 1127.4, 1131–32.10.)

5094. Dr. Febbo testified at trial that Illumina will not be able to "work together [with Grail] and find those specific areas where we can help them accelerate" Galleri's FDA approval until Illumina and Grail are combined. (Febbo (Illumina) Tr. 4344-45).

Response to Finding No. 5094:

Respondents have no specific response except to note that Dr. Febbo remains confident in Illumina's ability to accelerate Galleri's PMA once the companies are allowed to integrate. (Febbo (Illumina) Tr. 4345.)

(c) Illumina and Grail Have Not Engaged in Integration Planning Related to FDA Acceleration

5095. Integration planning between Illumina and Grail has not started. (Bishop (Grail) Tr. 1425; Freidin (Grail) Tr. 3153-54).

Response to Finding No. 5095:

The proposed finding is incomplete and misleading. Two slide decks were prepared relating to integration in October 2020 (RX0668 (GRAIL) and PX4096 (Illumina).) Mr. Freidin also testified that the two parties had been doing "planning-to-plan sessions" prior to March 2021. (Freidin (GRAIL) Tr. 3153.) In any event while Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well

knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5096. Grail's CEO, Hans Bishop, testified in his investigational hearing that integration planning has "yet to kick off in any meaningful way." (PX7069 (Bishop (Grail) IHT at 42)).

Response to Finding No. 5096:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5095, which Respondents incorporate herein. Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5097. At trial, Mr. Bishop testified that he could not answer how many employees Illumina plans on deploying to assist with the Illumina PMA "because to answer such a question, integration planning would have to be under way . . . and integration planning hasn't started." (Bishop (Grail) Tr. 1425).

Response to Finding No. 5097:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5095, which Respondents incorporate herein.

5098. Between March 22, 2021 and June 23, 2021, Illumina and Grail did not have any discussions regarding integration. (Freidin (Grail) Tr. 3153-54).

Response to Finding No. 5098:

The proposed finding is incomplete and misleading. Mr. Freidin testified that "we have to integrate somewhat as far as financial reporting. They -- you know, Illumina's team has to be able to do their fiduciary duties and responsibilities as they're rolling our financials up into theirs. So there's more than there was, but it's not -- it's not expansive". (Freidin (GRAIL) Tr. 3153–54.) While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182

(noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).).

5099. Besides financial reporting, no other integration has taken place since the close of the transaction. (Freidin (Grail) Tr. 3154).

Response to Finding No. 5099:

The proposed response is incomplete and misleading. Illumina and GRAIL fact witnesses testified extensively regarding the ways that Illumina could accelerate Galleri. (PFF ¶¶ 1130–33.26.) While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5100. A meeting between the Illumina and Grail R&D, regulatory, medical affairs and government affairs teams never happened. (Freidin (Grail) Tr. 3156).

Response to Finding No. 5100:

The proposed response is incomplete and misleading. Illumina and GRAIL fact witnesses testified extensively regarding the ways that Illumina could accelerate Galleri's regulatory approval in the U.S. and internationally. (PFF ¶¶ 1130–33.26.) While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5101. Grail's FDA lead, Deepshikha Bhandari, and her counterpart at Illumina never met. (Freidin (Grail) Tr. 3156-57).

Response to Finding No. 5101:

The proposed response is incomplete and misleading . Illumina and GRAIL fact witnesses testified extensively regarding the ways that Illumina could accelerate Galleri's

regulatory approval in the U.S. and internationally. (PFF ¶¶ 1130–33.26.) While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5102. Illumina's clinical affairs team is not currently collaborating with Grail's clinical affairs team. (Freidin (Grail) Tr. 3157).

Response to Finding No. 5102:

The proposed response is incomplete and misleading. Illumina and GRAIL fact witnesses testified extensively regarding the ways that Illumina could accelerate Galleri's regulatory approval and payor reimbursement in the U.S. and internationally. (PFF ¶¶ 1130–33.26.) While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5103. Illumina's regulatory affairs team is not currently collaborating with Grail's regulatory affairs team. (Freidin (Grail) Tr. 3157).

Response to Finding No. 5103:

The proposed response is incomplete and misleading. Illumina and GRAIL fact witnesses testified extensively regarding the ways that Illumina could accelerate Galleri's regulatory approval in the U.S. and internationally. (PFF ¶¶ 1130–33.26.) While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5104. A planned meeting between Illumina and Grail's commercial teams never happened. (Freidin (Grail) Tr. 3156).

Response to Finding No. 5104:

The proposed response is incomplete and misleading. Illumina and GRAIL fact witnesses testified extensively regarding the ways that Illumina could accelerate Galleri's commercialization and other efficiencies. (PFF ¶¶ 1130–33.26.) While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5105. A planned meeting between the Illumina and Grail lab operations teams never happened. (Freidin (Grail) Tr. 3156).

Response to Finding No. 5105:

The proposed response is incomplete and misleading. Illumina and GRAIL fact witnesses testified extensively regarding the ways that the Transaction would result in lab operations efficiencies. (PFF ¶¶ 1130–33.26, 1157–66) While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5106. Integration meetings to define where Illumina could accelerate Grail's objectives have not happened. (PX7108 (Freidin (Grail) Dep. at 283)).

Response to Finding No. 5106:

The proposed response is incomplete and misleading. Illumina and GRAIL fact witnesses testified extensively regarding the ways that Illumina could accelerate Galleri's commercialization. (PFF ¶¶ 1130–33.26.) While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows).

(CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5107. Mr. Bishop testified that he does not know how many Illumina employees will work on Grail's PMA submissions to the FDA. (Bishop (Grail) Tr. 1424-25).

Response to Finding No. 5107:

The proposed response is incomplete and misleading. Illumina and GRAIL fact witnesses testified extensively regarding the ways that Illumina could accelerate Galleri's regulatory approval in the U.S. and internationally. (PFF ¶¶ 1130–33.26.) While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5108. No one at Illumina has communicated to Mr. Bishop how many employees Illumina plans on deploying to assist with Galleri's PMA. (Bishop (Grail) Tr. 1425).

Response to Finding No. 5108:

The proposed response is incomplete and misleading. Illumina and GRAIL fact witnesses testified extensively regarding the ways that Illumina could accelerate Galleri's regulatory approval in the U.S. and internationally. (PFF ¶¶ 1130–33.26.) While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5109. Grail does not know whether Illumina is planning to transfer employees to Grail. (PX7066 (Freidin (Grail) IHT at 258)).

Response to Finding No. 5109:

The proposed response is incomplete and misleading. Illumina and GRAIL fact witnesses testified extensively regarding the ways that Illumina could accelerate Galleri. (PFF

¶¶ 1130–33.26.) While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).) Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5110. Any changes to Grail's post-acquisition organizational structure have not been determined yet. (PX7066 (Freidin (Grail) IHT at 257)).

Response to Finding No. 5110:

The proposed response is incomplete and misleading. While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).) Respondents also note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5111. Francis deSouza does not get involved in the details of the FDA submissions. (deSouza (Illumina) Tr. 2418).

Response to Finding No. 5111:

Respondents have no specific response other than to note that Illumina has a regulatory team dedicated to FDA submissions (Febbo (Illumina) Tr. 4343–44; Qadan (Illumina) Tr. 4113; RX6001 (Deverka Trial Dep. at 65)) and that Mr. deSouza did testify that he sometimes gets involved in the strategy of FDA approval. (deSouza (Illumina) Tr. 2418.)

5112. Francis deSouza did not look through the resumes of the Grail employees and, accordingly, is unfamiliar with their expertise. (deSouza (Illumina) Tr. 2419).

Response to Finding No. 5112:

The proposed finding is misleading and incomplete. In his deposition, Mr. deSouza made clear that while he had not looked through the resumes of GRAIL employees he knew that GRAIL does "not have the depth of experience they would need in house" to get any type of clinical test approved at the FDA. (PX7107 (deSouza (Illumina) Dep. at 40).)

5113. [redacted] (Freidin (Grail) Tr. 3110 (*in camera*)); PX7066 (Freidin (Grail) IHT at 268-269).

Response to Finding No. 5113:

The proposed finding is incomplete and misleading. Mr. Freidin testified that [redacted] (Freidin (GRAIL) Tr. 3109–10.) Respondents also note that Dr. Ofman testified in detail about [redacted] (Ofman (GRAIL) Tr. 3325–26.) He said that it was [redacted] (Ofman (GRAIL) Tr. 3326–27.) Dr. Ofman also explained how [redacted] (Ofman (GRAIL) Tr. 3332–33.) He also testified that [redacted]

[redacted] (Ofman (GRAIL) Tr. 3344.) He concluded that [redacted] (Ofman (GRAIL) Tr. 3352.) In contrast, he testified that [redacted] (Ofman (GRAIL) Tr. 3347.)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5114. [redacted] (Ofman (Grail) Tr. 3380 (*in camera*)).

Response to Finding No. 5114:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5113, which Respondents incorporate herein. Dr. Ofman testified that [redacted] (Ofman (GRAIL) Tr. 3352.) Further, Respondents also refer to their responses to CCFF ¶ 5113. While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5115. [redacted]

[redacted] (Ofman (Grail) Tr. 3380 (*in camera*)).

Response to Finding No. 5115:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5113, which Respondents incorporate herein. Dr. Ofman testified that [redacted] (Ofman (GRAIL) Tr. 3352.) Further, Respondents also refer to their responses to CCFF ¶ 5113. While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5116. According to Phil Febbo, Illumina's Chief Medical Officer, Illumina will not be able to "work together [with Grail] and find those specific areas where [Illumina] can help [Grail] accelerate" until Illumina and Grail are combined. (Febbo (Illumina) Tr. 4344-45).

Response to Finding No. 5116:

The proposed finding is incomplete and misleading. While Dr. Febbo testified that Illumina and GRAIL could not "get into the details, the depth of details" regarding the specifics of acceleration, he was confident in Illumina's ability to accelerate GRAIL's PMA. (Febbo (Illumina) Tr. 4345.) He said he had seen Illumina's regulatory team address "regulatory challenges" with its "incredible depth of expertise". (Febbo (Illumina) Tr. 4345–46.) He described Illumina developing its quality management system over a seven year period ("longer than GRAIL's been a company"), which would benefit GRAIL's FDA approval efforts once the two companies reunify. (Febbo (Illumina) Tr. 4347–49.) While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as

the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5117. [redacted] (Ofman (Grail) Tr. 3380-81 (*in camera*)).

Response to Finding No. 5117:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5113, which Respondents incorporate herein. Respondents also note that Dr. Ofman testified that [redacted] (Ofman (GRAIL) Tr. 3352.) While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5118. [redacted] (Ofman (Grail) Tr. 3381-82 (*in camera*)).

Response to Finding No. 5118:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5113, which Respondents incorporate herein. Respondents also note that Dr. Ofman testified that [redacted] (Ofman (GRAIL) Tr. 3352.) While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5119. Mr. Freidin is Grail's point person for integration with Illumina. (Freidin (Grail) Tr. 3138).

Response to Finding No. 5119:

Respondents have no specific response.

5120. Mr. Freidin asked to see Illumina's deal model. (Freidin (Grail) Tr. 3138-39).

Response to Finding No. 5120:

Respondents have no specific response.

5121. Illumina did not make its deal model available to Mr. Freidin. (Freidin (Grail) Tr. 3139).

Response to Finding No. 5121:

Respondents have no specific response except to note that Mr. Freidin also testified that it was "not uncommon for . . . the buyer to not provide their model to the seller." (Freidin (GRAIL) Tr. 3139.)

5122. Illumina did not ask Mr. Freidin to review its deal model to stress test it. (Freidin (Grail) Tr. 3139).

Response to Finding No. 5122:

Respondents have no specific response except to note that Mr. Freidin also testified that it was "not uncommon for . . . the buyer to not provide their model to the seller." (Freidin (GRAIL) Tr. 3139.)

5123. At trial, Mr. Freidin testified that he has not seen Illumina's financial model for the Illumina-Grail deal. (Freidin (Grail) Tr. 3139).

Response to Finding No. 5123:

Respondents have no specific response except to note that Mr. Freidin also testified that it was "not uncommon for . . . the buyer to not provide their model to the seller." (Freidin (GRAIL) Tr. 3139.)

5124. [redacted] (PX4096 (Grail) at 009 (Email from A. Freidin,

Grail, to H. Bishop, Grail, M.L. Song, Grail, M. Young, Grail, Oct. 24, 2020, attaching "Grail Integration Planning and Pre-Closing Activities," Oct. 23, 2020) (*in camera*); PX7066 (Freidin (Grail) IHT at 277-278)).

Response to Finding No. 5124:

The proposed finding is incomplete and misleading. As is clear from Mr. Freidin's IH testimony and PX4096, the titles in the slide deck are preliminary and not necessarily determinative of Mr. Freidin's role. Mr. Freidin made clear in his IHT that this slide deck and structure is "very preliminary", and "no longer applicable". (PX7066 (Freidin (GRAIL) IHT at 278).) He said that "the only certainties [were] that [he] talk to Christen [Cotter] and Paul [Scagnetti]", and that the "governance structure of all of it is to be determined". (PX7066 (Freidin (GRAIL) IHT at 278).) [redacted]

(PX4096 (GRAIL) at 001, 008–10 (Email from A. Freidin, GRAIL, to H. Bishop, GRAIL, M.L. Song, GRAIL, M. Young, GRAIL, Oct. 24, 2020, attaching "Grail Integration Planning and Pre-Closing Activities," Oct. 23, 2020) (*in camera*).)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5125. [redacted] (PX7066 (Freidin (Grail) IHT at 280); PX4096 (Grail) at 014 (Email from A. Freidin, Grail, to H. Bishop, Grail, M.L. Song, Grail, M. Young, Grail, Oct. 24, 2020, attaching "Grail Integration Planning and Pre-Closing Activities," Oct. 23, 2020) (*in camera*)).

Response to Finding No. 5125:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5113 and 5116, which Respondents incorporate herein. Mr. Freidin made clear in his IHT that the slide deck, PX4096, is "very preliminary", and "no longer applicable". (PX7066 (Freidin (GRAIL) IHT at 278).) Its contents are not necessarily determinative of work that followed its creation. [redacted] (PX4096 (GRAIL) at 001, 008–10 (Email from A. Freidin, GRAIL, to H. Bishop, GRAIL, M.L. Song, GRAIL, M. Young, GRAIL, Oct. 24, 2020, attaching "Grail Integration Planning and Pre-Closing Activities," Oct. 23, 2020) (in camera).) Mr. Freidin testified that he believed the Transaction would accelerate Galleri's regulatory approval. (Freidin (GRAIL) Tr. 2979–82.) And numerous fact witnesses have testified to the same. (PFF ¶¶ 1130–33.26.) While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5126. [redacted] (PX4222 (Grail) at 001, 009 (Grail, Email from C. Cotter, Grail, to A. Freidin, Grail, Paul Scagnetti, Illumina, Mar. 15, 2021, attaching "Preparing for Day 1," Mar 15, 2021) (*in camera*)).

Response to Finding No. 5126:

The proposed finding is incomplete and misleading. [redacted] (PX4222 (Grail) at 001, 009 (Grail, Email from C. Cotter, Grail, to A. Freidin, Grail, Paul Scagnetti, Illumina, Mar. 15, 2021, attaching "Preparing for Day 1," Mar 15, 2021) (in camera).) While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

(d) Illumina and Grail Do Not Address the Costs Associated with Attempting to Accelerate FDA Approval

5127. Under the Horizontal Merger Guidelines, "[c]ognizable efficiencies are assessed net of costs produced by the merger or incurred in achieving those efficiencies." (Horizontal Merger Guidelines § 10; *see also* PX6092 (Rothman Rebuttal Report) ¶ 39).

Response to Finding No. 5127:

Respondents object to the proposed finding on the ground that it is not a finding of fact. Respondents also object because the Horizontal Merger Guidelines "are not binding" on any court, "are not intended to describe how the Agencies will conduct the litigation of cases," and "neither dictate nor exhaust the range of evidence the Agencies may introduce in litigation." U.S. Dep't of Justice & Fed. Trade Comm'n, *Horizontal Merger Guidelines* § 4 (rev. Aug. 19, 2010); *see also FTC v. Thomas Jefferson Univ.*, 505 F. Supp. 3d 522, 539 n.7 (E.D. Pa. 2020) ("The *Merger Guidelines* are not binding but may be used as persuasive authority".) Further, the Transaction is a vertical merger to which the Horizontal Merger Guidelines do not apply in any case.

5128. [redacted] (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 21 (RFA No. 28) (*in camera*)).

Response to Finding No. 5128:

The proposed finding is irrelevant, incomplete and misleading. As is admitted by Complaint Counsel's expert, Dr. Rothman, verification of an efficiency by reasonable means does not mean defining the specific dollar amount of the efficiency, nor do the Vertical Merger Guidelines require that costs be specified by a dollar amount. (PFF ¶¶ 2190.4–90.5.) Respondents experts have quantified the likely benefits associated with acceleration of Galleri by one year as *at least* $37 billion dollars. (RX6000 (Carlton Tr. 73–74.) While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5129. [redacted] (RX3867 (Deverka Rebuttal Report) ¶ 147 (*in camera*); PX7084 (Qadan (Illumina) Dep. at 183-85) ([redacted]) (*in camera*)).

Response to Finding No. 5129:

The proposed finding is irrelevant, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5128, which Respondents incorporate herein.

5130. [redacted] (PX7140 (Rothman Trial Dep. at 27) (*in camera*); *see also* PX6092 (Rothman Rebuttal Report) ¶¶ 29-30 (*in camera*)).

Response to Finding No. 5130:

The proposed finding relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Dr. Rothman admitted that he had no expertise in market access, including seeking FDA approval and payor coverage. (PFF ¶ 1134.4.)

5131. [redacted] (PX7140 (Rothman Trial Dep. at 27) (*in camera*); *see also* PX6092 (Rothman Rebuttal Report) ¶ 30 (*in camera*)).

Response to Finding No. 5131:

The proposed finding relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Dr. Rothman admitted that he had no expertise in market access, including seeking FDA approval and payor coverage. (PFF ¶ 1134.4.)

5132. Dr. Deverka testified that if Illumina's acquisition of Grail results in de-prioritization of projects due to a constraint on Illumina's employees' ability to work both on Illumina and Grail projects, Illumina could need to hire additional personnel to work on the projects. (PX7130 (Deverka Dep. at 173-174)).

Response to Finding No. 5132:

The proposed finding is incomplete and misleading. Dr. Deverka did not say that Illumina would divert any of these resources from GRAIL. Rather, she said that Illumina would engage in "priority setting and things -- people with the best skills for, you know, ensuring Galleri got sufficient attention, and that meant that other less important projects or potentially equally important projects were de-prioritized, then I would consider bringing in additional new hires, for example, to do that work. There's some, you know, potential opportunity with Galleri that has to be resourced." (PX7130 (Deverka Dep. at 173–174)). In addition, Respondents note that Illumina is currently expanding its market access team. Mr. Qadan testified that there were seven positions open within his market access team and Illumina is looking to expand its market access function regardless of the merger. (Qadan (Illumina) Tr. 4289.)

5133. [redacted] (Ofman (Grail) Tr. 3382 (*in camera*)).

Response to Finding No. 5133:

The proposed finding is incomplete and misleading to the extent it suggests that Dr. Ofman would have had the opportunity to speak to anyone at Illumina about which employees would be reassigned to work on Galleri. As the FTC well knows, Illumina and GRAIL have not engaged in integration planning because they are not legally permitted to do so. (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5134. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 29 (*in camera*)).

Response to Finding No. 5134:

The proposed finding relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Dr. Rothman admitted that he had no expertise in market access, including seeking FDA approval and payor coverage. (PFF ¶ 1134.4.) Respondents also note that given the expected benefits of the merger and Illumina's commitment to accelerating Galleri the cost of deploying additional employees to GRAIL would not be a significant factor.

5135. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 30 (*in camera*)).

Response to Finding No. 5135:

The proposed finding relies on improper lay opinion testimony and accordingly, should be given no weight. (See Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Dr. Rothman admitted that he had no expertise in market access, including seeking FDA approval and payor coverage. (PFF ¶ 1134.4.) In any event, Dr. Rothman's opinion is nonsensical and inconsistent with fact witness testimony. Dr. Rothman fails to explain why Illumina would re-deploy its personnel to GRAIL absent a merger between the companies. Illumina and GRAIL witnesses testified that they could not contract for these efficiencies if they were separate entities because Illumina does not provide such services to any third-party entities and doing so would require GRAIL to share its confidential information with Illumina. (PFF ¶ 1175.3 ("It would require GRAIL to share, you know, its knowledge of all of its technology, its assays, its bioinformatics. On the payer and FDA aspects of the efficiencies, they would need to share details of its clinical trials, the results, you know, of them, you know,

how they were conducted, proprietary information that it wouldn't . . . otherwise share."); [redacted] The fact testimony is consistent with expert testimony. (PFF ¶ 1175.4.1–2) (Dr. Carlton explained, that "Illumina does not offer regulatory help or market access services to customers. My understanding is Illumina would not provide, in absence of this transaction, a service to GRAIL to help it get FDA approval or payer approval." and "GRAIL would not tell Illumina in absence of this transaction, a lot of information that would be useful for Illumina to know to accelerate the improve – the approval. In particular, GRAIL is very concerned about its proprietary information in its machine-learning algorithm, and it's not going to give that information to Illumina if this transaction doesn't go through." (PFF ¶ 1175.4.2.)

(e) FDA Approval of MCED Tests Requires a PMA Supported by Clinical Trials

5136. [redacted] (PX6056 (Illumina Narrative Response to Second Request) at 015 (Spec. No. 2(c) (quoting www.fda.gov/medical-devices/premarket-submissions/premarket-approvalpma)).

Response to Finding No. 5136:

Respondents have no specific response.

5137. Grail's Galleri test is a Class III diagnostic test that will require Premarket Approval from the FDA. (Febbo (Illumina) Tr. 4445).

Response to Finding No. 5137:

The proposed finding is misleading to the extent it implies that Galleri requires a PMA in order to be commercialized. Dr. Febbo testified that "in order to get through the FDA, Class III devices must obtain what is called premarket approval". (Febbo (Illumina) Tr. 4445). While a PMA is required for FDA approval, test developers can choose to commercialize tests by other means, including as an LDT. (PFF ¶ 187.)

5138. [redacted] (Febbo (Illumina) Tr. 4335 (*in camera*)).

Response to Finding No. 5138:

Respondents have no specific response.

5139. MCED test developers must conduct clinical trials for their tests to obtain regulatory approval. (Della Porta (Grail) Tr. 584).

Response to Finding No. 5139:

Respondents have no specific response.

5140. [redacted] (Rabinowitz (Natera) Tr. 394-95 (*in camera*)).

Response to Finding No. 5140:

The proposed finding is incomplete and misleading to the extent that it implies that proof of safety and effectiveness is all that a test must show in order to receive a PMA. Because FDA has never cleared or approved a multi-cancer detection test, it is difficult to predict what information GRAIL will need to submit to obtain pre-market approval (PMA) from FDA for a proposed intended use, or if GRAIL will be able to obtain such approval on a timely basis or at all. (PFF ¶ 69.5.) The proposed finding relies on improper lay opinion testimony and accordingly, should be given no weight. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).) Dr. Rabinowitz is not an expert on the FDA or regulatory issues.

5141. [redacted] (Rabinowitz (Natera) Tr. 395 (*in camera*)).

Response to Finding No. 5141:

The proposed finding is inaccurate, incomplete and misleading, and relies on improper lay opinion testimony. Dr. Rabinowitz is not an expert on the FDA or regulatory issues. (*See*

Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

[redacted]

[redacted]

5142. "Illumina admits that the FDA has never granted a PMA for an NGS-based early cancer screening test." (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 007 (RFA No. 2); *see also* Freidin (Grail) Tr. 3106).

Response to Finding No. 5142:

Respondents have no specific response except to note that GRAIL's multi-cancer detection tests are a new approach to cancer screening, which present a number of novel and complex issues for FDA review. Because FDA has never cleared or approved a multi-cancer detection test, it is difficult to predict what information GRAIL will need to submit to obtain pre-market approval (PMA) from FDA for a proposed intended use, or if GRAIL will be able to obtain such approval on a timely basis or at all. (PFF ¶ 69.5.)

5143. "Illumina admits that the FDA has never granted a PMA for an NGS-based liquid biopsy test for early cancer screening in asymptomatic individuals." (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 007 (RFA No. 3)).

Response to Finding No. 5143:

Respondents have no specific response except to note that GRAIL's multi-cancer detection tests are a new approach to cancer screening, which present a number of novel and complex issues for FDA review. Because FDA has never cleared or approved a multi-cancer detection test, it is difficult to predict what information GRAIL will need to submit to obtain pre-market approval (PMA) from FDA for a proposed intended use, or if GRAIL will be able to obtain such approval on a timely basis or at all. (PFF ¶ 69.5.)

5144. Grail's S-1 states that the "FDA has never granted marketing authorization for a multi-cancer detection test." (PX4082 (Grail) at 047 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, Morgan Stanley, et al., attaching "Amendment No. 1 to Form S-1 Registration Statement," Sept. 2020)).

Response to Finding No. 5144:

Respondents have no specific response except to note that GRAIL's multi-cancer detection tests are a new approach to cancer screening, which present a number of novel and complex issues for FDA review. Because FDA has never cleared or approved a multi-cancer detection test, it is difficult to predict what information GRAIL will need to submit to obtain pre-market approval (PMA) from FDA for a proposed intended use, or if GRAIL will be able to obtain such approval on a timely basis or at all. (PFF ¶ 69.5.)

5145. [redacted] (PX6093 (Navathe Rebuttal Report) ¶ 18 (*in camera*)).

Response to Finding No. 5145:

The proposed finding is misleading, incomplete and involves improper expert testimony that should be given no weight. While it is true that the exact nature of what the FDA will require in order to approve an MCED test is unknown, Illumina is better positioned than Galleri to navigate these new challenges. Illumina is highly experienced in obtaining FDA approval for NGS-based tests, whereas GRAIL is not. (PFF ¶¶ 1130, 1131.) As Dr. Febbo explained, through Illumina's past engagements with the FDA, including "formal discussions, informal discussions, educational sessions and also what's important is not only is -- do we understand the FDA better, but our internal team, our regulatory team, and all the teams that support the regulatory team in these submissions, because when we're engaged in a submission, we have our scientists from the laboratory participate, we have our bioinformaticians participate, we have our biostatisticians participate, the full ecosystem, quality -- our quality system folks, our manufacturing and supply chain folks, and so we have all of our folks, and each of those

individuals and each of those teams gain experience with each of those interactions. So over the past decade, as we've taken through the first test, the second test, the sequencers, and now our active applications, we've established a cadence, an understanding. We've helped the FDA understand, and we feel we know where we need to continue to help them move and understand our technology in a way that's scalable and will help realize the potential of precision medicine. But we also have internal teams that have gained understanding of the requirements that are evolving from the FDA. So that combination is very powerful, and I'm really excited to have that experience be applied to the success of the Galleri test." (Febbo (Illumina) Tr. 4343–44.) Numerous Illumina and GRAIL fact witnesses testified that the reunion of the two companies would accelerate Galleri's regulatory approval. (PFF ¶ 1133.) Dr. Navathe has not attempted to contend with this testimony, much less shown that it is wrong.

Further, Dr. Navathe admitted that he did not have relevant expertise in market access, and also that he did not have an opinion on acceleration, so his testimony is without value on this point. (PFF ¶¶ 1134.4–34.5.)

(f) Illumina Has Limited Relevant Experience Obtaining FDA PMA Approvals

5146. The only Class III NGS-based diagnostic test for which Illumina has obtained Premarket Approval from the FDA is the Praxis therapy selection test. (Febbo (Illumina) Tr. 4445-46).

Response to Finding No. 5146:

Respondents have no specific response.

5147. Illumina's Praxis test identifies coding mutations in the RAS gene family that, if present, indicate that the patient would not benefit from Vectibix. (Febbo (Illumina) Tr. 4446).

Response to Finding No. 5147:

Respondents have no specific response except to note that the proposed finding is incomplete and misleading to the extent it suggests that the distinctions between the Praxis test

and Galleri is not relevant to Illumina's ability to accelerate Galleri's FDA approval merely because the Praxis test is not a cancer screening test. Dr. Febbo testified that Illumina's experience in securing clearances for tests (including Praxis) and sequencers has helped Illumina to understand the FDA better throughout the company; this includes an understanding of the FDA's evolving requirements. (Febbo (Illumina) Tr. 4338–44.) Illumina has established a cadence and understanding with the FDA that will help its efforts in the future, including with seeking approval for Galleri. (Febbo (Illumina) Tr. 4338–44.)

5148. Illumina's Praxis test sequences tumor tissue samples. (Febbo (Illumina) Tr. 4446).

Response to Finding No. 5148:

Respondents have no specific response except to note that the proposed finding is incomplete and misleading to the extent it suggests that the distinctions between the Praxis test and Galleri is not relevant to Illumina's ability to accelerate Galleri's FDA approval merely because the Praxis test is not a cancer screening test. Dr. Febbo testified that Illumina's experience in securing clearances for tests (including Praxis) and sequencers has helped Illumina to understand the FDA better throughout the company; this includes an understanding of the FDA's evolving requirements. (Febbo (Illumina) Tr. 4338–44.) Illumina has established a cadence and understanding with the FDA that will help its efforts in the future, including with seeking approval for Galleri. (Febbo (Illumina) Tr. 4338–44.)

5149. Illumina's Praxis test is not a liquid biopsy test. (Febbo (Illumina) Tr. 4446).

Response to Finding No. 5149:

Respondents have no specific response except to note that the proposed finding is incomplete and misleading to the extent it suggests that the distinctions between the Praxis test and Galleri is not relevant to Illumina's ability to accelerate Galleri's FDA approval merely

because the Praxis test is not a cancer screening test. Dr. Febbo testified that Illumina's experience in securing clearances for tests (including Praxis) and sequencers has helped Illumina to understand the FDA better throughout the company; this includes an understanding of the FDA's evolving requirements. (Febbo (Illumina) Tr. 4338–44.) Illumina has established a cadence and understanding with the FDA that will help its efforts in the future, including with seeking approval for Galleri. (Febbo (Illumina) Tr. 4338–44.)

5150. Illumina's Praxis test does not assay cell-free DNA from blood. (Febbo (Illumina) Tr. 4446).

Response to Finding No. 5150:

Respondents have no specific response except to note that the proposed finding is incomplete and misleading to the extent it suggests that the distinctions between the Praxis test and Galleri is not relevant to Illumina's ability to accelerate Galleri's FDA approval merely because the Praxis test is not a cancer screening test. Dr. Febbo testified that Illumina's experience in securing clearances for tests (including Praxis) and sequencers has helped Illumina to understand the FDA better throughout the company; this includes an understanding of the FDA's evolving requirements. (Febbo (Illumina) Tr. 4338–44.) Illumina has established a cadence and understanding with the FDA that will help its efforts in the future, including with seeking approval for Galleri. (Febbo (Illumina) Tr. 4338–44.)

5151. Illumina's Praxis test is indicated for people with metastatic colon cancer. (Febbo (Illumina) Tr. 4446).

Response to Finding No. 5151:

Respondents have no specific response except to note that the proposed finding is incomplete and misleading to the extent it suggests that the distinctions between the Praxis test and Galleri is not relevant to Illumina's ability to accelerate Galleri's FDA approval merely

because the Praxis test is not a cancer screening test. Dr. Febbo testified that Illumina's experience in securing clearances for tests (including Praxis) and sequencers has helped Illumina to understand the FDA better throughout the company; this includes an understanding of the FDA's evolving requirements. (Febbo (Illumina) Tr. 4338–44.) Illumina has established a cadence and understanding with the FDA that will help its efforts in the future, including with seeking approval for Galleri. (Febbo (Illumina) Tr. 4338–44.)

5152. Illumina's Praxis test does not screen healthy people for cancer. (Febbo (Illumina) Tr. 4446).

Response to Finding No. 5152:

Respondents have no specific response except to note that the proposed finding is incomplete and misleading to the extent it suggests that the distinctions between the Praxis test and Galleri is not relevant to Illumina's ability to accelerate Galleri's FDA approval merely because the Praxis test is not a cancer screening test. Dr. Febbo testified that Illumina's experience in securing clearances for tests (including Praxis) and sequencers has helped Illumina to understand the FDA better throughout the company; this includes an understanding of the FDA's evolving requirements. (Febbo (Illumina) Tr. 4338–44.) Illumina has established a cadence and understanding with the FDA that will help its efforts in the future, including with seeking approval for Galleri. (Febbo (Illumina) Tr. 4338–44.)

5153. [redacted] (Bishop (Grail) Tr. 1424; Freidin (Grail) Tr. 3106 (*in camera*)).

Response to Finding No. 5153:

Respondents have no specific response except to note that no one has obtained a PMA for any NGS-based cancer screening test and GRAIL's MCED test is a new approach to cancer screening and, as such, presents a number of novel and complex issues for FDA review. (PFF

¶ 69.5.) Further, the overwhelming evidence is that Illumina is highly experienced in obtaining FDA approval, and has a large team which has with expertise in this area; numerous witnesses testified to this. (PFF ¶¶ 1130–32.10.)

5154. Illumina has never engaged with the FDA regarding an MCED test. (Febbo (Illumina) Tr. 4451).

Response to Finding No. 5154:

Respondents have no specific response except to note that Illumina is very experienced more widely in obtaining FDA clearances and approvals for diagnostic tests. (PFF ¶ 1131.6.) It frequently interacts with the FDA, including through an educational program to teach the FDA about NGS technology. (PFF ¶ 1131.7.) Numerous witnesses testified to this experience and expertise, including, among many others, Francis deSouza, Illumina's CEO, who testified that Illumina has nearly ten years of experience working with the FDA and Dr. Febbo, Illumina's CMO, who testified that Illumina would bring this experience to Galleri. (PFF ¶ 1132–32.10.)

5155. [redacted] (PX6093 (Navathe Rebuttal Report) ¶ 17 (*in camera*)).

Response to Finding No. 5155:

The proposed finding is incomplete, misleading and relies on improper expert testimony that should be given no weight. Dr. Navathe admitted that he does not have relevant expertise in seeking FDA approval for an MCED test or how the FDA will evaluate such a test, and as such his view on this this point lacks value. (PFF ¶ 1134.4.) Illumina's experience with Praxis is relevant because Praxis, like Galleri, was an NGS-based test. Indeed, there is overwhelming evidence that Illumina and GRAIL personnel believe that Illumina's experience with Praxis and other tests will be helpful to Galleri. (PFF ¶ 1131–33.26 and 1383.) Additionally, the proposed

finding is misleading to the extent it suggests that the distinctions between the Praxis test and Galleri is not relevant to Illumina's ability to accelerate Galleri's FDA approval merely because the Praxis test is not a cancer screening test. Dr. Febbo testified that Illumina's experience in securing clearances for tests (including Praxis) and sequencers has helped Illumina to understand the FDA better throughout the company; this includes an understanding of the FDA's evolving requirements. (Febbo (Illumina) Tr. 4338–44.) Illumina has established a cadence and understanding with the FDA that will help its efforts in the future, including with seeking approval for Galleri. (Febbo (Illumina) Tr. 4338–44.)

5156. [redacted] (PX6093 (Navathe Rebuttal Report) ¶ 16 (*in camera*)).

Response to Finding No. 5156:

The proposed finding is incomplete, misleading and relies on improper expert testimony that should be given no weight. Dr. Navathe admitted that he does not have relevant expertise in seeking FDA approval for an MCED test or how the FDA will evaluate such a test, and as such his view on this this point lacks value. (PFF ¶ 1134.4.) Illumina's experiences obtaining approval for the MiSeqDx and Nextseq 500 Dx platforms are relevant because they involve the approval of NGS-based technology. Indeed, there is overwhelming evidence that Illumina's experience obtaining approval for the MiSeqDx and Nextseq 500 Dx platforms will be helpful to Galleri. (PFF ¶ 1131–33.26.)

5157. [redacted] (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 014 (RFA No. 14) (*in camera*); *see also* Febbo (Illumina) Tr. 4429 (*in camera*)).

Response to Finding No. 5157:

Respondents have no specific response except to note that no one has obtained a PMA for any NGS-based cancer screening test and GRAIL's MCED test is a new approach to cancer screening and, as such, presents a number of novel and complex issues for FDA review. (PFF ¶ 69.5.) Nevertheless, Illumina is in a better positioned than GRAIL and other companies to seek approval for NGS-based tests because it is highly experienced in obtaining FDA approval, and has a large team which has with expertise in this area. (PFF ¶¶ 1130–32.10.)

5158. Illumina has never sponsored any clinical study that the FDA has relied on to grant a PMA to a Class III diagnostic test. (Febbo (Illumina) Tr. 4448).

Response to Finding No. 5158:

Respondents have no specific response except to note that no one has obtained a PMA for any NGS-based cancer screening test and GRAIL's MCED test is a new approach to cancer screening and, as such, presents a number of novel and complex issues for FDA review. (PFF ¶ 69.5.) Nevertheless, Illumina is in a better position than GRAIL and other companies to seek approval for NGS-based tests because it is highly experienced in obtaining FDA approval, and has a large team which has with expertise in this area. (PFF ¶¶ 1130–32.10.)

5159. Illumina's Praxis test received its PMA from the FDA before Illumina's current Chief Medical Officer, Dr. Phillip Febbo, joined the company in 2018. (Febbo (Illumina) Tr. 4447, 4451).

Response to Finding No. 5159:

The proposed finding is misleading to the extent it suggests that the Praxis approval is irrelevant simply because Dr. Febbo was not at Illumina at the time it was received. Dr. Febbo testified that GRAIL will benefit from Illumina's experience receiving a PMA for Praxis, not that he himself had such experience. (Febbo (Illumina) Tr. 4338, 4347.) Moreover, Dr. Febbo has other experience working with the FDA. (Febbo (Illumina) Tr. 4305 ("my interaction with

the FDA has been since I've come into industry, where I've participated both directly in the submission and review of tests that are under review by the agency. I've also participated in several educational sessions that we've had at Illumina, and in some of my activities, both in academia and as part of industry, I've participated on organizations and educational activities together with members of the FDA".)

5160. Since Dr. Febbo, Illumina's Chief Medical Officer, joined the company in 2018, Illumina has not obtained a PMA for any NGS-based diagnostic test. (Febbo (Illumina) Tr. 4450-51).

Response to Finding No. 5160:

The proposed finding is incomplete and misleading insofar as it omits the fact that [redacted] (Febbo (Illumina) Tr. 4389–90.)

5161. Since Dr. Febbo joined the company in 2018, Illumina has not submitted a final PMA application to the FDA for any NGS-based diagnostic test. (Febbo (Illumina) Tr. 4451).

Response to Finding No. 5161:

The proposed finding is incomplete and misleading insofar as it omits the fact that [redacted] (Febbo (Illumina) Tr. 4389–90.)

5162. [redacted] (Febbo (Illumina) Tr. 4429 (*in camera*)).

Response to Finding No. 5162:

The proposed finding is incomplete and misleading without further context. Dr. Febbo testified that he had experience with the FDA when he was in academia, noting that "one of [his] trials, in particular, required the submission of an investigational device exception". (Febbo

(Illumina) Tr. 4305.) He also explained that he had "participated both directly in the submission and review of tests that are under review by the agency." (Febbo (Illumina) Tr. 4305.)

5163. [redacted] (PX6093 (Navathe Rebuttal Report) ¶ 25 (*in camera*)).

Response to Finding No. 5163:

The proposed finding is incomplete, misleading and relies on improper expert testimony and therefore should be given no weight. Dr. Navathe admitted that he had "never been involved in seeking FDA approval for a multicancer early detection test" and that was not an expert in "how the FDA is going to handle the evaluation of MCED tests". (PX7139 (Navathe Trial Dep. at 97–98).) Dr. Navathe further admitted his lack of experience with the FDA in any relevant context. He has never: consulted for the FDA, had experience obtaining FDA approval for any product, given advice on seeking approval, been involved in seeking a PMA, built a team seeking approval or studied FDA approval of medical diagnostic tests. These admissions render Dr. Navathe's views of Illumina's efforts to seek FDA approval for an MCED test outside of his expertise. (PX7139 (Navathe Trial Dep. at 97–100).)

When confronted with Dr. Navathe's criticism of delays with Project Denali, Dr. Febbo stated that [redacted] (Febbo (Illumina) Tr. 4384-85.) Respondents further note that Dr. Febbo explained [redacted] (Febbo (Illumina) Tr. 4436.) In fact, Dr. Febbo noted that [redacted] (Febbo (Illumina) Tr. 4383 and 4390.) Dr. Febbo also testified that [redacted]

[redacted] (Febbo (Illumina) Tr. 4402.)

5164. [redacted] (Freidin (Grail) Tr. 3113 (*in camera*)).

Response to Finding No. 5164:

The proposed finding is incomplete and misleading to the extent it suggests that [redacted] Dr. Febbo testified that Illumina's experiences with the FDA would accelerate Galleri's PMA regardless of those experiences being for different kinds of technology: he explained that Illumina across the board understands the FDA better as a result of previous dealings with the agency, and that Illumina's work to help the FDA understand NGS technology would also be useful. (Febbo (Illumina) Tr. 4343–44.) [redacted] Early cancer screening tests are used in asymptomatic individuals to detect cancer at the earliest, most treatable stage. (PFF ¶ 126.) Whereas diagnostic aid to cancer tests are used to help confirm the presence of cancer or to better specify the type of cancer in someone who has cancer. (PFF ¶ 130.)

5165. [redacted] (Freidin (Grail) Tr. 3113 (*in camera*)).

Response to Finding No. 5165:

The proposed finding is incomplete and misleading to the extent it suggests that [redacted]

[redacted] Dr. Febbo testified that Illumina's experiences with the FDA would accelerate Galleri's PMA regardless of those experiences being for different kinds of technology: he explained that Illumina across the board understands the FDA better as a result of previous dealings with the agency, and that Illumina's work to help the FDA understand NGS technology would also be useful. (Febbo (Illumina) Tr. 4343–44.)

5166. [redacted] (Freidin (Grail) Tr. 3115 (*in camera*)).

Response to Finding No. 5166:

The proposed finding is incomplete and misleading to the extent it suggests that [redacted] Dr. Febbo testified that Illumina's experiences with the FDA would accelerate Galleri's PMA regardless of those experiences being for different kinds of technology: he explained that Illumina across the board understands the FDA better as a result of previous dealings with the agency, and that Illumina's work to help the FDA understand NGS technology would also be useful. (Febbo (Illumina) Tr. 4343–44.)

(i) Illumina's Praxis Therapy Selection Test Was Approved on the Basis of a Third Party's Clinical Study

5167. Illumina's Praxis therapy selection test is a companion diagnostic test for the drug Vectibix. (Febbo (Illumina) Tr. 4446).

Response to Finding No. 5167:

Respondents have no specific response.

5168. Illumina's PMA application for the Praxis test relied upon the PRIME clinical study. (Febbo (Illumina) Tr. 4448).

Response to Finding No. 5168:

Respondents have no specific response.

5169. Amgen sponsored the PRIME clinical study, not Illumina. (Febbo (Illumina) Tr. 4448; PX0388, ClinicalTrials.gov, PRIME: Panitumumab Randomized Trial in Combination with Chemotherapy for Metastatic Colorectal Cancer to Determine Efficacy (ClinicalTrials.gov Identifier: NCT00364013), https://clinicaltrials.gov/ct2/show/record/NCT00364013?term=PRIME&spons=Amgen&draw=2&rank=2 (last visited Sept. 23, 2021) (listing Amgen as the sole "sponsor" for the PRIME study)).

Response to Finding No. 5169:

Respondents have no specific response.

5170. Amgen is listed as the sole "responsible party" on ClinicalTrials.gov for the PRIME study validating the safety and effectiveness of Praxis. PX0388, ClinicalTrials.gov, PRIME: Panitumumab Randomized Trial in Combination with Chemotherapy for Metastatic Colorectal Cancer to Determine Efficacy (ClinicalTrials.gov Identifier: NCT00364013), https://clinicaltrials.gov/ct2/show/record/NCT00364013?term=PRIME&spons=Amgen&draw=2&rank=2 (last visited Sept. 23, 2021)).

Response to Finding No. 5170:

Respondents have no specific response.

5171. The PRIME study was the only clinical study Illumina submitted to the FDA as part of the Praxis PMA application. (Febbo (Illumina) Tr. 4448; PX0392 at 028-30 (FDA, Summary of Safety and Effectiveness Data, Praxis™ Extended RAS Panel, June 29, 2017) (describing a single study).

Response to Finding No. 5171:

Respondents have no specific response.

5172. Illumina is not listed as either a sponsor or collaborator for the PRIME study on ClinicalTrials.gov. PX0391, ClinicalTrials.gov Search Results for "Illumina," (last visited Sept. 23, 2021)).

Response to Finding No. 5172:

Respondents have no specific response.

(ii) [redacted]

5173. [redacted] (PX7099 (Febbo (Illumina) Dep. at 88-89) (*in camera*)).

Response to Finding No. 5173:

Respondents have no specific response.

5174. [redacted] (Febbo (Illumina) Tr. 4381 (*in camera*)).

Response to Finding No. 5174:

Respondents have no specific response.

5175. [redacted] (Febbo (Illumina) Tr. 4381 (*in camera*)).

Response to Finding No. 5175:

Respondents have no specific response.

5176. [redacted] (Febbo (Illumina) Tr. 4405 (*in camera*)).

Response to Finding No. 5176:

Respondents have no specific response.

5177. "Illumina admits that the FDA has not granted a PMA for Illumina's NIPT in vitro diagnostic test, including because Illumina has not completed submission of its PMA for its NIPT in vitro diagnostic test." (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 13 (RFA No. 12)).

Response to Finding No. 5177:

Respondents have no specific response except to note [redacted] (Febbo (Illumina) Tr. 4383 (*in camera*)). Dr. Febbo also

testified that [redacted] (Febbo (Illumina) Tr. 4401–02.)

5178. [redacted] (Febbo (Illumina) Tr. 4381 (*in camera*)).

Response to Finding No. 5178:

Respondents have no specific response.

5179. [redacted] (Febbo (Illumina) Tr. 4381-82 (*in camera*)).

Response to Finding No. 5179:

Respondents have no specific response.

5180. [redacted] (Febbo (Illumina) Tr. 4382 (*in camera*)).

Response to Finding No. 5180:

Respondents have no specific response except to note [redacted] (Febbo (Illumina) Tr. 4382 (*in camera*)).

5181. [redacted] (Febbo (Illumina) Tr. 4383 (*in camera*)).

Response to Finding No. 5181:

Respondents have no specific response.

5182. [redacted] (Febbo (Illumina) Tr. 4383 (*in camera*)).

Response to Finding No. 5182:

Respondents have no specific response.

5183. [redacted] (Febbo (Illumina) Tr. 4383 (*in camera*).

Response to Finding No. 5183:

Respondents have no specific response.

5184. [redacted] (Febbo (Illumina) Tr. 4406 (*in camera*)).

Response to Finding No. 5184:

The proposed finding is incomplete and misleading. Dr. Febbo also testified that [redacted] (Febbo (Illumina) Tr. 4383.) He also testified that [redacted] (Febbo (Illumina) Tr. 4391.)

5185. [redacted] (Febbo (Illumina) Tr. 4406 (*in camera*)).

Response to Finding No. 5185:

Respondents have no specific response.

5186. [redacted] (PX2587 (Illumina) at 006 [redacted] (*in camera*)).

Response to Finding No. 5186:

The proposed finding is incomplete and misleading. Dr. Febbo testified [redacted]

[redacted] (Febbo (Illumina) Tr. 4385 (*in camera*).) He explained that [redacted] (Febbo (Illumina) Tr. 4385–86 (*in camera*).) He further testified [redacted] (Febbo (Illumina) Tr. 4386 (*in camera*).)

5187. [redacted] (Febbo (Illumina) Tr. 4383-84, 4406 (*in camera*)).

Response to Finding No. 5187:

Respondents have no specific response.

5188. [redacted] (Febbo (Illumina) Tr. 4383-84, 4406-07 (*in camera*)).

Response to Finding No. 5188:

Respondents have no specific response.

5189. [redacted] (Febbo (Illumina) Tr. 4407-08 (*in camera*)).

Response to Finding No. 5189:

Respondents have no specific response.

5190. [redacted] (Febbo (Illumina) Tr. 4410 (*in camera*)).

Response to Finding No. 5190:

The proposed finding is incomplete and misleading. Dr. Febbo testified [redacted] (Febbo (Illumina) Tr. 4386–87 (*in camera*).) He explained that [redacted] (Febbo (Illumina) Tr. 4385–86 (*in camera*).) He further testified [redacted] (Febbo (Illumina) Tr. 4386 (*in camera*).)

5191. [redacted] (Febbo (Illumina) Tr. 4410-11 (*in camera*)).

Response to Finding No. 5191:

The proposed findings is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5190, which Respondents incorporate herein.

5192. [redacted] (Febbo (Illumina) Tr. 4411 (*in camera*)).

Response to Finding No. 5192:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5190, which Respondents incorporate herein

5193. [redacted] (Febbo (Illumina) Tr. 4410 (*in camera*)).

Response to Finding No. 5193:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5190, which Respondents incorporate herein.

5194. [redacted] (Febbo (Illumina) Tr. 4410 (*in camera*)).

Response to Finding No. 5194:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5190, which Respondents incorporate herein.

5195. [redacted] (Febbo (Illumina) Tr. 4408 (*in camera*)).

Response to Finding No. 5195:

Respondents have no specific response.

5196. [redacted] (Febbo (Illumina) Tr. 4409 (*in camera*)).

Response to Finding No. 5196:

Respondents have no specific response except to note [redacted] (Febbo (Illumina) Tr. 4409).

5197. [redacted] (Febbo (Illumina) Tr. 4411 (*in camera*)).

Response to Finding No. 5197:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5190, which Respondents incorporate herein.

5198. [redacted] (PX2585 (Illumina) at 002 [redacted] (*in camera*)).

Response to Finding No. 5198:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5190, which Respondents incorporate herein.

5199. [redacted] (PX2585 (Illumina) at 002 [redacted] (*in camera*)).

Response to Finding No. 5199:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5190, which Respondents incorporate herein. Respondents also [redacted] (Febbo (Illumina) Tr. 4411 (*in camera*).)

5200. [redacted] (Febbo (Illumina) Tr. 4409) (*in camera*).

Response to Finding No. 5200:

Respondents have no specific response.

5201. [redacted] (Febbo (Illumina) Tr. 4411 (*in camera*)).

Response to Finding No. 5201:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5190, which Respondents incorporate herein. Respondents also note that Dr. Febbo testified [redacted] (Febbo (Illumina) Tr. 4388 (*in camera*).)

5202. [redacted] (Febbo (Illumina) Tr. 4411-4412 (*in camera*)).

Response to Finding No. 5202:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5190, which Respondents incorporate herein.

5203. [redacted] (PX2584 (Illumina) at 001 [redacted] (*in camera*)).

Response to Finding No. 5203:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5190, which Respondents incorporate herein.

5204. [redacted] (PX2584 (Illumina) at 001 [redacted] (*in camera*)).

Response to Finding No. 5204:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5190, which Respondents incorporate herein.

5205. [redacted] (Febbo (Illumina) Tr. 4416-4417 (*in camera*)).

Response to Finding No. 5205:

Respondents have no specific response.

5206. [redacted] (Febbo (Illumina) Tr. 4417 (*in camera*)).

Response to Finding No. 5206:

Respondents have no specific response.

5207. [redacted] (Febbo (Illumina) Tr. 4417 (*in camera*)).

Response to Finding No. 5207:

Respondents have no specific response.

5208. [redacted] (PX2590 (Illumina) at 001-02 (Email from K. Davy, Illumina, to J. Godsey and P. Febbo, Illumina, Nov. 19, 2020) (*in camera*)).

Response to Finding No. 5208:

The proposed finding is incomplete and misleading. Dr. Febbo testified that [redacted]

[redacted] (Febbo (Illumina) (Tr. 4438–39.)

5209. [redacted] (PX2590 (Illumina) at 001 (Email from K. Davy, Illumina, to J. Godsey and P. Febbo, Illumina, Nov. 19, 2020) (*in camera*)).

Response to Finding No. 5209:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5208, which Respondents incorporate herein. Dr. Febbo testified that the [redacted] (Febbo (Illumina) Tr. 4383.) He also testified that [redacted] (Febbo (Illumina) Tr. 4387.)

5210. [redacted] (Febbo (Illumina) Tr. 4418 (*in camera*)).

Response to Finding No. 5210:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5208, which Respondents incorporate herein.

5211. [redacted] (PX2590 (Illumina) at 001 (Email from K. Davy, Illumina, to J. Godsey and P. Febbo, Illumina, Nov. 19, 2020) (*in camera*)).

Response to Finding No. 5211:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5208, which Respondents incorporate herein. Dr. Febbo

testified [redacted] (Febbo (Illumina) Tr. 4386–87 (*in camera*).) Dr. Febbo testified that the [redacted] (Febbo (Illumina) Tr. 4383.) He also testified that [redacted] (Febbo (Illumina) Tr. 4387.)

5212. [redacted] (Febbo (Illumina) Tr. 4419-20 (*in camera*)).

Response to Finding No. 5212:

Respondents have no specific response.

5213. [redacted] (Febbo (Illumina) Tr. 4420-21 (*in camera*)).

Response to Finding No. 5213:

The proposed finding is incomplete and misleading. At trial, Dr. Febbo explained that [redacted] (Febbo (Illumina) Tr. 4421–22.)

5214. [redacted] (PX2591 (Illumina) at 001 (Email from P. Febbo, Illumina, to K. Gutekunst, Illumina, Dec. 3, 2020) (*in camera*)). [redacted] (Febbo (Illumina) Tr. 4421-22 (*in camera*)).

Response to Finding No. 5214:

The proposed finding is incomplete and misleading. At trial, Dr. Febbo explained that

(Febbo (Illumina) Tr. 4421–22.)

5215. (Febbo (Illumina) Tr. 4414-15 (*in camera*)).

Response to Finding No. 5215:

Respondents have no specific response.

5216. (Febbo (Illumina) Tr. 4415-16 (*in camera*)).

Response to Finding No. 5216:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5190, which Respondents incorporate herein.

5217. (PX2587 (Illumina) at 001-02 (*in camera*)).

Response to Finding No. 5217:

Respondents have no specific response.

5218. (PX2587 (Illumina) at 006

[redacted] (*in camera*)).

Response to Finding No. 5218:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5190, which Respondents incorporate herein.

5219. [redacted] (*in camera*)).

Response to Finding No. 5219:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5190, which Respondents incorporate herein.

5220. [redacted] (*in camera*)).

Response to Finding No. 5220:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5190, which Respondents incorporate herein.

5221. [redacted] (Febbo (Illumina) Tr. 4416 (*in camera*)).

Response to Finding No. 5221:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5190, which Respondents incorporate herein. Dr. Febbo also testified that the [redacted] (Febbo (Illumina) Tr. 4383.)

5222. [redacted] (Febbo (Illumina) Tr. 4416 (*in camera*)).

Response to Finding No. 5222:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5190, which Respondents incorporate herein.

(iii) [redacted]

5223. [redacted] (Febbo (Illumina) Tr. 4422 (*in camera*)).

Response to Finding No. 5223:

Respondents have no specific response.

5224. [redacted] (Febbo (Illumina) Tr. 4422 (*in camera*)).

Response to Finding No. 5224:

Respondents have no specific response.

5225. [redacted] (Febbo (Illumina) Tr. 4422-23 (*in camera*)).

Response to Finding No. 5225:

Respondents have no specific response except to note that Dr. Febbo testified [redacted] (Febbo (Illumina) Tr. 4389 (*in camera*).)

5226. [redacted] (Febbo (Illumina) Tr. 4389, 4423 (*in camera*)).

Response to Finding No. 5226:

Respondents have no specific response.

5227. [redacted] (Febbo (Illumina) Tr. 4423 (*in camera*)).

Response to Finding No. 5227:

Respondents have no specific response.

5228. [redacted] (Febbo (Illumina) Tr. 4423 (*in camera*)).

Response to Finding No. 5228:

Respondents have no specific response.

5229. "Illumina admits that the FDA has not granted a PMA for Illumina's TSO Comp, including because Illumina has not completed submission of its PMA for its TSO Comp." (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 13-14 (RFA No. 13)).

Response to Finding No. 5229:

The proposed finding is incomplete and misleading. Dr. Febbo testified [redacted] (Febbo (Illumina) Tr. 4390 (*in camera*).) [redacted] (Febbo (Illumina) Tr. 4389.) Dr. Febbo also testified that the [redacted] (Febbo (Illumina) Tr. 4390–91.)

5230. [redacted] (Febbo (Illumina) Tr. 4390 (*in camera*)).

Response to Finding No. 5230:

Respondents have no specific response.

5231. [redacted] (Febbo (Illumina) Tr. 4389 (*in camera*)).

Response to Finding No. 5231:

Respondents have no specific response.

5232. [redacted] (Febbo (Illumina) Tr. 4390 (*in camera*)).

Response to Finding No. 5232:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5229, which Respondents incorporate herein.

5233. [redacted] (Febbo (Illumina) Tr. 4390 (*in camera*)).

Response to Finding No. 5233:

Respondents have no specific response.

5234. [redacted] (Febbo (Illumina) Tr. 4390 (*in camera*)).

Response to Finding No. 5234:

Respondents have no specific response.

5235. [redacted] (PX2593 (Illumina) at 002-14 (Letter from R. Philip, FDA, to J. Fleming, Illumina, Jan. 21, 2021) (*in camera*)).

Response to Finding No. 5235:

Respondents have no specific response.

5236. [redacted] (Febbo (Illumina) Tr. 4391 (*in camera*)).

Response to Finding No. 5236:

The proposed finding is incomplete and misleading. Dr. Febbo testified that [redacted] (Febbo (Illumina) Tr. 4391.)

5237. [redacted] (PX2593 (Illumina) at 002-14 (Letter from R. Philip, FDA, to J. Fleming, Illumina, Jan. 21, 2021) (*in camera*)).

Response to Finding No. 5237:

The proposed finding is incomplete and misleading. Dr. Febbo testified that [redacted]

[redacted]

(Febbo (Illumina) Tr. 4391.)

5238. [redacted] (Febbo (Illumina) Tr. 4426 (*in camera*)).

Response to Finding No. 5238:

The proposed finding is incomplete and misleading. Dr. Febbo testified that [redacted] (Febbo (Illumina) Tr. 4391.) Dr. Febbo testified that [redacted] (Febbo (Illumina) Tr. 4396–97.) Dr. Febbo also

testified that [redacted] (Febbo (Illumina) Tr. 4397–98.)

5239. [redacted] (PX2593 (Illumina) at 002-14 (Letter from R. Philip, FDA, to J. Fleming, Illumina, Jan. 21, 2021) (*in camera*)).

Response to Finding No. 5239:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5238, which Respondents incorporate herein.

5240. [redacted] (PX2593 (Illumina) at 001 (Email from J. Fleming, Illumina, to K. Gutekunst, Illumina, and J. McMullen, Illumina, Jan. 22, 2021) (*in camera*)).

Response to Finding No. 5240:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5238, which Respondents incorporate herein. Dr. Febbo explained [redacted]

(Febbo (Illumina) Tr. 4340–41 (*in camera*).)

5241. (PX2593 (Illumina) at 001 (Email from K. Gutekunst, Illumina, to P. Febbo, Illumina, Jan. 22, 2021) (*in camera*)).

Response to Finding No. 5241:

The proposed finding is incomplete and misleading for the reasons stated in the responses to CCFF ¶ 5239, which is incorporated herein. Dr. Febbo explained in the context of this email that (Febbo (Illumina) Tr. 4425–26.)

5242. (Febbo (Illumina) Tr. 4427-28 (*in camera*)).

Response to Finding No. 5242:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5238, which Respondents incorporate herein. Dr. Febbo explained (Febbo (Illumina) Tr. 4427–28.) (Febbo (Illumina) Tr. 4427.) He also explained that

[redacted] (Febbo (Illumina) Tr. 4427–28.)

5243. [redacted] (Febbo (Illumina) Tr. 4426-27 (*in camera*)).

Response to Finding No. 5243:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5242, which Respondents incorporate herein. Dr. Febbo specifically testified that [redacted] (Febbo (Illumina) Tr. 4426–27 (*in camera*).) Respondents also refer to their responses to CCFF ¶ 5242.

5244. [redacted] (Febbo (Illumina) Tr. 4423-24 (*in camera*)).

Response to Finding No. 5244:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5242, which Respondents incorporate herein.

5245. [redacted] (Febbo (Illumina) Tr. 4425-26 (*in camera*)).

Response to Finding No. 5245:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5242, which Respondents incorporate herein.

5246. [redacted] (Febbo (Illumina) Tr. 4428 (*in camera*)).

Response to Finding No. 5246:

Respondents have no specific response.

5247. [redacted] (Febbo (Illumina) Tr. 4429 (*in camera*)).

Response to Finding No. 5247:

Respondents have no specific response.

5248. [redacted] (PX2582 (Illumina) at 001 (Email from J. Godsey, Illumina, to S. Tousi, K. Reeves, J. Goswami, R. Ragusa, and P. Febbo, Illumina, Apr. 14, 2021) (*in camera*)).

Response to Finding No. 5248:

Respondents have no specific response other than to note that Dr. Febbo testified [redacted] (Febbo (Illumina) Tr. 4399–4400 (*in camera*).)

5249. [redacted] (Febbo (Illumina) Tr. 4423 (*in camera*)).

Response to Finding No. 5249:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5242, which Respondents incorporate herein.

(g) If Illumina Could Meaningfully Accelerate Galleri, It Has the Incentive to Do So Absent the Merger

5250. [redacted] (PX7138 (Scott Morton Trial Dep. at 54-55) (*in camera*)).

Response to Finding No. 5250:

The proposed finding is incomplete and misleading. In light of Illumina's pre-merger royalty and equity stake in GRAIL, Illumina makes much more money if a customer uses a GRAIL test than that of a purported rival, meaning that there is already an incentive for Illumina to favor GRAIL even absent the Transaction. (PFF ¶ 818.) [redacted] (PFF ¶ 819.) More broadly, Dr Scott Morton ignores the unique nature of GRAIL's royalty arrangement with Illumina in her analysis of Illumina's incentives; once corrected, it is clear that Illumina has an incentive to favor GRAIL even absent the Transaction. (PFF ¶¶ 820–22.3.)

5251. Dr. Alex Aravanis, Illumina's Chief Technology Officer, testified that Illumina has an incentive to accelerate the adoption of sequencing-based cancer screening tests even absent an acquisition of Grail. (PX7065 (Aravanis (Illumina) IHT at 225-226)).

Response to Finding No. 5251:

The proposed finding is incomplete and misleading. Specifically, it implies that Illumina would be able to help accelerate the adoption of Galleri absent the Transaction: this is not the case. Illumina and GRAIL witnesses testified that they could not contract for market

acceleration efficiencies if they were separate entities because Illumina does not provide such services to any third party entities and doing so would require GRAIL to share its confidential information with Illumina. (*See e.g.* Aravanis (Illumina) Tr. 1969–70 ("It would require GRAIL to share, you know, its knowledge of all of its technology, its assays, its bioinformatics. On the payer and FDA aspects of the efficiencies, they would need to share details of its clinical trials, the results, you know, of them, you know, how they were conducted, proprietary information that it wouldn't necessarily – it wouldn't otherwise share".); Febbo (Illumina) Tr. 4369 ("you don't see total alignment between two companies, and nor can you get into the depth of understanding of the processes and the special sauce that a lot of these companies, including Illumina, have in order to fully realize efficiencies, fully realize where you have the best opportunity to improve a test, to improve or speed regulatory, improve reimbursement. You just don't see the layer of engagement that's necessary to get to the full realization of those benefits through partnerships".); [redacted] Dr. Carlton testified that "Illumina does not offer regulatory help or market access services to customers. My understanding is Illumina would not provide, in absence of this transaction, a service to GRAIL to help it get FDA approval or payer approval". (RX6000 (Carlton Trial Dep. at 60).) He also testified that GRAIL does not share confidential information: "GRAIL would not tell Illumina in absence of this transaction, a lot of information that would be useful for Illumina to know to accelerate the improve – the approval. In particular, GRAIL is very concerned about its proprietary information in its machine-learning algorithm, and it's not going to give that information to Illumina if this transaction doesn't go through". (RX6000 (Carlton Trial Dep. at 60–61).)

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5252. [redacted] (PX7140 (Rothman Trial Dep. at 21-22) (*in camera*)).

Response to Finding No. 5252:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5251, which Respondents incorporate herein. Dr. Rothman admitted that he lacks expertise in FDA approval and payor coverage, and so his testimony on this point is of no value. (PFF ¶ 1134.4.)

5253. [redacted] (PX6090 (Scott Morton Report) ¶¶ 238-39 (*in camera*)).

Response to Finding No. 5253:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5251, which Respondents incorporate herein.

5254. [redacted] (PX6090 (Scott Morton Report) ¶ 239 (*in camera*)).

Response to Finding No. 5254:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5251, which Respondents incorporate herein.

5255. [redacted]

[redacted]
(PX6090 (Scott Morton Report) ¶ 239 (*in camera*)).

Response to Finding No. 5255:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5251, which Respondents incorporate herein.

5256. [redacted] (PX6090 (Scott Morton Report) ¶ 239 (*in camera*)).

Response to Finding No. 5256:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5251, which Respondents incorporate herein.

5257. [redacted]

[redacted]

(PX6090 (Scott Morton Report) ¶ 240 (*in camera*)).

Response to Finding No. 5257:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5251, which Respondents incorporate herein.

5258. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 84 (*in camera*)).

Response to Finding No. 5258:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5251, which Respondents incorporate herein. Respondents also note that Dr. Rothman admitted that he lacks expertise in FDA approval and payor coverage, and so his testimony on this point is of no value and should be given no weight. (PFF ¶ 1134.4.)

(h) Grail Is Already Pursuing FDA Approval Aggressively as an Independent Company

5259. [redacted] (Bishop (Grail) Tr. 1345; PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*) ([redacted]).

Response to Finding No. 5259:

The proposed finding is incomplete and misleading. GRAIL witnesses testified that GRAIL's timelines for PMA approval had been pushed back and could be pushed back further. For example, Dr. Ofman testified [redacted] (Ofman (Grail) Tr. 3351–52).

Numerous witnesses also testified that Illumina would accelerate Galleri's regulatory approval by one year. (PFF ¶ 1122.)

5260. [redacted] (Bishop (Grail) Tr. 1345; PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021 (*in camera*) ([redacted])).

Response to Finding No. 5260:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5259, which Respondents incorporate herein. Mr. Bishop agreed that [redacted] but he did not use the term "already". (Bishop (GRAIL) Tr. 1345).

5261. [redacted] (Ofman (Grail) Tr. 3351 (*in camera*); *see* PX7069 (Bishop (Grail) IHT at 193-34); PX4082 (Grail) at 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020); *see also* Febbo (Illumina) Tr. 4430 (*in camera*) ([redacted]); PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 5261:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5259, which Respondents incorporate herein. Dr. Ofman testified [redacted] (Ofman (Grail) Tr. 3351-52). [redacted] (Ofman (Grail) Tr. 3351–52)

5262. [redacted]

[redacted] (PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 5262:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5261, which Respondents incorporate herein.

5263. [redacted] (PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 5263:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5261, which Respondents incorporate herein.

5264. [redacted] (PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 5264:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5261, which Respondents incorporate herein.

5265. [redacted] (Ofman (Grail) Tr. 3351 (*in camera*)).

Response to Finding No. 5265:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5261, which Respondents incorporate herein.

5266. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 53 (*in camera*)).

Response to Finding No. 5266:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5259–61, which Respondents incorporate herein. The proposed finding also relies on improper expert testimony. Dr. Rothman lacks the expertise to opine on FDA regulations, rendering his opinions unreliable. (*See* Resps.' Post-Trial Br. at 269; PX7140 (Rothman Trial Dep. at 43–44.) Dr. Rothman testified that he is not offering an opinion as to whether Respondents' support for the asserted efficiencies satisfies the relevant legal burden of proof. (PX7140 (Rothman Trial Dep. at 62–63);

5267. (PX6092 (Rothman Rebuttal Report) ¶ 28 (*in camera*)).

Response to Finding No. 5267:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5259–61 and 5266, which Respondents incorporate herein.

5268. [redacted] (Ofman (Grail) Tr. 3384 (*in camera*)).

Response to Finding No. 5268:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5259–61, which Respondents incorporate herein. While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5269. [redacted] (PX6069 (Illumina) at 016-17 (Illumina Responses & Objections to FTC Requests for Admissions) (*in camera*)).

Response to Finding No. 5269:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5259–61, which Respondents incorporate herein. While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5270. [redacted] (Ofman (Grail) Tr. 3384-85 (*in camera*)).

Response to Finding No. 5270:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5259–61, which Respondents incorporate herein. While

Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

(i) [redacted]

5271. [redacted] (Bishop (Grail) Tr. 1437) (*in camera*)).

Response to Finding No. 5271:

The proposed finding is incomplete and misleading. GRAIL has created many long range plans over the years. See, e.g., PX7106 (Della Porta (GRAIL) Dep. at 153) (referencing older revenue forecast), [redacted]. In the cited testimony, Complaint Counsel asked [redacted]

5272. [redacted] (Bishop (Grail) Tr. 1437-38) (*in camera*)).

Response to Finding No. 5272:

The proposed finding is incomplete and misleading. GRAIL has created many long range plans over the years. See, e.g., PX7106 (Della Porta (Grail) Dep. at 153)(referencing older revenue forecast), [redacted]. The cited testimony is ambiguous regarding which long range plan is being discussed.

5273. [redacted] (Bishop (Grail) Tr. 1438) (*in camera*)).

Response to Finding No. 5273:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5272, which Respondents incorporate herein.

5274. [redacted] (Bishop (Grail) Tr. 1441) (*in camera*)).

Response to Finding No. 5274:

Respondents have no specific response.

5275. [redacted] (Bishop (Grail) Tr. 1442-43 (*in camera*); PX7083 (Bishop (Grail) Dep. at 145) (*in camera*); PX5044 (Grail) at 003 (LRP Review, Aug. 20, 2020) (*in camera*)).

Response to Finding No. 5275:

The proposed finding is incomplete and misleading. [redacted] *See also*, PX7106 (Della Porta (Grail) Dep. at 153) (referencing older revenue forecast), [redacted]. The cited testimony relates to PX5044. In response to whether [redacted]

5276. [redacted] (Bishop (Grail) Tr. 1449) (*in camera*)).

Response to Finding No. 5276:

Respondents have no specific response.

5277. [redacted] (Bishop (Grail) Tr. 1449-50) (*in camera*)).

Response to Finding No. 5277:

The proposed finding is incomplete and misleading. Mr. Bishop testified that [redacted]

5278. [redacted] ((Bishop (Grail) Tr. 1452) (*in camera*); PX5046 (Grail) at 007 [redacted] (*in camera*)).

Response to Finding No. 5278:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5275 and 5277, which Respondents incorporate herein.

5279. According to Mr. Bishop, FDA approval "will likely be a prerequisite for getting broad-based reimbursement." (PX7069 (Bishop (Grail) IHT at 94-95)).

Response to Finding No. 5279:

Respondents have no specific response.

5280. [redacted] (Freidin (Grail) Tr. 3171 (*in camera*)).

Response to Finding No. 5280:

The proposed finding is incomplete and misleading. Mr. Freidin testified, [redacted] Respondents incorporate their responses to CCFF ¶ 5275 herein.

(ii) [redacted]

5281. [redacted] (Bishop (Grail) Tr. 1466-68 (*in camera*); PX4489 (Grail) at 011 (Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020) (*in camera*)).

Response to Finding No. 5281:

Respondents have no specific response.

5282. [redacted] (Bishop (Grail) Tr. 1466-68 (*in camera*)).

Response to Finding No. 5282:

Respondents have no specific response.

5283. [redacted] (Bishop (Grail) Tr. 1466-68 (*in camera*); PX4489 (Grail) at 011 (Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020) (*in camera*)).

Response to Finding No. 5283:

The proposed finding is incomplete and misleading. PX4489 states that [redacted] PX4489 (Grail) at 009 **(Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020**)); **(Bishop (GRAIL) Tr. 1467–1468)**.

5284. [redacted] (Bishop (Grail) Tr. 1466-68 (*in camera*); PX4489 (Grail) at 011 (Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020) (*in camera*)). [redacted] (PX4489 (Grail) at 011 (Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020) (*in camera*)).

Response to Finding No. 5284:

The proposed finding is incomplete and misleading. PX4489 states that the [redacted] (PX4489 (Grail) at 012 (**Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020**)).

[redacted]

[redacted] (PX4489 (Grail) at 011 (**Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020)**). [redacted] (PX4489 (Grail) at 011 (**Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020)**).

5285. [redacted] (Bishop (Grail) Tr. 1466-68 (*in camera*); PX4489 (Grail) at 011 (Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020) (*in camera*)). [redacted] (PX4489 (Grail) at 011 (Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020) (*in camera*)).

Response to Finding No. 5285:

Respondents have no specific response except to note that this objective is described in PX4489 as [redacted]. PX4489 (Grail) at 012 (Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020). This proposed finding undermines Complaint Counsel's assertion that Galleri is not clinically validated to detect 50 cancer types. (CCFF at Appendix B).

5286. [redacted] (Bishop (Grail) Tr. 1466-68 (*in camera*); PX4489 (Grail) at 011 (Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020) (*in camera*)). [redacted] (Bishop (Grail) Tr. 1466-68 (*in camera*); PX4489 (Grail) at 011 (Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020) (*in camera*)).

Response to Finding No. 5286:

The proposed finding is incomplete and misleading. This objective is described in PX4489 as merely to [redacted]. PX4489 (Grail) at 012 (Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021

Budget, Dec. 9, 2020). At trial, Dr. Ofman testified that [redacted] (Ofman (GRAIL) 3392). Dr. Ofman further testified that [redacted] (Ofman (GRAIL) Tr. 3351–3352). More to the point, the fact that GRAIL was on target for PMA approval does not mean that Illumina could not accelerate Galleri's PMA approval.

5287. In its August 2020 testing-the-waters meetings for a potential IPO, Grail identified "CCGA3 clinical results validating Galleri" as a "key milestone" expected in the first half of 2021. (PX4159 (Grail) at 009 (Email from J. Craighead, Grail, to Grail-BOD et al, Grail, Aug. 20, 2020)). Dr. Ofman testified that Grail achieved that milestone on schedule. (Ofman (Grail) Tr. 3442).

Response to Finding No. 5287:

Respondents have no specific response except to note that this proposed finding undermines Complaint Counsel's assertion that Galleri is not clinically validated to detect 50 cancer types. (CCFF at Appendix B). Respondents also note that the fact that GRAIL achieved certain milestones does not mean that Illumina could not accelerate Galleri's PMA approval.

5288. In its August 2020 testing-the-waters meetings for a potential IPO, Grail identified "PATHFINDER results" as a "key milestone" expected in the first half of 2021. (PX4159 (Grail) at 009 (Email from J. Craighead, Grail, to Grail-BOD et al, Grail, Aug. 20, 2020)). Dr. Ofman testified at trial that Grail achieved that milestone by presenting PATHFINDER results at ASCO. (Ofman (Grail) Tr. 3442). The interim results for PATHFINDER were presented at ASCO in the first half of 2021. (RX3041 at 001 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021)).

Response to Finding No. 5288:

Respondents have no specific response. Respondents also note that the fact that GRAIL achieved certain milestones does not mean that Illumina could not accelerate Galleri's PMA approval.

5289. In its August 2020 testing-the-waters meetings for a potential IPO, Grail identified "Channel & regional partner announcements" as a "key milestone" expected in 2020-2021. (PX4159 (Grail) at 009 (Email from J. Craighead, Grail, to Grail-BOD et al, Grail, Aug. 20, 2020)). Dr. Ofman testified at trial that Grail achieved that milestone on schedule. (Ofman (Grail) Tr. 3444).

Response to Finding No. 5289:

Respondents have no specific response except to note that the fact that GRAIL achieved certain milestones does not mean that Illumina could not accelerate Galleri's PMA approval.

5290. In its August 2020 testing-the-waters meetings for a potential IPO, Grail identified "Multi-cancer laboratory developed test (LDT) launch" as a "key milestone" expected in 2021. (PX4159 (Grail) at 009 (Email from J. Craighead, Grail, to Grail-BOD et al, Grail, Aug. 20, 2020)). Dr. Ofman testified at trial that Grail achieved that milestone on schedule. (Ofman (Grail) Tr. 3444).

Response to Finding No. 5290:

The proposed finding is not supported by the evidence cited. Dr. Ofman did not testify that GRAIL achieved this milestone on schedule. Dr. Ofman agreed that "Galleri LDT launched in June of this year." (Ofman (GRAIL) Tr. 3444). The evidence shows that [redacted] Respondents also note that the fact that GRAIL achieved certain milestones does not mean that Illumina could not accelerate Galleri's PMA approval.

(iii) Grail Has a Well-Established Regulatory Team

5291. [redacted] (Freidin (Grail) Tr. 3108).

Response to Finding No. 5291:

Respondents have no specific response.

5292. Dr. Ofman has worked on bringing technology to patients for about 25 years. (Ofman (Grail) Tr. 3449).

Response to Finding No. 5292:

Respondents have no specific response.

5293. There is a group of Grail employees already working to obtain a PMA for Galleri. (Bishop (Grail) Tr. 1345).

Response to Finding No. 5293:

The proposed finding is irrelevant, incomplete and misleading. Mr. Bishop testified that Illumina's experience would allow GRAIL to accomplish its goals faster. (Bishop (GRAIL) Tr. 1371–73.) Mr. Freidin testified that "Illumina has those resources to do those things and have demonstrated doing it in the past. . . Compared to what GRAIL's internal capabilities are and what our history is with the FDA today." (Freidin (GRAIL) Tr. 2979–80.) In fact, Illumina's regulatory team has extensive experience obtaining FDA clearances and approvals for diagnostic tests. Illumina has successfully obtained 510(k) clearance for a cystic fibrosis test and a PMA in cancer treatment selection for an extended RAS panel called Praxis. (Febbo (Illumina) Tr. 4338–43; 4113.) [redacted] (Febbo (Illumina) Tr. 4381–92.) Illumina also has experience bringing its next-generation sequencing products through FDA clearance. (Febbo (Illumina) Tr. 4338–39.) Illumina frequently interacts with the FDA, including through an educational program to teach the FDA about next-generation sequencing. (Febbo Tr. 4341.) Dr. Febbo testified that "both

through my personal interactions and discussions with the FDA and FDA leaders, I have compliments that we have helped them understand next-generation sequencing, and I've seen -- you know, I have seen evolution and improvements in their approach to next-generation sequencing." (Febbo Tr. 4342–43.) Illumina is therefore well-placed to help GRAIL traverse this admittedly challenging landscape.

Further, GRAIL's multi-cancer detection tests are a new approach to cancer screening, which present a number of novel and complex issues for FDA review. Because FDA has never cleared or approved a multi-cancer detection test, it is difficult to predict what information GRAIL will need to submit to obtain pre-market approval (PMA) from FDA for a proposed intended use, or if GRAIL will be able to obtain such approval on a timely basis or at all. (PFF ¶ 69.5.)

5294. [redacted] (PX4615 (Grail) at 064 [redacted] (*in camera*)).

Response to Finding No. 5294:

The proposed finding is incomplete and misleading. [redacted]

[redacted] Importantly, even if GRAIL had these capabilities it would not change the fact that Illumina's experience and capabilities could accelerate GRAIL's capabilities.

5295. [redacted] (PX4615 (Grail) at 068 [redacted] (*in camera*)).

Response to Finding No. 5295:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5294, which Respondents incorporate herein..

(iv) Grail Launched the Largest Clinical Study Program of Its Kind Without Illumina

5296. [redacted] (PX7092 (Ofman (Grail) Dep. at 266-67) (*in camera*)).

Response to Finding No. 5296:

The proposed finding is incomplete and misleading. Numerous GRAIL fact witnesses testified that the Transaction would eliminate risks associated with GRAIL's future needs for capital. (Bishop (GRAIL) Tr. 1372–73 ("There is always a very meaningful future financing risk. And being part of a stable, successful company such as Illumina will give real predictability to the ongoing investment we need to make in our people and our technology");

Freidin (GRAIL) Tr. 3000 ("So, you know, as part of our long-range plan and our financial process, you know, we've -- we have an estimate or an idea of how much more capital we would need to raise until the point that we are self-sufficient and we could fund ourselves. We knew that we would have to go out and to raise a significant amount of capital and more than -- and more than once over the, you know, next five or six years, and so by Illumina acquiring us, you know, we don't have to worry about that anymore. Illumina is a, you know, multibillion-dollar, profitable business that generates cash flows. And if they ever ran out of cash flows or we needed to spend more, they have successfully raised debt and done other offerings, so it -- in my view, it derisked our capital needs and accelerated our ability to put capital to work immediately and was another positive benefit of the acquisition.").)

5297. [redacted] (Ofman (Grail) Tr. 3323-24 (*in camera*)).

Response to Finding No. 5297:

The proposed finding is incomplete and misleading. The Transaction will help accelerate GRAIL's ability to scale Galleri and generate the data referenced in Dr. Ofman's testimony. (*See e.g.*, PFF ¶ 1141.)

5298. Dr. Ofman testified that the clinical study program Grail has launched as an independent company is "one of the largest I've seen." (Ofman (Grail) Tr. 3445).

Response to Finding No. 5298:

The proposed finding is incomplete and misleading to the extent it suggests that the fact that GRAIL has a large clinical study program means that GRAIL would not benefit from Illumina's expertise and experience in seeking regulatory approval and gaining market access. To the contrary, numerous witnesses testified that Illumina would help accelerate GRAIL's

regulatory approval and the generation of real world evidence necessary for obtaining public and private payor reimbursement. (*See e.g.*, PFF ¶¶ 1127-45; 1395; 1590.)

5299. Grail describes its clinical study program as "one of the largest clinical study programs ever conducted in genomic medicine." (RX0694 (Grail) at 002 (Email from J. Ofman, Grail, to M. Burns and K. Grossman, Grail, attaching "Grail Announces Validation of Its Multi-Cancer Early Detection Test Published in Annals of Oncology," Apr. 13, 2020)).

Response to Finding No. 5299:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses CCFF ¶ 5298, which are incorporated herein.

5300. Grail's Form S-1 states that Grail has "invested significant capital and resources in [its] foundational studies, which have collectively enrolled approximately 115,000 participants, to build what we believe are the largest linked datasets of genomic and clinical data in the cancer field." (PX4082 (Grail) at 008 (Email attaching Grail 2020 S-1/Amended, Sept. 2020); PX7069 (Bishop (Grail) IHT at 191-92 (testifying that Grail has built the largest linked datasets of genomic and clinical data in the cancer field)).

Response to Finding No. 5300:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses CCFF ¶ 5298, which are incorporated herein.

5301. As Grail explained in its S-1 filing, many companies do not have "the financial resources to invest in population-scale clinical trials and rigorous analytics to compete with [Grail's] products." (PX4082 (Grail) at 128 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 5301:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses CCFF ¶ 5298, which are incorporated herein. Respondents also note that the proposed finding undermines Complaint Counsel's assertion that there are MCED tests that will compete with Galleri in the near future. (CC Post-Trial Br. at 18-23.)

5302. Grail has directly enrolled more than ten times the number of patients that Illumina has directly enrolled in clinical studies. (Febbo (Illumina) Tr. 4449).

Response to Finding No. 5302:

The proposed finding is incomplete and misleading. Dr. Febbo testified that Illumina has "participated and supported studies of many more patients and the use of genomics in patients, such as our collaboration with the U.K. with Genomics England that involved a hundred thousand patients getting whole genome sequencing where we performed the whole genome sequencing on participants in that study. So for direct participation and sponsorship, I'd say in aggregate we are about 10,000, but as far as participating in studies that enrolled through collaboration many more, tens of thousands." (Febbo (Illumina) Tr. 4449).

5303. [redacted] (Bishop (Grail) Tr. 1481 (*in camera*)).

Response to Finding No. 5303:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses CCFF ¶ 5298, which are incorporated herein. Moreover, the fact that GRAIL has many achievements does not mean that Illumina will not be able to accelerate Galleri.

5304. Grail designed its clinical study program as an independent company. (Qadan (Illumina) Tr. 4261).

Response to Finding No. 5304:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses CCFF ¶ 5298, which are incorporated herein. Respondents also note that in response to Complaint Counsel's question "GRAIL has designed and launched its clinical study program as an independent company. Is that right?" Mr. Qadan replied, "Yes. That's as far as I know, yeah." (Qadan (Illumina) Tr. 4261).

5305. Grail launched its clinical study program as an independent company. (Qadan (Illumina) Tr. 4261).

Response to Finding No. 5305:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses CCFF ¶ 5298, which are incorporated herein. In response to Complaint Counsel's question "GRAIL has designed and launched its clinical study program as an independent company. Is that right?" Mr. Qadan replied, "Yes. That's as far as I know, yeah." (Qadan (Illumina) Tr. 4261).

5306. [redacted] (Ofman (Grail) Tr. 3307; PX7092 (Ofman (Grail) Dep. at 187) (*in camera*)).

Response to Finding No. 5306:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses CCFF ¶ 5298, which are incorporated herein. Respondents also note the fact that GRAIL has implemented clinical studies on its own does not mean that Illumina will not be able to accelerate Galleri.

5307. Grail conducted its CCGA study as an independent company. (Qadan (Illumina) Tr. 4261).

Response to Finding No. 5307:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses CCFF ¶ 5298, which are incorporated herein. The fact that GRAIL has implemented clinical studies on its own does not mean that Illumina will not be able to accelerate Galleri.

5308. [redacted] (PX5044 (Grail) at 027 (LRP Review, Aug. 20, 2020) (*in camera*)).

Response to Finding No. 5308:

Respondents have no specific response.

5309. Grail has directly enrolled over 130,000 participants in clinical studies. (PX0390 ClinicalTrials.gov Search Results for "Grail," Sept. 23, 2021).

Response to Finding No. 5309:

The proposed finding is vague and ambiguous with respect to the meaning of "directly enrolled." PX0390 lists the enrollment of GRAIL's clinical studies and various sponsors/collaborators for each study. (PX0390 ClinicalTrials.gov Search Results for "Grail," Sept. 23, 2021). Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 4), and therefore should not be entitled to rely on it to establish anything beyond the words on the page.

5310. The largest number of participants that Illumina has directly enrolled in a clinical study is three thousand participants. (Febbo (Illumina) Tr. 4450; PX0391 (ClinicalTrials.gov Search Results for "Illumina," Sept. 23, 2021)).

Response to Finding No. 5310:

The proposed finding is vague and ambiguous with respect to the meaning of "directly enrolled." PX0391 lists the enrollment of nineteen of Illumina's clinical studies and various sponsors/collaborators for each study. PX0391 (ClinicalTrials.gov Search Results for "Illumina," Sept. 23, 2021)). Further, the proposed finding is incomplete and misleading. Dr. Febbo testified that the largest study that Illumina has conducted in "a prospective manner" is the Denali study. (Febbo (Illumina) Tr. 4449). Dr. Febbo further testified that Illumina has "participated and supported studies of many more patients and the use of genomics in patients, such as our collaboration with the U.K. with Genomics England that involved a hundred thousand patients getting whole genome sequencing where we performed the whole genome sequencing on participants in that study. So for direct participation and sponsorship, I'd say in aggregate we are about 10,000, but as far as participating in studies that enrolled through collaboration many more, tens of thousands." (Febbo (Illumina) Tr. 4449).Complaint Counsel

did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 4), and therefore should not be entitled to rely on it to establish anything beyond the words on the page.

5311. Grail has directly enrolled more than ten times the number of participants that Illumina has directly enrolled in clinical studies. (Febbo (Illumina) Tr. 4449).

Response to Finding No. 5311:

The proposed finding is vague and ambiguous for the reasons explained in Respondents' responses to CCFF ¶ 5310, which Respondents incorporate herein.

5312. Grail has directly enrolled more than 30 times the number of participants in a single clinical study that Illumina has directly enrolled in a single clinical study. (Febbo (Illumina) Tr. 4450; PX0390 ClinicalTrials.gov Search Results for "Grail," Sept. 23, 2021; PX0391 (ClinicalTrials.gov Search Results for "Illumina," Sept. 23, 2021)).

Response to Finding No. 5312:

The proposed finding is misleading and not supported by the cited evidence. Dr. Febbo testified that the largest study that Illumina has conducted in "a prospective manner" is the Denali study. (Febbo (Illumina) Tr. 4449). Dr. Febbo testified that Illumina has "participated and supported studies of many more patients and the use of genomics in patients, such as our collaboration with the U.K. with Genomics England that involved a hundred thousand patients getting whole genome sequencing where we performed the whole genome sequencing on participants in that study. So for direct participation and sponsorship, I'd say in aggregate we are about 10,000, but as far as participating in studies that enrolled through collaboration many more, tens of thousands." (Febbo (Illumina) Tr. 4449). In addition, the proposed finding is vague and ambiguous with respect to the meaning of "directly enrolled." Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at

trial in this case, (CC Exhibit Index at 4), and therefore should not be entitled to rely on it to establish anything beyond the words on the page.

5313. Illumina's largest prospective clinical study relates to its Denali program. (Febbo (Illumina) Tr. 4449-50). Illumina has directly enrolled two to three thousand participants in its Denali-related study. (Febbo (Illumina) Tr. 4450).

Response to Finding No. 5313:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶ 5310, which Respondents incorporate herein.

5314. Grail's proven ability to partner with other institutions shows they have the ability to generate clinical utility data. (Qadan (Illumina) Tr. 4261-63).

Response to Finding No. 5314:

The proposed finding is contradicted by the cited testimony. Mr. Qadan testified that the studies GRAIL has conducted are for test performance, not clinical utility. (Qadan (Illumina) Tr. 4261-63); *see also* Resp.'s PFF ¶196.3 (providing definition of clinical utility).

5315. Grail has completed one clinical study for the Galleri test and has three more clinical studies ongoing for Galleri. (PX7069 (Bishop (Grail) IHT at 79); PX4082 (Grail) at 124-27 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, Morgan Stanely, attaching Grail 2020 S-1/Amended, Sept. 2020); PX0086 (Press Release: GRAIL Presents Interventional PATHFINDER Study Data at 2021 ASCO Annual Meeting and Introduces Galleri, a Groundbreaking Multi-Cancer Early Detection Blood Test, June 4, 2021)).

Response to Finding No. 5315:

The proposed finding is incorrect. GRAIL has four clinical studies ongoing for Galleri. *See* CCFF ¶ 5316.

5316. Grail has the STRIVE, SUMMIT, PATHFINDER, and U.K. NHS studies ongoing at various stages. (Ofman (Grail) Tr. 3293-94).

Response to Finding No. 5316:

Respondents have no specific response.

5317. Dr. Ofman explained that Grail undertook the SUMMIT and STRIVE studies because, after the CCGA study, "we needed to also study our assay in what we call the intended use population." (Ofman (Grail) Tr. 3294-95).

Response to Finding No. 5317:

The proposed finding is incomplete and misleading. Dr. Ofman testified that GRAIL wanted to understand the performance of the test in two important populations—screening-eligible women undergoing mammograms and smokers. (Ofman (GRAIL) Tr. 3295).

5318. STRIVE and SUMMIT are "two very large cohort studies" that are "noninterventional." The two cohorts are women getting mammograms and men and women getting low-dose CT for high-risk lung cancer screening. (Ofman (Grail) Tr. 3293).

Response to Finding No. 5318:

Respondents have no specific response.

5319. [redacted] (PX0086 at 002 ("GRAIL Presents Interventional PATHFINDER Study Data at 2021 ASCO Annual Meeting and Introduces Galleri, a Groundbreaking Multi-Cancer Early Detection Blood Test," June 4, 2021); PX6092 (Rothman Rebuttal Report) ¶ 66 (*in camera*)).

Response to Finding No. 5319:

The proposed finding is incomplete and misleading. The cited exhibit, PX0086, states that GRAIL plans to "establish a real-world evidence study, REFLECTION, to understand the experience and clinical outcomes of 35,000 individuals in the U.S. who are prescribed the Galleri test from a healthcare provider." (PX0086 at 002 ("GRAIL Presents Interventional PATHFINDER Study Data at 2021 ASCO Annual Meeting and Introduces Galleri, a Groundbreaking Multi-Cancer Early Detection Blood Test," June 4, 2021). Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 2), and therefore should not be entitled to rely on it to establish anything beyond the words on the page.

5320. Grail designed and enrolled patients in its Strive study. (Qadan (Illumina) Tr. 4262).

Response to Finding No. 5320:

The proposed finding is incomplete and misleading. Mr. Qadan testified that Strive "was a GRAIL study." (Qadan (Illumina) Tr. 4262).

5321. [redacted] (Febbo (Illumina) Tr. 4450; PX0390 (ClinicalTrials.gov Search Results for "Grail," Sept. 23, 2021); PX4430 (Grail) at 021 [redacted] (*in camera*)).

Response to Finding No. 5321:

The proposed finding is vague and ambiguous with respect to the meaning of "directly enrolled." The cited slide in PX4430 merely notes that [redacted] PX4430 (Grail) at 021 (Email from J. Ofman, Grail, to R. Klausner, Grail, June 6, 2020). Complaint Counsel did not present PX0390 or PX4430 to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 4, 48), and therefore should not be entitled to rely on it to establish anything beyond the words on the page. Dr. Febbo only testified that it was his "understanding" that GRAIL has enrolled just under 100,000 participants in its STRIVE study". (Febbo (Illumina) Tr. 4450.)

5322. [redacted] (PX6093 (Navathe Rebuttal Report) at Table 2 (*in camera*); RX3134 (National Institutes of Health, U.S. National Library of Medicine, The STRIVE Study: Development of a Blood Test for Early Detection of Multiple Cancer Types, https://clinicaltrials.gov/ct2/show/NCT03085888) (last visited Jan. 3, 2022)).

Response to Finding No. 5322:

The proposed finding is incomplete and misleading to the extent that it suggests that GRAIL has sufficient market access expertise and experience to bring Galleri to market as quickly as possible. Numerous fact witnesses have testified to Illumina's expertise and

experience in market access, leading to an estimated one-year acceleration of Galleri coming to market. (PFF ¶¶ 1127–35.)

5323. Grail partnered with the Mayo Institute in connection with the Strive study. (Qadan (Illumina) Tr. 4262).

Response to Finding No. 5323:

The proposed finding is incomplete and misleading to the extent that it suggests that GRAIL has sufficient market access expertise and experience to bring Galleri to market as quickly as possible. Numerous fact witnesses have testified to Illumina's expertise and experience in market access, leading to an estimated one-year acceleration of Galleri coming to market. (PFF ¶¶ 1127–35.)

5324. Grail partnered with the Cleveland Clinical in connection with the Strive study. (Qadan (Illumina) Tr. 4262-63).

Response to Finding No. 5324:

The proposed finding is incomplete and misleading to the extent that it suggests that GRAIL has sufficient market access expertise and experience to bring Galleri to market as quickly as possible. Numerous fact witnesses have testified to Illumina's expertise and experience in market access, leading to an estimated one-year acceleration of Galleri coming to market. (PFF ¶¶ 1127–35.)

5325. Grail partnered with the Henry Ford Health System in connection with the Strive study. (Qadan (Illumina) Tr. 4262-63).

Response to Finding No. 5325:

The proposed finding is incomplete and misleading to the extent that it suggests that GRAIL has sufficient market access expertise and experience to bring Galleri to market as quickly as possible. Numerous fact witnesses have testified to Illumina's expertise and

experience in market access, leading to an estimated one-year acceleration of Galleri coming to market. (PFF ¶¶ 1127–35.)

5326. Grail partnered with the Dana-Farber Cancer Institute in connection with the Strive study. (Qadan (Illumina) Tr. 4262-63).

Response to Finding No. 5326:

The proposed finding is incomplete and misleading to the extent that it suggests that GRAIL has sufficient market access expertise and experience to bring Galleri to market as quickly as possible. Numerous fact witnesses have testified to Illumina's expertise and experience in market access, leading to an estimated one-year acceleration of Galleri coming to market. (PFF ¶¶ 1127–35.)

5327. Grail designed and enrolled patients in its Pathfinder study. (Qadan (Illumina) Tr. 4262).

Response to Finding No. 5327:

The proposed finding is not supported by the cited evidence. Mr. Qadan testified that he did not know the details of the Pathfinder study and that "ass far as I can say, Pathfinder is a GRAIL study." (Qadan (Illumina) Tr. 4261–62).

5328. PATHFINDER is "an interventional study, which is what we call a real-world clinical practice study" of 6,600 screening eligible population with no suspicion of cancer. (Ofman (Grail) Tr. 3293).

Response to Finding No. 5328:

Respondents have no specific response.

5329. According to Dr. Ofman, Grail felt that PATHFINDER, "which was an actual return of results study, interventional, in actual clinical practice, would be a more powerful way to add to our clinical validation than [STRIVE and SUMMIT]." (Ofman (Grail) Tr. 3296).

Response to Finding No. 5329:

The proposed finding is incomplete and misleading. STRIVE and SUMMIT are cohort studies that enrolled screening-eligible women undergoing mammograms and men and women

smokers. (Ofman (Grail) Tr. 3295.) Dr. Ofman testified that the results of PATHFINDER "would be a more powerful way to add to our clinical validation than those cohort studies." (Ofman (Grail) Tr. 3296.)

5330. As part of PATHFINDER, patients received results from their test and were tracked for one year. (Ofman (Grail) Tr. 3293).

Response to Finding No. 5330:

Respondents have no specific response.

5331. [redacted] (Ofman (Grail) Tr. 3330 (*in camera*)).

Response to Finding No. 5331:

The proposed response is incomplete and misleading. Dr. Ofman testified that [redacted] (Ofman (Grail) Tr. 3330–31.)

5332. [redacted] (Ofman (Grail) Tr. 3330 (*in camera*)).

Response to Finding No. 5332:

The response is incomplete and misleading. [redacted] (Ofman (Grail) Tr. 3332.)

5333. [redacted] (Ofman (Grail) Tr. 3293-94; PX7092 (Ofman (Grail) Dep. at 123); RX3523 (NHS) at 002 ("NHS to pilot potentially revolutionary blood test that detects more than 50 cancers," Nov. 27, 2020); PX6092 (Rothman Rebuttal Report) ¶ 66 (*in camera*))).

Response to Finding No. 5333:

The proposed finding is incomplete and misleading to the extent it suggests that GRAIL would not benefit from Illumina's expertise and experience in seeking regulatory approval and gaining market access; Respondents incorporate their responses to CCFF ¶ 5298 herein. Respondents further note that the citation to Dr. Rothman's rebuttal report is improper because Dr. Rothman admitted that he had no expertise in market access, including seeking FDA approval and payor coverage. (PFF ¶ 1134.4.)

5334. [redacted] (Ofman (Grail) Tr. 3293-94; PX7092 (Ofman (Grail) Dep. at 123); RX3523 at 2 ("NHS to pilot potentially revolutionary blood test that detects more than 50 cancers," Nov. 27, 2020);PX6092 (Rothman Rebuttal Report) ¶ 66 (*in camera*)).

Response to Finding No. 5334:

The proposed finding is incomplete and misleading to the extent it suggests that GRAIL would not benefit from Illumina's expertise and experience in seeking regulatory approval and gaining market access; Respondents incorporate their responses to CCFF ¶ 5298 herein. Respondents further note that the citation to Dr. Rothman's rebuttal report is improper because Dr. Rothman admitted that he had no expertise in market access, including seeking FDA approval and payor coverage. (PFF ¶ 1134.4.)

5335. At trial, Dr. Ofman summarized the U.K. study protocol: "It's 140,000 screening-eligible individuals randomized to getting Galleri or not getting Galleri along with standard of care screening, and we'll be following patients for three consecutive years." (Ofman (Grail) Tr. 3293-94).

Response to Finding No. 5335:

The proposed finding is incomplete and misleading to the extent it suggests that GRAIL would not benefit from Illumina's expertise and experience in seeking regulatory approval and gaining market access; Respondents incorporate their responses to CCFF ¶ 5298 herein.

5336. The U.K. study is the largest trial for any cancer screening test ever. (Freidin (Grail) Tr. 3162).

Response to Finding No. 5336:

The proposed finding is incomplete and misleading to the extent it suggests that GRAIL would not benefit from Illumina's expertise and experience in seeking regulatory approval and gaining market access; Respondents incorporate their responses to CCFF ¶ 5298 herein.

5337. Grail signed the agreement for the U.K.-based trial in December 2020. (Freidin (Grail) Tr. 3161).

Response to Finding No. 5337:

The proposed finding is incomplete and misleading to the extent it suggests that GRAIL would not benefit from Illumina's expertise and experience in seeking regulatory approval and gaining market access; Respondents incorporate their responses to CCFF ¶ 5298 herein.

5338. Grail negotiated its agreement with NHS before Illumina acquired Grail. (Freidin (Grail) Tr. 3161).

Response to Finding No. 5338:

The proposed finding is incomplete and misleading to the extent it suggests that GRAIL would not benefit from Illumina's expertise and experience in seeking regulatory approval and gaining market access; Respondents incorporate their responses to CCFF ¶ 5298 herein.

5339. Grail's international operations include 10-20 people in the United Kingdom to facilitate the NHS study. (Freidin (Grail) Tr. 3008).

Response to Finding No. 5339:

The proposed finding is incomplete and misleading to the extent it suggests that GRAIL would not benefit from Illumina's expertise and experience in seeking regulatory approval and gaining market access; Respondents incorporate their responses to CCFF ¶ 5298 herein. Illumina has a large and experienced team that will bolster GRAIL's resources. (Qadan (Illumina) Tr. 4173–74.)

5340. Grail is currently enrolling patients in its real-world evidence study in the United Kingdom. (Qadan (Illumina) Tr. 4263).

Response to Finding No. 5340:

The proposed finding is incomplete and misleading to the extent it suggests that GRAIL would not benefit from Illumina's expertise and experience in seeking regulatory approval and gaining market access; Respondents incorporate their responses to CCFF ¶ 5298 herein. Mr. Qadan only testified that he "heard" about GRAIL's study in the United Kingdom. (Qadan (Illumina) Tr. 4263).

5341. The U.K. NHS study launched in September 2021 and is the "largest, real-world, what we call a pragmatic, randomized clinical trial" ever in genomics. (Ofman (Grail) Tr. 3293-94; Freidin (Grail) Tr. 3008, 3161).

Response to Finding No. 5341:

The proposed finding is incomplete and misleading to the extent it suggests that GRAIL would not benefit from Illumina's expertise and experience in seeking regulatory approval and gaining market access; Respondents incorporate their responses to CCFF ¶ 5298 herein.

(v) Grail Has Met Regularly with the FDA

5342. [redacted] (PX4615 (Grail) at 070 [redacted] (*in camera*)).

Response to Finding No. 5342:

Respondents have no specific response, except to note that Complaint Counsel failed to establish any foundation this document, and should not be entitled to rely on it to establish anything beyond the words on the page. (Ofman (GRAIL) Tr. 3428.)

5343. Grail's Form S-1 explains the status of Grail's conversations with the FDA as follows:

> We are engaged in ongoing discussions with FDA regarding the data that will be needed to support a successful PMA for a multi-cancer test for our planned indications, including whether we would need to provide additional analyses

and information beyond that which we are currently planning to produce based on the designs of our current and planned clinical studies.

(PX4082 (Grail) at 047 (Email from J. Ofman, Grail, to R. Klausner, Grail, June 6, 2020 (*in camera*)).

Response to Finding No. 5343:

Respondents have no specific response.

5344. [redacted]

Response to Finding No. 5344:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

5345. [redacted]

Response to Finding No. 5345:

Respondents have no specific response except to note that Dr. Ofman testified [redacted] (Ofman (GRAIL) Tr. 3395).The fact that GRAIL successfully made this outreach is not relevant to the question of whether Illumina can accelerate Galleri's FDA approval and does not mean that GRAIL would not benefit from Illumina's expertise and experience in seeking regulatory approval and gaining market access; Respondents incorporate their responses to CCFF ¶ 5298 herein.

5346. [redacted]

Response to Finding No. 5346:

Respondents have no specific response.

5347. [redacted] (PX4323 (Grail) at 001, Email from Deepshikha Bhandari, Grail, to Grail executive team, Dec. 28, 2020) (*in camera*)).

Response to Finding No. 5347:

Respondents have no specific response except to note that Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 44), or in any deposition, and should not be entitled to rely on it to establish anything beyond the words on the page. The fact that [redacted]

(vi) [redacted]

5348. [redacted] (Bishop (Grail) Tr. 1466-68 (*in camera*); PX4489 (Grail) at 011 (Email attaching Grail BoD 2021 Budget, Dec. 2020) (*in camera*)).

Response to Finding No. 5348:

Respondents have no specific response.

5349. [redacted] (Bishop (Grail) Tr. 1468 (*in camera*); PX4489

(Grail) at 011 (Email from S. Green, Grail, to Grail Board of Directors, attaching Grail BoD 2021 Budget, December 9, 2020, (*in camera*)).

Response to Finding No. 5349:

The proposed finding is incomplete and misleading. This objective is described in PX4489 as merely to [redacted]. PX4489 (Grail) at 012 (Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020). At trial, Dr. Ofman testified that [redacted] (Ofman (GRAIL) 3392). Dr. Ofman further testified that [redacted] (Ofman (GRAIL) Tr. 3351-3352). The fact that GRAIL stated that it achieved its internal goals is not relevant to the question of whether Illumina can accelerate Galleri's FDA approval and does not mean that GRAIL would not benefit from Illumina's expertise and experience in seeking regulatory approval and gaining market access; Respondents incorporate their responses to CCFF ¶ 5298 herein.

5350. [redacted]
(PX4213 (Grail) at 009 (Email and Presentation from A. Freidin, Grail, to C. Friedman, M. Ho, B. Rastetter, Grail, Dec. 3, 2020)).

Response to Finding No. 5350:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5349, which is incorporate herein. Respondents also note that PX4213 states [redacted] (PX4213 (Grail) at 009 (Email and Presentation from A. Freidin, Grail, to C. Friedman, M. Ho, B. Rastetter, Grail, Dec. 3, 2020)). The document does not say anything about [redacted] The fact that GRAIL stated that it [redacted] is not relevant to the question of whether Illumina can accelerate Galleri's FDA approval and does not mean that GRAIL would not benefit from Illumina's expertise and experience in seeking regulatory approval and gaining market access; Respondents incorporate their responses to CCFF ¶ 5298 herein.

(vii) Grail Successfully Achieved Breakthrough Device Designation from the FDA for Galleri and Received FDA Approval of an Investigational Device Exemption Application Related to Galleri

5351. [redacted] (Rabinowitz (Natera) Tr. 395 (*in camera*)).

Response to Finding No. 5351:

The proposed finding relies on improper lay opinion testimony. Complaint Counsel has not established that Dr. Rabinowitz is an expert on FDA or regulatory issues. [redacted]

5352. [redacted] (Chudova (Guardant) Tr. 1206) (*in camera*).

Response to Finding No. 5352:

The proposed finding is inaccurate, incomplete, misleading and relies on improper lay opinion testimony. The FDA denied [redacted]

5353. "When a technology is needing FDA approval or a company is working with the FDA, the FDA can grant breakthrough designation which says that the technology is important key technology which can substantially impact healthcare in the United States." (Rabinowitz (Natera) Tr. 301).

Response to Finding No. 5353:

The proposed finding relies on improper lay opinion testimony. Complaint Counsel has not established that Dr. Rabinowitz is an expert on FDA or regulatory issues. [redacted]

5354. Breakthrough device status "will accelerate the processes of approval for that technology." (Rabinowitz (Natera) Tr. 301).

Response to Finding No. 5354:

The proposed finding relies on improper lay opinion testimony. Complaint Counsel has not established that Dr. Rabinowitz is an expert on FDA or regulatory issues. [redacted]

5355. [redacted] (Nolan (Freenome) Tr. 2848 (*in camera*)).

Response to Finding No. 5355:

The proposed finding relies on improper lay opinion testimony that should be given no weight. Respondents note that [redacted] **(**CC Post-Trial Br. at 18-23.)

5356. An investigational device designation provides an exemption that allows a device without full FDA approval be used in certain Medicare programs. (PX7139 (Navathe Trial Dep. at 53)). Data generated through an investigational device study can be used in Medicare coverage decisions without requiring a USPSTF A or B recommendation. (PX7139 (Navathe Trial Dep. at 53)).

Response to Finding No. 5356:

The proposed finding is incomplete, misleading and relies on improper expert testimony which should be given no weight. [redacted]

[redacted]. Dr. Navathe is not an expert on FDA evaluation of MCED tests, including Galleri. (PX7139 (Navathe Trial Dep. at 97–99.) Dr. Navathe does not have any experience in obtaining FDA approval for any product, including building and supervising a team seeking FDA approval or analyzing a company's capability to get FDA approval. (PX7139 (Navathe Trial Dep. at 101.)

5357. Grail independently obtained an investigational device exemption from the FDA for Galleri. (Febbo (Illumina) Tr. 4451).

Response to Finding No. 5357:

The proposed finding is incomplete and misleading. GRAIL received an investigational device exemption ("IDE") from the FDA for studies like PATHFINDER. (Ofman (GRAIL) Tr. 3306.) [redacted] (Ofman (GRAIL) Tr. 3306.) Galleri received an IDE in 2018—four years before Galleri became commercially available as an LDT. [(Ofman (GRAIL) Tr. 3305–06.)]. The fact that Galleri received an IDE does not guarantee that Galleri will ultimately receive FDA approval. (Ofman (GRAIL) Tr. 3305–06.) [redacted]

(viii) [redacted]

5358. [redacted] (Ofman (Grail) Tr. 3383 (*in camera*)).

Response to Finding No. 5358:

The proposed finding is vague and ambiguous as to how Grail has been "growing rapidly" and it is not immediately clear how the finding is relevant to this case.

5359. [redacted] (Bishop (Grail) Tr. 1466 (*in camera*); PX4489 (Grail) at 001 (Email attaching Grail BoD 2021 Budget, Dec. 2020) (*in camera*)).

Response to Finding No. 5359:

Respondents have no specific response.

5360. [redacted] (Bishop (Grail) Tr. 1469-70 (*in camera*); PX4489 (Grail) at 017 (Email attaching Grail BoD 2021 Budget, Dec. 2020) (*in camera*)).

Response to Finding No. 5360:

The proposed finding is incomplete and misleading without further context. Mr. Bishop testified [redacted] (Bishop (Grail) Tr. 1470.)

5361. [redacted] (Bishop (Grail) Tr. 1470 (*in camera*); PX4489 (Grail) at 017 (Email attaching Grail BoD 2021 Budget, Dec. 2020) (*in camera*)).

Response to Finding No. 5361:

Respondents have no specific response.

5362. [redacted] (Bishop (Grail) Tr. 1471 (*in camera*); PX4489 (Grail) at 017 (Email from S. Green, Grail, to Grail Board of Directors, attaching Grail BoD 2021 Budget, December 9, 2020) (*in camera*)).

Response to Finding No. 5362:

Respondents have no specific response.

5363. [redacted] (Ofman (Grail) Tr. 3398 (*in camera*)).

Response to Finding No. 5363:

The proposed finding is incomplete and misleading. [redacted] **(Ofman (GRAIL) Tr. 3397.)** In contrast, "Illumina has a large regulatory team that's experienced in FDA submissions. It has processes, templates, infrastructure for doing and writing and submitting […] PMA applications." (Aravanis (Illumina) Tr. 1944 –45.)

(3) The Claimed FDA Acceleration Efficiency Is Not Verifiable Because It Is Not Quantifiable

5364. Respondents' expert, Dr. Carlton, testified that he did not independently quantify how much Illumina can accelerate the process for Galleri to achieve FDA approval. (RX6000 (Carlton Trial Dep. at 96-97); PX7134 (Carlton Dep. at 191)).

Response to Finding No. 5364:

The proposed finding is incomplete and misleading. Dr. Carlton testified that while he had not independently quantified the acceleration efficiency, "he was relying on others for that" and it was "plausible from an economic point of view". (RX6000 (Carlton Trial Dep. at 96–97.)) Dr. Carlton also testified that while he relied on other witnesses and documents in forming his opinions, he came to his own independent conclusion based on the evidence that the reunion of Illumina and GRAIL will result in substantial efficiencies. (RX6000 (Carlton Trial Dep. at 96–97.)) Further, although it is difficult to quantify the extent to which the Transaction will accelerate the adoption of Galleri, Illumina has estimated that a reunited Illumina and GRAIL will accelerate Galleri's adoption by at least one year. (Febbo (Illumina) Tr. 4360 ("We determined that, in aggregate, these efficiencies will accelerate the adoption and availability of the Galleri test by approximately at least one year."); PX7073 (Aravanis (Illumina) IHT at 77)

[redacted]

[redacted]

[redacted]; PX6066 (Illumina) at 8 ("Illumina expects that, as a result of the efficiencies summarized above, after the Proposed Transaction, it will be able to accelerate Galleri reaching patients at scale by at least one year."); PX2613 (Illumina) (applying an acceleration of one year to calculate lives saved).)

5365. Dr. Carlton relies on Illumina's deal model as a primary input into his calculation of the future quantity demanded of Galleri. (PX7134 (Carlton Dep. at 173-174)).

Response to Finding No. 5365:

The proposed finding is incomplete and misleading. Dr. Carlton testified that he used the stand-alone deal model in order to estimate what will happen absent the Transaction and accelerates that by one year. (RX6000 (Carlton Trial Dep. at 73).) Dr. Carlton then uses the model to estimate how many additional tests will be sold. (RX6000 (Carlton Trial Dep. at 73).) He then uses the estimates in the literature about how Galleri testing will save lives to estimate the range of lives that will be saved by a one year acceleration. (RX6000 (Carlton Trial Dep. at 74).) This range is 7,429 to 10,441. (RX6000 (Carlton Trial Dep. at 73).) He then uses a conservative value of live saved of $5 million per life to calculate a low end value of the acceleration efficiency of $37 billion, assuming 7,429 lives saved and a higher end estimate of $100 billion assuming 10,441 lives saved. (RX6000 (Carlton Trial Dep. at 74).) Dr. Carlton confirmed the general size of the efficiencies using an alternative value of life years saved calculation. (RX6000 (Carlton Trial Dep. at 76).) The estimate of how many life years would be saved by a one year acceleration was confirmed by a conversation and follow up email with Dr. Kansal, Director, Health Economics and Outcomes Research, GRAIL. (RX6000 (Carlton Trial Dep at 115 –16).)

Dr. Carlton's calculations are conservative in a number of ways, including: *First*, these estimates could be significantly higher if the value of a life saved was greater than $5 million or the number of lives saves was greater than 10,441. (RX6000 (Carlton Trial Dep. at 74).) *Second*, these estimates do not include the value of acceleration internationally, which would double the value of the lives saved. (RX6000 (Carlton Trial Dep. at 75).) *Third*, the estimates do not include any improvements to Galleri's performance from generating more data more quickly. (RX6000 (Carlton Trial Dep. at 78).) *Fourth*, the calculations assume annual testing which underestimates the value of an acceleration in testing. (RX6000 (Carlton Trial Dep. at 78 –79.)

While it is true that Dr. Carlton uses the deal model as one input into his lives saved analysis, Complaint Counsel has provided no basis for doubting the assumptions in the deal model regarding the future quantity demanded of Galleri. Respondents further note that none of Complaint Counsel's criticisms changes the fundamental conclusion: thousands of lives will be saved by the Transaction and the value of those lives is in the billions of dollars. (PFF ¶ 1126.5.) In fact, Dr. Carlton testified that he had no doubt that accelerating the adoption of the Galleri test will save lives. (RX6000 (Carlton Trial Dep. at 198).)

5366. Dr. Carlton did not attempt to independently assess the accuracy of Illumina's forecasts contained in its deal model. (PX7134 (Carlton Dep. at 174)).

Response to Finding No. 5366:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5365, which Respondents incorporate herein.

5367. Dr. Carlton relies on the Hubbell paper as a critical input into his acceleration analysis and lives saved analysis. (PX7134 (Carlton Dep. at 211)).

Response to Finding No. 5367:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5365, which is incorporated herein. Respondents further note that Dr. Carlton testified that "[t]he Hubble [sic] paper estimates the ability to detect cancer using the Galleri test. It's the only published paper I'm aware of that does so, and it's peer-reviewed, and as I said, it's the only existing estimate of the ability of the Galleri test to be successful in saving lives and by detecting cancer. In that paper, there's a range of outcomes, and I used the range that was suggested." ((RX6000 (Carlton Trial Dep. at 197).) Dr. Carlton discussed the Hubbell paper with Dr. Hubbell and confirmed that the analysis did not result on a training data set that biases the results. (RX6000 (Carlton Trial Dep. at 77).) Dr. Carlton said that he had no reason to doubt the reliability of the Hubbell paper and that changing the assumptions to account for criticisms raised by Complaint Counsel would result in a larger number of lives saved rather than fewer. (RX6000 (Carlton Trial Dep. at 197 –98).)

5368. Dr. Carlton did not conduct an independent analysis of the Hubbell paper. (PX7134 (Carlton Dep. at 211)).

Response to Finding No. 5368:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5365 and 5366, which Respondents incorporate herein. Respondents also note that Dr. Carlton testified that he discussed the Hubbell paper with Dr. Hubbell, and confirmed multiple aspects of the paper with him. (PFF ¶ 1126.3; RX6000 (Carlton Trial Dep. 78–79).) He also testified that he had no reason to doubt the reliability of the Hubbell paper. (RX6000 (Carlton Trial Dep. at 197–98).)

5369. [redacted] (*see* PX7134 (Carlton Dep. at 214-221) (*in camera*) [redacted] PX7134 (Carlton Dep. at 214-221) (*in camera*)).

Response to Finding No. 5369:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5365 and 5366, which Respondents incorporate herein. Dr. Carlton discussed the Hubbell paper with Dr. Hubbell, and confirmed multiple aspects of the paper with him. (PFF ¶ 1126.3; RX6000 (Carlton Trial Dep. 78–79).) Dr. Carlton testified that he had no reason to doubt the reliability of the Hubbell paper and that changing the assumptions to account for criticisms raised by Complaint Counsel would result in a larger number of lives saved rather than fewer. (RX6000 (Carlton Trial Dep. at 197–98).)

5370. [redacted] (PX7134 (Carlton Dep. at 221-232) (*in camera*)).

Response to Finding No. 5370:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5365 and 5366, which Respondents incorporate herein.

5371. [redacted] (RX3864 (Carlton Rebuttal Report) ¶ 121, n. 294 (*in camera*)).

Response to Finding No. 5371:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5365 and 5366, which Respondents incorporate herein.

5372. [redacted] (PX7134 (Carlton Dep. at 227) (*in camera*)).

Response to Finding No. 5372:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5365 and 5366, which Respondents incorporate herein. Dr. Carlton testified that [redacted]

[redacted] (PX7134 (Carlton Dep. at 227.) Dr. Carlton testified that he had no reason to doubt the reliability of the information he relied on from Dr. Kansal. (RX6000 (Carlton Trial Dep. at 197).)

5373. [redacted] (PX7134 (Carlton Dep. at 227-228) (*in camera*)).

Response to Finding No. 5373:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5365, 5366 and 5372, which Respondents incorporate herein.

5374. [redacted] (PX7134 (Carlton Dep. at 227-228) (*in camera*)).

Response to Finding No. 5374:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5365, 5366 and 5372, which Respondents incorporate herein. Dr. Carlton testified that he had "an understanding. In other words, he has a population distribution in his article, and he's using that population distribution to take account of when he's detecting things and then using that to estimate the life-years saved." (RX6000 (Carlton Trial Dep. at 117).)

5375. [redacted] (PX6093 (Navathe Rebuttal Report) ¶¶ 99-103 (*in camera*)).

Response to Finding No. 5375:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5365, 5366 and 5372, which Respondents incorporate herein. Dr. Navathe's opinion is also incomplete because it was arrived at prior to trial when Respondents put in their affirmative evidence of acceleration.

5376. [redacted] (PX6093 (Navathe Rebuttal Report) ¶¶ 99-103 (*in camera*)).

Response to Finding No. 5376:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5365, 5366 and 5372, which Respondents incorporate herein. Dr. Carlton testified that the lives-saved years estimate demonstrates that the benefit of acceleration "is a tremendous benefit to the United States as well as to the world" even if it does not result in a "particular, precise number". (RX6000 (Carlton Trial Dep. at 76).) Dr. Navathe's opinion is also incomplete because it was arrived at prior to trial when Respondents put in their affirmative evidence of acceleration.

5377. [redacted] (PX6093 (Navathe Rebuttal Report) ¶¶ 99-103 (*in camera*)).

Response to Finding No. 5377:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5365, 5366, 5372 and 5376, which Respondents incorporate herein. Further, as Dr. Carlton explained, that he analyzed the value of a statistical life as opposed to the value of life years gained does not render the analysis unverifiable. "[T]he point is no matter how you do this, it's billions of dollars that are benefiting U.S. society." (RX6000 (Carlton Trial Dep. at 75).)

5378. [redacted] (PX6093 (Navathe Rebuttal Report) ¶¶ 99-103 (*in camera*)).

Response to Finding No. 5378:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5365, 5366, 5372 and 5376, which Respondents incorporate herein.

(4) The Claimed FDA Acceleration Efficiency Is Not Merger Specific

5379. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 41) (*in camera*) (citing PX0338 at 030 n.13 (*Horizontal Merger Guidelines* § 10, Aug. 19, 2010)).

Response to Finding No. 5379:

The proposed finding relies on improper expert witness testimony. *First*, Dr. Rothman's opinion regarding the Horizontal Merger Guideline's standard for substantiating efficiencies "invades the province of the court" by purporting to tell the factfinder "what result to reach" and to "define legal terms" or rules, *Berry v. City of Detroit*, 25 F.3d 1342, 1353–54 (6th Cir. 1994), or to "apply[] those legal rules to facts". *Neal v. Second Sole of Youngstown*, 2018 WL 1740140, at *4 (N.D. Ohio Apr. 11, 2018); *See In re Initial Pub. Offering Sec. Litig.*, 174 F. Supp. 2d 61, 64 (S.D.N.Y. 2001) ("[E]very circuit has explicitly held that experts may not invade the court's province by testifying on issues of law.").

Second, Dr. Rothman's application of the guidelines are irrelevant because the Horizontal Merger Guidelines "are not binding" on any court, "are not intended to describe how the Agencies will conduct the litigation of cases," and "neither dictate nor exhaust the range of evidence the Agencies may introduce in litigation." *See also FTC v. Thomas Jefferson Univ.*, 505 F. Supp. 3d 522, 539 n.7 (E.D. Pa. 2020).

Third, Dr. Rothman's discussion of the Horizontal Merger Guidelines are irrelevant because they do not apply to this merger. It is undisputed that this merger is a vertical, not a horizontal case. In the case of a vertical merger it is incumbent on the government to prove that the merger is anticompetitive in light of the efficiencies. Accordingly, citations to the Horizonal Merger Guidelines are irrelevant and misguided.

Respondents further note that, to the extent Respondents are required to meet the requirements of the Horizontal Merger Guidelines in this case, they have done so. (PFF § VIII.)

The proposed finding is inaccurate and misleading insofar as it suggest that the Transaction's efficiencies could be achieved absent the Transaction: each of the efficiencies, including the acceleration efficiencies are merger specific because it would not have been possible to achieve them without the Transaction. (PFF ¶ 1175.) Illumina and GRAIL witnesses testified that they could not contract for market acceleration efficiencies if they were separate entities because Illumina does not provide such services to any third party entities and doing so would require GRAIL to share its confidential information with Illumina. (Aravanis (Illumina) Tr. 1969–70 ("It would require GRAIL to share, you know, its knowledge of all of its technology, its assays, its bioinformatics. On the payer and FDA aspects of the efficiencies, they would need to share details of its clinical trials, the results, you know, of them, you know, how they were conducted, proprietary information that it wouldn't necessarily – it wouldn't otherwise share".); Febbo (Illumina) Tr. 4369 ("you don't see total alignment between two companies, and nor can you get into the depth of understanding of the processes and the special sauce that a lot of these companies, including Illumina, have in order to fully realize efficiencies, fully realize where you have the best opportunity to improve a test, to improve or speed regulatory, improve reimbursement. You just don't see the layer of engagement that's necessary to get to the full realization of those benefits through partnerships".); [redacted] Dr. Carlton testified that "Illumina does not offer regulatory help or market access services to customers. My understanding is Illumina would not provide, in absence of this transaction, a service to

GRAIL to help it get FDA approval or payer approval". (RX6000 (Carlton Trial Dep. at 60).) He also testified that GRAIL does not share confidential information: "GRAIL would not tell Illumina in absence of this transaction, a lot of information that would be useful for Illumina to know to accelerate the improve – the approval. In particular, GRAIL is very concerned about its proprietary information in its machine-learning algorithm, and it's not going to give that information to Illumina if this transaction doesn't go through". (RX6000 (Carlton Trial Dep. at 60–61).)

5380. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 42 (*in camera*) (citing PX0338 at 029-031 (*Horizontal Merger Guidelines* § 10, Aug. 19, 2010)).

Response to Finding No. 5380:

The proposed finding relies on improper expert witness testimony and is misleading to the extent it suggests that the efficiencies are not merger specific for the reasons explained in Respondents' responses to CCFF ¶ 5379, which Respondents incorporate herein. Respondents also note that the proposed finding is misleading insofar as it suggests the Horizontal Merger Guidelines require that efficiencies be verified by reasonable means. Dr. Rothman admitted that the Horizontal Merger Guidelines do not use the phrase "reasonable means". (PFF ¶ 2190.1.) He also conceded that the Guidelines do not require a specific dollar amount to be defined for a given efficiency. (PFF ¶ 2190.5.) Finally, Respondents have presented unrefuted fact witness testimony that verifies each of their efficiencies. (PFF ¶¶ 1174–79.)

5381. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 40 (*in camera*) (citing PX0338 at 030 n.13 (*Horizontal Merger Guidelines* § 10, Aug. 19, 2010)).

Response to Finding No. 5381:

The proposed finding relies on improper expert witness testimony and is misleading to the extent it suggests that the efficiencies are not merger specific for the reasons explained in Respondents' responses to CCFF ¶ 5379, which Respondents incorporate herein. The proposed finding is misleading insofar as it suggests that the Transaction's efficiencies merely relate to timing. While the ultimate result of the market access efficiencies is the acceleration of Galleri's rollout (for which the evidence the overwhelming (*see* PFF ¶¶ 1127–35)), there are specific efficiencies to the Transaction beyond that, including Illumina's expertise and experience in obtaining FDA approval and payor coverage, as well as those listed in Table 12 at PFF ¶ 1133.26. (PFF ¶ 1131–32.10, 1133.26.) Moreover, as Dr. Carlton's testimony demonstrated, the value of the acceleration of Galleri alone is *at least* $37 billion dollars. (RX6000 (Carlton Trial Dep. at 73–75.)

(a) Grail Could Enhance Its Regulatory Capabilities With Consultants or Hiring, Rather Than Merging With Illumina

5382. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 28 (*in camera*)).

Response to Finding No. 5382:

The proposed finding is incomplete and misleading and relies on improper expert testimony. Dr. Rothman admitted that he is not an expert in FDA approval or payor coverage, and so his testimony on those points lacks value. (PFF ¶ 1134.4.)

The evidence also shows that it would not be a simple matter for GRAIL to achieve Illumina's regulatory and market access capabilities by simply hiring Illumina employees. Dr.

Febbo explained that Illumina's "regulatory and -- personnel work together and work across teams, and the experience we have is cross-functional. . . GRAIL could hire one, two,. Even three of those, but taking an individual out of the environment, out of the cross-functional and multidisciplinary approach to our filings, to success with the agency that we've achieved over years, of course, we have had a critical mass that have worked over years to generate this institutional insight that is not dependent on any single employee." (Febbo (Illumina) Tr. 4366–67.) Further, Mr. Qadan, Global Head of Market Access at Illumina, testified that it would be very difficult to replicate Illumina's market access functions elsewhere. (Qadan (Illumina) Tr. 4170.) Illumina's institutional knowledge has been developed over time and its relationships would also be very hard to replicate from one company to another. (Qadan (Illumina) Tr. 4170–71.) Simply hiring people from Illumina's regulatory or market access team would not enable GRAIL to replicate its expertise and experience, or lead to the same good results. Mr. Qadan explained that another difficulty "is related to the image that Illumina has built over time". (Qadan (Illumina) Tr. 4170–71.) He added that even with his expertise, he would not be able to take Illumina's image with him to a different company. (Qadan (Illumina) Tr. 4170–71.) Mr. Freidin testified [redacted] (Freidin (GRAIL) Tr. 3062 –63.)

5383. [redacted] (RX6001 (Deverka Trial Dep. at 148) (*in camera*)).

Response to Finding No. 5383:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5382, which Respondents incorporate herein. Respondents also note that the statement by Dr. Deverka is taken out of context as she was not testifying about whether GRAIL could hire a team with the same skills as Illumina but rather whether the employees GRAIL hired for particular job functions fit that job function. (RX6001 (Deverka Trial Dep. at 148.)

5384. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 70 (*in camera*)).

Response to Finding No. 5384:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5382, which Respondents incorporate herein. Mr. Qadan testified that he was aware of GRAIL hiring two employees from Illumina, neither of which were from the market access function. (Qadan (Illumina) Tr. 4171–73.) While Mr. Gautam Kollu worked in market development, Mr. Qadan explained that that differed from market access, which focuses on payor coverage (as opposed to societies and similar bodies for the market development group). (Qadan (Illumina) Tr. 4171–73.)

5385. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 70 (*in camera*); *see* Freidin (Grail) Tr. 3165-66 (testifying that Grail's Chief Commercial Officer (Gautam Kollu), Grail's Senior VP of Software Engineering (Satnam Alag), and others were former employees of Illumina)).

Response to Finding No. 5385:

The proposed finding is incomplete and misleading and relies on improper expert testimony for the reasons explained in Respondents' responses to CCFF ¶ 5382, which Respondents incorporate herein.

5386. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 70 (*in camera*); Freidin (Grail) Tr. 3165-66).

Response to Finding No. 5386:

The proposed finding is incomplete and misleading and relies on improper expert testimony for the reasons explained in Respondents' responses to CCFF ¶ 5382, which Respondents incorporate herein. Mr. Qadan testified that Dr. Kollu's role in the Harvard Pilgrim risk-sharing agreement was as a "cross-functional team member", as he worked in market development, rather than market access. (Qadan (Illumina) Tr. 4171–72.) He further testified that Dr. Kollu did not have market expertise to his knowledge, but that Dr. Kollu's NIPT subject-matter expertise (from his time at Verinata) enabled him to be useful on the Harvard Pilgrim partnership. (Qadan (Illumina) Tr. 4171–72.) Mr. Qadan, Global Head of Market Access at Illumina, was only aware of two hires of Illumina employees by GRAIL, and neither were from the market access function. (Qadan (Illumina) Tr. 4171–73.)

5387. [redacted] (PX7111 (Fesko (Natera) Dep. at 219-220) (*in camera*)).

Response to Finding No. 5387:

The proposed finding is incomplete and misleading and relies on improper expert testimony for the reasons explained in Respondents' responses to CCFF ¶ 5382, which

Respondents incorporate herein. Respondents further note that hiring researchers is not indicative of an ability to produce a strong regulatory or market access department at GRAIL.

5388. [redacted] (Freidin (Grail) Tr. 3112 (*in camera*); PX7066 (Freidin (Grail) IHT at 275-76).

Response to Finding No. 5388:

The proposed finding is incomplete and misleading. Numerous fact witnesses testified that consultants are unable to provide the support necessary to build a regulatory team. Dr. Febbo testified that acceleration could not be achieved by hiring FDA consultants: "I've worked through this process and overseen the process with regulatory authorities multiple times, and what's clear is you need an internal core team that has experience with the authorities based on time at Illumina and prior experience, but they've also had time and experience with the technology that is foundational to the test going through the process. And I know through our use of consultants and our hiring of individuals into regulatory, into market access, across our personnel, is that there's just not a deep, rich bench of experience available for consultants, and the model of a consultant driving that just doesn't work as effectively as having internal employees." (Febbo (Illumina) Tr. 4365.) Mr. Freidin testified: [redacted] Other fact witnesses with personal knowledge also testified that GRAIL could not achieve these efficiencies by hiring additional personnel or outside consultants because the pool of individuals with such experience is limited and it can take a long time for consultants to get up to speed on the specific needs in a new area

such as screening. (PFF ¶¶ 1175.1–1175.2.4.) Even if consultants could be used effectively by companies without regulatory capabilities that does not mean that Illumina's in-house regulatory and market access team wouldn't accelerate Galleri's launch beyond what could be done by GRAIL alone or with consultants. The proposed finding also relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5389. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 71 (*in camera*) (citing PX7090 (Sood (Guardant) Dep. at 96-97); PX7110 (Conroy (Exact) Dep. at 27) (*in camera*)).

Response to Finding No. 5389:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5388, which Respondents incorporate herein. Further, Dr. Rothman admitted that he is not an expert in seeking FDA approval or payor coverage, and so his view of what GRAIL may or may not need regarding market access should be given no weight. (PFF ¶ 1134.4.)

5390. [redacted] (PX7092 (Ofman (Grail) Dep. at 80-81) (*in camera*)).

Response to Finding No. 5390:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5388, which Respondents incorporate herein. Dr. Ofman also testified that [redacted]

[redacted] As such, she was uniquely placed to help Dr. Ofman at that stage; she is not representative of regulatory consultants, who, ordinarily cannot replicate the work done by a company's own market access team (as made clear in Respondents' responses to CCFF ¶ 5388.)

5391. [redacted] (PX7092 (Ofman (Grail) Dep. at 82) (*in camera*)).

Response to Finding No. 5391:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5388 and 5390, which Respondents incorporate herein. . Respondents also note that Dr. Ofman testified that [redacted] (PX7092 (Ofman (GRAIL) Dep. at 85–86.) [redacted] (PX7092 (Ofman (GRAIL) Dep. at 85.)

5392. [redacted] (PX7092 (Ofman (Grail) Dep. at 83) (*in camera*)).

Response to Finding No. 5392:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5388, 5390 and 5391, which Respondents incorporate herein.

5393. [redacted] (PX7092 (Ofman (Grail) Dep. at 83-84) (*in camera*)).

Response to Finding No. 5393:

The proposed finding is incomplete and misleading for the reasons described in Respondents' responses to CCFF ¶¶ 5388, 5390 and 5391, which Respondents incorporate herein.

5394. [redacted] (PX7110 (Conroy (Exact) Dep. at 27) (*in camera*)).

Response to Finding No. 5394:

The proposed finding is incomplete and misleading for the reasons described in Respondents' responses to CCFF ¶¶ 5388, 5390 and 5391, which Respondents incorporate herein.

5395. [redacted] (PX7110 (Conroy (Exact) Dep. at 27) (*in camera*)).

Response to Finding No. 5395:

The proposed finding is incomplete and misleading for the reasons described in Respondents' responses to CCFF ¶¶ 5388, 5390 and 5391, which Respondents incorporate herein.

5396. [redacted] (PX7092 (Ofman (Grail) Dep. at 80-87) (*in camera*)).

Response to Finding No. 5396:

The proposed finding is incomplete and misleading for the reasons described in Respondents' responses to CCFF ¶¶ 5388, 5390 and 5391, which Respondents incorporate herein.

5397. [redacted] (PX7092 (Ofman (Grail) Dep. at 259-260) (*in camera*)).

Response to Finding No. 5397:

The proposed finding is incomplete and misleading for the reasons described in Respondents' responses to CCFF ¶¶ 5388 and 5390, which Respondents incorporate herein.

5398. [redacted] (PX6049 (Grail) at 089-90 (Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 5398:

The proposed finding is incomplete and misleading for the reasons described in Respondents' responses to CCFF ¶¶ 5388 and 5390, which Respondents incorporate herein .

5399. [redacted] (*in camera*)).

Response to Finding No. 5399:

Respondents have no specific response.

5400. Nitin Sood, Guardant's Chief Commercial Officer, testified that it was "beneficial for us [Guardant] to use outside consultants who can bring prior expertise, as Guardant itself had never gone through FDA approval prior to the approval of Guardant360." (PX7090 (Sood (Guardant) Dep. at 96-97)).

Response to Finding No. 5400:

The proposed finding is incomplete and misleading for the reasons described in Respondents' responses to CCFF ¶¶ 5388 and 5390, which Respondents incorporate herein.

5401. [redacted] (PX7110 (Conroy (Exact) Dep. at 26-27) (*in camera*)).

Response to Finding No. 5401:

The proposed finding is incomplete and misleading for the reasons described in Respondents' responses to CCFF ¶¶ 5388 and 5390, which Respondents incorporate herein. Further, Illumina has its own quality management system compliant with FDA requirements that it developed itself over seven years. (PFF ¶ 1131.8.) Indeed, this is one of the many benefits that Illumina can offer GRAIL, and one factor that provides executives from both companies with confidence that the Transaction will accelerate Galleri by one year. (PFF ¶¶ 1131–33.26.)

(b) Companies Other Than Illumina Have Experience Relevant to Obtaining FDA PMA Approvals

5402. Illumina is not the only company to have received PMA approval from the FDA. (Ofman (Grail) Tr. 3446).

Response to Finding No. 5402:

Respondents have no specific response, other than to note that Illumina offers GRAIL multiple, significant benefits that will combine in order to accelerate Galleri's market access, not even to speak of the efficiencies beyond acceleration. (PFF ¶ 1127–27.5.) Illumina's large team of experienced experts, along with Illumina's own name and reputation in the market access field will aid Galleri's entry into the market. (*See* PFF ¶ 1127–35 generally.)

5403. Dr. Ofman testified that he did not know how many companies other than Illumina have successfully obtained PMA approval for IVD tests. (Ofman (Illumina) Tr. 3446-47).

Response to Finding No. 5403:

Respondents have no specific response other than to refer to their responses to CCFF ¶ 5402, which Respondents incorporate herein.

5404. Dr. Ofman testified that there are presumably many companies, other than Illumina, with quality management systems that have met with FDA approval for IVD tests. (Ofman (Illumina) Tr. 3446) ("Q. In fact, there are many companies, other than Illumina, with quality management systems that have met with FDA approval for IVD tests. A. Presumably, yes.")).

Response to Finding No. 5404:

Respondents to refer to their responses to CCFF ¶ 5402, which Respondents incorporate herein.

5405. Dr. Ofman testified that Foundation Medicine and Myriad Genetics Laboratories have both successfully obtained FDA approval for NGS-based IVD tests. (Ofman (Grail) Tr. 3447-48).

Response to Finding No. 5405:

Respondents have no specific response other than to refer to their responses to CCFF ¶ 5402, which Respondents incorporate herein.

5406. Foundation Medicine has obtained Class III, single-site PMAs for three different NGS-based diagnostic tests and holds more Class III PMAs for NGS-based diagnostic tests than Illumina. (Febbo (Illumina) Tr. 4447-48).

Response to Finding No. 5406:

Respondents have no specific response other than to refer to their responses to CCFF ¶ 5402, which Respondents incorporate herein.

5407. Multiple other companies, including Thermo Fisher and Guardant, have also obtained PMA approval for NGS-based diagnostic tests. (*See, e.g.,* RX1659 (Illumina) at 069 (Email from Dan Poulson, Illumina, to Brian Blanchett, Illumina, June 8, 2020, attaching Decibio Liquid Biopsy Report 2019) (noting that Thermo Fisher has obtained PMA approval for an NGS-based diagnostic test, Oncomie Dx Target); RX3299 (FDA, Guardant360 CDx – P200010, https://www.fda.gov/medical-devices/recently-approved-devices/guardant360-cdx-p200010 (last visited Feb. 10, 2022); RX3217 (FDA, PMA Database Product Listing Raw Data Full List) (listing "Approval order for Guardant360® CDx" and describing Guardant360 CDx as "a qualitative next generation sequencing-based in vitro diagnostic device")).

Response to Finding No. 5407:

Respondents have no specific response other than to refer to their responses to CCFF ¶ 5402, which Respondents incorporate herein.

5408. Numerous companies, including Abbott, Becton Dickinson, Biogenex Laboratories, Bio-Merieux, Epigenomics AG, Exact Sciences, Foundation Medicine, Gen-Probe Inc., Guardant Health, Hologic, Invivoscribe, Myriad, Roche, Siemens, and Thermo Fisher, among others, have received PMA approval for IVD tests. (*See, e.g.,* RX3217 (FDA, PMA

Database Product Listing Raw Data Full List) (including, among others, P190032, P190014, P200010, P160045, P970007, P160044, B160037, P040030, P120014, P130001, P130017, P020011, P080015, P160040, P190014, P140021, and P110041); RX1659 (Illumina) at 069 (Email from Dan Poulson, Illumina, to Brian Blanchett, Illumina, June 8, 2020, attaching Decibio Liquid Biopsy Report 2019)).

Response to Finding No. 5408:

Respondents have no response other than to refer to their responses to CCFF ¶ 5402,

which Respondents incorporate herein.

b) Payer Acceleration

(1) Background on Payer Reimbursement

5409. "Reimbursement" refers to payment for a medical product or service by a public or private payer. (PX7139 (Navathe Trial Dep. at 50-51)).

Response to Finding No. 5409:

Respondents have no specific response.

5410. "Coverage" refers to a payer being willing, by policy, to pay for a particular medical product or service. (PX7139 (Navathe Trial Dep. at 51)).

Response to Finding No. 5410:

Respondents have no specific response.

5411. Private or commercial insurance coverage refers to companies like Aetna, BlueCross BlueShield, and UnitedHealthcare. (Freidin (Grail) Tr. 2988).

Response to Finding No. 5411:

Respondents have no specific response.

5412. Millions of people are covered by commercial or private health insurance. (Freidin (Grail) Tr. 2987).

Response to Finding No. 5412:

Respondents have no specific response.

5413. 67.5 percent of adults ages 18 to 64 have insurance through a commercial or private payer. (Freidin (Grail) Tr. 2988).

Response to Finding No. 5413:

Respondents have no specific response.

5414. "Public payers are government entities that finance or provide directly health insurance coverage… and also maintain relationships with healthcare providers to reimburse . . . for the provision of healthcare services to covered members or beneficiaries. (PX7139 (Navathe Trial Dep. at 10-11)).

Response to Finding No. 5414:

Respondents have no specific response.

5415. Medicare is an example of a public payer. (PX7139 (Navathe Trial Dep. at 11)).

Response to Finding No. 5415:

Respondents have no specific response.

5416. Individuals 65 or over are covered by Medicare. (Freidin (Grail) Tr. 2991).

Response to Finding No. 5416:

Respondents have no specific response.

5417. Some individuals over 65 have both Medicare coverage and private insurance coverage. (*See* Freidin (Grail) Tr. 2991).

Response to Finding No. 5417:

Respondents have no specific response.

5418. Exact's CEO, Kevin Conroy, testified at trial that reimbursement of an MCED test will depend on many factors, including sensitivity and specificity of the test. (Conroy (Exact) Tr. 1735).

Response to Finding No. 5418:

Respondents have no specific response except to note that Mr. Conroy's list of factors is not comprehensive.

5419. Mr. Conroy testified at trial that reimbursement of an MCED test will also depend on whether the test is reliable, safe, effective, and medically necessary. (Conroy (Exact) Tr. 1735).

Response to Finding No. 5419:

Respondents have no specific response except to note that Mr. Conroy's list of factors is not comprehensive.

(2) The Claimed Payer Acceleration Efficiency Is Not Verifiable Because It Is Unlikely that Illumina Can Accelerate Payer Approval Compared to Grail on Its Own

(a) [redacted]

For evidence that Illumina and Grail's ordinary course documents did not model FDA acceleration, see Section VIII.C.1.a.2..a.

5420. Illumina's claimed reimbursement acceleration efficiency is not reflected in the base case of Illumina's deal model. (Febbo (Illumina) Tr. 4360-61).

Response to Finding No. 5420:

The proposed finding is incomplete and misleading. Dr. Febbo explained this non-inclusion as follows: "[w]ell, as we looked at GRAIL and developed a model to get to an acquisition price of GRAIL, we looked at GRAIL as a stand-alone opportunity, the value of GRAIL as a company in and of itself. So we did not take into account all the value that we could bring to GRAIL because that's not the acquisition price. The acquisition price is given GRAIL, given its operations, given its teams' experience that they had already developed, of what was our best assessment of the current value, and so that model did not include the efficiencies we've discussed." (Febbo (Illumina) Tr. 4361.) He also testified that Illumina considered the one year acceleration of Galleri in evaluating the transaction: "[w]ell, during the transaction, what we did do is we looked at, you know, any -- a lot of the variables that were important to the model in the valuation of GRAIL, and we did what I would call sensitivity training where we looked at what would happen if, you know, things were accelerated by a year. What would it impact? So we

did model acceleration, for example, of regulatory approval by a year and saw the impact that could have on testing and on the value of GRAIL." (Febbo (Illumina) Tr. 4361–62.)

Further, Dr. Febbo confirmed his confidence in Illumina's ability to accelerate access to Galleri by at least one year. (Febbo (Illumina) Tr. 4362.) Mr. Qadan, the head of Illumina's market access team also testified that Illumina would accelerate Galleri's public and private payor approval. (Qadan (Illumina) Tr. 4158–59.) The acceleration efficiency's non-inclusion in Illumina's financial model in no way diminishes it, or proves that Illumina did not consider it.

5421. [redacted] (Febbo (Illumina) Tr. 4432 (*in camera*)).

Response to Finding No. 5421:

The proposed finding is misleading and incomplete. Dr. Febbo testified that Illumina had a plan for how it would achieve accelerated payor coverage for Galleri. (Febbo (Illumina) Tr. 4349.) He testified that Mr. Qadan was in charge of the plan to speed up time to reimbursement. (Febbo (Illumina) Tr. 4349–50.) He explained that Illumina would be willing invest a billion dollars or more to secure broad payor coverage for Galleri; he sees Illumina's financial resources as one of the major benefits of the acquisition. (Febbo (Illumina) Tr. 4350–51.)

Mr. Qadan testified that "when we did the due diligence for the test, we have seen the challenges around clinical and economic utility, and so we had initially to think about what needs to be done to manage that, because, if there was no plan or there was no way to manage that, why would Illumina, you know, buy GRAIL." (Qadan (Illumina) Tr. 4161). He also testified that Illumina has developed a plan to achieve the acceleration of market access. "[I]n the U.S., we will be working on accelerating CMS approval through clinical utility data and through accelerating the regulatory approval . . . Outside the U.S., there will be a lot of work needed with

single-payer healthcare systems and countries, like what we have done, for example, with Genomics England, like what we have done with Germany, to accelerate the availability of Galleri in Europe, and third, as I mentioned, also the work that we can do in China to accelerate the availability of Galleri in China considering that there is a favorable environment in China for lab-developed tests now that did not exist before. So there are many things. Our group's experience then based on what we have done so far and the expertise we have developed, we can take many of those initiatives to accelerate Galleri's availability and reimbursement in the different markets." (Qadan (Illumina) Tr. 4162–63.) He testified in some detail about Illumina's further plans, which include: leveraging Galleri as a diagnostic aid to cancer, using its partnership with United Healthcare Group, and using its significant international presence to accelerate access outside of the US. (PFF ¶¶ 1133.11–33.21.)

While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5422. [redacted] (PX7066 (Freidin (Grail) IHT at 281); *see* PX4096 (Grail) at 014 (Email from A. Freidin, Grail, to H. Bishop, et. al, Grail, attaching Integration Planning and Pre-Closing Activities, Oct. 23, 2020) (*in camera*)).

Response to Finding No. 5422:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5421, which Respondents' incorporate herein. Mr. Freidin made clear that while he was not aware of active work on this topic "that's just not my area. . . [Illumina is] proposing it as a place where they could help, per this document, so I'm assuming they've got something they can do or they wouldn't have proposed it. That's kind of how I look

at each of these topics. Like these are areas where they have a plan or a path where they can help us." (RX7066 (Freidin (GRAIL) IHT at 279–80).) Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5423. [redacted] (deSouza (Illumina) Tr. 2286 (*in camera*)).

Response to Finding No. 5423:

Respondents have no specific response.

5424. [redacted] (deSouza (Illumina) Tr. 2286 (*in camera*)).

Response to Finding No. 5424:

The proposed finding is misleading. Mr. Qadan is Global Head of Market Access at Illumina. (Qadan (Illumina) Tr. 4098–99.) Mr. deSouza testified that [redacted]. (deSouza (Illumina) Tr. 2286.)

5425. [redacted] (Febbo (Illumina) Tr. 4432 (*in camera*)).

Response to Finding No. 5425:

Respondents have no specific response except to note that Dr. Febbo and other Illumina executives have estimated that the Transaction will accelerate Galleri's adoption (including payor coverage) by one year. (PFF ¶¶ 1122–22.2.) Dr. Deverka testified that it is more likely than not that the reimbursement efficiencies will come to pass. (Deverka Trial Dep. at 63 –64.) Further, Respondents refer to their responses to CCFF ¶ 5421, which is incorporated herein.

5426. [redacted] (Febbo (Illumina) Tr. 4436 (*in camera*)).

Response to Finding No. 5426:

Respondents have no specific response except to note that Dr. Febbo and other Illumina executives have estimated that the Transaction will accelerate Galleri's adoption (including payor coverage) by one year. (PFF ¶¶ 1122–22.2.) Further, Respondents refer to their responses to CCFF ¶ 5421, which is incorporated herein.

5427. [redacted] (Febbo (Illumina) Tr. 4436 (*in camera*)).

Response to Finding No. 5427:

Respondents have no specific response except to note that Dr. Febbo and other Illumina executives have estimated that the Transaction will accelerate Galleri's adoption (including payor coverage) by one year. (PFF ¶¶ 1122–22.2.) Further, Respondents refer to their responses to CCFF ¶ 5421, which is incorporated herein.

5428. [redacted] (Febbo (Illumina) Tr. 4433-34 (*in camera*)).

Response to Finding No. 5428:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5421, which Respondents incorporate herein. Dr. Febbo testified that [redacted] (Febbo (Illumina) Tr. 4434.) Further, [redacted]

[redacted] (PFF ¶ 1131.16.)

5429. [redacted] (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 18-19 (RFA No. 23) (*in camera*)).

Response to Finding No. 5429:

Respondents have no specific response other than to note that Dr. Febbo and other Illumina executives have estimated that the Transaction will accelerate Galleri's adoption (including payor coverage) by one year. (PFF ¶¶ 1122–22.2.) Further, Respondents refer to their responses to CCFF ¶ 5421, which Respondents' incorporate herein.

5430. [redacted] (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 22-23 (RFA No. 30) (*in camera*)).

Response to Finding No. 5430:

Respondents have no specific response other than to note that Dr. Febbo and other Illumina executives have estimated that the Transaction will accelerate Galleri's adoption (including payor coverage) by one year. (PFF ¶¶ 1122–22.2.) Further, Respondents refer to their responses to CCFF ¶ 5421, which Respondents' incorporate herein.

5431. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 48-49 (*in camera*)).

Response to Finding No. 5431:

The proposed finding is inaccurate, incomplete misleading for the reasons explained in Respondents' responses to CCFF ¶ 5421, which Respondents incorporate herein**.** [redacted]

[redacted] Respondents note that Dr. Febbo explained why the acceleration benefits were not included in the deal model: "Well, as we looked at GRAIL and developed a model to get to an acquisition price of GRAIL, we looked at GRAIL as a stand-alone opportunity, the value of GRAIL as a company in and of itself. So we did not take into account all the value that we could bring to GRAIL because that's not the acquisition price. The acquisition price is given GRAIL, given its operations, given its teams' experience that they had already developed, of what was our best assessment of the current value, and so that model did not include the efficiencies we've discussed." (Febbo (Illumina) Tr. 4361.) Further, Dr. Rothman admitted that he is not an expert in market access and his opinion should therefore be given little weight. (PFF ¶ 1134.4.)

5432. Respondents' expert, Dr. Carlton, testified that he is "not the source" for the opinion that Illumina can accelerate the process for Galleri to achieve payer reimbursement. (RX6000 (Carlton Trial Dep. at 96-97); PX7134 (Carlton Dep. at 190-91)).

Response to Finding No. 5432:

The proposed finding is incomplete and misleading. Dr. Carlton testified that while he relied on other witnesses and documents, he came to his own independent conclusion based on the evidence that the reunion of Illumina and GRAIL will generate substantial efficiencies and that he is the source for the opinions expressed in his report and in his direct examination. (RX6000 (Carlton Tr. 196–97.) Respondents also note that they have presented evidence that the Transaction is estimated to accelerate the adoption of Galleri by at least one year. (PFF ¶¶ 1122–22.2.)

(b) Illumina and Grail Have Not Planned the Details of How Illumina Would Accelerate Coverage or Reimbursement for Galleri

For evidence that Illumina and Grail have not engaged in integration or identified specific steps for achieving FDA acceleration, see Sections VIII.C.1.a.2.b.-c.

5433. [redacted] (deSouza (Illumina) Tr. 2286-87 (*in camera*)).

Response to Finding No. 5433:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5421, which Respondents incorporate herein.

5434. [redacted] (deSouza (Illumina) Tr. 2286-87 (*in camera*)).

Response to Finding No. 5434:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5421, which Respondents incorporate herein.

5435. Mr. Freidin confirmed that Illumina and Grail's sales teams are not currently collaborating. (Freidin (Grail) Tr. 3157).

Response to Finding No. 5435:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5421, which Respondents incorporate herein.

5436. [redacted] (deSouza (Illumina) Tr. 2288 (*in camera*)).

Response to Finding No. 5436:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5421, which Respondents incorporate herein.

5437. [redacted] (Febbo (Illumina) Tr. 4434 (*in camera*)).

Response to Finding No. 5437:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5421, which Respondents incorporate herein.

5438. [redacted] (PX7066 (Freidin (Grail) IHT at 278); PX4096 (Grail) at 009 (Email from A. Freidin, Grail, to H. Bishop, et. al, Grail, attaching Grail Integration Planning and Pre-Closing Activities, Oct. 23, 2020) (*in camera*)).

Response to Finding No. 5438:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5421, which Respondents incorporate herein. As is clear from Mr. Freidin's IH testimony and PX4096, the titles in the slide deck are preliminary and not necessarily determinative of what was or was not [redacted]. Mr. Freidin made clear in his IHT that this slide deck and structure is "very preliminary", and "no longer applicable". (PX7066 (Freidin (GRAIL) IHT at 278).) He said that "the only certainties [were] that [he] talk to Christen [Cotter] and Paul [Scagnetti]", and that the "governance structure of all of it is to be determined". (PX7066 (Freidin (GRAIL) IHT at 278).) [redacted]

[redacted] (PX4096 (GRAIL) at 001, 008–10 (Email from A. Freidin, GRAIL, to H. Bishop, GRAIL, M.L. Song, GRAIL, M. Young, GRAIL, Oct. 24, 2020, attaching "Grail Integration Planning and Pre-Closing Activities," Oct. 23, 2020) (in camera).) Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

5439. [redacted] (Qadan (Illumina) Tr. 4245 (*in camera*)).

Response to Finding No. 5439:

The proposed finding is incomplete and misleading. Mr. Qadan testified [redacted] (Qadan (Illumina) Tr. 4244 (*in camera*).) He added that [redacted] (Qadan (Illumina) Tr. 4243 (*in camera*).) [redacted] (Qadan (Illumina) Tr. 4244–46 (*in camera*).) [redacted] (Qadan (Illumina) Tr. 4193 (*in camera*).) He also explained [redacted]

[redacted] (Qadan (Illumina) Tr. 4245–46 (*in camera*).)

5440. [redacted] (Qadan (Illumina) Tr. 4232-33 (*in camera*)).

Response to Finding No. 5440:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5439, which Respondents incorporate herein. The cited evidence selectively quotes from Mr. Qadan's deposition: Mr. Qadan explained [redacted] (RX3810 (Qadan (Illumina) Dep. at 141)) [redacted] (Qadan (Illumina) Tr. 4192–93 (*in camera*).) Further, in his deposition, Mr. Qadan testified that it made [redacted] (RX3810 (Qadan (Illumina) Dep. at 142-43)) He also explained that [redacted] (RX3810 (Qadan (Illumina) Dep. at 143)) He added that there [redacted] (RX3810 (Qadan (Illumina) Dep. at 143))

5441. [redacted] (Febbo (Illumina) Tr. 4435-36 (*in camera*)).

Response to Finding No. 5441:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5439, which Respondents incorporate herein. Mr. Qadan, Illumina's Global Head of Market Access, testified that in [redacted] (Qadan (Illumina) Tr. 4192–93.) He also testified that [redacted] (Qadan (Illumina) Tr. 4192–93.)

5442. [redacted] (Febbo (Illumina) Tr. 4435 (*in camera*)).

Response to Finding No. 5442:

The proposed finding is incomplete and misleading. Dr. Febbo testified that [redacted] (Febbo (Illumina) Tr. 4433.) He also explained that [redacted] (Febbo (Illumina) Tr. 4434.) Mr. Qadan, the Global Head of Market Access at Illumina, testified [redacted]

[redacted] (Qadan (Illumina) Tr. 4198 (*in camera*).)

5443. [redacted] (Febbo (Illumina) Tr. 4435 (*in camera*)).

Response to Finding No. 5443:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 54421, which Respondents incorporate herein.

(c) Illumina Lacks the Resources to Effect the Alleged Payer Adoption and Market Access Efficiencies

For details on Illumina's limited relevant experience with FDA PMA approvals, see Section VIII.C.1.a.2.f.

5444. [redacted] (Qadan (Illumina) Tr. 4236 (*in camera*)).

Response to Finding No. 5444:

The proposed finding is incomplete and misleading. Mr. Qadan testified that Illumina does not provide market access consulting services to other companies, and that he was not aware of any players in the industry doing so. He said that Illumina focused its resources on its current three clinical areas, which were its own products, and that the team had to prioritize with its resources. (Qadan (Illumina) Tr. 4168.)

5445. Illumina's Market Access group consists of only 13 employees. (Qadan (Illumina) Tr. 4289).

Response to Finding No. 5445:

The proposed response is misleading. Mr. Qadan emphasized that it was "very important" to have cross-functional teams. He testified that in "evidence generation", a "big

element of that [is] done by medical affairs or by clinical affairs", thereby indicating that the market access function's workload is spread across different parts of Illumina. (Qadan (Illumina) Tr. 4107.) He also explained that he worked with a wide range of teams in the company, including medical affairs, clinical affairs, regulatory affairs, marketing, commercialization, and the GMs in each relevant region. (Qadan (Illumina) Tr. 4107.) Mr. Qadan also explained that Illumina had significantly expanded the size and budget of the market access group in the last three to four years, and that this process had been challenging. (Qadan (Illumina) Tr. 4117–19.) Mr. Qadan also testified at length about the significant successes that Illumina's market access team of 13 people has achieved. (PFF ¶¶ 1451–66.) Dr. Febbo confirmed that "our regulatory and -- personnel work together and work across teams, and the experience we have is cross-functional". (Febbo (Illumina) Tr. 4366.)

5446. [redacted] (Qadan (Illumina) Tr. 4233 (*in camera*)).

Response to Finding No. 5446:

The proposed finding is misleading to the extent it suggests that Illumina's market access team would not be able to handle working on Galleri's market access requirements. Mr. Qadan testified that [redacted] (Qadan (Illumina) Tr. 4234.)

5447. [redacted]

[redacted]

(PX7140 (Rothman Trial Dep. at 28) (*in camera*); PX6092 (Rothman Rebuttal Report) ¶ 29 (*in camera*)).

Response to Finding No. 5447:

The proposed finding relies on improper expert testimony for the reasons explained in Respondents' responses to CCFF ¶ 5014, which Respondents incorporate herein. In addition, Dr. Rothman admitted that he is not an expert in FDA approval or payor coverage, and so his testimony on those points lacks value. (PFF ¶ 1134.4.) The proposed finding is also inaccurate, incomplete and misleading. Numerous fact witnesses testified that Illumina intends to dedicate significant resources to accelerating GRAIL's market access. (PFF ¶ 1133.) For example, Dr. Febbo, Chief Medical Officer of Illumina, testified that Illumina would be willing to spend more than one billion dollars on trials for evidence generation for payor coverage alone. (Febbo (Illumina) Tr. 4350.) He sees this as one of the major benefits of the acquisition; Illumina is a profitable company, and has factored major investment into its model for the acquisition, knowing that reimbursement is critical to Galleri's success. (Febbo (Illumina) Tr. 4350–51.) And given the magnitude of the claimed efficiency, Complaint Counsel has not explained why Illumina would not invest significant resources in accelerating Galleri.

5448. [redacted] (PX7140 (Rothman Trial Dep. at 29) (*in camera*)).

Response to Finding No. 5448:

The proposed finding relies on improper expert testimony for the reasons explained in Respondents' responses to CCFF ¶ 5014, which Respondents incorporate herein. In addition, Dr. Rothman admitted that he is not an expert in FDA approval or payor coverage, and so his

testimony on those points lacks value. (PFF ¶ 1134.4.) The proposed finding is also misleading and incomplete. Illumina fully intends for its expert market access team to work on accelerating Galleri's availability. (PFF ¶¶ 1132–32.10.) Mr. Qadan testified that Illumina would be able to integrate the GRAIL market access team into his team. (Qadan (Illumina) Tr. 4173–74.) He further explained that the team could prioritize its workload to manage working on Galleri, and also noted that the team was expanding, which would be aided by the inclusion of GRAIL employees. (Qadan (Illumina) Tr. 4173–74.) And given the magnitude of the claimed efficiency, Complaint Counsel has not explained why Illumina would not invest significant resources in accelerating Galleri.

5449. [redacted] (Qadan (Illumina) Tr. 4234 (*in camera*)).

Response to Finding No. 5449:

The proposed finding relies on improper expert testimony for the reasons explained in Respondents' responses to CCFF ¶ 5446, which Respondents incorporate herein.

5450. [redacted] (Qadan (Illumina) Tr. 4234 (*in camera*)).

Response to Finding No. 5450:

The proposed finding relies on improper expert testimony for the reasons explained in Respondents' responses to CCFF ¶ 5446, which Respondents incorporate herein.

5451. [redacted] (Qadan (Illumina) Tr. 4236-37 (*in camera*)).

Response to Finding No. 5451:

The proposed finding relies on improper expert testimony for the reasons explained in Respondents' responses to CCFF ¶ 5446, which Respondents incorporate herein. In addition, Respondents note that Mr. Qadan's statement referred to the reasons why Illumina would not

contract with third party companies to offer its market access services. Mr. Qadan's point was that if Illumina and GRAIL were fully integrated, Galleri projects would be prioritized the same way other Illumina projects are.

5452. Illumina's Mr. Qadan estimated that Grail would need half a billion to a billion dollars to develop clinical utility data for regulatory and market access purposes. (Qadan (Illumina) Tr. 4267).

Response to Finding No. 5452:

Respondents have no specific response except to note that Dr. Febbo, Chief Medical Officer of Illumina, testified that Illumina would be willing to spend more than one billion dollars on trials for evidence generation for payor coverage. (Febbo (Illumina) Tr. 4350.)

5453. Mr. Qadan testified that Illumina's Market Access group does not have the budget available for the clinical studies Galleri will require. (Qadan (Illumina) Tr. 4267-68).

Response to Finding No. 5453:

The proposed finding is incomplete and misleading. Mr. Qadan testified that this budget does not come just from the market access function; it comes from multiple functions. (Qadan (Illumina) Tr. 4267–68.) Respondents also note that Dr. Febbo, Chief Medical Officer of Illumina, testified that Illumina would be willing to spend more than one billion dollars on trials for evidence generation for payor coverage alone. (Febbo (Illumina) Tr. 4350.)

5454. [redacted] (Conroy (Exact) Tr. 1691 (*in camera*)).

Response to Finding No. 5454:

The proposed finding is based on hearsay and should be given no weight. The proposed finding is also inaccurate, misleading and incomplete. Illumina has a well-established sales force that sells to health systems and deals with physicians on a regular basis. Illumina can rapidly scale up its sales force to sell directly to physicians and serve Galleri's needs. Mr. deSouza

testified that "there's a bunch of work we do that hits doctors across the spectrum". (PX7107 (deSouza (Illumina) Dep. at 92.) In particular, he explained that [redacted] (PX7107 (deSouza (Illumina) Dep. at 84–87).) Mr. deSouza testified that post-merger "we have been and will continue to do so. And we'll expand" targeting general practice physicians as part of its sales strategy. (PX7107 (deSouza (Illumina) Dep. at 92).) More to the point, Illumina's strategy for accelerating market access to Galleri does not depend on a direct to physician sales strategy but instead focuses on leveraging relationships with payors and developing real world evidence, among other things. (Qadan (Illumina) Tr. 4162–65.)

5455. "Illumina admits that in the U.S., Illumina's commercial sales team generally does not sell oncology products directly to primary care physicians, oncology physicians or outpatient services, and primarily focuses on selling its oncology products (such as its TSO500 therapy selection product) to pathologists in laboratories and research institutions." (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 26 (RFA No. 36)).

Response to Finding No. 5455:

Respondents have no specific response other than to note that Illumina has a well-established sales force that sells to health systems and deals with physicians on a regular basis. Illumina can rapidly scale up its sales force to sell directly to physicians and serve Galleri's needs. Mr. deSouza testified that "there's a bunch of work we do that hits doctors across the spectrum". (PX7107 (deSouza (Illumina) Dep. at 92).) In particular, he explained that [redacted]

[redacted] (PX7107 (deSouza (Illumina) Dep. at 84–87).) Mr. deSouza testified that post-merger "we have been and will continue to do so. And we'll expand" targeting general practice physicians as part of its sales strategy. (PX7107 (deSouza (Illumina) Dep. at 92).) More to the point, Illumina's strategy for accelerating market access to Galleri does not depend on a direct to physician sales strategy but instead focuses on leveraging relationships with payors and developing real world evidence, among other things. (Qadan (Illumina) Tr. 4162–65.)

5456. [redacted] (PX7061 (Davy (Illumina) IHT at 217-218) (*in camera*). [redacted] (PX7061 (Davy (Illumina) IHT at 218) (*in camera*)).

Response to Finding No. 5456:

The proposed finding is misleading and incomplete. Illumina has a well-established sales force that sells to health systems and deals with physicians on a regular basis. Illumina can rapidly scale up its sales force to sell directly to physicians and serve Galleri's needs. Mr. deSouza testified that "there's a bunch of work we do that hits doctors across the spectrum". (PX7107 (deSouza (Illumina) Dep. at 92).) In particular, he explained that [redacted] (PX7107 (deSouza (Illumina) Dep. at 84–87).) Mr. deSouza testified that post-merger "we have been and will continue to do so. And we'll expand" targeting general practice physicians as part of its sales strategy. (PX7107 (deSouza (Illumina) Dep. at 92).) More to the point, Illumina's strategy for accelerating market access to Galleri does not depend on a direct to physician sales strategy

but instead focuses on leveraging relationships with payors and developing real world evidence, among other things. (Qadan (Illumina) Tr. 4162–65.)

Further, the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5457. [redacted] (deSouza (Illumina) Tr. 2249-2250 (*in camera*); PX2549 (Illumina) at 021 (Illumina, Board of Directors Meeting, Apr. 28, 2020) (*in camera*)). [redacted] (deSouza (Illumina) Tr. 2249-2250 (*in camera*); PX2549 (Illumina) at 021 (Illumina, Board of Directors Meeting, Apr. 28, 2020) (*in camera*)).

Response to Finding No. 5457:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5456, which Respondents incorporate herein. Respondents also note that Dr. Goswami testified that this document was [redacted] (PX7064 (Goswami (Illumina) IHT at 162–63.) [redacted] (PX7064 (Goswami (Illumina) IHT at 163.) Dr. Goswami further explained that [redacted] (PX7087 (Goswami (Illumina) Dep. at 106–07).) [redacted] (PX7064

(Goswami (Illumina) IHT at 163–64.) Mr. Qadan testified at length about Illumina's expertise in this area. (PFF ¶¶ 1445–66.)

5458. [redacted] (deSouza (Illumina) Tr. 2261-63 (*in camera);* PX5027 (Illumina) at 0011 [redacted] (*in camera*)).

Response to Finding No. 5458:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5456, which Respondents incorporate herein.

5459. [redacted] (deSouza (Illumina) Tr. 2261-2263 (*in camera*); PX5027 (Illumina) at 0011 [redacted] (*in camera*)).

Response to Finding No. 5459:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5456, which Respondents incorporate herein.

5460. One of Illumina's Wall Street analysts reported shortly after the announcement of the acquisition that Grail:

> represents a far stretch from [Illumina]'s core expertise, as early cancer detection through liquid biopsy requires significant market development involving lengthy large-scale clinical trials and regulatory approvals, clinical guidelines and reimbursement, as well as commercial infrastructure investment from scratch, none of which have much to leverage from [Illumina]'s core business today.

(PX2138 (Illumina) at 008 (JPMorgan, Illumina, Inc.: Searching for the (Un) Holy Grail: Deal Brings More Dilution than Test Sensitivity..., Sept. 21, 2020)).

Response to Finding No. 5460:

The proposed finding relies entirely on hearsay and should be given no weight. The author of this analyst report issued the day after the deal closed was not deposed and Complaint Counsel has not attempted to ascertain whether his opinions have changed.

The Transaction will result in significant efficiencies that leverage Illumina's unique areas of expertise and potentials for the two companies to work together. (PFF ¶¶ 1106–79.)

5461. Illumina analyst Cowen Equity Research wrote:

> [W]e don't see the clear fit for acquiring a company that . . . is still at a stage where clinical studies and clinical product development are still critical and will be for years, and . . . would benefit from true clinical commercial infrastructure/reach that does not really exist at Illumina, and . . . arguably would benefit most from accessing new technologies that do not currently reside at Illumina.

(PX2138 (Illumina) at 013 (Cowen, Illumina: Reports Indicate ILMN Is Buying Grail, Sept. 21, 2020)).

Response to Finding No. 5461:

The proposed finding relies entirely on hearsay and should be given no weight. The author of this analyst report issued the day after the deal closed was not deposed and Complaint Counsel has not attempted to ascertain whether his opinions have changed. The Transaction will result in significant efficiencies that leverage Illumina's unique areas of expertise and potentials for the two companies to work together. (PFF ¶¶ 1106–79.)

5462. As Respondents lay out in their post-trial findings, the Transaction will result in significant efficiencies that leverage Illumina's unique areas of expertise and potentials for the two companies to work together. (PFF ¶¶ 1107–79.) [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 36 (*in camera*)). [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 36 (*in camera*)).

Response to Finding No. 5462:

The proposed finding is inaccurate, misleading and incomplete. Illumina and GRAIL witnesses testified that they could not contract for these efficiencies if they were separate entities because Illumina does not provide such services to any third party entities and doing so would require GRAIL to share its confidential information with Illumina. (Aravanis (Illumina) Tr. 1969–70 ("It would require GRAIL to share, you know, its knowledge of all of its technology, its assays, its bioinformatics. On the payer and FDA aspects of the efficiencies, they would need to share details of its clinical trials, the results, you know, of them, you know, how they were conducted, proprietary information that it wouldn't necessarily – it wouldn't otherwise share".); Febbo (Illumina) Tr. 4369 ("you don't see total alignment between two companies, and nor can you get into the depth of understanding of the processes and the special sauce that a lot of these companies, including Illumina, have in order to fully realize efficiencies, fully realize where you have the best opportunity to improve a test, to improve or speed regulatory, improve reimbursement. You just don't see the layer of engagement that's necessary to get to the full realization of those benefits through partnerships".); [redacted]

Dr. Carlton confirmed this: "Illumina does not offer regulatory help or market access services to customers. My understanding is Illumina would not provide, in absence of this transaction, a service to GRAIL to help it get FDA approval or payer approval". (RX6000 (Carlton Trial Dep. at 60).) He also explained that "GRAIL would not tell Illumina in absence of this transaction, a lot of information that would be useful for Illumina to know to accelerate the improve – the approval. In particular, GRAIL is very concerned about its proprietary

information in its machine-learning algorithm, and it's not going to give that information to Illumina if this transaction doesn't go through". (RX6000 (Carlton Trial Dep. at 60–61).)

5463. [redacted] (PX7140 (Rothman Trial Dep. at 24) (*in camera*)).

Response to Finding No. 5463:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5463, which Respondents incorporate herein. Dr. Rothman's logic is entirely circular and concludes that because an efficiency is not achieved but for the merger it cannot be merger-specific. This result is absurd. If Dr. Rothman were right, then no efficiencies could ever be credited because by definition they do not occur prior to the merger.

5464. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 80 (*in camera*)).

Response to Finding No. 5464:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5463–64, which Respondents incorporate herein.

5465. [redacted] (Qadan (Illumina) Tr. 4236 (*in camera*)).

Response to Finding No. 5465:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5462, which Respondents incorporate herein. Mr. Qadan testified that Illumina does not provide market access consulting services to other companies, and that he was not aware of any players in the industry doing so. He said that Illumina focused

its resources on its current three clinical areas, which were its own products, and that the team had to prioritize with its resources. (Qadan (Illumina) Tr. 4168.)

(d) The Relevance of Illumina's Payer-Related Experience Is Questionable

(i) Illumina Has No Experience Obtaining Reimbursement for a Clinical MCED Test

5466. Illumina has never received, for any product, a USPSTF recommendation. (Freidin (Grail) Tr. 3166).

Response to Finding No. 5466:

The proposed finding is misleading and incomplete. Mr. Freidin testified he was not "aware" of any such products. Mr. Freidin also testified that Illumina has a strong track record of successful partnerships with government agencies and private payors, including Harvard Pilgrim, Bule Cross Blue Shield and the State of Michigan. (Freidin (GRAIL) Tr. 2999.) Respondents note that Illumina's market access team has extensive experience working with CMS and private payors. Illumina has extensive relationships and partnerships that will be able to help demonstrate Galleri's economic value. (PFF ¶ 1131.9.)

5467. Illumina "admit[s] that no employee, officer, director, agent, or any individual on behalf of Illumina has met with any official of CMS or the USPSTF to discuss Medicare reimbursement coverage for GRAIL's Galleri screening test." (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 17 (RFA No. 20)).

Response to Finding No. 5467:

Respondents have no specific response except to note that the reason Illumina has not begun reaching out to CMS or USPSTF on behalf of Galleri is that they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).) Respondents also refer to the responses to CCFF ¶ 5421, which is incorporated herein.

5468. Respondents' Counsel represented at trial that "[t]he principal part of [Illumina's] business is not clinical, which is what we're focused on here, but instead research and development. . . ." (Opening Statement (Illumina) Tr. 59).

Response to Finding No. 5468:

The proposed finding is incomplete and misleading . Respondents' Counsel was answering a question from the court about whether the NGS platform was the major part of Illumina's business. As can be seen from the full excerpt below, Respondents' Counsel responded that sequencing equipment, instruments and consumables was Illumina's *major product* and that the *principal part* of the *sequencing business* focused on research and development customers.

> JUDGE CHAPPELL: From what I'm hearing, it sounds like the NGS system, platform, whatever -- is that the major part of Illumina's business? Is it a hundred percent of Illumina's business? Is it, you know -- and we're in public session, but is that the major product that your client provides?
> MR. MARRIOTT: Our major product, Your Honor, is in fact sequencing equipment, instruments and consumables. The principal part of the business is not clinical, which is what we're focused on here, but instead research and development, but yes, Your Honor, sequencing instruments and consumables are a very important part of the business.

(Opening Statement Tr. 59-60.) The fact that a major portion of Illumina's sequencing sales are focused on R&D is not relevant to assessing Illumina's relevant market access experience or whether it can accelerate Galleri.

5469. [redacted] (PX7139 (Navathe Trial Dep. at 70-71 (*in camera*)). [redacted] (PX7139 (Navathe Trial Dep. at 70-71 (*in camera*)). [redacted] (PX7139 (Navathe Trial Dep. at 70-71 (*in camera*)).

Response to Finding No. 5469:

The proposed finding is incomplete and misleading. The evidence shows that the real world evidence partnerships that Illumina has entered into will help it to accelerate market access for Galleri. (PFF ¶¶ 1131.9–31.16.) For example, [redacted] (Qadan (Illumina) Tr. 4198.) Similarly, [redacted]. (Qadan (Illumina) Tr. 4200–01.)

In addition, Dr. Ofman refuted Dr. Navathe's assertions that there would be pressure on payers to extend coverage to Galleri even without Illumina's support or the real world evidence that Illumina will help GRAIL generate. (Ofman (GRAIL) Tr. 3368–69 [redacted].) Dr. Ofman also refuted Dr. Navathe's claim that the [redacted]

[redacted] (Ofman (GRAIL) Tr. 3370–71.)

(ii) Illumina's NIPT-Related Experience Is Not Directly Relevant to Accelerating Reimbursement for Galleri

For evidence on Illumina experiencing multiple delays with the FDA in the NIPT market, see Section VIII.C.1.a..2.f.ii. (Illumina's Effort to Obtain a PMA for Its NIPT Product (Project Denali) Has Experienced Multiple Delays).

5470. [redacted] (PX6093 (Navathe Rebuttal Report) ¶¶ 51-53 (*in camera*)). [redacted] (PX6093 (Navathe Rebuttal Report) ¶ 52 (*in camera*)). [redacted] (PX6093 (Navathe Rebuttal Report) ¶ 52 (*in camera*)).

Response to Finding No. 5470:

The proposed finding is inconsistent with unrebutted fact witness testimony. [redacted] (Ofman (GRAIL) Tr. 3368–69.) Mr. Qadan testified that the clinical and economic utility principles from NIPT can be applied to Galleri. (Qadan (Illumina) Tr. 4254–55.) Dr. Febbo testified that the Galleri test and the NIPT tests are very similar in their approach. (Febbo (Illumina) Tr. 4400–01 [redacted]

[redacted].)

5471. A reason that Galleri will require different types of evidence and studies than NIPT is because NIPT has a different product profile than cancer screening. (Qadan (Illumina) Tr. 4258-59).

Response to Finding No. 5471:

The proposed finding is incomplete and misleading. Mr. Qadan's full answer was "Yes. They are different in terms of profile, but, again, the clinical and economic utility principles might be the same." (Qadan (Illumina) Tr. 4258.) Mr. Qadan also testified that "the principles of clinical and economic utility, especially the economic utility, when payers look at economic utility, there is a threshold that goes across applications, even across healthcare innovations, including pharmaceuticals, when it comes to budget impact. . . the expertise that we built working on NIPT and other applications within Illumina helps us a lot think about Galleri. (Qadan (Illumina) Tr. 4255–56.) Respondents refer to their responses to CCFF ¶ 5470, which they incorporate herein.

(iii) Illumina's Experience with Its Praxis Therapy-Selection Test Is Not Directly Relevant to Accelerating Reimbursement for Galleri

For evidence on Illumina's limited FDA experience related to its Praxis test, see Section VIII.C.1.a.2.f.i. (Illumina's Praxis Therapy Selection Test Was Approved on the Basis of a Third Party's Clinical Study).

(iv) Illumina Has Only Completed One Risk-Sharing Agreement, Which Involved NIPT

5472. Illumina has completed only one risk-sharing agreement. (Qadan (Illumina) Tr. 4249).

Response to Finding No. 5472:

The proposed finding is incomplete and misleading. Illumina has completed one risk-sharing agreement in NIPT. But it has also completed two other risk-sharing agreements relating to whole genome sequencing: one with Harvard Pilgrim and another with the state of Queensland in Australia. (PFF ¶ 1462; Qadan (Illumina) Tr. 4249, 4136.)

5473. Illumina's one completed risk-sharing agreement did not generate economic and clinical utility data for Grail's Galleri test. (Qadan (Illumina) Tr. 4252).

Response to Finding No. 5473:

The proposed finding is irrelevant, incomplete and misleading. Illumina has also entered into two other risk-sharing agreements: another with Harvard Pilgrim, this time relating to whole genome sequencing; and another with the state of Queensland in Australia also relating to whole genome sequencing. (PFF ¶ 1462.) The NIPT risk sharing agreement was not related to Galleri's test and therefore it is irrelevant that it did not generate data for the Galleri test. Mr. Qadan testified that the expertise developed while working on NIPT risk-sharing agreements would help with regard to thinking about Galleri. (Qadan (Illumina) Tr. 4256.) Mr. Qadan also testified that "the principles of clinical and economic utility, especially the economic utility, when payers look at economic utility, there is a threshold that goes across applications, even across healthcare innovations, including pharmaceuticals, when it comes to budget impact. . . the expertise that we built working on NIPT and other applications within Illumina helps us a lot think about Galleri. (Qadan (Illumina) Tr. 4255–56.)

5474. Illumina's one completed risk-sharing agreement related to NIPT. (Qadan (Illumina) Tr. 4252).

Response to Finding No. 5474:

The proposed finding is irrelevant and incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5474, which Respondents incorporate herein. Respondents also note that Mr. Qadan testified that the success of this NIPT risk-sharing agreement enabled Harvard Pilgrim and Illumina to enter into a further agreement regarding whole genome sequencing (RUGD). (PFF ¶ 1465.) Dr. Deverka testified that the "ability to successfully execute" the NIPT risk-sharing agreement with Harvard Pilgrim "and the internal learnings on the part of both organizations from having conducted one of these from initiation to results dissemination -- that's a long process. It's a multiyear process-- that that experience would be able to be translated into other clinical applications". (PX6001 (Deverka Trial Dep. at 75–76).)

5475. According to Ammar Qadan, Illumina's Vice President of Growth and Market Access, NIPT is not a good comparison for Galleri in terms of payor uptake. (Qadan (Illumina) Tr. 4254-55).

Response to Finding No. 5475:

The proposed finding is incomplete and misleading. Mr. Qadan testified that "Correct, as payer uptake, which means that the test uptake by payers, but the risk-sharing agreement and the principles of developing clinical and economic utility are basically the same." (Qadan (Illumina) Tr. 4254–55.)

5476. Generating clinical and economic utility evidence for Galleri will require a different strategy than what Illumina used to generate data in NIPT. (Qadan (Illumina) Tr. 4255-56).

Response to Finding No. 5476:

The proposed finding is incomplete and misleading. Mr. Qadan testified that "[b]eing in cancer, it requires a different type of study, but, again, the principles of clinical and economic

utility, especially the economic utility, when payers look at economic utility, there is a threshold that goes across applications, even across healthcare innovations, including pharmaceuticals, when it comes to budget impact." (Qadan (Illumina) Tr. 4256.)

5477. Dr. Deverka testified during her trial deposition that Illumina has only entered into risk-sharing agreements with Harvard Pilgrim in the United States. (RX6001 (Deverka Trial Dep. at 183).

Response to Finding No. 5477:

The proposed finding is incomplete and misleading. Dr. Deverka also testified that the "ability to successfully execute" the NIPT risk-sharing agreement with Harvard Pilgrim "and the internal learnings on the part of both organizations from having conducted one of these from initiation to results dissemination -- that's a long process. It's a multiyear process -- that that experience would be able to be translated into other clinical applications". (PX6001 (Deverka Trial Dep. at 75–76).) She also testified that these sorts of agreements are not particularly common in diagnostics and even rarer in next-generation sequencing, but are becoming more common. (PX6001 (Deverka Trial Dep. at 76).)

5478. Ammar Qadan, Illumina's Vice President and Global Head of Market Access, testified that [redacted] (PX7084 (Qadan (Illumina) Dep. at 61) (*in camera*); PX6092 (Rothman Rebuttal Report) ¶ 63 (*in camera*)).

Response to Finding No. 5478:

The proposed finding is incomplete and misleading. [redacted] (RX3810 (Qadan (Illumina) Dep. at 61.)

(e) Grail Already Is Independently Capable of Many of the Alleged Efficiencies from the Acquisition

5479. Dr. Deverka believes Grail can obtain reimbursement and coverage for Galleri on its own. (RX6001 Deverka Trial Dep. at 130-31).

Response to Finding No. 5479:

The proposed finding is incomplete and misleading without additional context. Dr. Deverka also testified that it is more likely than not that the combined company would be able to accelerate adoption by payors relative to GRAIL on its own. (PX6001 (Deverka Trial Dep. at 131).) She also testified that Illumina "would be able to accelerate market access for Galleri because they could help to develop better evidence of clinical utility faster." (RX6001 (Deverka Trial Dep. at 66).) She also explained that this faster process was not simply a result of having a larger team; Illumina's people's "institutional knowledge and [] track record" will allow this acceleration, compared to GRAIL attempting to go to market itself. (RX6001 (Deverka Trial Dep. at 66–67).)

5480. Grail recently launched Galleri as an LDT in April 2021. (RX3285 (Grail, *GRAIL Confirms Q2 2021 Introduction of Galleri*, https://grail.com/press-releases/grail-confirms-q2-2021-introduction-of-galleri-first-of-kind-multi-cancer-early-detection-blood-test) (last visited Aug. 12, 2021)).

Response to Finding No. 5480:

Respondents have no specific response.

5481. Grail's Galleri test is commercially available to patients in the United States. (Freidin (Grail) Tr. 2968-69).

Response to Finding No. 5481:

Respondents have no specific response.

5482. Galleri became commercially available nationwide in June of 2021. (Bishop (Grail) Tr. 1322).

Response to Finding No. 5482:

Respondents have no specific response.

5483. [redacted] (RX3867 (Deverka Rebuttal Report) ¶ 112 & Table 6-1 (*in camera*)).

Response to Finding No. 5483:

5484. Currently, a patient between the age of 50 and 80 can order a Galleri test from their doctor. (Freidin (Grail) Tr. 2996).

Response to Finding No. 5484:

Respondents have no specific response.

5485. Grail has a nationwide partnership with Quest Diagnostics for blood sample collection services. (Bishop (Grail) Tr. 1375-76).

Response to Finding No. 5485:

Respondents have no specific response.

5486. Galleri is "being made available under a set of regulations called laboratory-developed test." (Bishop (Grail) Tr. 1322-23).

Response to Finding No. 5486:

Respondents have no specific response.

5487. A laboratory-developed test ("LDT") is "the route to market that a very significant number of diagnostic tests are first made available to the public and doctors." (Bishop (Grail) Tr. 1323).

Response to Finding No. 5487:

Respondents have no specific response except to note that widespread adoption of Galleri will require FDA, CMS and payor approval. (PFF ¶ 1129.1.) [redacted]

[redacted] As Dr. Deverka further explained: A novel test like Galleri "needs to have a premarket authorization, so clearance by the FDA. And how that's relevant for payers is that for the Medicare pathway it's actually a requirement to have an FDA-approved or cleared test. And while private payers can choose to pay for a laboratory-developed test, they sometimes pay addition -- give additional weight to the fact that a test has received FDA approval because it's essentially an imprimatur of quality and that the FDA with its rigorous process has approved the test." (RX 6001 (Deverka Trial Dep. at 39).) [redacted] (PFF ¶ 1129.5.)

5488. Grail has "built all of the infrastructure, laboratory infrastructure, necessary to reliably deliver [Galleri] in full compliance with all of the regulatory requirements of running such a test in a lab." (Bishop (Grail) Tr. 1366-67).

Response to Finding No. 5488:

Respondents have no specific response except to clarify that the quotation refers only to running Galleri as an LDT from GRAIL's lab. Respondents refer to their responses to CCFF ¶ 5487, which are incorporated herein.

5489. Grail's Galleri test received New York State Department of Health approval. (Ofman (Grail) Tr. 3440).

Response to Finding No. 5489:

Respondents have no specific response except to clarify that the cited statement refers only to running Galleri as an LDT from GRAIL's lab. Respondents refer to their responses to CCFF ¶ 5487, which are incorporated herein.

5490. Since Galleri's commercialization in June 2021 through time of trial, Grail has sold approximately 3,000 Galleri tests in the United States. (Freidin (Grail) Tr. 2969).

Response to Finding No. 5490:

Respondents have no specific response.

(i) Grail Is Pursuing Its Own Market Access Strategy

5491. [redacted] (PX7058 (Conroy (Exact) IHT at 103-04) (*in camera*)).

Response to Finding No. 5491:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Mr. Conroy testified at trial that [redacted] (Conroy (Exact/Thrive) Tr. 1662.) Mr. Conroy testified that [redacted] (Conroy (Exact/Thrive) Tr. 1662–63.) Accordingly his testimony should be accorded no weight.

5492. [redacted] (*See, e.g.*, PX4209 (Grail) at 003 (Grail, Market Access Strategy, June 2020) (*in camera*) [redacted] PX7058 (Conroy (Exact) IHT at 142) (*in camera*); PX7051 (Lengauer (Third Rock Ventures) IHT at 146-147) (*in camera*); PX4082 (Grail) at 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 5492:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) Galleri was already

offered on a limited basis in April 2021 and was launched as an LDT in June 2021. (RX3279 (GRAIL) at 20-3) (Grail Cancer Early Detection Test Performance Holds Steady as Q2 Launch Approaches); Bishop (GRAIL) Tr. 1322.)

5493. According to Mr. Freidin, "total addressable market" is how many individuals could buy the product that is being sold. (Freidin (Grail) Tr. 2967-68).

Response to Finding No. 5493:

Respondents have no specific response.

5494. Grail estimates that in 2030 it will reach between 13 and 16 percent market penetration of the 108 million patients in its total addressable market. (Freidin (Grail) Tr. 2969).

Response to Finding No. 5494:

The proposed finding is incomplete and misleading. Mr. Freidin testified that such estimates were based off of GRAIL's "2020 long-range plan" (Freidin (GRAIL) Tr. 2969) and that [redacted] Mr. Della Porta testified that [redacted]

5495. Grail is currently focused on marketing its Galleri test to large physician groups, health systems and employers. (Freidin (Grail) Tr. 2995; Della Porta (Grail) Tr. 456-57).

Response to Finding No. 5495:

Respondents have no specific response, except to note that Mr. Della Porta testified at trial that [redacted]; *see also* RX2803 (GRAIL) at 002–003 (April 3 Commercial Forecast

Review) (noting that 2021 April sales forecast had been revised downward by 7% relative to November 2020 forecast). Widespread market access to Galleri will depend on FDA, CMS and payor approval. (Bishop (GRAIL) Tr. 1343–45); Conroy (Exact/Thrive) Tr. 1734-35; Gao (Singlera) Tr. 2889–91; [redacted]; Rabinowitz (Natera) Tr. 298–99.) GRAIL would like to make Galleri more widely adopted and Illumina can help GRAIL reach that goal. (Bishop (GRAIL) Tr. 1405–06.) Although GRAIL would prefer to sell to a wider audience, at present, Galleri is currently selling for $949, a price that many individuals cannot afford. (deSouza (Illumina) Tr. 2342.) [redacted]

5496. Grail has approximately 30 to 40 people on its sales team. (Della Porta (Grail) Tr. 459).

Response to Finding No. 5496:

Respondents have no specific response except to note that Mr. Della Porta testified that [redacted] Specifically, Illumina's previous experience launching products in NIPT and its additional resourcing across functions, including regulatory, market access and sales, would accelerate the adoption of Galleri; and Illumina could help increase Galleri's sales in the health system, employer and physician channels through its relationships, footprint, reputation and resources. [redacted]

[redacted]

5497. [redacted] (Della Porta (Grail) Tr. 525 (*in camera*)).

Response to Finding No. 5497:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 5496 herein.

5498. Grail hired its sales team as part of its overall commercial plan to launch Galleri. (PX7106 (Della Porta (Grail) Dep. at 42)).

Response to Finding No. 5498:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 5496 herein.

5499. [redacted] (Ofman (Grail) Tr. 3399 (*in camera*)).

Response to Finding No. 5499:

The proposed finding is incomplete and misleading. [redacted] Respondents further note that at the time of trial, GRAIL had only sold around 3,000 Galleri tests. (Freidin (GRAIL) Tr. 2969.) [redacted]

[redacted]

5500. To improve market penetration of Galleri, Grail plans to get FDA approval and then CMS coverage. (Freidin (Grail) Tr. 2996).

Response to Finding No. 5500:

Respondents have no specific response except to note that Dr. Ofman testified at trial that [redacted] Illumina is highly experienced in obtaining FDA approval. (RX6001 (Deverka Trial Dep. 62–64, 65); Febbo (Illumina) Tr. 4113, 4319, 4338–43, 4347, [redacted].) Numerous Illumina and GRAIL fact witnesses testified that the reunion of Illumina and GRAIL will accelerate Galleri's path to FDA approval. (Aravanis (Illumina) Tr. 1945, 1948; Febbo (Illumina) Tr. 4345–46, 4360; Flatley (Illumina) Tr. 4082; Bishop (GRAIL) Tr. 1417; [redacted]; Freidin (GRAIL) Tr. 2980); [redacted] Echoing this unrefuted fact testimony, Dr. Deverka testified

that the reunion of Illumina and GRAIL will accelerate FDA approval. (RX6001 (Deverka Trial Dep. At 62-64, 81; RX3867 (Deverka Expert Report ¶ 121.)

5501. [redacted] (PX0043 at 115, 132 (Grail 2020 Form S-1); PX7058 (Conroy (Exact) IHT at 87-88) (*in camera*); PX7092 (Ofman (Grail) Dep. at 175-176)).

Response to Finding No. 5501:

Complaint Counsel chose not to discuss PX0043 at trial, (CC Exhibit Index at 1), or in any deposition, and should not be entitled to rely on it to establish anything beyond the words on the page.

5502. [redacted] (PX6093 (Navathe Rebuttal Report) ¶ 38 (*in camera*)).

Response to Finding No. 5502:

The proposed finding relies on improper expert testimony. Dr. Navathe lacks the expertise to opine on FDA regulations or payer reimbursement, rendering his opinions unreliable. (*See* Resps.' Post-Trial Br. at 266.) [redacted] The proposed finding is also incomplete and misleading for the reasons stated in the responses to CCFF ¶¶ 5499 and 5502, which are incorporated herein. [redacted]

[redacted] In contrast, Illumina can accelerate payor coverage and reimbursement of Galleri because: Illumina has nearly a decade of experience working with payers to obtain approval of genomic tests and will utilize its experience and relationships for approval of Galleri, (deSouza (Illumina) Tr. 2351–53); Illumina has helped one billion people around the world obtain payer reimbursement for genomic tests and has deep expertise, innovative tools and deep relationship that it can utilize to accelerate payer coverage of Galleri; (deSouza (Illumina) Tr. 2342–43.)

5503. [redacted] (PX4531 (Grail) at 185 (Grail, Market Access Strategy, June 2020) (*in camera)*). [redacted] (PX4280 (Grail) at 003-04 [redacted] (*in camera)* ([redacted])). Grail successfully executed contracts with multiple concierge medical practices as launch partners for Galleri. (Della Porta (Grail) Tr. 464).

Response to Finding No. 5503:

Respondents incorporate their responses to CCFF ¶¶ 5499 and 5502 herein. Respondents also note that Complaint Counsel chose not to discuss PX4280 and PX4531 at trial, (CC Exhibit Index at 42, 51), or in any deposition, and should not be entitled to rely on it to establish anything beyond the words on the page.

5504. Grail's Form S-1 states that Grail's "market research indicates that there is a significant addressable market opportunity we can access even before approval under traditional fee-for-service Medicare reimbursement." (PX4082 (Grail) at 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 5504:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5499 and 5502, which Respondents incorporate herein. [redacted] **S**he further testified that "[i]f Illumina's resources and prior experience dealing with the FDA are brought to bear with the merged companies that [she] predict[s] that . . . could accelerate regulatory approval for Galleri, which would then have the downstream impact of further accelerating payer and Medicare coverage." (RX6001 (Deverka Trial Dep. at 81); RX3867 (Deverka Expert Report) ¶ 121).) Respondents also incorporate their responses to CCFF ¶¶ 5499 and 5502 herein.

5505. [redacted] (PX4415 (Grail) at 017-018 (Grail, Transforming Cancer Outcomes with Early Detection Testing, Feb. 24, 2021 (*in camera*)).

Response to Finding No. 5505:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5499 and 5502, which Respondents incorporate herein. GRAIL is an R&D company with limited commercial sales experience and capabilities (Freidin (GRAIL) Tr. 3000–02); that [redacted]

[redacted] Respondents also note that Complaint Counsel chose not to discuss PX4415 at trial (CC Exhibit Index at 47), or in any deposition, and should not be entitled to rely on it to establish anything beyond the words on the page.

5506. [redacted] (Ofman (Grail) Tr. 3372-75 (*in camera*)).

Response to Finding No. 5506:

The proposed finding is incomplete and misleading or the reasons explained in Respondents' responses to CCFF ¶¶ 5499 and 5502, which Respondents incorporate herein. [redacted] The largest healthcare system with an agreement with GRAIL, Providence, [redacted] (PX7098 (Morgan (Grail) Dep. at 127). [redacted] (Ofman (Grail) Tr. 3374–75). [redacted] (Ofman (Grail) Tr. 3375). [redacted] (Ofman (Grail) Tr. 3375.)

(ii) Grail Is Marketing Galleri to Health Systems

5507. Grail is targeting and selling Galleri to progressive integrated health systems. (Bishop (Grail) Tr. 1332).

Response to Finding No. 5507:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5499 and 5502, which Respondents incorporate herein. Respondents note that the proposed finding overstates what Mr. Bishop said. Mr. Bishop was

asked "GRAIL is currently *trying* to sell Galleri to progressive, integrated health systems; correct" and responded "To some of them. Yes." (Bishop (GRAIL) Tr. 1332.)

5508. An integrated health system is "a health system that includes various different provisions of care ranging from primary care to hospital-delivered care and may also include payers." (Bishop (Grail) Tr. 1332).

Response to Finding No. 5508:

Respondents have no specific response.

5509. Hospitals, clinics, and physicians are associated with health systems. (Della Porta (Grail) Tr. 456-57).

Response to Finding No. 5509:

Respondents have no specific response.

5510. [redacted] (Ofman (Grail) Tr. 3372 (*in camera*)).

Response to Finding No. 5510:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5499 and 5502, which Respondents incorporate herein. [redacted]

5511. Providence St. Joseph is an example of a health system. (Della Porta (Grail) Tr. 457).

Response to Finding No. 5511:

Respondents have no specific response.

5512. [redacted] (PX6093 (Navathe Rebuttal Report) ¶ 65 (*in camera*)).

Response to Finding No. 5512:

Respondents have no specific response.

5513. Providence is a "large, respected health system that includes primary care practices and hospitals." (PX7069 (Bishop (Grail) IHT at 132)).

Response to Finding No. 5513:

Respondents have no specific response except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5514. [redacted] (Ofman (Grail) Tr. 3372-73 (*in camera*)).

Response to Finding No. 5514:

Respondents have no specific response.

5515. Mark Morgan, Grail's Senior Vice President of Market Access and Health Systems Partnerships [redacted] (PX7098 (Morgan (Grail) Dep. at 127) (*in camera*); *see* PX6092 (Rothman Rebuttal Report) ¶ 66, n. 104 (*in camera*)).

Response to Finding No. 5515:

To the extent Complaint Counsel intends to rely on Dr. Rothman's expert report to establish this proposed fact, that is improper.

5516. Grail has secured a partnership with Providence. (Della Porta (Grail) Tr. 457).

Response to Finding No. 5516:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5499 and 5502, which Respondents incorporate herein. Providence [redacted] (PX7098 (Morgan (GRAIL) Dep. at 127.)

5517. Providence has agreed to offer Galleri to its patients. (Della Porta (GRAIL) Tr. 457.)

Response to Finding No. 5517:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5499, 5506 and 5516, which Respondents incorporate herein.

5518. [redacted] (PX4239 (Grail) at 003 (Email from M. Morgan, Grail, to C. Della Porta, Grail, Mar. 2, 2021) ("Even the suggestion that a large system will be going public soon as a GRAIL partner is generating interest…..FOMO is strong!")); *see* PX6092 (Rothman Rebuttal Report) ¶ 66 (*in camera*)).

Response to Finding No. 5518:

The proposed finding is inaccurate, incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5499, 5506 and 5516, which Respondents incorporate herein. Mr. Morgan testified [redacted] (PX7098 (Morgan (GRAIL) Dep. at 127, 166-168) (discussing PX4239) (emphasis added). To the extent Complaint Counsel intends to rely on Dr. Rothman's expert report to establish this proposed fact, that is improper.

5519. [redacted] (Ofman (Grail) Tr. 3399 (*in camera*)).

Response to Finding No. 5519:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5499, 5506 and 5516, which Respondents incorporate herein. [redacted]

5520. [redacted] (PX4610 (Grail) at 002-03 (Email from J. Ofman, Grail, to S. Guttendorf, Grail, July 19, 2021) (*in camera*)). [redacted] (PX4610 (Grail) at 002-03 (Email from J. Ofman, Grail, to S. Guttendorf, Grail, July 19, 2021) (*in camera*)).

Response to Finding No. 5520:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5499, 5506 and 5516, which Respondents incorporate herein.

[redacted] GRAIL has had to revise its forecasts in the Health Systems channel downward. RX2803 (GRAIL) at 006 ([redacted]).

5521. Mr. Della Porta testified at trial that Grail's health systems team is also in conversations with other potential health system partners. (Della Porta (Grail) Tr. 457).

Response to Finding No. 5521:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5499, 5506 and 5516, which Respondents incorporate herein.

5522. Grail's S-1 estimates the total U.S. addressable market for integrated health systems is 27 million people. (PX4082 (Grail) at 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 5522:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5499, 5506 and 5516, which Respondents incorporate herein.

(iii) Grail Is Marketing Galleri to Concierge Physicians

5523. A concierge practice is a "term used to describe primary care practices where the members of that practice or the patients pay a fee to get preferred access to highly qualified doctors." (Bishop (Grail) Tr. 1333).

Response to Finding No. 5523:

Respondents have no specific response.

5524. Concierge physicians are "physicians who in general have a membership fee for access for their patients, and . . . have a smaller numbers of patients typically." (Della Porta (Grail) Tr. 462).

Response to Finding No. 5524:

Respondents have no specific response.

5525. Grail's growth strategy team was tasked with securing initial concierge physician customers. (Della Porta (Grail) Tr. 462-63).

Response to Finding No. 5525:

The proposed finding is incomplete and misleading. [redacted] (Ofman (GRAIL) Tr. 3372.) [redacted] (Ofman (GRAIL) Tr. 3375.) Dr. Ofman testified that [redacted] (Ofman (GRAIL) Tr. 3375.) [redacted]

[redacted]

(Della Porta (GRAIL) Tr. 540.)

5526. Grail's sales team currently sells Galleri to concierge physicians. (Della Porta (Grail) Tr. 579; Bishop (Grail) Tr. 1333).

Response to Finding No. 5526:

The proposed finding is incomplete and misleading for the reasons explained in

Respondents' responses to CCFF ¶ 5526, which Respondents incorporate herein..

5527. Grail learned from market research that concierge physicians "tend to be early adopters of new products that their patients are interested in." (Della Porta (Grail) Tr. 462).

Response to Finding No. 5527:

The proposed finding is incomplete and misleading for the reasons explained in

Respondents' responses to CCFF ¶ 5526, which Respondents incorporate herein.

5528. The goal of this 2020 market research was to assess concierge physicians' interest in the Galleri test before Galleri was launched. (Della Porta (Grail) Tr. 462).

Response to Finding No. 5528:

Respondents have no specific response.

5529. Grail's 2020 market research included interviews with concierge physicians. (Della Porta (Grail) Tr. 463).

Response to Finding No. 5529:

Respondents have no specific response.

5530. Interviews between Grail and concierge physicians took place at the direction of Grail's Chief Commercial Officer, Gautam Kollu. (Della Porta (Grail) Tr. 463).

Response to Finding No. 5530:

Respondents have no specific response.

5531. Mr. Della Porta participated in some concierge physician interviews. (Della Porta (Grail) Tr. 463).

Response to Finding No. 5531:

Respondents have no specific response.

5532. [redacted] (Della Porta (Grail) Tr. 526-27 (*in camera*)).

Response to Finding No. 5532:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5526, which Respondents incorporate herein. .

5533. [redacted] (Della Porta (Grail) Tr. 527 (*in camera*)).

Response to Finding No. 5533:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5526, which Respondents incorporate herein.

5534. Some concierge physicians accept insurance. (Della Porta (Grail) Tr. 462).

Response to Finding No. 5534:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5526, which Respondents incorporate herein. Mr. Della Porta testified that concierge physicians "in general have a membership fee for access for their patients, and some take insurance, some do not, and so they have smaller numbers of patients typically". (Della Porta (GRAIL) Tr. 462.)

5535. Mr. Della Porta believes that some concierge physicians were likely to adopt Galleri. (Della Porta (Grail) Tr. 463).

Response to Finding No. 5535:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5526, which Respondents incorporate herein.

5536. Grail's growth strategy team pursued deals with concierge physicians. (Della Porta (Grail) Tr. 463).

Response to Finding No. 5536:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5526, which Respondents incorporate herein. Grail's growth strategy team successfully executed deals with approximately 15 concierge physicians. (Della Porta (Grail) Tr. 464).

5537. Grail's growth strategy team successfully executed deals with approximately 15 concierge physicians. (Della Porta (Grail) Tr. 464).

Response to Finding No. 5537:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5526, which Respondents incorporate herein.

5538. Included in these 15 concierge physicians were two of the largest concierge networks in the United States. (Della Porta (Grail) Tr. 464).

Response to Finding No. 5538:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5526, which Respondents incorporate herein.

5539. The two largest concierge networks in the United States represent over 500,000 patients. (Della Porta (Grail) Tr. 464).

Response to Finding No. 5539:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5526, which Respondents incorporate herein. Mr. Della Porta qualified that these numbers were "at [the concierge practice's] maximum. (Della Porta (GRAIL) Tr. 464.)

5540. Grail's S-1 estimates the total U.S. addressable market for concierge practices and executive health programs is 1 million people. (PX4082 (Grail) at 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 5540:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5526, which Respondents incorporate herein.

(iv) Grail Is Marketing Galleri to Self-Insured Employers

5541. The employer channel includes self-insured employers. (Della Porta (Grail) Tr. 457).

Response to Finding No. 5541:

Respondents have no specific response.

5542. Self-insured employers are responsible for the healthcare costs of their employees. (Della Porta (Grail) Tr. 457-58).

Response to Finding No. 5542:

Respondents have no specific response.

5543. Grail has an employer partnership team that is tasked with establishing relationships with employers. (Della Porta (Grail) Tr. 458).

Response to Finding No. 5543:

Respondents have no specific response.

5544. [redacted] (Ofman (Grail) Tr. 3374-75 (*in camera*)).

Response to Finding No. 5544:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5499 which Respondents incorporate herein. [redacted] (Ofman (Grail) Tr. 3374–75). The other is Valmont which in April 2021 GRAIL forecast would purchase only 120 tests. RX2803 (GRAIL) at 017.

5545. [redacted] (Ofman (Grail) Tr. 3374-75 (*in camera*)).

Response to Finding No. 5545:

Respondents have no specific response, except to note that in April 2021 GRAIL forecast that Valmont would purchase only 120 tests. RX2803 (GRAIL) at 017.

5546. [redacted] (Della Porta (Grail) Tr. 525 (*in camera*)).

Response to Finding No. 5546:

Respondents have no specific response, except to note that in April 2021 GRAIL forecast that Illumina would purchase only 188 tests. RX2803 (GRAIL) at 017.

5547. [redacted] (Della Porta (Grail) Tr. 525 (*in camera*)).

Response to Finding No. 5547:

Respondents incorporate their responses to CCFF ¶ 5546 herein.

5548. [redacted] (PX4610 (Grail) at 003-04 (Email from J. Ofman, Grail, to S. Guttendorf, Grail, July 19, 2021) (*in camera*)).

Response to Finding No. 5548:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5499, which Respondents incorporate herein. [redacted] Moreover, the volume forecast for these deals is low. (RX2803 (GRAIL) at 017).

5549. [redacted] (PX4610 (Grail) at 002 (Email from J. Ofman, Grail, to S. Guttendorf, Grail, July 19, 2021) (*in camera*)).

Response to Finding No. 5549:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5499, which Respondents incorporate herein. [redacted]

(v) Grail Is Marketing Galleri to Life Insurance Companies

5550. Grail is in the "early stages" of securing deals with customers in the life insurance channel for Galleri. (Della Porta (Grail) Tr. 458).

Response to Finding No. 5550:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5526, which Respondents incorporate herein. Respondents note that [redacted] (Della Porta (GRAIL) Tr. 527-28.) [redacted] (Della Porta (GRAIL) Tr. 529.) [redacted] (Della Porta (GRAIL) Tr. 529.) GRAIL's agreements with life insurers to use Galleri will not have any impact on the willingness of private health insurers to cover the test. (Qadan (Illumina) Tr. 4174–78.)

5551. [redacted] (Della Porta (Grail) Tr. 529 (*in camera*)).

Response to Finding No. 5551:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5499 and 5526, which Respondents incorporate herein.

5552. [redacted] (Della Porta (Grail) Tr. 529 (*in camera*)).

Response to Finding No. 5552:

The proposed finding is incomplete and misleading without further context for the reasons explained in Respondents' responses to CCFF ¶¶ 5499 and 5526, which Respondents incorporate herein.

5553. [redacted] (PX4610 (Grail) at 002 (Email from J. Ofman, Grail, to S. Guttendorf, Grail, July 19, 2021) (*in camera*)).

Response to Finding No. 5553:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5499 and 5526, which Respondents incorporate herein.

(vi) Grail Is Exploring Additional Innovative Channels for the Sale of Galleri

5554. Grail's new channels work involves approaching potential partners for the sale of Galleri. (Della Porta (Grail) Tr. 456).

Response to Finding No. 5554:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5499, which Respondents incorporate herein. Mr. Della Porta indicated that imaging manufacturers would be an unlikely channel for sale, but are considered for co-marketing partnerships. (Della Porta (GRAIL) Tr. 458.).

5555. [redacted] (Della Porta (Grail) Tr. 525-26 (*in camera*)).

Response to Finding No. 5555:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5499, 5550 and 5553, which Respondents incorporate herein. [redacted] (Della Porta (GRAIL) Tr. 526.)

5556. [redacted] (Della Porta (Grail) Tr. 530 (*in camera*)).

Response to Finding No. 5556:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5499 and 5554, which Respondents incorporate herein. Mr. Della Porta indicated that imaging manufacturers would be an unlikely channel for sale, but are considered for co-marketing partnerships. (Della Porta (GRAIL) Tr. 458.)

5557. [redacted] (Della Porta (Grail) Tr. 530 (*in camera*)).

Response to Finding No. 5557:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5499 and 5554, which Respondents incorporate herein.

5558. Grail will publish articles in physician journals about Galleri to educate physicians about the test. (Freidin (Grail) Tr. 2995).

Response to Finding No. 5558:

The proposed finding is incomplete and misleading. Mr. Freidin testified that he believed "we have some -- some publications in like physician journals, so to educate physicians, sort of make them aware of it." (Freidin (GRAIL) 2995.)

(vii) Grail Has Paths to Medicare Coverage for Galleri Independent of Illumina

5559. Grail's Dr. Ofman has worked on bringing technology to patients for about 25 years. (Ofman (Grail) Tr. 3449).

Response to Finding No. 5559:

Respondents have no specific response except to note that Dr. Ofman testified that he has "worked in *the space* of bringing technology to patients for about 25 years". (Ofman (GRAIL) Tr. 3449.)

5560. Dr. Ofman and Grail's Head of Government Affairs, Rodger Currie, refined Grail's reimbursement strategy to accelerate opportunities for coverage through Medicare modernization. (Ofman (Grail) Tr. 3449).

Response to Finding No. 5560:

Respondents have no specific response, except to note that Complaint Counsel's expert

[redacted] Even if that pathway is created, CMS will look for FDA approval and for additional evidence of clinical utility before granting coverage. (Qadan (Illumina) Tr. 4151–53.) [redacted]

5561. Grail has brought in a highly skilled group of professionals, including Mr. Currie, to help achieve Grail's reimbursement strategy. (Ofman (Grail) Tr. 3449).

Response to Finding No. 5561:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5560, which Respondents incorporate herein. Reimbursement for an MCED test has never been achieved. [redacted]

[redacted] Mr. Freidin explained that GRAIL has no experience obtaining private insurer reimbursement, has a small team and lacks resources to pursue private payor reimbursement. (Freidin (GRAIL) Tr. 2997–98.) Illumina, however, has capabilities and expertise as well as successful partnerships with government agencies and private payors, including Harvard Pilgrim, Blue Cross Blue Shield and the State of Michigan. (Freidin (GRAIL) Tr. 2999.)

5562. Grail has always made its reimbursement strategy a priority. (Ofman (Grail) Tr. 3449-50).

Response to Finding No. 5562:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5560-61, which Respondents incorporate herein.

5563. In Dr. Ofman's judgment, Grail's reimbursement strategy has received the attention it needs. (Ofman (Grail) Tr. 3450).

Response to Finding No. 5563:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5560–61, which Respondents incorporate herein.

5564. Under Dr. Ofman's leadership, Grail implemented a strategy to align Grail's interests with those of stakeholders who were trying to modernize Medicare. (Ofman (Grail) Tr. 3450).

Response to Finding No. 5564:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5560–61, which Respondents incorporate herein.

5565. Grail has assembled a team in Washington, D.C. that is capable of executing on Grail's Medicare reimbursement strategy. (Ofman (Grail) Tr. 3450).

Response to Finding No. 5565:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5560–61, which Respondents incorporate herein.

5566. [redacted] (Ofman (Grail) Tr. 3352-53 (*in camera*)).

Response to Finding No. 5566:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5560–61, which Respondents incorporate herein.

5567. The Medicare MCED Screening Coverage Act would give CMS the authority to reimburse FDA-approved cancer screening tests including Galleri. (Bishop (Grail) Tr. 1324).

Response to Finding No. 5567:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5560–61, which Respondents incorporate herein.

5568. If CMS identifies MCED tests as an area requiring statutory change, it could approach the congressional committees of jurisdiction to propose a statutory change to provide for coverage of MCED tests by Medicare. (PX7139 (Navathe Trial Dep. at 58-61)).

Response to Finding No. 5568:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5560–61, which Respondents incorporate herein.

5569. [redacted] (Ofman (Grail) Tr. 3356 (*in camera*)).

Response to Finding No. 5569:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5560–61, which Respondents incorporate herein.

Respondents also note that Dr. Ofman explained [redacted]

[redacted] (Ofman (GRAIL) Tr. 3357.)

5570. [redacted] (Ofman (Grail) Tr. 3356 (*in camera*)).

Response to Finding No. 5570:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5560–61 and 5569, which Respondents incorporate herein.

5571. [redacted] (Ofman (Grail) Tr. 3357 (*in camera*)).

Response to Finding No. 5571:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5560–61 and 5569, which Respondents incorporate herein.

5572. [redacted] (Ofman (Grail) Tr. 3353-54 (*in camera*)).

Response to Finding No. 5572:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5560–61, which Respondents incorporate herein.

[redacted] For example, the Medicare Coverage of Innovative Technology (MCIT) Pathway, the pathway is limited to FDA-approved or cleared devices and offers only a temporary coverage window of four years, after which a qualifying device loses coverage if not granted coverage via LCD (Local Coverage Determinations, which are regionally developed policies by Medicare Administrative Contractors) or NCD (National Coverage

Determinations, which are policies that determine coverage for Medicare patients nationally). (RX3228 (CMS); RX6001 (Deverka Trial Dep. at 54–55); [redacted].)

5573. [redacted] (Ofman (Grail) Tr. 3354 (*in camera*)).

Response to Finding No. 5573:

The proposed finding is incomplete and misleading for the reasons stated in Respondents' responses to CCFF ¶¶ 5560-5561 and 5569, which are incorporated herein.

5574. [redacted] (Ofman (Grail) Tr. 3360 (*in camera*)).

Response to Finding No. 5574:

The proposed finding is incomplete and misleading. Dr. Ofman also testified [redacted] (Ofman (GRAIL) Tr. 3361.) .

5575. [redacted] (Ofman (Grail) Tr. 3355 (*in camera*)).

Response to Finding No. 5575:

Respondents have no specific response.

5576. [redacted] (Ofman (Grail) Tr. 3355 (*in camera*)).

Response to Finding No. 5576:

Respondents have no specific response.

5577. [redacted] (Freidin (Grail) Tr. 3140; PX5044 (Grail) (LRP Review, Aug. 20, 2020) (*in camera*)).

Response to Finding No. 5577:

Respondents have no specific response.

5578. [redacted] (Freidin (Grail) Tr. 3171 (*in camera*); Bishop (Grail) Tr. 1442-43 (*in camera*); PX5044 (Grail) at 003 (LRP Review, Aug. 20, 2020) (*in camera*))).

Response to Finding No. 5578:

The proposed finding is incomplete and misleading. [redacted] Mr. Della Porta testified that [redacted]

5579. [redacted] (Freidin (Grail) Tr. 3171-72 (*in camera*)).

Response to Finding No. 5579:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5578, which Respondents incorporate herein.

5580. [redacted] (Della Porta (Grail) Tr. 522 (*in camera*)). [redacted] (Della Porta (Grail) Tr. 522 (*in camera*)).

Response to Finding No. 5580:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5578, which Respondents incorporate herein.

5581. [redacted] (Della Porta (Grail) Tr. 522 (*in camera*)).

Response to Finding No. 5581:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5578, which Respondents incorporate herein.

5582. [redacted] (Della Porta (Grail) Tr. 522-24 (*in camera*)).

Response to Finding No. 5582:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5578, which Respondents incorporate herein.

5583. [redacted] (Conroy (Exact) Tr. 1629 (*in camera*)).

Response to Finding No. 5583:

The proposed finding improperly relies on lay opinion testimony. The proposed finding is also incomplete and misleading as Mr. Conroy testified that [redacted]

[redacted] (Conroy (Exact/Thrive) Tr. 1629.) Dr. Deverka testified that without a change in the current law, an MCED test would need to receive an A or B rating from the USPSTF before getting Medicare coverage. (RX6001 (Deverka Trial Dep. at 50).)

5584. [redacted] (PX7139 (Navathe Trial Dep. at 53-57)).

Response to Finding No. 5584:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5578, which Respondents incorporate herein. [redacted] The bill presents several challenges for MCED test manufacturers. *First*, manufacturers may expend resources in advocating for a bill that may ultimately lose traction and fail to become law, as seen with the bill's predecessor, H.R. 8845. *Second*, assuming the bill is passed, manufacturers will be required to achieve FDA approval or clearance to qualify as a product under the new benefit category. (RX6001 (Deverka Trial Dep. at 49–50, 52; [redacted]

5585. [redacted] (PX7139 (Navathe Trial Dep. at 52)).

[redacted] (PX7139 (Navathe Trial Dep. at 52-53).

Response to Finding No. 5585:

The proposed finding is irrelevant and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5578, which Respondents incorporate herein. [redacted] The Parallel Review Pilot Program ("Parallel Review") was established in October 2011 and permanently extended in 2016 to create a mechanism for the FDA and CMS to simultaneously review clinical data, decreasing the time between FDA approval and CMS NCD development. (RX3556 (FDA) at 3; [redacted])

Since the program's inception, only two tests, Foundation One CDx and Cologuard, have successfully navigated Parallel Review, despite 26 applications and over 60 inquiries. (RX3052 (RAPS) at 1–2; RX3867 (Deverka Expert Report) ¶ 56.) If a test receives a positive coverage determination via the Parallel Review process, private payors must cover the test for their Medicare Advantage population, but do not need to cover the test for their non-Medicare Advantage beneficiaries. (RX3138 (Podemska-Mikluch, 2018) at 1; RX3867 (Deverka Expert Report) ¶ 56.)

As a result of statutory restrictions preventing Medicare from covering preventive services, Parallel Review will not be an option for a MCED test like Galleri unless there is legislative action to add MCED tests as a Medicare benefit category, or alternatively, if the test first receives a grade of A or B following successful USPSTF review. (RX3646 (Social Security

Act § 1833 [42 U.S.C. 1395l]); RX6001 (Deverka Trial Dep. at 53–54); RX3867 (Deverka Expert Report) ¶ 57.)

5586. [redacted] (PX7058 (Conroy (Exact) IHT at 26-27, 32-33) (*in camera*)).

Response to Finding No. 5586:

Respondents incorporate their responses to CCFF ¶ 5585 herein.

5587. [redacted] (Conroy (Exact) Tr. 1629 (*in camera*)).

Response to Finding No. 5587:

Respondents incorporate their responses to CCFF ¶ 5585 herein.

(viii) Grail Is Capable of Developing Its Own Real-World Evidence-Generating Relationships

5588. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 66 (*in camera*))).

Response to Finding No. 5588:

The proposed finding improperly relies on expert testimony to establish a factual proposition. By his own admission, Dr. Rothman lacks the expertise to opine on FDA approval and payor reimbursement and any of his opinions on these topics should also be given no weight. (PFF ¶¶ 2194–94.7.) This is not the first time Dr. Rothman has offered opinions for which he lacks the requisite expertise, which has led other courts, including this court, to find his economic analysis to be flawed. *See, e.g.,* Initial Decision at 91, *In re Altria Group, Inc. & JUUL Labs, Inc.*, No. 933 (F.T.C. Feb. 23, 2022) ("Dr. Rothman's post-Transaction HHI calculations are not economically sound"); *Aya Healthcare Servs., Inc. v. AMN Healthcare, Inc.*, 2020 WL 3414662, at *4 (S.D. Cal. June 22, 2020) ("Dr. Rothman's study allegedly showing supracompetitive prices is seriously flawed," based on a "bare assertion," and devoid of any

"economic analysis"); *Aya Healthcare Sers., Inc. v. AMN Healthcare, Inc.*, 2020 WL 2553181, at *18 (S.D. Cal. May 20, 2020) (his analysis is "unreliable under the *Daubert* standard and of marginal relevance"), *aff'd* 9 F.4th 1102 (9th Cir. 2021); *Evonik*, 436 F. Supp. 3d at 319 & n.33 (Dr. Rothman's product and geographic markets are "ill-conceived" and his calculation of a GUPPI is "unreliable" and inapplicable to the industry at issue).

5589. [redacted] (PX4208 (Grail) at 017 (Galleri Offering to Customers, June 2020) (*in camera*); *see* PX6092 (Rothman Rebuttal Report) ¶ 63).

Response to Finding No. 5589:

The proposed finding is misleading. [redacted] To the extent Complaint Counsel relies on Dr. Rothman for this finding, the proposed finding improperly relies on expert testimony to establish a factual proposition. By his own admission, Dr. Rothman lacks experience with medical device evidence generation and medical technology risk-sharing agreements. (PX7140 (Rothman Trial Dep. at 46.) Dr. Rothman also lacks the expertise to opine on FDA approval and payor reimbursement and any of his opinions on these topics should also be given no weight. (PFF ¶¶ 2194–94.7.)

5590. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 63 (*in camera*)).

Response to Finding No. 5590:

The proposed finding is incomplete and misleading. [redacted] The proposed finding also improperly relies on expert testimony to establish a factual proposition. By his own admission, Dr. Rothman lacks experience with

medical device evidence generation and medical technology risk-sharing agreements. (PX7140 (Rothman Trial Dep. at 46.) Dr. Rothman also lacks the expertise to opine on FDA approval and payor reimbursement and any of his opinions on these topics should also be given no weight. (PFF ¶¶ 2194–94.7.)

5591. Illumina has entered [redacted] (PX4381 (Grail) at 001-002 (Email from A. Wilbekin, Grail, to M. Morgan, Grail, Apr. 12, 2021) (*in camera*)).

Response to Finding No. 5591:

Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 46), or in any deposition, and should not be entitled to rely on it to establish anything beyond the words on the page. [redacted] (Qadan (Illumina) Tr. 4198.) (*in camera*)

5592. [redacted] (Ofman (Grail) Tr. 3404-05 (*in camera*)).

Response to Finding No. 5592:

The proposed finding is incomplete and misleading. Dr. Ofman testified that [redacted] (Ofman (GRAIL) Tr. 3404). And there is abundant unrefuted evidence in the record going to Illumina's experience and relationships with payors. (PFF ¶ 1132.)

5593. [redacted] (PX4381 (Grail) at 001-002 (Email from A. Wilbekin, Grail, to M. Morgan, Grail, Apr. 12, 2021) (*in camera*)).

Response to Finding No. 5593:

Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 46), or in any deposition, and should not be entitled to rely on it to establish anything beyond the words on the page. The use of the term "engaged" is vague and ambiguous as PX4381 does not mention an "engagement" in a pilot program. Respondents also note [redacted] (PX4381 (GRAIL) at 001-002 (Email from A. Wilbekin, Grail, to M. Morgan, Grail, Apr. 12, 2021)).

5594. Dr. Rothman and Grail sales executive, Mark Morgan, noted that "Grail is [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 63 (*in camera*); *see* PX7098 (Morgan (Grail) Dep. at 81) (*in camera*)).

Response to Finding No. 5594:

The proposed finding relies on improper expert testimony that should be given no weight. Dr. Rothman lacks the expertise to opine on payor reimbursement, rendering his opinions unreliable. (*See* Resps.' Post-Trial Br. at 269.) Moreover, the proposed finding is misleading. Mr. Morgan testified at his deposition in June 2021 that many [redacted]

[redacted]

5595. [redacted] (PX7139 (Navathe Trial Dep. at 65-66) (*in camera*)).

Response to Finding No. 5595:

The proposed finding relies on improper expert testimony that should be given no weight. Dr. Navathe lacks the expertise to opine on payor reimbursement, rendering his opinions unreliable. (*See* Resps.' Post-Trial Br. at 266.) In addition, the proposed finding is misleading. [redacted]

5596. Grail's growth strategy, market access, and sales teams all report to Grail's Chief Commercial Officer Gautam Kollu. (Della Porta (Grail) Tr. 459-60).

Response to Finding No. 5596:

Respondents have no specific response.

5597. Gautam Kollu, Grail's Chief Commercial Officer, is a former Illumina employee. (Della Porta (Grail) Tr. 454-455, 578; PX7062 (Kollu (Grail) IHT at 4, 17-18)).

Response to Finding No. 5597:

Respondents have no specific response.

5598. While at Illumina, Mr. Kollu was involved in the development of Illumina's first risk-sharing agreement as a cross-functional team member. (Qadan (Illumina) Tr. 4253-54).

Response to Finding No. 5598:

The proposed finding is incomplete and misleading. Mr. Qadan testified that Mr. Kollu did not have the market access function. (Qadan (Illumina) Tr. 4171–73.) While Mr. Gautam Kollu worked in market development, Mr. Qadan explained that that differed from market access, which focuses on payor coverage (as opposed to societies and similar bodies for the market development group). (Qadan (Illumina) Tr. 4171–73.)

5599. Dr. Deverka testified during her trial deposition that she believes Gautam Kollu, Grail's Chief Commercial Officer, has relevant experience in obtaining market access. (RX6001 (Deverka Trial Dep. at 142)).

Response to Finding No. 5599:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 5598 herein.

5600. [redacted] (Ofman (Grail) Tr. 3405 (*in camera*)).

Response to Finding No. 5600:

The proposed finding is incomplete and misleading. Dr. Ofman testified [redacted] (Ofman (GRAIL) Tr. 3405).

5601. [redacted] (PX7139 (Navathe Trial Dep. at 65-66); PX6093 (Navathe Rebuttal Report) ¶¶ 42, 49 (*in camera*)).

Response to Finding No. 5601:

The proposed finding is irrelevant and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5595, which Respondents incorporate herein.

5602. [redacted] (PX7092 (Ofman (Grail) Dep. at 122-123); *see* PX6092 (Rothman Rebuttal Report) ¶ 66 (*in camera*)).

Response to Finding No. 5602:

To the extent Complaint Counsel rely on Dr. Rothman for this finding, the proposed finding improperly relies on expert testimony to establish a factual proposition. By his own admission, Dr. Rothman lacks experience with medical device evidence generation and medical technology risk-sharing agreements. (PX7140 (Rothman Trial Dep. at 46.) Dr. Rothman also lacks the expertise to opine on FDA approval and payor reimbursement and any of his opinions on these topics should also be given no weight. (PFF ¶¶ 2194–94.7.)

5603. [redacted] (PX4438 (Grail) at 012 [redacted] (*in camera*)).

Response to Finding No. 5603:

Respondents have no specific response, except to note that Complaint Counsel did not present the exhibit cited in the proposed finding to any fact witnesses during discovery or at trial in this case, (CC Exhibit Index at 48), and therefore should not be entitled to rely on it to establish anything beyond the words on the page. Respondents also note that the fact that GRAIL successfully met with the FDA regarding a joint pilot is not relevant to the question of whether Illumina can accelerate Galleri's FDA approval.

5604. [redacted] (PX7098 (Morgan (Grail) Dep. at 127, 167-168); *see* PX6092 (Rothman Rebuttal Report) ¶ 66 (*in camera*)).

Response to Finding No. 5604:

The proposed finding is incomplete, and misleading. Mr. Morgan testified [redacted] (PX7098 (Morgan (GRAIL) Dep. at 127). Mr. Morgan's cited testimony [redacted] (PX7098 (Morgan (GRAIL) Dep. at 127, 167–168). To the extent Complaint Counsel intends to

rely on Dr. Rothman's expert report to establish this proposed fact, that is improper. Moreover, Dr. Rothman lacks experience with medical device evidence generation. (PX7140 (Rothman Trial Dep. at 46.).

5605. [redacted] (PX4239 (Grail) at 003 (Email from M. Morgan, Grail, to C. Della Porta, Grail, Mar. 2, 2021) ([redacted]) (*in camera*); *see* PX6092 (Rothman Rebuttal Report) ¶ 66 (*in camera*)).

Response to Finding No. 5605:

The proposed finding is incomplete and misleading. Mr. Morgan testified [redacted] (PX7098 (Morgan (GRAIL) Dep. at 127, 166-168) (discussing PX4239) (emphasis added)). To the extent Complaint Counsel intends to rely on Dr. Rothman's expert report to establish this proposed fact, that is improper. Moreover, Dr. Rothman lacks experience with medical device evidence generation. (PX7140 (Rothman Trial Dep. at 46).)

5606. [redacted] (PX7139 (Navathe Trial Dep. at 72-73) (*in camera*)).

Response to Finding No. 5606:

The proposed finding is incomplete and misleading. Dr. Navathe admitted [redacted] (PX7139 (Navathe Trial Dep. at 72–73)). As Mr. Morgan testified [redacted] (PX7098 (Morgan (GRAIL) Dep. at 127).

5607. [redacted] (PX4213 (Grail) at 011 [redacted] (*in camera*).

Response to Finding No. 5607:

Respondents have no specific response.

5608. [redacted] (PX7139 (Navathe Trial Dep. at 67-68) (*in camera*)).

Response to Finding No. 5608:

The proposed finding relies on improper expert testimony that should be given no weight. Dr. Navathe lacks the expertise to opine on payor reimbursement, rendering his opinions unreliable. (*See* Resps.' Post-Trial Br. at 266.). Dr. Deverka has opined that [redacted] (RX3867 (Deverka Expert Report) ¶ 127.)

5609. [redacted] (PX6093 (Navathe Rebuttal Report) ¶ 60 (*in camera*)).

Response to Finding No. 5609:

The proposed finding relies on improper expert testimony that should be given no weight. [redacted] (*See* Resps.' Post-Trial Br. at 266.). When read this passage in her trial deposition, Dr. Deverka stated that Dr. Navathe "mak[es] many leaps here that are unsubstantiated by

evidence." (RX6001 (Deverka Trial Dep. at 116).) In particular, "payers will have questions about what is the incremental benefit of adding -- Galleri is not a substitute for standard of care screening, so we are adding Galleri to existing standard of care. They will want to understand what is the incremental benefit and harms of doing this. We've never had multicancer early detection tests even on the market before, and there -- nothing from what GRAIL has published about the clinical benefits of Galleri lead to a conclusion of cost savings. They may offset some medical costs, and they are likely to be highly cost-effective, which means you pay more to reduce cancer-specific mortality, but they will not reduce medical costs. That means -- implies cost savings." (RX6001 (Deverka Trial Dep. at 116).) Dr. Deverka also testified that "with the benefit of Illumina's health system relationships and implementation resources, which for me means study-related resources to implement and conduct the study, then GRAIL would be more likely to collect the real-world evidence necessary to reach widespread adoption". (RX6001 (Deverka Trial Dep. at 161).)

(ix) Grail Is Hitting Its Strategic Targets Toward the Commercialization of Galleri Without Illumina's Assistance

5610. [redacted] (Bishop (Grail) Tr. 1444 (*in camera*); PX5044 (Grail) at 003 (LRP Review, Aug. 20, 2020) (*in camera*)).

Response to Finding No. 5610:

The proposed finding is incomplete and misleading. The evidence shows that [redacted]

[redacted] Galleri's launch was as an LDT and it still has a long way to go before it achieves widespread adoption. (PFF ¶ 295.1.)

5611. [redacted] (PX4159 (Grail) at 009 (Email from J. Craighead, Grail, to Grail-BOD, Grail, attaching "Investor Presentation," Aug. 20, 2020) (*in camera*)). Dr. Ofman testified that Grail achieved that milestone on schedule. (Ofman (Grail) Tr. 3442).

Response to Finding No. 5611:

Respondents have no specific response except to note that Illumina's acceleration of Galleri by one year is not undermined by the fact that GRAIL met prior milestones on time.

5612. [redacted] (PX4159 (Grail) at 009 (Email from J. Craighead, Grail, to Grail-BOD, Grail, attaching "Investor Presentation," Aug. 20, 2020) (*in camera*)). Dr. Ofman testified at trial that Grail achieved that milestone by presenting PATHFINDER results at ASCO, but said he was not sure if that occurred in the first or second half of 2021. (Ofman (Grail) Tr. 3442).

Response to Finding No. 5612:

Respondents have no specific response except to note that Illumina's acceleration of Galleri by one year is not undermined by the fact that GRAIL met prior milestones on time.

5613. The interim results for PATHFINDER were presented at ASCO in the first half of 2021. (RX3041 at 001 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021).

Response to Finding No. 5613:

Respondents have no specific response.

5614. [redacted] (PX4159 (Grail) at 009 (Email from J. Craighead, Grail, to Grail-BOD, Grail, attaching "Investor Presentation," Aug. 20, 2020) (*in camera*)). Dr. Ofman testified at trial that Grail achieved that milestone on schedule. (Ofman (Grail) Tr. 3444).

Response to Finding No. 5614:

Respondents have no specific response except to note that Illumina's acceleration of Galleri by one year is not undermined by the fact that GRAIL met prior milestones on time.

5615. [redacted] (PX4159 (Grail) at 009 (Email from J. Craighead, Grail, to Grail-BOD, Grail, attaching "Investor Presentation," Aug. 20, 2020) (*in camera*)). Dr. Ofman testified at trial that Grail achieved that milestone on schedule. (Ofman (Grail) Tr. 3444).

Response to Finding No. 5615:

Respondents have no specific response except to note that Illumina's acceleration of Galleri by one year is not undermined by the fact that GRAIL met prior milestones on time.

5616. [redacted] (Freidin (Grail) Tr. 3100 (*in camera*)).

Response to Finding No. 5616:

Respondents have no specific response.

5617. [redacted] (Freidin (Grail) Tr. 3100 (*in camera*)).

Response to Finding No. 5617:

Respondents have no specific response.

5618. [redacted] (Bishop (Grail) Tr. 1466-68 (*in camera*); PX4489 (Grail) at 011 (Email from S. Green, Grail, to Grail-BOD, Grail, attaching BoD 2021 Budget, Dec. 2020) (*in camera*)).

Response to Finding No. 5618:

Respondents have no specific response.

5619. [redacted] (Freidin (Grail) Tr. 3101 (*in camera*); PX4213 (Grail) at 001 [redacted]

[redacted] (*in camera*)).

Response to Finding No. 5619:

Respondents have no specific response.

5620. [redacted] (Freidin (Grail) Tr. 3101-102 (*in camera*); PX4213 (Grail) at 003 [redacted] (*in camera*)).

Response to Finding No. 5620:

The proposed finding is incomplete and misleading. PX4213 states that [redacted] PX4213 (GRAIL) at 003 ([redacted]). In any event, Illumina's acceleration of Galleri by one year is not undermined by the fact that GRAIL met prior milestones on time.

5621. [redacted] (PX4213 (Grail) at 003 [redacted] (*in camera*)).

Response to Finding No. 5621:

Respondents have no specific response except to note that Illumina's acceleration of Galleri by one year is not undermined by the fact that GRAIL met prior milestones on time.

5622. [redacted] (PX4213 (Grail) at 005 [redacted] (*in camera*)).

Response to Finding No. 5622:

The proposed finding is misleading. [redacted] (PX4213 (GRAIL) at 006 ([redacted]) [redacted] (PX4213 (GRAIL) at 009) (emphasis added). In any event, Illumina's acceleration of Galleri by one year is not undermined by the fact that GRAIL met prior milestones on time.

5623. [redacted] (PX4213 (Grail) at 005 [redacted] (*in camera*)).

Response to Finding No. 5623:

The proposed finding is misleading. [redacted] (PX4213 (GRAIL) at 010 ([redacted])). In any event, Illumina's acceleration of Galleri by one year is not undermined by the fact that GRAIL met prior milestones on time.

5624. [redacted] (PX4213 (Grail) at 005 [redacted] (*in camera*)).

Response to Finding No. 5624:

The proposed finding is misleading. [redacted] (PX4213 (GRAIL) at 010 ([redacted]). In any event, Illumina's acceleration of Galleri by one year is not undermined by the fact that GRAIL met prior milestones on time.

5625. [redacted] (Bishop (Grail) Tr. 1468 (*in camera*); PX4489 (Grail) at 011 [redacted] (*in camera*)).

Response to Finding No. 5625:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶ 5263, which Respondents incorporate herein.

5626. [redacted] (Bishop (Grail) Tr. 1468 (*in camera*); PX4489 (Grail) at 011 (Email from S. Green, Grail, to Grail-BOD, Grail, attaching BoD 2021 Budget, Dec. 9, 2020) (*in camera*)).

Response to Finding No. 5626:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶ 5264, which Respondents incorporate herein.

5627. [redacted] (PX4213 (Grail) at 008 [redacted]

[redacted] (*in camera*)).

Response to Finding No. 5627:

Respondents have no specific response, except to note that at the time of trial, GRAIL had only sold around 3,000 Galleri tests. (Freidin (GRAIL) Tr. 2969.) Further, GRAIL has been unable to accept offers to provide its Galleri product to other countries due to a lack of capacity. (Freidin (GRAIL) Tr. 3009 ("Q. And what ability do you have to develop international sales today? A. Yeah. So we've got a very small corporate development team of three people, and we — we have people — we have enough people to talk to people but not enough to actually do anything, so we've often in a position of people reaching out to do things and us, you know, being polite and having to say we just can't take it on right now".).) In any event, Illumina's acceleration of Galleri by one year is not undermined by the fact that GRAIL met prior milestones on time.

5628. [redacted] (PX4213 (Grail) at 008 [redacted] (*in camera*)).

Response to Finding No. 5628:

The proposed finding is incomplete and misleading. As PX4213 states, [redacted]

[redacted]); *see also* RX2803 (GRAIL) at 002–003 (April 3

Commercial Forecast Review) (noting that 2021 April sales forecast had been revised downward by 7% relative to November 2020 forecast). In any event, Illumina's acceleration of Galleri by one year is not undermined by the fact that GRAIL met prior milestones on time.

5629. [redacted] (PX4213 (Grail) at 011 [redacted] (*in camera*)).

Response to Finding No. 5629:

Respondents have no specific response.

5630. [redacted] (Freidin (Grail) Tr. 3102 (*in camera*)).

Response to Finding No. 5630:

Respondents have no specific response, except to note that [redacted]

(x) Grail Has the Resources to Independently Commercialize Galleri at Scale

For details on Grail's access to non-merger alternatives, fundraising, and an IPO, see Section VIII.D.2.

For evidence that Grail has built an established regulatory team that has met and surpassed Grail's internal goals, see Section VIII.C.1.a.2.h. (Grail Is Already Pursuing FDA Approval Aggressively as an Independent Company).

For evidence that Grail has invested in laboratory efficiencies, including constructing a new lab in North Carolina capable of running large commercial volume covering Grail's expected volumes through 2025-2027, see Section VIII.C.5.b.).

(3) The Claimed Payer Acceleration Efficiency Is Not Verifiable Because It Is Not Quantifiable

For evidence that the claimed payer acceleration efficiency is not verifiable, see Section VIII.C.1.a.3. (The Claimed FDA Acceleration Efficiency Is Not Verifiable Because It Is Not Quantifiable).

(4) The Claimed Payer Acceleration Efficiency Is Not Merger Specific

(a) Illumina Has Provided Market Access Assistance to Other Companies

5631. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 83 (*in camera*)).

Response to Finding No. 5631:

The proposed finding improperly relies on Dr. Rothman's expert report to establish the proposed fact and relies on improper expert testimony that should be given no weight. Dr. Rothman has admitted he is not an expert in market access, and so his understanding of what constitutes relevant technical assistance in this area lacks value. (PFF ¶ 1134.4) The proposed finding is also incomplete and misleading. The cited [redacted] (*See e.g.*, Goswami (Illumina) Tr. 3188 (noting that in an IVD partnership, Illumina's responsibility "really focuses on the Dx platform that this developer uses, right. But the developer then takes responsibility for all the clinical trial that they have to run to -- to validate the test, to submit the clinical trial results, both analytical and clinical validation to the FDA, and then they take on the burden of then making sure that they are manufacturing the distributable kit according to FDA guidelines and maintaining the quality of that kit going forward.").) The evidence is overwhelming that Illumina and GRAIL would not be able to contract for the market acceleration efficiencies that would result from the Transaction. Illumina and GRAIL witnesses testified that they could not contract for these

efficiencies if they were separate entities because Illumina does not provide such services to any third party entities and doing so would require GRAIL to share its confidential information with Illumina. (Aravanis (Illumina) Tr. 1969–70 ("It would require GRAIL to share, you know, its knowledge of all of its technology, its assays, its bioinformatics. On the payer and FDA aspects of the efficiencies, they would need to share details of its clinical trials, the results, you know, of them, you know, how they were conducted, proprietary information that it wouldn't necessarily – it wouldn't otherwise share".); Febbo (Illumina) Tr. 4369 ("you don't see total alignment between two companies, and nor can you get into the depth of understanding of the processes and the special sauce that a lot of these companies, including Illumina, have in order to fully realize efficiencies, fully realize where you have the best opportunity to improve a test, to improve or speed regulatory, improve reimbursement. You just don't see the layer of engagement that's necessary to get to the full realization of those benefits through partnerships".); [redacted] Dr. Carlton reiterates this point: "Illumina does not offer regulatory help or market access services to customers. My understanding is Illumina would not provide, in absence of this transaction, a service to GRAIL to help it get FDA approval or payer approval". (RX6000 (Carlton Trial Dep. at 60).) He added that "GRAIL would not tell Illumina in absence of this transaction, a lot of information that would be useful for Illumina to know to accelerate the improve – the approval. In particular, GRAIL is very concerned about its proprietary information in its machine-learning algorithm, and it's not going to give that information to Illumina if this transaction doesn't go through". (RX6000 (Carlton Trial Dep. at 60–61).)

5632. [redacted] (PX7107 (deSouza (Illumina) Dep. at 248-251; *see* PX6092 (Rothman Rebuttal Report) ¶ 83, n.135 (*in camera*)).

Response to Finding No. 5632:

The proposed finding is incomplete, misleading and relies on improper expert testimony for the reasons explained in Respondents' responses to CCFF ¶ 5631, which Respondents incorporate herein.

5633. In the September 3, 2019 JPM Life Sciences CEO conference call, Mr. deSouza stated that, of the 70 companies that are doing liquid biopsy:"[w]e continue to support them in some cases, it's making sure that they have access to the best of our workflow even on the front end or on the back end." (deSouza (Illumina) Tr. 2213; PX2544 (Illumina) at 019 (Transcript of JPM Life Sciences CEO Conference Call, Sept. 3, 2019)). Mr. deSouza explained to investors that "it's planning with them what their path to a regulated offering could be, cleared offering" and that "we're continuing to work with them in a number of different ways to enhance their ability to expand their market, because, what's good for them is obviously good for us too." (deSouza (Illumina) Tr. 2213; PX2544 (Illumina) at 019 (Transcript of JPM Life Sciences CEO Conference Call, Sept. 3, 2019)).

Response to Finding No. 5633:

The proposed finding is incomplete, misleading and relies on improper expert testimony for the reasons explained in Respondents' responses to CCFF ¶ 5631, which Respondents incorporate herein.

(b) Illumina Provided Advantages to Grail While Grail Was a Separate Corporate Entity

For additional information on how Illumina gave Grail preferential, exclusive, and customized treatment when it owned more than 50 percent of Grail (but not once it spunoff Grail), see Sections I.A.2.–3. (Formation of Grail & Spinoff of Grail (Reducing Ownership to Less Than 50 Percent) and VII.D.1. (Illumina Identified Tools When it Launched and Spun Off Grail).

5634. As noted in Illumina's board minutes, when Illumina owned a majority stake in Grail before selling it to outside investors, Illumina provided Grail with preferential terms and agreed not to "launch, invest in, or provide special discounts to competitive business[es]." (PX2557 (Illumina) at 017 (Minutes of the Meeting of the Board of Directors of Illumina, Inc., Dec. 20, 2015)).

Response to Finding No. 5634:

The proposed finding is incomplete, and misleading. Respondents also note that any special pricing and other benefits Illumina may have provided to GRAIL in its original supply agreement when GRAIL was formed and controlled by Illumina are irrelevant to evaluating the effects of the Transaction on competition. At the time of GRAIL's formation, the objective of creating a cancer screening test was a moonshot concept, and Illumina believed that without deep discounting, it would be impossible for GRAIL to develop a cancer screening test: As Dr. Aravanis, who helped form GRAIL, testified, the industry reaction to the formation of GRAIL was "very, very skeptical" because the conventional wisdom was that, while GRAIL's mission was "noble", "it will be very hard, may not work at a scientific level and, even if it did, will take a very long time and be very challenging from a cost and clinical development" perspective. (Aravanis (Illumina) Tr. 1873–74.)

As Illumina's contemporaneous internal documents noted, at the time, Illumina believed that "no customer has the ability to implement a pan-cancer screening test responsibly and economically anytime in the next 5 years"; therefore, to accelerate the growth of the segment, Illumina "felt an imperative to organize an entity" focused on that moon-shot mission. (RX1088 (Illumina) at 7; (PX7079 (Flatley (Illumina) Dep. at 111–12)).) In other words, there was no one else pursuing the goal that Illumina set GRAIL on a path to pursue, and any special pricing at that time was not designed to put rivals at a disadvantage—there were no rivals, and the goal was in fact to accelerate the development of the cancer screening space by years, which would benefit others who might seek to invest in the space. (Aravanis (Illumina) Tr. 1873–74; RX1088 (Illumina) at 7.))

These considerations from the time of GRAIL's formation no longer exist for many reasons, including because (i) the cost of sequencing has come down since 2016 (PFF ¶ 22); and (ii) Illumina's assumptions about the volume of sequencing required to develop a cancer screening test were significantly higher than what is actually required. (PX7079 (Flatley (Illumina) Dep. at 118–20)).) For example, GRAIL's Galleri test does not use "ultra-deep sequencing", but relies on targeted methylation for cancer signal detection and localization. *(See, e.g.*, PFF ¶¶ 56, 345, 384, 981, 1289.)

Respondents further note that Complaint Counsel chose not to discuss the cited document at trial, (CC Exhibit Index at 23), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

5635. In a December 2015 board presentation prior to Grail's spinoff, Illumina planned to provide Grail with "[s]pecial [p]ricing," a 75 percent discount that would save Grail $100 million over three years. (PX2069 (Illumina) at 003 (Python Board Approval, Dec. 20, 2015)).

Response to Finding No. 5635:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5634, which Respondents incorporate herein. In addition, the proposed finding is also incorrect to the extent it suggests that GRAIL receives "forward pricing" today that is not available to other test developers. The sequencing costs today are the same for GRAIL as they are for any putative MCED test developer. Any customer that signs the Open Offer "shall have access to Volume-Based Net Prices (under Appendix 1)" for sequencing instruments and core consumables "that are no less favorable (i.e., the same or better) than the Volume-Based Net Prices provided to GRAIL." (PFF ¶¶ 1013, 1021.1; deSouza (Illumina) Tr. 2402–03; PX0064 (Illumina) at 7–8.) If a customer chooses Universal Pricing, it will receive

"most favored nation" pricing relative to other customers: that customer's prices will be no less favorable than the pricing any other equivalent customer receives. (Berry (Illumina) Tr. 893; PX0064 (Illumina) at 7–8.) Further, if an equivalent customer receives a discretionary discount higher than those listed in the Open Offer, then that discount will be offered to all other equivalent customers. (Berry (Illumina) Tr. 893–94; RX6002 (Guerin-Calvert Trial Dep. at 38–39).) As an additional protection, under the Open Offer if GRAIL (or another customer) receives more favorable pricing than another customer, then Illumina is required to notify that other customer promptly and to refund any difference. (Berry (Illumina) Tr. 894, 914.)

(c) Illumina Has Incentives to Accelerate Commercialization of Galleri Without the Merger

For evidence relevant to Illumina's incentives to accelerate Galleri without a merger, see Section VIII.C.1.g. (If Illumina Could Meaningfully Accelerate Galleri, It Has the Incentive to Do So Absent the Merger).

(d) Grail Could Finance Commercialization of Galleri at Scale Through an IPO or Other Fundraising

For evidence that Grail had non-merger alternatives to commercializing Galleri, see Section VIII.D. (Non-Merger Alternatives Could Replicate Illumina's Claimed Efficiencies).

(e) Experience Forming Payer Relationships Can Be Accessed Outside of Illumina

5636. Other companies than Illumina are able to enter into relationships with payers. (Freidin (Grail) Tr. 3164).

Response to Finding No. 5636:

Respondents have no specific response except to note that Illumina has extensive experience working with payors both in and outside of the US, and has entered into several groundbreaking partnerships, including with [redacted], Harvard Pilgrim, Genomics England and the State of Queensland. (PFF ¶¶ 1133.11–33.21.) The evidence is overwhelming

that Illumina's experience and expertise in this area will accelerate Galleri's rollout. (PFF ¶ 1127–35.)

5637. Illumina did not invent risk-sharing agreements. (Qadan (Illumina) Tr. 4249).

Response to Finding No. 5637:

Respondents have no specific response except to note that Illumina has entered into three risk-sharing agreements (one relating to NIPT with Harvard Pilgrim, another with Harvard Pilgrim relating to whole genome sequencing, and a third with the State of Queensland also related to whole genome sequencing). (PFF ¶ 1462.) Mr. Qadan testified that to his knowledge, no manufacturer had entered into a risk-sharing agreement involving NGS prior to Illumina; that risk-sharing agreements are not common between manufacturers and payors or health systems, and are rather more common between payors and healthcare providers, because they are easier to administer; that when there are risk-sharing agreements involving a manufacturer, they typically involve pharmaceuticals, rather than genomics or diagnostics; that risk-sharing agreements are not common in diagnostics and genomics because the data associated with genomics is much more complicated than that of pharmaceuticals. (Qadan, (Illumina) Tr. 4140–43.) Mr. Qadan also testified that the success of the initial NIPT risk-sharing agreement with Harvard Pilgrim enabled Illumina and Harvard Pilgrim to enter into another risk-sharing agreement in RUGD. (Qadan (Illumina) Tr. 4145.) Mr. Qadan added that Illumina's work with risk-sharing agreements is relevant to improving market access for Galleri, due to the reduced learning curve for any future agreements: while the NIPT agreement took 10 months to negotiate, the agreement for RUGD took roughly half the time despite the fact that Illumina had to analyze over 2,000 billing codes. (Qadan (Illumina) Tr. 4146.)

5638. [redacted] (PX7139 (Navathe Trial Dep. at 62-63) (*in camera*); PX6093 (Navathe Rebuttal Report) ¶¶ 39-40 (*in camera*)).

Response to Finding No. 5638:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶ 5637, which Respondents incorporate herein. Further, Dr. Navathe admitted that he was not an expert in payor coverage, and so his view on this point lacks value. (PFF ¶ 1134.4.)

5639. [redacted] (PX7139 (Navathe Trial Dep. at 63-64; PX6093 (Navathe Rebuttal Report) ¶ 40 (*in camera*)).

Response to Finding No. 5639:

The proposed finding is incomplete and misleading. Mr. Qadan testified that to his knowledge, no manufacturer had entered into a risk-sharing agreement involving NGS prior to Illumina; that risk-sharing agreements are not common between manufacturers and payors or health systems, and are rather more common between payors and healthcare providers, because they are easier to administer; that when there are risk-sharing agreements involving a manufacturer, they typically involve pharmaceuticals, rather than genomics or diagnostics; that risk-sharing agreements are not common in diagnostics and genomics because the data associated with genomics is much more complicated than that of pharmaceuticals. (Qadan, (Illumina) Tr. 4140–43.) Additionally, he explained that the NIPT risk-sharing agreement with Harvard Pilgrim involved such complex data that there was no guarantee of its success from the outset. (Qadan (Illumina) Tr. 4143–44.) Further, Illumina's whole genome agreement with Harvard Pilgrim involved analyzing over 2,000 billing codes. (Qadan (Illumina) Tr. 4146.) Respondents generally refer to their responses to CCFF ¶ 5638, and note that Dr. Navathe is not an expert in payor coverage, and so his view lacks value. (PFF ¶ 1134.4.)

5640. [redacted] (PX6093 (Navathe Rebuttal Report) ¶ 40 (*in camera*)).

Response to Finding No. 5640:

The proposed finding is incomplete and misleading. [redacted] Mr. Qadan testified that to his knowledge, no manufacturer had entered into a risk-sharing agreement involving NGS prior to Illumina; that risk-sharing agreements are not common between manufacturers and payors or health systems, and are rather more common between payors and healthcare providers, because they are easier to administer; that when there are risk-sharing agreements involving a manufacturer, they typically involve pharmaceuticals, rather than genomics or diagnostics; that risk-sharing agreements are not common in diagnostics and genomics because the data associated with genomics is much more complicated than that of pharmaceuticals. (Qadan, (Illumina) Tr. 4140–43.) Respondents generally refer to their responses to CCFF ¶ 5638, and note that Dr. Navathe is not an expert in payor coverage, and so his opinions should be given no weight. (PFF ¶ 1134.4.)

5641. Harvard Pilgrim gained experience in risk-based contracts after completing its risk-based agreement with Illumina. (Qadan (Illumina) Tr. 4272).

Response to Finding No. 5641:

Respondents have no specific response except to note that the fact that Harvard Pilgrim gained experience with risk sharing agreements through Illumina supports the important role that Illumina can play in accelerating Galleri's market access.

5642. [redacted] (PX6093 (Navathe Rebuttal Report) ¶¶ 43-46 (*in camera*)).

Response to Finding No. 5642:

The proposed finding is misleading and incomplete. Such risk-sharing agreements are rare and complex, so experience of them would be hard to come by; Respondents' incorporate their responses to CCFF ¶ 5638 herein. Illumina's experience in this area is unique (having been the first manufacturer to enter into an NGS-related risk-sharing agreement. (PFF ¶ 1463.) Illumina's experience cannot simply by hired via its employees, as Mr. Qadan testified: the company has built-up its institutional knowledge and image over time. (Qadan (Illumina) Tr. 4170–71.) Fact witnesses with personal knowledge also testified that GRAIL could not achieve these efficiencies by hiring additional personnel or outside consultants because the pool of individuals with such experience is limited and it can take a long time for consultants to get up to speed on the specific needs in a new area such as screening. (PFF ¶¶ 1175.1–1175.2.4.) Mr. Freidin testified: [redacted] Other fact witnesses with personal knowledge also testified that GRAIL could not achieve these efficiencies by hiring additional personnel or outside consultants because the pool of individuals with such experience is limited and it can take a long time for consultants to get up to speed on the specific needs in a new area such as screening. (PFF ¶¶ 1175.1–1175.2.4.) Dr. Febbo testified that "I know through our use of consultants and our hiring of individuals into regulatory, into market access, across our personnel, is that there's just not a deep, rich bench of experience available for consultants, and the model of a consultant driving

that just doesn't work as effectively as having internal employees". (Febbo (Illumina) Tr. 4365.) As Mr. Qadan explained, "you build institutional capability over time internally that might not be the subject-matter expertise of those consultants, because, again, consultants are teams that come and go, so they do not have that institutional expertise. . . . [T]hat's really the main reason why . . . a group of consultants cannot do the work with companies. And our, again, experience when we needed to use consultants even for strategy work, it has been a steep learning curve in many cases when it comes to the applications or clinical applications we're dealing with". (Qadan (Illumina) Tr. 4167–68.) [redacted]

Further, Dr. Navathe admitted that he did not have expertise in seeking payor coverage, so his view on this point lacks value. (PFF ¶ 1134.4.)

5643. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 78 (*in camera*)).

Response to Finding No. 5643:

The proposed finding is inaccurate. The evidence is clear that the market acceleration benefits of the Transaction are merger specific. *First*, Illumina's experience and expertise in this area cannot be replicated, and has taken years to build. (PFF ¶ 1175.1.) *Second*, Consultants lack the deep knowledge required to help in this process. (PFF ¶¶ 1175.2–75.4.) *Third*, the

evidence is clear that Illumina and GRAIL could not contract for these efficiencies absent the Transaction: Illumina does not supply market access support to third parties, and GRAIL would be unwilling to share its confidential information with Illumina in that case. (PFF ¶¶ 1175.3–75.4.3.)

(f) Clinical Research Organizations and Consultants Can Help to Develop Evidence of Clinical Utility

5644. Mr. Qadan testified that companies can recruit clinical research organizations to run the operational aspects of a clinical utility study. (Qadan (Illumina) Tr. 4268).

Response to Finding No. 5644:

Respondents have no specific response except to note that Illumina's strategy to accelerate market access to Galleri is through its relationships with payors and its experience executing a market access strategy. (PFF ¶ 1133.)

5645. [redacted] (PX7139 (Navathe Trial Dep. at 77) (*in camera*)).

Response to Finding No. 5645:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5642, which Respondents incorporate herein. The evidence is clear that consultants cannot provide sufficient knowledge and expertise to secure payor coverage – particularly not when compared with Illumina's abilities. (PFF ¶¶ 1175.2–75.4.) As Mr. Qadan explained: "So whether in during my work in -- at Illumina or my work before Illumina, I used consultants consistently in two ways. One is for building the strategy. And second is for building metrics, performance metrics, to evaluate whether that strategy is working or not. But I did not use them for execution; i.e., I cannot use them to go and act on my behalf as Illumina to talk to payers." (Qadan (Illumina) Tr. 4166.) Further, Dr. Navathe admitted that he

did not have expertise in seeking payor coverage, so his view on this point lacks value. (PFF ¶ 1134.4.)

(g) Consultants Are Available in Connection with Market Access and to Assist in Obtaining Payer Reimbursement

In addition to the below, see Section VIII.C.1.a.4.a. (Grail Could Enhance Its Regulatory Capabilities With Consultants or Hiring, Rather Than Merging With Illumina).

5646. Companies can hire consultants to understand how commercial payers would look at a particular test. (Qadan (Illumina) Tr. 4268).

Response to Finding No. 5646:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5642, which Respondents incorporate herein. Mr. Qadan also added that consultants would help to understand the strategy of payor coverage, but not the execution. (Qadan (Illumina) Tr. 4268.) As Mr. Qadan explained elsewhere in his testimony: "So whether in during my work in -- at Illumina or my work before Illumina, I used consultants consistently in two ways. One is for building the strategy. And second is for building metrics, performance metrics, to evaluate whether that strategy is working or not. But I did not use them for execution; i.e., I cannot use them to go and act on my behalf as Illumina to talk to payers." (Qadan (Illumina) Tr. 4166.) More generally, the evidence is clear that consultants cannot provide sufficient knowledge and expertise to secure payor coverage – particularly not when compared with Illumina's abilities. (PFF ¶¶ 1175.2–75.4.)

5647. Mr. Morgan testified that Grail has consulted with ClearView regarding pricing. (PX7098 (Morgan (Grail) Dep. at 64-65)).

Response to Finding No. 5647:

The proposed finding is vague and misleading. Mr. Morgan actually testified that ClearView's analysis was "run before [he] arrived" at GRAIL and he did not know who actually

created the analysis. (PX7098 (Morgan (GRAIL) Dep. at 64-65, 76.) Even so, to the best of Mr. Morgan's recollection, Clearview's analysis only "provided some insight into pricing elasticity or willingness to pay." (PX7098 (Morgan (GRAIL) Dep. at 64-65.)

5648. In a presentation prepared for [redacted] (PX4138 (Grail) at 124 (Email from M. Morgan, Grail, to N. Aceto, Grail, copying G. Kollu and J. Ofman, Grail, June 22, 2020) (*in camera*); PX6092 (Rothman Rebuttal Report) ¶ 63 (*in camera*)).

Response to Finding No. 5648:

The proposed finding is misleading and incorrect. [redacted]

5649. Mr. Morgan testified that Grail consulted with ADVI regarding Medicare adoption. (PX7098 (Morgan (Grail) Dep. at 65). ADVI provided Grail with "insights and inputs that help [Grail] shape [its] strategy on the government side." (PX7098 (Morgan (Grail) Dep. at 64)).

Response to Finding No. 5649:

The proposed finding is vague, incomplete and misleading. Mr. Morgan testified that ADVI provided "general knowledge" about the "adoption of lab-developed tests in a Medicare setting," including general estimates about the length of time required to achieve such adoption (PX7098 (Morgan (GRAIL) Dep. at 66.) ADVI did not provide advice beyond this for Galleri. PX7098 (Morgan (GRAIL) Dep. at 66-67.)

Furthermore, the advice that GRAIL received was of limited value: [redacted]

5650. Mr. Morgan testified that ADVI provided Grail with insights into how to "put the best submission forward to a Medicare administrative contractor as possible" and "the type of evidence, clinical evidence," that Medicare may value. (PX7098 (Morgan (Grail) Dep. at 65)).

Response to Finding No. 5650:

The proposed finding is vague, incomplete and misleading. ADVI's advice regarding submissions was not related to Galleri. (PX7098 (Morgan (GRAIL) Dep. at 66-67).) [redacted] (PX7098 (Morgan (GRAIL) Dep. at 66-67).) [redacted] (PX7098 (Morgan (GRAIL) Dep. at 66-67).)

Furthermore, the advice that GRAIL received was of limited value: [redacted]

[redacted]

5651. Mr. Morgan testified that Grail consulted with McDermott regarding the "complexity associated with coding to help . . . GRAIL understand how to navigate that [Medicare] landscape." (PX7098 (Morgan (Grail) Dep. at 68-69).

Response to Finding No. 5651:

The proposed finding is misleading. [redacted]

5652. Mr. Morgan testified that [redacted] (PX7098 (Morgan (Grail) Dep. at 131-132) (*in camera*)).

Response to Finding No. 5652:

The proposed finding is misleading for the reasons stated in Respondents' responses to CCFF ¶ 5650, which are incorporated herein.

5653. [redacted] (PX7092 (Ofman (Grail) Dep. at 80-87) (*in camera*)).

Response to Finding No. 5653:

The proposed finding is misleading without for the reasons stated in Respondents' responses to CCFF ¶ 5650, which are incorporated herein. [redacted]

5654. Ammar Qadan, Illumina's Vice President and Global Head of Market Access, testified that Illumina has [redacted] (PX7084 (Qadan (Illumina) Dep. at 27-29) (*in camera*)).

Response to Finding No. 5654:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶ 5650, which Respondents incorporate herein. Mr. Qadan also testified that a team of consultants could not provide the functionality for Illumina that its market access group provides; that consultants are teams that come and go, and do not have institutional expertise that is built up over time; and that, even for strategy work, it is a steep learning curve for consultants to develop the required understanding. (Qadan (Illumina) Tr. 4167–68.) Mr. Qadan further explained that in his work at Illumina and beforehand, he had used consultants: first, to build strategy and second, to build metrics to evaluate whether that strategy is working or not; and that

he could not use consultants for execution, i.e., to go and talk to payors on Illumina's behalf. (Qadan (Illumina) Tr. 4165.)

5655. Mr. Qadan testified that [redacted] (PX7084 (Qadan (Illumina) Dep. at 27-29) (*in camera*)).

Response to Finding No. 5655:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶ 5654, which Respondents incorporate herein.

5656. Mr. Qadan testified that [redacted] (PX7084 (Qadan (Illumina) Dep. at 27-29) (*in camera*)).

Response to Finding No. 5656:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶ 5654, which Respondents incorporate herein .

5657. Illumina hired Dr. Lee Newcomer as a consultant to understand how commercial payers would look at the Galleri test. (Qadan (Illumina) Tr. 4268).

Response to Finding No. 5657:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶ 5654, which Respondents incorporate herein. Mr. Qadan also testified that Dr. Newcomer's "feedback was in line with what we thought." (Qadan (Illumina) Tr. 4268.)

5658. [redacted] (PX7084 (Qadan (Illumina) Dep. at 118-119) (*in camera*)).

Response to Finding No. 5658:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶ 5654, which Respondents incorporate herein. Mr. Qadan testified that Dr. Newcomer's "feedback was in line with what we thought." (Qadan (Illumina) Tr. 4268.)

5659. Illumina's market access group uses Ipsos, a consulting firm, to develop its monthly dashboard regarding global coverage and reimbursement for Illumina's products. (Qadan (Illumina) Tr. 4275).

Response to Finding No. 5659:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶ 5654, which Respondents incorporate herein.

5660. Illumina's market access group hired Bruce Quinn Associates as a consultant. (Qadan (Illumina) Tr. 4275).

Response to Finding No. 5660:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶ 5654, which Respondents incorporate herein.

5661. Illumina has used Deloitte as a consultant to build strategy for rare, undiagnosed genetic diseases. (Qadan (Illumina) Tr. 4275).

Response to Finding No. 5661:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶ 5654, which Respondents incorporate herein.

5662. Illumina has consulted Deloitte regarding "innovative contracting mechanisms." (Qadan (Illumina) Tr. 4275-76).

Response to Finding No. 5662:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶ 5654, which Respondents incorporate herein.

5663. An Illumina employee involved in developing Illumina's NIPT risk-sharing agreement with Harvard Pilgrim, Rick Nida, left Illumina and is now a principal and senior vice president at GenoSan Genomic and Diagnostic Commercialization Consulting. (Qadan (Illumina) Tr. 4254).

Response to Finding No. 5663:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶ 5654, which Respondents incorporate herein. Mr. Qadan was not aware of Rick

Nida's current title and employer until informed by Complaint Counsel. (Qadan (Illumina) Tr. 4254) ("Q. And Mr. Nida is now principal and senior vice president at GenoSan Genomic and Diagnostic Commercialization Consulting. Is that correct? A. Yes. That's how far I know from you, yeah.")

5664. [redacted] (PX7139 (Navathe Trial Dep. at 76-77) (*in camera*)).

Response to Finding No. 5664:

The proposed finding is incomplete and misleading. Dr. Navathe admitted that he had "never been involved in seeking FDA approval for a multicancer early detection test" and that was not an expert in "how the FDA is going to handle the evaluation of MCED tests". (PX7139 (Navathe Trial Dep. at 97–98).) Dr. Navathe further admitted his lack of experience with the FDA in any relevant context. He has never: consulted for the FDA, had experience obtaining FDA approval for any product, given advice on seeking approval, been involved in seeking a PMA, built a team seeking approval or studied FDA approval of medical diagnostic tests. (PX7139 (Navathe Trial Dep. at 97–100).) These admissions render Dr. Navathe's views of Illumina's efforts to seek FDA approval for an MCED test – and whether consultants can aide this process - outside of his expertise. [redacted] (PX7139 (Navathe Trial Dep. at 120).) [redacted] (PX7139 (Navathe Trial Dep. at 120–121).)

5665. [redacted] (PX7139 (Navathe Trial Dep. at 77) (*in camera*)).

Response to Finding No. 5665:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶ 5654, which Respondents incorporate herein.

(h) Grail Can Hire Employees to Build Relationships and Fill Any Gaps in Its Experience

In addition to the below, for more evidence on Grail's plans and ability to hire relevant experience, see Section VIII.C.1.a.4.a. (Grail Could Enhance Its Regulatory Capabilities With Consultants or Hiring, Rather Than Merging With Illumina).

5666. [redacted] (PX7083 (Bishop (Grail) Dep. at 155) (*in camera*)).

Response to Finding No. 5666:

The proposed finding is incomplete and misleading insofar as it suggests that GRAIL would be able to bolster its market access function by hiring new personnel. The evidence is clear that this is not the case: Dr. Febbo testified that "I know through our use of consultants and our hiring of individuals into regulatory, into market access, across our personnel, is that there's just not a deep, rich bench of experience available". (Febbo (Illumina) Tr. 4365.) Dr. Febbo explained that Illumina's "regulatory and -- personnel work together and work across teams, and the experience we have is cross-functional. . . GRAIL could hire one, two, even three of those, but taking an individual out of the environment, out of the cross-functional and multidisciplinary approach to our filings, to success with the agency that we've achieved over years, of course, we have had a critical mass that have worked over years to generate this institutional insight that is not dependent on any single employee." (Febbo (Illumina) Tr. 4366-67.) Mr. Qadan, Global Head of Market Access at Illumina, testified that it would be very difficult to replicate Illumina's market access functions elsewhere. (Qadan (Illumina) Tr. 4170.) Illumina's institutional knowledge has been developed over time and its relationships would also be very hard to replicate from one company to another. (Qadan (Illumina) Tr. 4170–71.) Simply hiring people

from Illumina's regulatory or market access team would not enable GRAIL to replicate its expertise and experience, or lead to the same good results. Mr. Qadan explained that another difficulty "is related to the image that Illumina has built over time". (Qadan (Illumina) Tr. 4170–71.) He also explained that Illumina's market access function went beyond solely its employees: Illumina's name and institutional knowledge could not simply be 'hired'. (Qadan (Illumina) Tr. 4170–71.) He added that even with his expertise, he would not be able to take Illumina's image with him to a different company. (Qadan (Illumina) Tr. 4170–71.) As Mr. Qadan explained, "you build institutional capability over time internally". (Qadan (Illumina) Tr. 4167.) Further, Mr. Freidin testified that [redacted] (Freidin (GRAIL) Tr. 3062–63.)

5667. Grail previously has hired multiple employees from Illumina, including executive-level employees involved in market access, sales, software, and other project areas, such as Gautam Kollu (Grail Chief Commercial Officer), Linda Mansolillo (Grail Senior Director, National Accounts), and Satnam Alag (Grail Senior VP of Software Engineering and Chief Security Officer). (Freidin (Grail) Tr. 3165-66).

Response to Finding No. 5667:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶ 5666, which Respondents incorporate herein. .

5668. [redacted] (PX6093 (Navathe Rebuttal Report) ¶ 63 (*in camera*); PX7116 (Dolan (Quest) IHT at 1170-72)). Once employed by Grail, Ms. Mansolillo continued to work with Quest to conclude a phlebotomy collaboration for Galleri. (PX7116 (Dolan (Quest) IHT at 169-174)). [redacted] (PX4585 (Grail) at 002-003 (Email from L. Mansolillo, Grail, to M. Westlund, Providence, July 31, 2020) (*in camera*); PX6093 (Navathe Rebuttal Report) ¶ 63 (*in camera*)).

Response to Finding No. 5668:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5666, which Respondents incorporate herein. Mr. Qadan also noted that Ms. Mansolillo did not come from Illumina's market access function. (Qadan (Illumina) Tr. 4171.)

5669. [redacted] (RX6001 (Deverka Trial Dep. at 148) (discussing RX3867 (Deverka Rebuttal Report) ¶¶ 112-13 (*in camera*)).

Response to Finding No. 5669:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5666, which Respondents incorporate herein. Respondents note that the statement by Dr. Deverka is taken out of context as she was not testifying about whether GRAIL could hire a team with the same skills as Illumina but rather whether the employees GRAIL hired for particular job functions fit that job function. (RX6001 (Deverka Trial Dep. at 148).)

(i) Illumina's Alleged Technology and Process Benefits to Grail Are Not Unique to Illumina

5670. [redacted] (RX2762 (Grail) at 033 (Email from M. Ramirez, Grail, to B. Chang, Grail, attaching "Science, Medicine & Technology Committee Meeting Materials," May 26, 2021) (*in camera*)).

Response to Finding No. 5670:

The proposed finding is not relevant to Illumina's ability to accelerate Galleri's payor reimbursement because the relevant document is [redacted] The evidence is clear that the reunion of Illumina and GRAIL will lead to the

acceleration of Galleri by one year, in large part due to Illumina's experience and relationships. (PFF 1127, 1131–33.26.)

5671. [redacted] (Ofman (Grail) Tr. 3389 (*in camera*); RX2762 (Grail) at 033 (Email from M. Ramirez, Grail, to B. Chang, Grail, attaching "Science, Medicine & Technology Committee Meeting Materials," May 26, 2021) (*in camera*)).

Response to Finding No. 5671:

The proposed finding is not relevant to Illumina's ability to accelerate Galleri's payor reimbursement because the relevant document is [redacted] Respondents have no specific response other than to note that Illumina's regulatory and market access functions have significant experience and great expertise. The evidence is clear that the reunion of Illumina and GRAIL will lead to the acceleration of Galleri by one year, in large part due to Illumina's excellence in the field. (PFF 1127, 1131–33.26.)

5672. [redacted] (PX6092 (Rothman Rebuttal Report) ¶¶ 73-84 (*in camera*)).

Response to Finding No. 5672:

The proposed finding is incomplete, misleading and relies on improper expert testimony that should be given no weight. The fact that GRAIL could gain relevant expertise does not change the fact that Illumina has that expertise today. Illumina's particular expertise and experience in market access is clear from the evidence. (PFF ¶¶ 1127, 1131–33.26.) It is also clear that Illumina and GRAIL could not contract for these market acceleration benefits absent the Transaction. (PFF ¶¶ 1175–75.5.) Further, Dr. Rothman admitted that he was not an expert in market access, so his view on this point should carry no weight. (PFF ¶ 1134.4.)

(i) Exact/Thrive

5673. Exact was able to build capacity from a very small lab to now the ability to offer millions of Cologuard tests and hundreds of thousands of Oncotype DX tests and other tests, and constantly invests in those clinical laboratory capabilities. (Conroy (Exact) Tr. 1534-35).

Response to Finding No. 5673:

The proposed finding is incomplete and misleading. Mr. Conroy testified that it took Exact over 12 years to develop these capabilities. (Conroy (Exact/Thrive) Tr. 1532.) In fact, Mr. Conroy testified that Exact had been trying to develop a multi-cancer screening test as early as 2009 but still do not have a test on the market. (Conroy (Exact/Thrive) Tr. 1539-40; [redacted].) The fact that GRAIL could build out marketing capabilities over many years is irrelevant to whether Illumina could accelerate that process today.

5674. Exact recruited its sales force from "[a]ll over the country from people primarily who had experience calling on healthcare providers and in particular primary care healthcare providers." (Conroy (Exact) Tr. 1536).

For evidence on how Exact built its salesforce as a start-up firm and formed a sales partnership with Pfizer, see Section VI.A.8.c. (Exact Built its Salesforce from Scratch, Expanding as Cologuard Received Regulatory Approvals and Reimbursement Status) and

Response to Finding No. 5674:

The proposed finding is misleading for the reasons stated in the responses to CCFF ¶ 5673, which is incorporated herein.

2. Elimination of Double Marginalization

5675. Dr. Scott Morton explained that [redacted] (PX6090 (Scott Morton Report) ¶ 279 (*in camera*)).

Response to Finding No. 5675:

Respondents have no specific response.

5676. Dr. Scott Morton explained that [redacted] (PX6090 (Scott Morton Report) ¶ 279 (*in camera*)).

Response to Finding No. 5676:

Respondents have no specific response.

5677. [redacted] (PX6090 (Scott Morton Report) ¶¶ 284-286 (*in camera*)).

Response to Finding No. 5677:

The proposed finding is inaccurate and misleading, and is unreliable and based on speculation. Notably, Dr. Scott Morton admits [redacted] (PX7138 (Scott Morton Trial Dep. at 334–36.) The only basis for this proposed finding is Dr. Scott Morton's [redacted] (PX7138 (Scott Morton Trial Dep. at 338.) Moreover, Dr. Scott Morton [redacted] (PX7138 (Scott Morton Trial Dep. at 100).) Dr. Scott Morton also admitted she is unable "to conduct an accurate merger simulation that generates a reliable quantitative prediction of the ultimate effects of EDM and RRC on the future

prices of MCED tests." (RX3864 (Carlton Expert Report) ¶ 86, n.229 (citing PX6090 (Scott Morton Expert Report) ¶ 295).)

The unrefuted factual evidence contradicts Dr. Scott Morton's speculative and baseless theory that EDM could be eliminate by contract in the absence of the Transaction. The parties have an existing contractual relationship that does not result in EDM. (deSouza (Illumina) Tr. 2359–60 (noting that Illumina and GRAIL each charged a margin prior to the transaction); Aravanis (Illumina) Tr. 1960 (same). As Dr. Carlton explained, "[i]f you look at the data, if you look, for example, at the deal model, what is Illumina projecting is going to be happening, say, in -- you know, in the future, there's double marginalization, period. That's what the evidence is. What about now? Yes. There is just no question, double-marginalization is going on now, double-marginalization in the sense that price that is being charged to GRAIL is not marginal cost. That's just crystal clear in the data. So they haven't gotten rid of double-marginalization. As far as I can tell, Illumina has never gotten rid of double-marginalization with GRAIL". (RX6000 (Carlton Trial Dep. at 67).)

When asked about Dr. Scott Morton's theory Dr. Carlton stated: "Well, you can say anything can happen. The fact of the matter is it hasn't happened. The reason why the evidence in this case is so strong, I think, to refute what Dr. Scott Morton is saying, is because it's obvious that, absent the merger, Illumina will charge GRAIL and does charge GRAIL and expects to charge GRAIL a price above its marginal cost, period. It's crystal clear from the documents." (RX6000 (Carlton Trial Dep. at 67).) Indeed, Dr. Scott Morton's theory that EDM can be achieved via contract is squarely opposed to well-established antitrust law and economic theory, as it would eliminate the rationale for every vertical merger, as all EDM benefits (as well as any other efficiencies) could be achieved by contract. *See e.g., United States v. AT&T Inc.*, 310 F.

Supp. 3d 161, 193 (D.C. Cir. 2018) ("EDM effect is 'generally accepted as a potential procompetitive benefit resulting from vertical mergers'") (quoting the DOJ's proposed findings of fact.)

a) EDM Is Not Merger Specific

5678. [redacted] (PX7138 (Scott Morton Trial Dep. at 68-69); PX6090 (Scott Morton Report) ¶ 280 (*in camera*)).

Response to Finding No. 5678:

The proposed finding is inaccurate and misleading, and is unreliable and based on speculation, for the reasons explained in Respondents' responses to CCFF ¶ 5677, which Respondents incorporate herein.

5679. [redacted] (PX6090 (Scott Morton Report) ¶ 280 (*in camera*)).

Response to Finding No. 5679:

The proposed finding is inaccurate and misleading, and is unreliable and based on speculation, for the reasons explained in Respondents' responses to CCFF ¶ 5677, which Respondents incorporate herein. As Dr. Carlton explained, the evidence belies Dr. Scott Morton's claim: [redacted]

[redacted]

(RX3864 (Carlton Expert Report) ¶ 105.)

5680. [redacted] (PX7138 (Scott Morton Trial Dep. at 68-69) (*in camera*); PX6090 (Scott Morton Report) ¶ 280 (*in camera*)).

Response to Finding No. 5680:

The proposed finding is inaccurate and misleading, and is unreliable and based on speculation, for the reasons explained in Respondents' responses to CCFF ¶ 5677, which Respondents incorporate herein. As Dr. Carlton explained, the evidence belies Dr. Scott Morton's claim: [redacted]

(RX3864 (Carlton Expert Report) ¶ 105.)

5681. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 39 (*in camera*)). Thus, [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 39 (*in camera*)).

Response to Finding No. 5681:

The proposed finding is inaccurate and misleading, and is unreliable and based on speculation, for the reasons explained in Respondents' responses to CCFF ¶ 5677, which Respondents incorporate herein. As Dr. Carlton explained, the evidence belies Dr. Scott

Morton's claim: [redacted]

(RX3864 (Carlton Expert Report) ¶ 105.)

5682. [redacted] PX6090 (Scott Morton Report) ¶ 280 (*in camera*)). [redacted] (PX6090 (Scott Morton Report) ¶ 281 (*in camera*)).

Response to Finding No. 5682:

The proposed finding is incomplete and misleading. Respondents have no specific response. As Dr. Carlton explained, there is no evidence that Illumina has eliminated double marginalization in its contracts with GRAIL or any other purported MCED test developer. (RX6000 (Carlton Trial Dep. at 67) ("As far as I can tell, Illumina has never gotten rid of double-marginalization with GRAIL or any of these third-party MCED developers.").)

5683. [redacted] (PX6090 (Scott Morton Report) ¶¶ 181-182 (*in camera*)).

Response to Finding No. 5683:

The proposed finding is incomplete and misleading. The notion that Illumina can and would eliminate double marginalization with GRAIL by contract absent the Transaction is complete speculation and refuted by the facts. As Dr. Carlton explained, there is no evidence that Illumina has eliminated double marginalization in its contracts with GRAIL or any other

purported MCED test developer. (RX6000 (Carlton Trial Dep. at 67) ("As far as I can tell, Illumina has never gotten rid of double-marginalization with GRAIL or any of these third-party MCED developers.").)

5684. [redacted] (PX6090 (Scott Morton Report) ¶ 181 (*in camera*)).

Response to Finding No. 5684:

Respondents have no specific response.

5685. Dr. Carlton testified that the premerger relationship between Illumina and Grail had some non-linear pricing elements, including volume-based discounts, royalties, and Illumina's partial ownership interest in Grail. ((RX6000 (Carlton Trial Dep. at 144-145)).

Response to Finding No. 5685:

The proposed finding is incomplete and misleading. The presence of non-linear price elements does not mean that the parties are able to eliminate double marginalization in absence of the merger. "If you look at the data, if you look, for example, at the deal model, what is Illumina projecting is going to be happening, say, in -- you know, in the future, there's double marginalization, period. That's what the evidence is. What about now? Yes. There is just no question, double-marginalization is going on now, double-marginalization in the sense that price that is being charged to GRAIL is not marginal cost. That's just crystal clear in the data. So they haven't gotten rid of double-marginalization. As far as I can tell, Illumina has never gotten rid of double-marginalization with GRAIL". (RX6000 (Carlton Trial Dep. at 67).)

As Dr. Carlton explained in the cited portion of the transcript, if Dr. Scott Morton's theory were true, there would be no need for mergers since everything could be accomplished by contract. (RX6000 (Carlton Trial Dep. at 144) ("In theory anything is possible. That is, in

theory, there's no -- if you can do everything by contract, there's no need to have any merger, vertical or horizontal".)

5686. [redacted] (PX7123 (Fellis (Illumina) Dep. at 27-30, 35) (*in camera*)).

Response to Finding No. 5686:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5685, which Respondents incorporate herein. [redacted] (PX7123 (Fellis (Illumina) Dep. at 27-30, 35-36) (*in camera*).)

5687. [redacted] (PX7076 (Berry (Illumina) Dep. at 115-119) (*in camera*); *see* PX7123 (Fellis (Illumina) Dep. at 53-54) (*in camera*)).

Response to Finding No. 5687:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5685, which Respondents incorporated herein. [redacted]

[redacted] PX7123 (Fellis (Illumina) Dep. at 52-53) (*in camera*).) Moreover, the entire cited testimony from Ms. Berry's deposition [redacted] (PX7076 (Berry (Illumina) Dep. at 115-119) (*in camera*).)

5688. [redacted] (PX7076 (Berry (Illumina) Dep. at 176-77) (*in camera*).

Response to Finding No. 5688:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5685, which Respondents incorporated herein. The proposed finding is also not supported by the cited testimony. The cited testimony relates only to an email communication relating to [redacted] and does not purport to describe Illumina's contracts generally. (PX7076 (Berry (Illumina) Dep. at 176-77) (*in camera*).)

5689. [redacted] (PX7076 (Berry (Illumina) Dep. at 177) (*in camera*)).

Response to Finding No. 5689:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5685, which Respondents incorporated herein. In fact, [redacted]

(PX7076 (Berry (Illumina) Dep. at 177) (*in camera*).)

5690. Ms. Berry testified that "different pricing sensitivity potentially could exist across different customer segments," and Illumina uses that in determining how to price its products. (PX7076 (Berry (Illumina) Dep. at 174); PX2387 (Illumina) at 001 (Email from N. Berry, Illumina, to T. Lialin, Illumina, Apr. 19, 2018) ([redacted]) (*in camera*)).

Response to Finding No. 5690:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5685, which Respondents incorporated herein. In fact, [redacted]

[redacted]

(PX7076 (Berry (Illumina) Dep. at 174) (*in camera*).)

5691. [redacted] (PX2391 (Illumina) at 001 (Email from N. Berry, Illumina, to P. Dueppen, Illumina, Jan. 29, 2021) (*in camera*)).

Response to Finding No. 5691:

Respondents have no specific response, [redacted] (PX2391 (Illumina) at 001 (Email from N. Berry, Illumina, to P. Dueppen, Illumina, Jan. 29, 2021) (*in camera*).)

5692. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 37 (*in camera*)).

Response to Finding No. 5692:

The proposed finding is inaccurate and misleading, and is unreliable and based on speculation, for the reasons explained in Respondents' responses to CCFF ¶¶ 5677, 5681 and 5685, which Respondents incorporate herein.

5693. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 39 (*in camera*)).

Response to Finding No. 5693:

The proposed finding is inaccurate and misleading, and is unreliable and based on speculation, for the reasons explained in Respondents' responses to CCFF ¶¶ 5677, 5681 and 5685, which Respondents incorporate herein.

5694. [redacted] (PX6090 (Scott Morton Report) ¶ 284 (*in camera*) (emphasis in original)).

Response to Finding No. 5694:

The proposed finding is inaccurate and misleading, and is unreliable and based on speculation, for the reasons explained in Respondents' responses to CCFF ¶¶ 5677, 5681 and 5685, which Respondents incorporate herein. Dr. Scott Morton's theory is also inconsistent with fact witness testimony that Illumina intends to eliminate the double margin after the merger. (deSouza (Illumina) Tr. 2359.) And it flies in the face of widespread consensus that vertical merges result in EDM. *See e.g.*, *AT&T I*, 310 F. Supp. 3d at 193 ("EDM effect is 'generally accepted as a potential procompetitive benefit resulting from vertical mergers'") (quoting the DOJ's proposed findings of fact).

5695. [redacted] (PX7138 (Scott Morton Trial Dep. at 68-69) (*in camera*); *see also* PX6090 (Scott Morton Report) ¶ 287 (*in camera*)).

Response to Finding No. 5695:

The proposed finding is inaccurate and misleading, and is unreliable and based on speculation, for the reasons explained in Respondents' responses to CCFF ¶¶ 5677, 5681 and 5685, which Respondents incorporate herein. The theoretical possibility that double

marginalization could be solved without merging does not mean it could happen under the facts of this particular case. As Dr. Carlton explained in his report: [redacted] (RX3864 (Carlton Expert Report) ¶ 106.)

5696. [redacted] (PX6090 (Scott Morton Report) ¶ 287 (*in camera*)).

Response to Finding No. 5696:

The proposed finding is inaccurate and misleading, and is unreliable and based on speculation, for the reasons explained in Respondents' responses to CCFF ¶¶ 5677, 5681 and 5685, which Respondents incorporate herein. The theoretical possibility that double marginalization could be solved without merging does not mean it could happen under the facts of this particular case. As Dr. Carlton explained in his report: [redacted] (RX3864 (Carlton Expert Report) ¶ 106.)

5697. [redacted] (PX7138 (Scott Morton Trial Dep. at 71) *see also* (PX6090 (Scott Morton Report) ¶ 287 (*in camera*)).

Response to Finding No. 5697:

The proposed finding is inaccurate and misleading, and is unreliable and based on speculation, for the reasons explained in Respondents' responses to CCFF ¶¶ 5677, 5681 and 5696, which Respondents incorporate herein. Dr. Scott Morton's logic is circular and would eliminate the rationale for every merger. As Dr. Carlton explained: "Dr. Scott Morton asserts that GRAIL and Illumina not having already achieved EDM is proof that EDM will not be realized after the proposed merger. This assertion follows from her unsupported assumption that EDM can easily be eliminated by contract. Hence, by her reasoning, if it has not been eliminated, then whatever exists must be the efficient outcome and cannot be improved upon. Such reasoning would eliminate the rationale for every merger, as all the benefits therefrom could be realized through her supposed contract. Her assertion contradicts the economic literature and the Vertical Merger Guidelines that EDM is a recognized benefit of vertical integration." (RX3864 (Carlton Expert Report) ¶ 107.)

5698. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 46 (*in camera*))).

Response to Finding No. 5698:

The proposed finding is inaccurate and misleading, and is unreliable and based on speculation, for the reasons explained in Respondents' responses to CCFF ¶¶ 5677, 5681, 5696 and 5697, which Respondents incorporate herein.

5699. [redacted] (PX7138 (Scott Morton Trial Dep. at 70-71) (*in camera*); PX6090 (Scott Morton Report) ¶¶ 285-286 (*in camera*)).

Response to Finding No. 5699:

The proposed finding is inaccurate and misleading, and is unreliable and based on speculation, for the reasons explained in Respondents' responses to CCFF ¶¶ 5677, 5681, 5696 and 5697, which Respondents incorporate herein.

5700. [redacted] (PX6090 (Scott Morton Report) ¶ 285 (*in camera*)).

Response to Finding No. 5700:

The proposed finding is inaccurate and misleading, and is unreliable and based on speculation, for the reasons explained in Respondents' responses to CCFF ¶¶ 5677, 5681, 5696 and 5697, which Respondents incorporate herein.

5701. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 37 (*in camera*)).

Response to Finding No. 5701:

The proposed finding is inaccurate and misleading, and is unreliable and based on speculation, for the reasons explained in Respondents' responses to CCFF ¶¶ 5677, 5681, 5696 and 5697, which Respondents incorporate herein.

5702. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 39 (*in camera*)).

Response to Finding No. 5702:

The proposed finding is inaccurate and misleading, and is unreliable and based on speculation, for the reasons explained in Respondents' responses to CCFF ¶¶ 5677, 5681, 5696 and 5697, which Respondents incorporate herein.

5703. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 37 (*in camera*)).

Response to Finding No. 5703:

The proposed finding is inaccurate and misleading, and is unreliable and based on speculation, for the reasons explained in Respondents' responses to CCFF ¶¶ 5677, 5681, 5966 and 5977, which Respondents incorporate herein. Dr. Carlton [redacted] (PFF ¶ 1154.)

5704. [redacted] (PX6090 (Scott Morton Report) ¶ 286 (*in camera*)).

Response to Finding No. 5704:

The proposed finding is inaccurate and misleading, and is unreliable and based on speculation, for the reasons explained in Respondents' responses to CCFF ¶¶ 5677, 5681, 5696 and 5697, which Respondents incorporate herein. Dr. Carlton [redacted] It is undisputed that after Illumina acquired Verinata to become vertically integrated in the NIPT space, the cost of NIPT tests decreased by over 90%,

contrary to Dr. Scott Morton's baseless speculation that Illumina would act to maintain prices at a "current level" following a vertical transaction. (Aravanis (Illumina) Tr. 1933–34.)

5705. [redacted] (PX6090 (Scott Morton Report) ¶ 293 (*in camera*)).

Response to Finding No. 5705:

The proposed finding is inaccurate and misleading, and is unreliable and based on speculation, for the reasons explained in Respondents' responses to CCFF ¶¶ 5677, 5681, 5696 and 5697, which Respondents incorporate herein. Dr. Carlton [redacted] Moreover, Illumina's acquisition of GRAIL will result in numerous additional efficiencies that far outweigh any alleged harm, including: saving lives, accelerating market access to Galleri, research and development efficiencies, the elimination of double marginalization, the elimination of the royalty GRAIL owes to Illumina, supply chain and operational efficiencies, and accelerating international availability of Galleri. (Aravanis (Illumina) Tr. 1935.)

b) EDM Is Not Verifiable (And, if Applicable, Not Quantified)

5706. Dr. Carlton testified that he did not "estimate[] a model or estimate the passthrough" to determine the net effect of EDM that will result from the Acquisition. ((PX7134 (Carlton Dep. at 122-123)).

Response to Finding No. 5706:

The proposed finding is incomplete and misleading, and selectively quotes only a portion of the cited testimony while omitting relevant context. Dr. Carlton explained that "I don't estimate[] a model or estimate the passthrough. What I attempted to do was to do a calculation

where I, you know, calculate what EDM is for a particular case with a hundred percent passthrough and then explain you can scale that but that the amount you have to scale it by will depend on the details of the vertical model. In order to figure out -- and, again, not to calculate EDM solely but to figure out the net effect of the merger in order to figure -- that's -- that's what you really have to figure out." (PX7134 (Carlton Dep. at 122-123).) Dr. Scott Morton has not presented a full vertical model that would allow Dr. Carlton to do this. (RX3864 (Carlton Expert Report) ¶ 104 n. 258 ([redacted]) (RX6000 (Carlton Trial Dep. at 65-66). Moreover, [redacted] (RX3864 (Carlton Expert Report) ¶ 104 n. 261.) In addition, [redacted] (RX3864 (Carlton Expert Report) ¶ 104 n. 259.)

5707. [redacted] ((RX6000 (Carlton Trial Dep. at 65-66) (*in camera*)).

Response to Finding No. 5707:

The proposed finding is inaccurate and misleading, for the reasons explained in Respondents' responses to CCFF ¶ 5706, which Respondents incorporate herein.

5708. [redacted] (RX6000 (Carlton Trial Dep. at 65-66) (*in camera*)).

Response to Finding No. 5708:

The proposed finding is incomplete and misleading, and selectively quotes only a portion of the cited testimony while omitting relevant context. In fact, [redacted] (RX6000 (Carlton Trial Dep. at 65-66) (*in camera*).)

5709. Dr. Carlton testified that, in order to properly quantify the value of EDM due to the Acquisition, he would need to rely on a full vertical model, including the amount of diversion, elasticity of demand, and the opportunity cost of not serving Grail's rivals. ((RX6000 (Carlton Trial Dep. at 134-135); PX7134 (Carlton Dep. at 123-124)).

Response to Finding No. 5709:

The proposed finding is misleading and incomplete, and mischaracterizes the cited testimony. Complaint Counsel's cited question referred to the fact that "quantification of EDM relies on a full vertical model that takes into account many economic factors, including", but not limited to, the items listed in the proposed finding, and Dr. Carlton agreed, explaining that "that's why I described Table 1 in the report and in the direct testimony as illustrative of the magnitude of the savings that are possible in Table 1. I also described Table 1 under the assumption of zero diversion, which is what would happen if you thought there was no possibility of raising rivals' costs." (RX6000 (Carlton Trial Dep. at 134-135).) Moreover, Dr. Scott Morton's failure to present a full vertical model is a flaw in Complaint Counsel's case, not Dr. Carlton's opinion.

5710. Dr. Carlton testified that he did not create a full vertical model to calculate the value of EDM resulting from the Acquisition. (RX6000 (Carlton Trial Dep. at 136-137)).

Response to Finding No. 5710:

The proposed finding is incomplete and misleading. In fact, Dr. Carlton's testimony focused on the lack of a vertical model as a "criticism of Dr. Scott Morton and how, in the absence of being willing to say anything quantitatively, it is very difficult to figure out why you should give credence to her opinion that there's a harm. I do say that even though -- and as I talked about in my direct testimony this morning -- even though you can't do that, there are inconsistencies with existing economic facts with her assumptions, and that's why I -- for both those reasons, I discount her conclusion." (RX6000 (Carlton Trial Dep. at 136-137).) Dr. Scott Morton's failure to present a full vertical model is a flaw in Complaint Counsel's case, not Dr. Carlton's opinion.

5711. Dr. Carlton testified that "I don't think you can assume necessarily any particular pass-through rate, and it's a mistake to think that you can solely calculate EDM without considering a model where you consider" factors such as price, marginal costs, and diversion ratio. (PX7134 (Carlton Dep. at 123-127)). [redacted] (PX7134 (Carlton Dep. at 126-127) (*in camera*)).

Response to Finding No. 5711:

Respondents have no specific response except to note that [redacted] (RX6000 (Carlton Trial Dep. at 65-66) (*in camera*).)

5712. [redacted] (RX3864 (Carlton Rebuttal Report) ¶¶ 11, 101 n.256, 104 n.258 (*in camera*)).

Response to Finding No. 5712:

The proposed finding is misleading and not supported by the cited evidence. In fact,

[redacted]

(RX3864 (Carlton Rebuttal Report) ¶¶ 11, 101 n.256, 104 n.258 (*in camera*).) [redacted] (RX6000 (Carlton Trial Dep. at 65-66) (*in camera*).)

5713. [redacted] (RX3864 (Carlton Rebuttal Report) ¶ 101 n.256 (*in camera*)).

Response to Finding No. 5713:

The proposed finding is incomplete. The cited footnote reads, in full, [redacted] (RX3864 (Carlton Rebuttal Report) ¶¶ 11, 101 n.256 (*in camera*).) [redacted] (RX6000 (Carlton Trial Dep. at 65-66) (*in camera*).) Finally, Dr. Scott Morton's failure to present a full vertical model is a flaw in Complaint Counsel's case, not Dr. Carlton's opinion.

5714. [redacted] (RX3864 (Carlton Rebuttal Report) ¶ 104 n.258 (*in camera*)).

Response to Finding No. 5714:

The proposed finding is incomplete and misleading, for the reasons explained in Respondents' responses to CCFF ¶¶ 5712 and 5713, which Respondents incorporate herein.

5715. [redacted] (RX3864 (Carlton Rebuttal Report) ¶ 104 (*in camera*)).

Response to Finding No. 5715:

The proposed finding is incomplete and misleading, for the reasons explained in Respondents' responses to CCFF ¶¶ 5712 and 5713, which Respondents incorporate herein.

c) Respondents Fail to Demonstrate That Any Claimed Cost Savings from EDM Will Be Passed Through to Customers

5716. Dr. Carlton testified that he did not create a model to estimate the percentage of EDM that will be passed through to consumers as a result of the Acquisition. (PX7134 (Carlton Dep. at 122-123)).

Response to Finding No. 5716:

The proposed finding is incomplete and misleading, for the reasons explained in Respondents' responses to CCFF ¶¶ 5712 and 5713, which Respondents incorporate herein.

5717. Dr. Carlton testified that he did not estimate the percentage of EDM that will be passed through to consumers as a result of the Acquisition. (PX7134 (Carlton Dep. at 122-123)).

Response to Finding No. 5717:

The proposed finding is incomplete and misleading, for the reasons explained in Respondents' responses to CCFF ¶¶ 5712 and 5713, which Respondents incorporate herein. Dr. Carlton explained that "there are plenty of demand curves that have that characteristic. In a competitive industry, assuming the passthrough of a hundred percent, especially at the distribution stage, is not unusual, and that's been done in many cases that I've been involved in in court." (PX7134 (Carlton Dep. at 126–27.) [redacted]

[redacted]

(RX6000 (Carlton Trial Dep. at 65-66) (*in camera*).) This number could also be higher given some of Dr. Carlton's conservative assumptions. (RX3864 (Carlton Expert Report) ¶ 104 n. 259, 261.)

5718. Dr. Carlton testified that the pass through rate cannot be estimated without a fully specified model. (PX7134 (Carlton Dep. at 123-24)).

Response to Finding No. 5718:

The proposed finding is incomplete and misleading, for the reasons explained in Respondents' responses to CCFF ¶¶ 5712, 5713 and 5717, which Respondents incorporate herein.

5719. Dr. Carlton testified that the pass through rate cannot be estimated independent of the raising rivals' costs effect. (PX7134 (Carlton Dep. at 123-44)).

Response to Finding No. 5719:

The proposed finding is incomplete and misleading, for the reasons explained in Respondents' responses to CCFF ¶¶ 5712, 5713 and 5717, which Respondents incorporate herein.

5720. Dr. Carlton conceded that, in this case, he cannot necessarily assume any particular pass through rate. (PX7134 (Carlton Dep. at 126-7)).

Response to Finding No. 5720:

The proposed finding is incomplete and misleading, for the reasons explained in Respondents' responses to CCFF ¶¶ 5712, 5713 and 5717, which Respondents incorporate herein.

3. R&D Efficiencies

a) The Claimed R&D Efficiency Is Not Verifiable

5721. Dr. Rothman concluded that [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 86 (*in camera*)).

Response to Finding No. 5721:

The proposed finding is inaccurate and misleading, is contradicted by the weight of the evidence, is unreliable and based on speculation, and relies on improper expert testimony. Dr. Rothman's method for substantiating efficiencies is based solely on his own interpretation of the merger guidelines and invades the province of the Court, rendering his opinions unreliable. (*See* Resps.' Post-Trial Br. at 269–70.) Dr. Rothman does not have any prior experience analyzing the efficiencies of vertical mergers. (PX7140 (Rothman Trial Dep. at 42.) Dr. Rothman's report never cites a single economic treatise, study, or authority. Despite purporting to rely entirely on the FTC's and DOJ's Horizontal Merger Guidelines and Vertical Merger Guidelines for his analysis (PX7140 (Rothman Trial Dep. at 54–57), Dr. Rothman admits that neither the Vertical Merger Guidelines nor the Horizontal Merger Guidelines use his phrase "reasonable means". (PX7140 (Rothman Trial Dep. at 58–59, 64.) There is no evidence that anyone else has accepted, tested, or applied Dr. Rothman's personal method for efficiency substantiation.

Dr. Rothman also admits that the FTC withdrew the Vertical Merger Guidelines after his report was submitted (PX7140 (Rothman Trial Dep. at 60), that the Vertical Merger Guidelines do not dictate to a court how to assess the efficiencies of a vertical merger (PX7140 (Rothman Trial Dep. at 62), that verification of an efficiency by reasonable means does not mean defining the specific dollar amount of the efficiency (PX7140 (Rothman Trial Dep. at 67), that the Vertical Merger Guidelines and the Horizontal Merger Guidelines do not require that costs to achieve an efficiency have to be specified by a specific dollar amount (PX7140 (Rothman Trial

Dep. at 67), and that the Vertical Merger Guidelines and the Horizontal Merger Guidelines do not provide a precise timeline for when parties need to establish an efficiency in order for the efficiency to be cognizable. (PX7140 (Rothman Trial Dep. at 67.)

Furthermore, Dr. Rothman fails altogether to account for the undisputed ***fact*** testimony concerning R&D efficiencies; he simply ignores it. (PFF ¶¶ 1141-42; *see also* PX7079 (Flatley (Illumina) Dep. at 31; deSouza (Illumina) Tr. 2355–56; Aravanis (Illumina) Tr. 1952, 1954; Febbo (Illumina) Tr. 4356–57, 4359–60; Flatley (Illumina) Tr. 4082, 4088–89; Bishop (GRAIL) Tr. 1416; [redacted]; *see also* RX6000 (Carlton Trial, Dep. at 61–62). Instead, he admittedly only assessed the evidence in Dr. Carlton's report and did not assess any other evidence, including affirmative testimony offered by Respondents' witnesses at trial. (RX3854 (Rothman, Dep. at 74–78) ("A. . . My analysis is of the claims that – – certain claims that Dr. Carlton, Dr. Deverka and Mr. Serafin make in their reports. . . . Q So if – you don't know whether there is additional evidence out there that supports any of those claimed efficiencies beyond what they cited, do you? . . . A. My analysis was of what they offered as substantiation for certain claimed efficiencies. . . . Q. GRAIL and Illumina's witnesses have not yet offered their direct testimony at trial, have they? We can agree on that? A. Yes. Q. Okay. You don't know what those witnesses are going to say under direct examination, by definition, right? A. That's correct".).) Dr. Rothman also does not explain ***why*** understanding the exact costs of these efficiencies is necessary in order for them to be cognizable.

Dr. Rothman further ignores Illumina's actual track record of generating substantial R&D efficiency in a vertical transaction. The idea for Galleri came from another vertical transaction: Illumina's acquisition of Verinata, a company in the non-invasive prenatal testing business. (*See* Aravanis (Illumina) Tr. 1868–71, 1873–74; PX7048 (Klausner (GRAIL) IHT at 43–44, 49–54,

69–72); PX7079 (Flatley (Illumina) Dep. at 31–32); PX7048 (Klausner (GRAIL) IHT at 43-44); deSouza (Illumina) Tr. 2345; *see also* PX7140 (Rothman Trial Dep. at 97).)

5722. Dr. Rothman explained that [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 89, n. 146 (*in camera*)). [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 89, n. 146 (*in camera*)).

Response to Finding No. 5722:

The proposed finding is inaccurate and misleading, is contradicted by the weight of the evidence, is unreliable and based on speculation, and relies on improper expert testimony for the reasons explained in Respondents' responses to CCFF ¶ 5721, which Respondents incorporate herein. Reliance on Dr. Rothman's report to support a factual proposition is improper. Dr. Rothman's opinion is also inaccurate. Dr. Rothman relies on a 2015 email regarding Dr. Klausner's personal views at the early stages of GRAIL. (PX6092 (Rothman Rebuttal Report) ¶ 89, n. 146 (citing PX2006 (Email from M. Ronaghi, Illumina to R. Klausner, Grail, et al, July 14, 2015). During his IH, Dr. Klausner explained that these views no longer apply: "When we started this, I didn't know if it was possible. And no one did. And that's what the last five years has been. Now, we're ready to scale, commercialize, et cetera, all those other things that lots of companies know how to do well". (PX7048 (Klausner (GRAIL) IHT 81:1–17.)) To the extent there was a benefit to having GRAIL be a separate company in the early days, the opposite is now true.

5723. [redacted] (PX6092 (Rothman Rebuttal Report) ¶¶ 33 (*in camera*)).

Response to Finding No. 5723:

The proposed finding is inaccurate and misleading, is contradicted by the weight of the evidence, is unreliable and based on speculation, and relies on improper expert testimony for the reasons explained in Respondents' responses to CCFF ¶ 5721, which Respondents incorporate herein. Multiple fact witnesses from Illumina and GRAIL testified that based on their experience and business judgment the merger would result in substantial R&D efficiencies. (PFF ¶¶ 1141-42; *see also* PX7079 (Flatley (Illumina) Dep. at 31; deSouza (Illumina) Tr. 2355–56; Aravanis (Illumina) Tr. 1952, 1954; Febbo (Illumina) Tr. 4356–57, 4359–60; Flatley (Illumina) Tr. 4082, 4088–89; Bishop (GRAIL) Tr. 1416; [redacted].) These witnesses testified that Galleri specific efficiencies would arise, including improved performance, lower cost and better workflows. (PFF ¶ 1141.) They also testified that the Transaction would likely generate a number of non-Galleri related benefits including potential new technology related to Alzheimer's, Parkinson's and fatty liver disease. (PFF ¶ 1142.)

5724. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 33 (*in camera*)).

Response to Finding No. 5724:

The proposed finding is inaccurate and misleading, is contradicted by the weight of the evidence, is unreliable and based on speculation, and relies on improper expert testimony for the reasons explained in Respondents' responses to CCFF ¶ 5721, which Respondents incorporate herein. In particular, Dr. Rothman admits that neither the Vertical Merger Guidelines nor the Horizontal Merger Guidelines use his phrase "reasonable means". (PX7140 (Rothman Trial Dep. at 58–59, 64.) There is no evidence that anyone else has accepted, tested, or applied Dr.

Rothman's personal method for efficiency substantiation. And even if they did, the fact witness testimony presented in this case meets that standard. (PFF ¶¶ 1141-42; *see also* PX7079 (Flatley (Illumina) Dep. at 31; deSouza (Illumina) Tr. 2355–56; Aravanis (Illumina) Tr. 1952, 1954; Febbo (Illumina) Tr. 4356–57, 4359–60; Flatley (Illumina) Tr. 4082, 4088–89; Bishop (GRAIL) Tr. 1416; [redacted] *see also* RX6000 (Carlton Trial, Dep. at 61–62.)

5725. Dr. Rothman noted that [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 87 (*in camera*)).

Response to Finding No. 5725:

The proposed finding is inaccurate and misleading, is contradicted by the weight of the evidence, is unreliable and based on speculation, and relies on improper expert testimony for the reasons explained in Respondents' responses to CCFF ¶ 5721, which Respondents incorporate herein.

5726. Dr. Rothman explained that [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 88 (*in camera*)).

Response to Finding No. 5726:

The proposed finding is inaccurate and misleading, is contradicted by the weight of the evidence, is unreliable and based on speculation, and relies on improper expert testimony for the reasons explained in Respondents' responses to CCFF ¶ 5721, which Respondents incorporate herein. Dr. Carlton found that R&D efficiencies "will probabilistically increase the number of new health products available to consumers, thereby generating benefits from innovation" and that these are "potentially the most significant of the merger efficiencies." (RX3864 (Carlton

Expert Report) ¶ 104 n. 259, 261.) This is significant given that Dr. Carlton presented an estimate for the acceleration efficiencies of at least $37 billion dollars. (RX6000 (Carlton Trial Dep. at 74).) Dr. Rothman has not presented any evidence that the costs approach anywhere near those amounts. In any event, Dr. Rothman admits that the Vertical Merger Guidelines and the Horizontal Merger Guidelines do not require that costs to achieve an efficiency have to be specified by a specific dollar amount. (PX7140 (Rothman Trial Dep. at 67.)

5727. Dr. Carlton testified that he did not quantify the benefit of R&D efficiency in his report. (RX6000 (Carlton Trial Dep. at 120)).

Response to Finding No. 5727:

The proposed finding is incomplete and misleading without additional context, as well as contradicted by the weight of the evidence for the reasons explained in Respondents' responses to CCFF ¶ 5721, which Respondents incorporate herein. Dr. Carlton found that R&D efficiencies "will probabilistically increase the number of new health products available to consumers, thereby generating benefits from innovation" and that these are "potentially the most significant of the merger efficiencies." (RX3864 (Carlton Expert Report) ¶ 104 n. 259, 261.) This is significant given that Dr. Carlton presented an estimate for the acceleration efficiencies of at least $37 billion dollars. (RX6000 (Carlton Trial Dep. at 74).) In any event, as Dr. Rothman admits, the (withdrawn) Vertical Merger Guidelines do not dictate to a court how to assess the efficiencies of a vertical merger (PX7140 (Rothman Trial Dep. at 62), and verification of an efficiency by reasonable means does not mean defining the specific dollar amount of the efficiency. (PX7140 (Rothman Trial Dep. at 67.)

5728. Dr. Carlton testified that he has not attempted to estimate the scale of R&D efficiencies. (RX6000 (Carlton Trial Dep. at 120)).

Response to Finding No. 5728:

The proposed finding is incomplete and misleading without additional context, as well as contradicted by the weight of the evidence for the reasons explained in Respondents' responses to CCFF ¶ 5721, which Respondents incorporate herein. Dr. Carlton found that R&D efficiencies "will probabilistically increase the number of new health products available to consumers, thereby generating benefits from innovation" and that these are "potentially the most significant of the merger efficiencies." (RX3864 (Carlton Expert Report) ¶ 104 n. 259, 261.) This is significant given that Dr. Carlton presented an estimate for the acceleration efficiencies of at least $37 billion dollars. (RX6000 (Carlton Trial Dep. at 74).) In any event,, as Dr. Rothman admits, the (withdrawn) Vertical Merger Guidelines do not dictate to a court how to assess the efficiencies of a vertical merger (PX7140 (Rothman Trial Dep. at 62), and verification of an efficiency by reasonable means does not mean defining the specific dollar amount of the efficiency. (PX7140 (Rothman Trial Dep. at 67.)

5729. With regard to R&D efficiencies, Dr. Carlton testified, "I think it's hard to make predictions as to exactly what R&D efficiencies would result." (RX6000 (Carlton Trial Dep. at 120)).

Response to Finding No. 5729:

The proposed finding is incomplete and misleading without additional context, as well as contradicted by the weight of the evidence for the reasons explained in Respondents' responses to CCFF ¶ 5721, which Respondents incorporate herein. Dr. Carlton found that R&D efficiencies "will probabilistically increase the number of new health products available to consumers, thereby generating benefits from innovation" and that these are "potentially the most significant of the merger efficiencies." (RX3864 (Carlton Expert Report) ¶ 104 n. 259, 261.) This is significant given that Dr. Carlton presented an estimate for the acceleration efficiencies of

at least $37 billion dollars. (RX6000 (Carlton Trial Dep. at 74).) Fact witness testimony did predict the types of R&D efficiencies that would result from the merger. Witnesses testified that Galleri specific efficiencies would arise, including improved performance, lower cost and better workflows. (PFF ¶ 1141.) They also testified that the Transaction would likely generate a number of non-Galleri related benefits including potential new technology related to Alzheimer's, Parkinson's and fatty liver disease. (PFF ¶ 1142.)

In any event,, as Dr. Rothman admits, the (withdrawn) Vertical Merger Guidelines do not dictate to a court how to assess the efficiencies of a vertical merger (PX7140 (Rothman Trial Dep. at 62), verification of an efficiency by reasonable means does not mean defining the specific dollar amount of the efficiency, (PX7140 (Rothman Trial Dep. at 67), and the Vertical Merger Guidelines and the Horizontal Merger Guidelines do not provide a precise timeline for when parties need to establish an efficiency in order for the efficiency to be cognizable. (PX7140 (Rothman Trial Dep. at 67.)

5730. Dr. Carlton testified that he did not perform an independent calculation of costs associated with Illumina and Grail directing their efforts toward any R&D efficiencies. (RX6000 (Carlton Trial Dep. at 120-121)).

Response to Finding No. 5730:

The proposed finding is incomplete and misleading without additional context, as well as contradicted by the weight of the evidence for the reasons explained in Respondents' responses to CCFF ¶ 5721, which Respondents incorporate herein. Dr. Carlton found that R&D efficiencies "will probabilistically increase the number of new health products available to consumers, thereby generating benefits from innovation" and that these are "potentially the most significant of the merger efficiencies." (RX3864 (Carlton Expert Report) ¶ 104 n. 259, 261.) This is significant given that Dr. Carlton presented an estimate for the acceleration efficiencies of

at least $37 billion dollars. (RX6000 (Carlton Trial Dep. at 74).) Dr. Rothman has not presented any evidence that the costs approach anywhere near those amounts. In any event, as Dr. Rothman admits, the Vertical Merger Guidelines and the Horizontal Merger Guidelines do not require that costs to achieve an efficiency have to be specified by a specific dollar amount. (PX7140 (Rothman Trial Dep. at 67.)

5731. Dr. Carlton did not attempt to assign a specific probability to the likelihood that new health products will be identified through the claimed R&D efficiencies. (RX6000 (Carlton Trial Dep. at 121)).

Response to Finding No. 5731:

The proposed finding is incomplete and misleading without additional context, as well as contradicted by the weight of the evidence for the reasons explained in Respondents' responses to CCFF ¶ 5721, which Respondents incorporate herein. Dr. Carlton found that R&D efficiencies "will probabilistically increase the number of new health products available to consumers, thereby generating benefits from innovation" and that these are "potentially the most significant of the merger efficiencies." (RX3864 (Carlton Expert Report) ¶ 104 n. 259, 261.) This is significant given that Dr. Carlton presented an estimate for the acceleration efficiencies of at least $37 billion dollars. (RX6000 (Carlton Trial Dep. at 74).) Fact witness testimony did predict the types of R&D efficiencies that would result from the merger. Witnesses testified that Galleri specific efficiencies would arise, including improved performance, lower cost and better workflows. (PFF ¶ 1141.) They also testified that the Transaction would likely generate a number of non-Galleri related benefits including potential new technology related to Alzheimer's, Parkinson's and fatty liver disease. (PFF ¶ 1142.) In any event, as Dr. Rothman admits, the (withdrawn) Vertical Merger Guidelines do not dictate to a court how to assess the efficiencies of a vertical merger (PX7140 (Rothman Trial Dep. at 62), verification of an

efficiency by reasonable means does not mean defining the specific dollar amount of the efficiency, (PX7140 (Rothman Trial Dep. at 67), and the Vertical Merger Guidelines and the Horizontal Merger Guidelines do not provide a precise timeline for when parties need to establish an efficiency in order for the efficiency to be cognizable. (PX7140 (Rothman Trial Dep. at 67.)

5732. Dr. Carlton testified that he did not independently attempt to identify what specific products may result from the claimed R&D efficiencies. (RX6000 (Carlton Trial Dep. at 121-122)).

Response to Finding No. 5732:

The proposed finding is incomplete, misleading, and mischaracterizes the cited testimony. In fact, while Dr. Carlton was not the source of information concerning specific new products, he testified that he was aware of several specific products and targets, including "fatty liver disease", "neurodegenerative diseases, such as Alzheimers" and "cardiovascular diseases" as some potential areas "where the potential benefits could lie". (RX6000 (Carlton Trial Dep. at 121-122)). Fact witnesses testified that Galleri specific efficiencies would arise, including improved performance, lower cost and better workflows. (PFF ¶ 1141.) They also testified that the Transaction would likely generate a number of non-Galleri related benefits including potential new technology related to Alzheimer's, Parkinson's and fatty liver disease. (PFF ¶ 1142.)

5733. Mr. deSouza testified that Illumina has not developed a commercial plan for any test that might result from the claimed R&D efficiency. (deSouza (Illumina) Tr. 2425).

Response to Finding No. 5733:

The proposed finding is incomplete and misleading. In fact, Mr. deSouza testified that the merger could facilitate R&D efficiencies for other diseases, such as fatty liver disease and Parkinson's. (deSouza (Illumina) Tr. 2423). Mr. deSouza also explained that Illumina, unlike

GRAIL, can "dedicate a research team to say look, you know, this might not pan out. We did it. That's what research is. GRAIL wouldn't do that because they can't have a speculative team on Alzheimer's, a speculative team on Parkinson's, and a speculative team on fatty liver disease", illustrating why the Transaction will result in significant R&D efficiencies. (deSouza (Illumina) Tr. 2424).

5734. Mr. deSouza testified that Illumina has not formed the research teams to develop screening products for fatty liver disease and Parkinson's. (deSouza (Illumina) Tr. 2423).

Response to Finding No. 5734:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5733, which Respondents incorporate herein.

5735. Dr. Aravanis, Illumina's corporate representative, testified that as of Illumina's March 30, 2021, Rule 2.7(h) investigational hearing, "Illumina [had] not attempted to quantify these [claimed R&D efficiencies]." (PX7073 at 60 (Aravanis 2.7(h) IHT)).

Response to Finding No. 5735:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) The proposed finding is also incomplete and misleading, and mischaracterizes the cited testimony. Dr. Aravanis testified that "Again, we believe, based on many, many examples, such efficiencies will occur. There will be a cost-saving efficiency associated with them and/or an improvement in the product performance that will be of benefit to customers, but there was no need to attempt to quantify them, and that was not performed." (PX7073 at 60 (Aravanis 2.7(h) IHT)). Multiple fact witnesses at trial testified to the type and magnitude of potential R&D efficiencies. (PFF ¶ 1141-42.)

5736. [redacted]

[redacted] (PX6092 (Rothman Rebuttal Report) ¶ 33 (*in camera*)**;** ***see*** PX7107 (deSouza (Illumina) Dep. at 146, 164)). [redacted] (PX6092 (Rothman Rebuttal Report) ¶¶ 33, 88 (*in camera*)).

Response to Finding No. 5736:

The proposed finding is incomplete and misleading. Indeed, when read in context, the cited portions of Dr. Rothman's report appear to support the fact that the Transaction will likely result in merger-specific R&D efficiencies. Mr. deSouza was actually saying that the Transaction would allow the combined company to explore new discoveries that GRAIL wouldn't be able to do as a standalone company: "So at Illumina, you know, we have this expertise around deep bioinformatics and sequencing. That's stuff that we can accelerate to create those next set of life-saving tests in a way that GRAIL just wouldn't get to because they still have so much to do on cancer screening. So we'll accelerate everything they do and everything they plan to do in terms of getting this early detection of cancer test to the market. We'll accelerate the new products, like the MRD product -- which they don't yet even have a date because they're so swamped on launching their cancer screen -- that's something we can add resources and actually put an effort on to say, we're going to launch that MRD product, which is also life-saving and would be unique in the market. (PX7107 (deSouza (Illumina) Dep. at 146-47.).) As reflected in Dr. Carlton's expert report and testimony, collaboration yielding a higher probability of breakthrough discoveries often does not occur prior to an acquisition because of the well-known difficulty of collaboration by contract when proprietary IP (e.g., GRAIL's data and algorithm), and the inherent reservations about the disclosure of such confidential information, is involved, and it is exactly such collaboration in a vertical setting

(after Illumina's acquisition of Verinata) that led to discoveries that led to the formation of GRAIL. (RX3864 (Carlton Expert Report) ¶ 13); RX6000 (Carlton Trial Dep. at 61–63).)

5737. [redacted] (PX6092 (Rothman Rebuttal Report) ¶¶ 33, 88 (*in camera*) (citing PX0064 at 009 (Illumina Open Offer Agreement, Mar. 29, 2021)**).** [redacted] (PX6092 (Rothman Rebuttal Report) ¶¶ 33, 88 (*in camera*)). [redacted] (PX6092 (Rothman Rebuttal Report) ¶¶ 33, 88 (*in camera*)).

Response to Finding No. 5737:

The proposed finding is inaccurate and misleading as well as contradicted by the weight of the evidence, is unreliable and based on speculation, and relies on improper expert testimony for the reasons explained in Respondents' responses to CCFF ¶ 5721, which Respondents incorporate herein. The firewall provision is designed to protect against the sharing of third party confidential information and does not prevent Illumina and GRAIL from engaging in R&D activities. (RX3340 (Illumina Open Offer at 7–8) ("Illumina shall establish a firewall designed to prevent any GRAIL personnel (and any Illumina personnel carrying out activities with respect to the GRAIL business or products) from accessing any Confidential Information obtained by or made available to Illumina relating to Customer or its business or products, whether pursuant to this Supply Agreement or otherwise".).) Thus, it has no bearing on the R&D efficiencies shown at trial, and will not impede Illumina from realizing efficiencies from the merger. (Aravanis (Illumina) Tr. 1946, 1948, 1959.) Dr. Febbo testified that the firewall provisions in the Open Offer would not impede Illumina from achieving the efficiencies he testified about because the regulatory, market access and R&D efficiencies are "not dependent at all on having any knowledge about what other customers are doing in screening or what GRAIL's commercial

success is"; none of the teams that report to him have access to confidential information of Illumina's oncology customers and Illumina is not involved in the single-site PMA applications of its customers, nor does the FDA seek information from Illumina in connection with the review of a third party's single-site PMA application for tests running on Illumina instruments. (Febbo (Illumina) Tr. 4363–64.)

5738. [redacted] (Jamshidi (Grail) Tr. 4067 (*in camera*)).

Response to Finding No. 5738:

Respondents have no specific response, except to note that it does not undermine Respondents claim that new R&D efficiencies will result from the Transaction.

5739. [redacted] (Jamshidi (Grail) Tr. 4067-68 (*in camera*)).

Response to Finding No. 5739:

Respondents have no specific response, except to note that it does not undermine Respondents claim that new R&D efficiencies will result from the Transaction.

5740. [redacted] (Jamshidi (Grail) Tr. 4067-68 (*in camera*)).

Response to Finding No. 5740:

Respondents have no specific response, except to note that it does not undermine Respondents claim that new R&D efficiencies will result from the Transaction.

5741. [redacted] (Jamshidi (Grail) Tr. 4067 (*in camera*)).

Response to Finding No. 5741:

Respondents have no specific response, except to note that it does not undermine Respondents claim that new R&D efficiencies will result from the Transaction.

5742. [redacted] (PX4489 (Grail) at 066 (Grail BoD 2021 Budget, Dec. 2020) (*in camera*)).

Response to Finding No. 5742:

Respondents have no specific response, except to note that it does not undermine Respondents claim that new R&D efficiencies will result from the Transaction.

5743. [redacted] (Jamshidi (Grail) Tr. 4067 (*in camera*)).

Response to Finding No. 5743:

Respondents have no specific response, except to note that it does not undermine Respondents claim that new R&D efficiencies will result from the Transaction.

5744. [redacted] (RX3867 (Deverka Rebuttal Report) at Table 6-1 (*in camera*)).

Response to Finding No. 5744:

Respondents have no specific response, except to note that it does not undermine Respondents claim that new R&D efficiencies will result from the Transaction.

5745. [redacted] (Jamshidi (Grail) Tr. 4061 (*in camera*)).

Response to Finding No. 5745:

Respondents have no specific response, except to note that it does not undermine Respondents claim that new R&D efficiencies will result from the Transaction.

5746. [redacted] (Jamshidi (Grail) Tr. 4061 (*in camera*)).

Response to Finding No. 5746:

The proposed finding is misleading and not supported by the cited testimony. [redacted] (Jamshidi (Grail) Tr. 4061 (*in camera*)).

5747. [redacted] (Jamshidi (Grail) Tr. 4055 (*in camera*)).

Response to Finding No. 5747:

Respondents have no specific response, except to note that it does not undermine Respondents claim that new R&D efficiencies will result from the Transaction.

5748. [redacted] (Jamshidi (Grail) Tr. 4056 (*in camera*)).

Response to Finding No. 5748:

Respondents have no specific response, except to note that it does not undermine Respondents claim that new R&D efficiencies will result from the Transaction.

5749. [redacted] (Jamshidi (Grail) Tr. 4057 (*in camera*)).

Response to Finding No. 5749:

Respondents have no specific response, except to note that it does not undermine Respondents claim that new R&D efficiencies will result from the Transaction.

5750. [redacted] (Jamshidi (Grail) Tr. 4058 (*in camera*)).

Response to Finding No. 5750:

Respondents have no specific response, except to note that it does not undermine Respondents claim that new R&D efficiencies will result from the Transaction.

5751. [redacted] (Jamshidi (Grail) Tr. 4058 (*in camera*)).

Response to Finding No. 5751:

Respondents have no specific response, except to note that it does not undermine Respondents claim that new R&D efficiencies will result from the Transaction.

b) The Claimed R&D Efficiency Is Not Merger Specific

5752. Dr. Aravanis testified that "GRAIL has some preliminary findings that the methylation technology can be useful for detecting fatty liver disease and, in particular, a very advanced form of that disease." (Aravanis (Illumina) Tr. 1954-1955).

Response to Finding No. 5752:

Respondents have no specific response, except to note that the Transaction will enable the combined company to explore these discoveries more fully. (PX7107 (deSouza (Illumina) Dep. at 146-47.))

5753. Dr. Aravanis testified that, beyond fatty liver disease, "there's evidence of other types of diseases that can be detected using Grail's methylation technology. These include metabolic diseases, cardiovascular disease, you know, heart attacks, psychiatric diseases." (Aravanis (Illumina) Tr. 1955).

Response to Finding No. 5753:

Respondents have no specific response, except to note that the Transaction will enable the combined company to explore these discoveries more fully. (PX7107 (deSouza (Illumina) Dep. at 146-47.)

5754. Dr. Rothman explained that [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 91 (*in camera*)). [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 91 (*in camera*)).

Response to Finding No. 5754:

The proposed finding is inaccurate and misleading, is contradicted by the weight of the evidence, is unreliable and based on speculation, and relies on improper expert testimony for the reasons explained in Respondents' responses to CCFF ¶ 5721, which Respondents incorporate herein. Unrebutted fact witness testimony supports the fact that the idea for Galleri came from another vertical transaction: Illumina's acquisition of Verinata, a company in the non-invasive prenatal testing business. (Aravanis (Illumina) Tr. 1868–71, 1873–74; PX7048 (Klausner (GRAIL) IHT at 43–44, 49–54, 69–72); PX7079 (Flatley (Illumina) Dep. at 31–32); (PX7048 (Klausner (GRAIL) IHT at 43-44) (deSouza (Illumina) Tr. 2345).) Specifically, Illumina was operating Verinata, a noninvasive prenatal testing business Illumina had recently purchased, and in the first hundred thousand women that received that noninvasive prenatal test some unusual signs were identified. It turned out these signals were undiagnosed cancer. This led to the discovery that cancer detection from the blood might be possible. (Aravanis (Illumina) Tr. 1869.) Dr. Aravanis explained "the laboratory director *at Illumina* who was responsible for the testing collected these unusual signals. She approached leadership *at Illumina* about them, including the chief medical officer and also myself, you know, and told us, you know, that we should look into it in more detail. *We ultimately formed a team* and a program to, you know, evaluate these signals, to follow up with patients carefully and their prescribing physicians, which eventually led to the discovery that these women had undiagnosed cancers." (Aravanis (Illumina) Tr. 1869–

70 (emphasis added).) Dr. Aravanis testified that Verinata would not have pursued this application if they had not been acquired by Illumina; that Meredith Halks-Miller, the laboratory director who had seen the initial signs of cancer in the blood, told him that prior to the acquisition no one at Verinata would listen to her about pursuing this research, that it was a distraction and that Verinata did not have the resources to do this and that but for Illumina no one would have developed a program in this area and without GRAIL this interesting discovery and the potential benefits might never be realized. (Aravanis (Illumina) Tr. 1873–74.) It is exactly such collaboration in a vertical setting (after Illumina's acquisition of Verinata) that led to discoveries that led to the formation of GRAIL. (RX3864 (Carlton Expert Report) ¶ 13); RX6000 (Carlton Trial Dep. at 61–63).)

5755. (PX6091 (Scott Morton Rebuttal Report) ¶ 111 (*in camera*)).

Response to Finding No. 5755:

Respondents have no specific response, except to note that Illumina did not completely spin off GRAIL, but remained a significant investor at all times.

5756. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 111 (*in camera*)).

Response to Finding No. 5756:

The proposed finding improperly substitutes expert testimony for factual evidence, and is not based on any record evidence. Moreover, Dr. Scott Morton is not an expert in R&D and does not cite to any record evidence supporting her argumentative, speculative and self-serving statements. To the contrary, Illumina has a long track record of generating R&D efficiencies in connection with vertical transactions. (deSouza (Illumina) Tr. 2345 ("we believe that there are R&D synergies between the two teams, so just like our team discovered the possibility to see cancer in blood because we were processing NIPT samples, we believe that it is going to be possible to develop a diagnostic test, a blood diagnostic test, to look for fatty liver disease, Alzheimer's, Parkinson's. But that requires the capabilities of the two companies to be brought together, and so we believe there are R&D synergies there".); PX7079 (Flatley (Illumina) Dep. at 31–32) ("If you go back to the origin of GRAIL, one of the most important things that happened there was our acquisition of Verinata because it was that work that really was the light bulb moment . . . that caused us to realize that you can detect cancer by screening the blood. . . . So certainly some great opportunities would evolve there".).) The idea for Galleri came from Illumina's vertical acquisition of Verinata and investment in R&D. (Aravanis (Illumina) Tr. 1868–69; PX7048 (Klausner (GRAIL) IHT at 49–54).) Contrary to the unsupported argumentative statement of Dr. Scott Morton, every single fact witness to address the issue

testified—without exception—that it would take GRAIL years to develop the R&D capabilities Illumina has. (Aravanis (Illumina) Tr. 1967; deSouza (Illumina) Tr. 2354–57; Flatley (Illumina) Tr. 4086–87.)

4. Elimination of Grail Royalty

a) Elimination of the Royalty Is Not Merger Specific

5757. Grail entered into a supply agreement with Illumina in 2017. (Freidin (Grail) Tr. 2975).

Response to Finding No. 5757:

Respondents have no specific response.

5758. The Grail-Illumina supply agreement was entered into during Grail's Series B fund raise and deconsolidation from Illumina. (Freidin (Grail) Tr. 2975).

Response to Finding No. 5758:

Respondents have no specific response.

5759. According to Mr. Freidin, Grail agreed to pay a royalty on all the products that Grail creates in the cancer space in perpetuity. (Freidin (Grail) Tr. 2975-76).

Response to Finding No. 5759:

Respondents have no specific response.

5760. [redacted] (Freidin (Grail) Tr. 3029 (*in camera*)).

Response to Finding No. 5760:

Respondents have no specific response.

5761. GRAIL conducted analysis of the effect a royalty would have on Grail's ability to price and sell the Galleri product. (Freidin (Grail) Tr. 2976-77).

Response to Finding No. 5761:

Respondents have no specific response.

5762. Before Illumina offered to buy Grail, Grail evaluated ways to eliminate the Illumina royalty. (Freidin (Grail) Tr. 2978).

Response to Finding No. 5762:

Respondents have no specific response.

5763. Grail engaged with its advisor, Morgan Stanley, to run scenarios that could defer, eliminate, or decrease the Illumina royalty. (Freidin (Grail) Tr. 2978).

Response to Finding No. 5763:

Respondents have no specific response.

5764. [redacted] (Freidin (Grail) Tr. 3030 (*in camera*)).

Response to Finding No. 5764:

Respondents have no specific response.

5765. [redacted] (Freidin (Grail) Tr. 3083 (*in camera*)).

Response to Finding No. 5765:

Respondents have no specific response.

5766. [redacted] (Freidin (Grail) Tr. 3083 (*in camera*)).

Response to Finding No. 5766:

Respondents have no specific response.

5767. [redacted] (Freidin (Grail) Tr. 3084 (*in camera*)).

Response to Finding No. 5767:

The proposed finding is incomplete and misleading to the extent it suggests that [redacted]

[redacted] (Freidin (Grail) Tr. 3086 (*in camera*)).

5768. [redacted] (Freidin (Grail) Tr. 3084-85 (*in camera*)).

Response to Finding No. 5768:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5767, which Respondents incorporate herein.

5769. [redacted] (Freidin (Grail) Tr. 3085 (*in camera*)).

Response to Finding No. 5769:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5767, which Respondents incorporate herein.

5770. [redacted] (Freidin (Grail) Tr. 3085 (*in camera*); PX4235 (Grail) at 018 (Email from M. Podoll, Morgan Stanley, to A. Tosti, Grail, CC'ing A. Freidin, Grail, May 3, 2020 (*in camera*)).

Response to Finding No. 5770:

The proposed finding is misleading, mischaracterizes the cited testimony and is not supported by the trial evidence. [redacted]

[redacted] (Freidin (Grail) Tr. 3085-86 (*in camera*)

5771. [redacted] (Freidin (Grail) Tr. 3086 (*in camera*); PX4235 (Grail) at 018 (Email from M. Podoll, Morgan Stanley, to A. Tosti, Grail, CC'ing A. Freidin, Grail, May 3, 2020 (*in camera*)).

Response to Finding No. 5771:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5767 and 5770, which Respondents incorporate herein.

5772. [redacted] (Freidin (Grail) Tr. 3086 (*in camera*)).

Response to Finding No. 5772:

Respondents have no specific response.

5773. [redacted] (RX6000 (Carlton Trial Dep. at 126) (*in camera*)).

Response to Finding No. 5773:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5767, which Respondents incorporate herein.

5774. [redacted] (PX7066 (Freidin (Grail) IHT at 192-193; PX4235 (Grail) at 004 (Email from M. Podoll, Morgan Stanley, to A. Tosti, Grail, CC'ing A. Freidin, Grail, May 3, 2020 (*in camera*)).

Response to Finding No. 5774:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5767 and 5770, which Respondents incorporate herein.

[redacted]

[redacted] (Freidin (Grail) Tr. 3086 (*in camera*)).

5775. [redacted] (Freidin (Grail) Tr. 3086-87 (*in camera*); PX7066 (Freidin (Grail) IHT at 192-193)).

Response to Finding No. 5775:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

[redacted] (*See* Freidin (Grail) Tr. 3086-87 (*in camera*).)

5776. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 44 (*in camera*)).

Response to Finding No. 5776:

The proposed finding improperly relies on expert testimony to support a purported fact. The cited portion of Dr. Scott Morton's report cites no factual evidence but is simply an instance of Dr. Scott Morton argumentatively quibbling with Dr. Carlton's conclusions. Notably, neither the cited portion of Dr. Scott Morton's rebuttal report nor Complaint Counsel's proposed findings cite any factual evidence on this point. (*See* PX6091 (Scott Morton Rebuttal Report) ¶ 44 (*in camera*)).

5777. Dr. Carlton testified that he did not specifically opine on whether the royalty that Grail paid to Illumina could not have been eliminated absent the merger. (RX6000 (Carlton Trial Dep. at 125)).

Response to Finding No. 5777:

The proposed finding is incomplete and misleading. Dr. Carlton testified that the elimination of the royalty was merger specific: Well, the evidence is that premerger, the royalty was not removed. That seems to me the strongest evidence and the most direct evidence that contradicts any claim that this royalty efficiency isn't a merger -- isn't merger-specific. In fact, there was an attempt to eliminate the royalty. There were discussions about exactly this, I believe with Morgan Stanley -- I believe there has been testimony in this case about that -- and they failed to get rid of it." (RX6000 (Carlton Trial Dep. at 70).)

b) Elimination of the Royalty Is Not Verifiable

5778. [redacted] (RX3864 (Carlton Rebuttal Report) ¶ 110 (*in camera*)). [redacted] (RX3864 (Carlton Rebuttal Report) ¶ 110 n.270 (*in camera*)).

Response to Finding No. 5778:

The proposed finding is incomplete. The cited footnote continues, noting that [redacted] (RX3864 (Carlton Rebuttal Report) ¶ 110 & n.270 (*in camera*)).

5779. Dr. Carlton explained that [redacted] (RX3864 (Carlton Rebuttal Report) ¶ 110 n.270 (*in camera*)).

Response to Finding No. 5779:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5778, which Respondents incorporate herein.

c) Respondents Fail To Demonstrate That Elimination of the Royalty Will Be Passed Through to Customers

5780. [redacted] (*see* RX3864 (Carlton Rebuttal Report) (*in camera*)).

Response to Finding No. 5780:

The proposed finding is not supported by the trial evidence. Notably, the proposed finding does not cite to any specific page or section of Dr. Carlton's rebuttal report, and accordingly does not identify any source for the proposed finding. In fact, EDM and other efficiencies projected by Illumina are merger-specific, will be passed through to downstream customers, and are likely to be of significant magnitude. (RX3864 (Carlton Expert Report) ¶ 13); [redacted]

5781. To the extent that a reduction in royalty payments from Grail to Illumina reduces the margin charged by the combined firm post-Acquisition, such a reduction in margin will be offset by the issuance of CVRs. (PX0408 at 018 (Illumina Form 10-Q for Q3 2021)).

Response to Finding No. 5781:

The proposed finding is incomplete and misleading. Dr. Carlton's calculation of the benefits of the elimination of the royalty takes into account the effect of the CVRs. (RX3864 (Carlton Expert Report) ¶¶ 108-110.) Complaint Counsel put forward no calculations of its own as to what it claims is the "offset". Dr. Carlton did do the work, however, and his analysis is unrefuted, showing a significant increase in consumer surplus, even taking into account the partial offset of the royalty savings deriving from the CVRs. (PFF ¶¶ 1150–51.)

5782. [redacted] (Freidin (Grail) Tr. 3078 (*in camera*); PX4047 (Grail) at 045 (Email From M. Song, Grail, to Hans Bishop, Grail, et al., attaching Discussion Materials: Project Valor, Sept. 16, 2020)).

Response to Finding No. 5782:

Respondents have no specific response, [redacted]

5783. Illumina valued the CVR consideration owed to Grail's stockholders at $762 million as of the acquisition's August 18, 2021 completion date. (PX0408 at 018 (Illumina Form 10-Q for Q3 2021)). Illumina measured this CVR value using several assumptions that included "forecasted revenues for GRAIL." (PX0408 at 018 (Illumina Form 10-Q for Q3 2021)).

Response to Finding No. 5783:

Respondents have no specific response.

5784. On August 18, 2021, Illumina announced "Holders of approximately 47% of GRAIL equity interests and/or awards (on a fully diluted basis), or 54% excluding Illumina, elected to receive the CVR consideration." (PX0377 at 002 (Press Release: Illumina Acquires GRAIL to Accelerate Patient Access to Life-Saving Multi-Cancer Early-Detection Test, dated Aug. 18, 2021)).

Response to Finding No. 5784:

Respondents have no specific response.

5785. Dr. Carlton testified that he did not analyze the tax treatment of CVRs given to Grail shareholders compared to the tax treatment of royalties that Grail paid to Illumina. (RX6000 (Carlton Trial Dep. at 127)).

Response to Finding No. 5785:

Respondents have no specific response except to note that Dr. Carlton's calculation of the benefits of the elimination of the royalty takes into account the effect of the CVRs. (RX3864 (Carlton Expert Report) ¶¶ 108-110.)

5. Lab and Supply Chain Cost Savings

a) The Claimed Lab and Supply Chain Cost Savings Efficiency Is Not Verifiable (And, if Applicable, Not Quantified)

5786. Respondents did not include efficiencies related to supply chain and laboratory operations in their Answer. (*See generally* Respondents' Answer).

Response to Finding No. 5786:

The proposed finding is factually incorrect. As set forth on pages 12 and 13 of Respondents' Answer, the efficiencies created by the transaction include "Speed to Scale", which includes Illumina's "global operational infrastructure and experience operating regulated manufacturing and laboratory facilities to assist GRAIL in commercializing its tests at scale . . . . Illumina's operational and commercial infrastructure will allow GRAIL to make its test more widely available at a faster rate and at lower costs."

5787. [redacted] (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 20 (RFA No. 26) (*in camera*)).

Response to Finding No. 5787:

The proposed finding is incomplete and misleading. Illumina's dull response stated:

[redacted]

[redacted] (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 20 (RFA No. 26).)

5788. During the March 30, 2021, Illumina Rule 2.7(h) investigational hearing, Dr. Aravanis testified that Illumina's quantification of the claimed supply chain and laboratory operation efficiencies was prepared in the week prior to his testimony. (PX7073 (Aravanis (Illumina) IHT at 45-46); *see* PX6050 (Illumina) at 003-005 (Aravanis Investigational Hearing Notes)).

Response to Finding No. 5788:

The proposed finding is incomplete and misleading. Dr. Aravanis testified that these efficiencies were noted before the deal but that the addional quantification presented was performed one week prior to the IH: "the estimates of the previously noted efficiencies, so this quantification of the previously noted efficiencies that occurred prior to the deal, and as -- and in the previous white paper, these occurred, you know, over the last week to do this additional quantification." (PX7073 (Aravanis (Illumina) IHT at 45-46).) The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5789. [redacted] (Ofman (Grail) Tr. 3382 (*in camera*)).

Response to Finding No. 5789:

[redacted] (Ofman (Grail) Tr. 3382 (*in camera*)).

While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5790. [redacted] (Ofman (Grail) Tr. 3381 (*in camera*)).

Response to Finding No. 5790:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5789, which Respondents incorporate herein. [redacted] (Ofman (Grail) Tr. 3380 (*in camera*)). While Respondents have not completed integration planning, that is only because they are not legally permitted to do so (as the FTC well knows). (CC Post-Trial Br. at 182 (noting that Illumina committed to the European Commission to hold GRAIL as a separate entity).)

5791. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 92 (*in camera*)).

Response to Finding No. 5791:

The proposed finding is incomplete and misleading without additional context, as well as contradicted by the weight of the evidence for the reasons explained in Respondents' responses to CCFF ¶ 5721, which Respondents incorporate herein. [redacted]

[redacted]

In any event, multiple fact witnesses substantiated the lab operations and supply chain efficiencies at trial. (PFF ¶¶ 1156-67.)

5792. [redacted]
(PX6092 (Rothman Rebuttal Report) ¶ 93 (*in camera*)).

Response to Finding No. 5792:

The proposed finding is incomplete and misleading without additional context, as well as contradicted by the weight of the evidence for the reasons explained in Respondents' responses to CCFF ¶¶ 5721 and 5791, which Respondents incorporate herein. In any event, multiple fact witnesses substantiated the lab operations and supply chain efficiencies at trial. (PFF ¶¶ 1156-67.)

5793. [redacted]
(RX3864 (Carlton Rebuttal Report) ¶ 104 n. 262 (*in camera*) (citing PX2613 (Illumina) at 002 (Appendix A: Illumina/GRAIL Efficiency Analysis)).

Response to Finding No. 5793:

Respondents have no specific response except to note multiple fact witnesses substantiated the lab operations and supply chain efficiencies at trial. (PFF ¶¶ 1156-67.)

5794. [redacted] (PX2613 (Illumina) at 004 (Appendix A: Illumina/Grail Efficiency Analysis)).

Response to Finding No. 5794:

The proposed finding is not supported by the cited evidence. PX2613 is an appendix summarizing analysis of efficiencies. Complaint Counsel does not cite any testimony or other evidence concerning the basis for or method of conducting the analysis.

5795. [redacted] (PX2613 (Illumina) at 005 (Appendix A: Illumina/Grail Efficiency Analysis)).

Response to Finding No. 5795:

The proposed finding is not supported by the cited evidence. PX2613 is an appendix summarizing analysis of efficiencies. Complaint Counsel does not cite any testimony or other evidence concerning the basis for or method of conducting the analysis.

5796. Dr. Carlton testified that he is not the source of the claim that Illumina will achieve supply chain and operational efficiencies. (RX6000 (Carlton Trial Dep. at 127)).

Response to Finding No. 5796:

Respondents have no specific response except to note multiple fact witnesses substantiated the lab operations and supply chain efficiencies at trial. (PFF ¶¶ 1156-67.)

5797. Dr. Carlton testified that he did not perform an independent quantification of variable cost savings from supply chain and operational efficiencies. (RX6000 (Carlton Trial Dep. at 128)).

Response to Finding No. 5797:

Respondents have no specific response except to note multiple fact witnesses substantiated the lab operations and supply chain efficiencies at trial. (PFF ¶¶ 1156-67.)

5798. Dr. Carlton testified that he did not account for any costs associated with Illumina and Grail working to achieve supply chain and operational efficiencies. (RX6000 (Carlton Trial Dep. at 128-129)).

Response to Finding No. 5798:

The proposed finding is misleading and mischaracterizes the cited testimony. Dr. Carlton gave the following testimony: "Q. You didn't account for any costs associated with Illumina and GRAIL working to achieve supply chain and operational efficiencies, correct? A. I did not account for any extra costs, other than what I talk about in my report." (RX6000 (Carlton Trial Dep. at 128-129)). Among other things, Dr. Carlton's report does include assessments of certain costs of operations, including costs of goods sold, and criticizes Dr. Scott Morton for failing to take "margins and costs" into consideration in her analysis. (*See* Carlton Rept. ¶¶ 67-70, 170 (*in camera*).)

5799. Dr. Carlton testified that he did not independently attempt to quantify any costs associated with Illumina and Grail working to achieve supply chain and operational efficiencies. (RX6000 (Carlton Trial Dep. at 129)).

Response to Finding No. 5799:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5798, which Respondents incorporate herein. Dr. Carlton testified that he did rely on efficiencies estimated by Illumina, in the following exchange from the cited testimony: "You didn't -- you didn't independently attempt to quantify any costs associated with the combined Illumina/GRAIL working to try to achieve supply chain and operational efficiencies, correct? A. It is correct that I did not attempt to estimate any additional

costs associated with achieving these efficiencies, other than using the efficiencies that Illumina has estimated would arrive." (RX6000 (Carlton Trial Dep. at 129)).

b) The Claimed Lab and Supply Chain Cost Savings Efficiency Is Not Merger Specific

5800. Dr. Carlton did not perform an analysis to determine whether the supply chain and operational efficiencies claimed by Illumina are merger specific. (RX6000 (Carlton Trial Dep. at 128)).

Response to Finding No. 5800:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5798, which Respondents incorporate herein. Dr. Carlton testified that he did rely on efficiencies estimated by Illumina, in the following exchange from the cited testimony: "You didn't -- you didn't independently attempt to quantify any costs associated with the combined Illumina/GRAIL working to try to achieve supply chain and operational efficiencies, correct? A. It is correct that I did not attempt to estimate any additional costs associated with achieving these efficiencies, other than using the efficiencies that Illumina has estimated would arrive." (RX6000 (Carlton Trial Dep. at 129)).

5801. [redacted] (*See* PX4016 (Grail) at 025 (Grail Strategy Planning Roadmap (Workshop #2), Sept. 2, 2020) (*in camera*) [redacted]**;** *see also* PX4491 (Grail) at 007, 035-043 (Board of Directors Meeting, Apr. 30, 2019) (*in camera*)).

Response to Finding No. 5801:

Respondents have no specific response except to note that PX4016-025 [redacted]

[redacted]

, Illumina presently has facilities capable of running millions of tests per year, including Galleri. (deSouza (Illumina) Tr. 2370–72.)

Respondents also note that Complaint Counsel chose not to discuss PX2170 and PX4491 at trial (CC Exhibit Index at 10, 50), or in any deposition, and therefore these documents should be entitled to little weight.

5802. Grail has been running commercial tests in its Menlo Park lab. (Freidin (Grail) Tr. 3005).

Response to Finding No. 5802:

Respondents have no specific response.

5803. [redacted] (Freidin (Grail) Tr. 3104 (*in camera*)).

Response to Finding No. 5803:

Respondents have no specific response except to note that [redacted]

[redacted] (Freidin (GRAIL) Tr. 3104) In contrast, Illumina's facilities are capable of running millions of tests per year, including Galleri, and have done so for years. (deSouza (Illumina) Tr. 2370–72.)

5804. [redacted] (Ofman (Grail) Tr. 3386 (*in camera*)).

Response to Finding No. 5804:

Respondents have no specific response.

5805. [redacted] (Freidin (Grail) Tr. 3002; *see* PX4175 (Grail) at 099-108 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5805:

The proposed finding is misleading without further context. [redacted]

5806. [redacted] (Bishop (Grail) Tr. 1469-70 (*in camera*); PX4489 (Grail) at 017 (Email from S. Green, Grail, to grail-bod, attaching BoD 2021 Budget, Dec. 2020) (*in camera*)).

Response to Finding No. 5806:

Respondents have no specific response.

5807. Grail is pursuing a centralized approach at the RTP lab because it is "the fastest way" for Grail to process millions of tests. (Freidin (Grail) Tr. 3006-007).

Response to Finding No. 5807:

The proposed finding is misleading without further context. Mr. Freidin then testified that Illumina would be able to accelerate GRAIL's centralized laboratory efforts due to Illumina's extensive experience "run[ning] labs, process[ing] lots of tests, more so than we [GRAIL] have." (Freidin (GRAIL) Tr. 3007-08.) [redacted]

5808. Grail is building a second laboratory "to invest in additional test capacity to meet anticipated future demand" and because it is "investing very heavily in new technology, including robotics, to reduce the cost of the test and [] speed up the turnaround time of the test." (Bishop (Grail) Tr. 1377-78).

Response to Finding No. 5808:

Respondents have no specific response except to note that Bishop then testified that the RTP was a "huge undertaking" that "comes at enormous expense," including requiring GRAIL to "hire a workforce in an entirely different part of the country" and that all of GRAIL's "quality systems need to be upgraded to oversee . . . two different technical sites." (Bishop (GRAIL) Tr. 1377-78.) Successfully automating the lab will also be a "technically challenging task." (Bishop (GRAIL) Tr. 1378.) All of these challenges will be alleviated with Illumina's assistance and

expertise. (*See* Freidin (Grail) Tr. 2974 (discussing demonstrative RDX0010-2 outlining efficiencies of transaction).)

5809. [redacted] (Bishop (Grail) Tr. 1462 (*in camera*); *see* PX5045 (Grail) at 098-99 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5809:

Respondents have no specific response.

5810. [redacted] (PX6082 (Grail Responses & Objections to FTC Requests for Admissions) at 8 (RFA No. 6) (*in camera*)).

Response to Finding No. 5810:

Respondents have no specific response.

5811. Building a second lab will provide Grail with "uninterrupted ability to run clinical trials" and "create new capacity at [Grail's California] lab to support clinical trials." (Bishop (Grail) Tr. 1378).

Response to Finding No. 5811:

The proposed response is misleading without further context. Building a second lab—the RTP—is a "huge undertaking" that "comes at enormous expense," including requiring GRAIL to "hire a workforce in an entirely different part of the country" and that all of GRAIL's "quality systems need to be upgraded to oversee . . . two different technical sites." (Bishop (GRAIL) Tr. 1377-78.) Successfully automating the lab will also be a "technically challenging task." (Bishop (GRAIL) Tr. 1378.) [redacted] (Freidin (GRAIL) Tr. 3050, 3104).

However, these challenges will be alleviated with Illumina's assistance and expertise. *See* Freidin (GRAIL) Tr. 2974 (discussing demonstrative RDX0010-2 outlining efficiencies of transaction).) Illumina would be able to accelerate GRAIL's centralized laboratory efforts due to Illumina's extensive experience "run[ning] labs, process[ing] lots of tests, more so than we [GRAIL] have." (Freidin (GRAIL) Tr. 3007-08.) In fact, Illumina's facilities are capable of running millions of tests per year, including Galleri, and have done so for years. (deSouza (Illumina) Tr. 2370–72.)

5812. [redacted] (Freidin (Grail) Tr. 3104 (*in camera*)).

Response to Finding No. 5812:

The proposed finding is vague as to the meaning of [redacted] It is also misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 5805 and 5811 herein.

5813. [redacted] (Freidin (Grail) Tr. 3104 (*in camera*)).

Response to Finding No. 5813:

The proposed finding is vague and misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 5805 and 5811 herein.

5814. [redacted] (Freidin (Grail) Tr. 3104 (*in camera*)).

Response to Finding No. 5814:

The proposed finding is vague and misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 5805 and 5811 herein.

5815. [redacted] (PX7066 (Freidin (Grail) IHT at 44-45); PX4175 (Grail) at 099 (Grail Board Session Meeting Materials, Sept. 10, 2020 (*in camera*)).

Response to Finding No. 5815:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 5805 and 5811 herein. [redacted]

Furthermore, the proposed finding also relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5816. [redacted] (Bishop (Grail) Tr. 1464 (*in camera*); PX5045 (Grail) at 106 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5816:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 5805, 5811, and 5816 herein.

5817. Mr. Bishop testified that the building for the second laboratory has been constructed. (Bishop (Grail) Tr. 1427).

Response to Finding No. 5817:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 5805 and 5811 herein.

5818. Grail received a certificate of occupancy for the second laboratory. (Bishop (Grail) Tr. 1427).

Response to Finding No. 5818:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 5805 and 5811 herein.

5819. Grail has hired employees to work in the second laboratory. (Bishop (Grail) Tr. 1427).

Response to Finding No. 5819:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 5805 and 5811 herein.

5820. Grail has already purchased equipment for the RTP lab. (Bishop (Grail) Tr. 1427-28).

Response to Finding No. 5820:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 5805 and 5811 herein.

5821. [redacted] (Freidin (Grail) Tr. 3103 (*in camera*)).

Response to Finding No. 5821:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 5805 and 5811 herein.

5822. Grail expects to validate the new lab for the purpose of supplying Galleri towards the end of 2021. (Bishop (Grail) Tr. 1378-79).

Response to Finding No. 5822:

The proposed finding is misleading without further context. Mr. Bishop actually testified that "towards the end of [2021], we [GRAIL] expect to be in final validations for our first set of objectives with this new laboratory. But . . . there will be milestones ahead of us for several years associated with it." (Bishop (GRAIL) Tr. 1378-79.) These additional milestones include (1) "getting the final regulatory approvals," (2) "understanding new configurations associated with new versions of the test and higher degrees of automation," and (3) "additional build-outs for additional capacity." (Bishop (GRAIL) Tr. 1379.) Respondents also incorporate their responses to CCFF ¶¶ 5805 and 5811 herein.

5823. Grail plans to continue building out the new lab "for additional capacity" and gaining "regulatory approvals." (Bishop (Grail) Tr. 1379).

Response to Finding No. 5823:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 5805 and 5811 herein.

5824. [redacted] (Bishop (Grail) Tr. 1446-47 (*in camera*); PX5044 (Grail) at 016 (LRP Review, Aug. 20, 2020)).

Response to Finding No. 5824:

Respondents have no specific response except to note that [redacted]

[redacted] (Freidin (GRAIL) Tr. 3043.)

Illumina will be capable of assisting GRAIL with this build-out and automation immediately. (Bishop (GRAIL) Tr. 1404.) Illumina extensive expertise with laboratories and automation, including developing custom automation tools to run highly automated laboratories and software pipelines to analyze data from samples in a high throughput manner. (deSouza (Illumina) Tr. 2371–72.)

5825. Grail already incorporates automation into its processes for Galleri. (PX7066 (Freidin (Grail) IHT at 227-28)).

Response to Finding No. 5825:

The proposed finding is misleading without further context. [redacted] Respondents also incorporate their responses to CCFF ¶ 5824 herein.

Furthermore, the proposed finding also relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5826. [redacted] (Ofman (Grail) Tr. 3387 (*in camera*)).

Response to Finding No. 5826:

The proposed finding is misleading without further context. Respondents incorporate their responses to CCFF ¶¶ 5824 and 5825 herein.

5827. [redacted] (PX6082 (Grail Responses & Objections to FTC Requests for Admissions) at 9-10 (RFA No. 10) (*in camera*)).

Response to Finding No. 5827:

Respondents have no specific response except to note that [redacted] Respondents incorporate their responses to CCFF ¶ 5824 herein.

5828. [redacted] (Freidin (Grail) Tr. 3042 (*in camera*)).

Response to Finding No. 5828:

The proposed finding is misleading without further context for the reasons explained in Respondents' responses to CCFF ¶ 5824, which Respondents incorporate herein.

5829. [redacted] (Freidin (Grail) Tr. 3042 (*in camera*)).

Response to Finding No. 5829:

The proposed finding is misleading without further context for the reasons explained in Respondents' responses to CCFF ¶ 5824, which Respondents incorporate herein.

5830. [redacted] (Bishop (Grail) Tr. 1447 (*in camera*)).

Response to Finding No. 5830:

The proposed finding is misleading without further context for the reasons explained in Respondents' responses to CCFF ¶¶ 5824, 5825 and 5827, which Respondents incorporate herein.

5831. [redacted] (Freidin (Grail) Tr. 3042-43 (*in camera*)).

Response to Finding No. 5831:

The proposed finding is misleading without further context for the reasons explained in Respondents' responses to CCFF ¶¶ 5824 and 5825, which Respondents incorporate herein.

5832. [redacted] (Freidin (Grail) Tr. 3043 (*in camera*)).

Response to Finding No. 5832:

The proposed finding is misleading without further context for the reasons explained in Respondents' responses to CCFF ¶¶ 5824, 5825 and 5827, which Respondents incorporate herein.

5833. [redacted] (Freidin (Grail) Tr. 3042-43 (*in camera*)).

Response to Finding No. 5833:

The proposed finding is misleading without further context for the reasons explained in Respondents' responses to CCFF ¶¶ 5824 and 5825, which Respondents incorporate herein.

5834. Grail has a dedicated supply chain team to examine supply chain risk and a supplier review board. (PX7066 (Freidin (Grail) IHT at 146-47)).

Response to Finding No. 5834:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5835. [redacted] (PX7061 (Davy (Illumina) IHT at 232–233) (*in camera*); PX7063 (Berry (Illumina) IHT at 78)).

Response to Finding No. 5835:

The proposed finding is incomplete and misleading. The phrase [redacted] does not appear in Ms. Davy's IH and appears to have been taken from Ms. Berry's IH. Ms. Davy testified that [redacted] (PX7061 (Davy (Illumina) IHT at 232–233.) Ms. Berry stated that "Historically, lab services has not been a focus of Illumina's" in the context of a specific email chain. (PX7063 (Berry (Illumina) IHT at 78).) The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5836. [redacted] (PX7064 (Goswami (Illumina) IHT at 260) (*in camara*) (discussing PX2163 (Illumina) at 011 [redacted]; *see* PX7087 (Goswami (Illumina) Dep. at 166-167) [redacted]) (*in camera*)).

Response to Finding No. 5836:

The proposed finding is incomplete and misleading. Mr. Qadan testified that Illumina had a plan to do so but had not formally reached out to any payors. Specifically, he testified that "we did not discuss with payers outside the U.S. yet, but we have a plan for acceleration outside the U.S. as well." (Qadan (Illumina) Tr. 4277.)

6. Other Claimed Efficiencies Are Neither Verifiable nor Merger Specific

a) Acceleration of International Testing and Expansion of Galleri Is Not Verifiable or Merger Specific

5837. At the time of Mr. Qadan's May 26, 2021, deposition, Illumina had not discussed acceleration of Galleri with payers outside the United States. (Qadan (Illumina) Tr. 4277; PX7084 (Qadan (Illumina) Dep. at 176-77)).

Response to Finding No. 5837:

The proposed finding is incomplete and misleading. Mr. Qadan testified that Illumina had a plan to do so but had not formally reached out to any payors. Specifically, he testified that "we did not discuss with payers outside the U.S. yet, but we have a plan for acceleration outside the U.S. as well." (Qadan (Illumina) Tr. 4277.)

5838. Illumina did not analyze how payer adoption outside the United States would impact coverage in the United States. (Qadan (Illumina) Tr. 4278).

Response to Finding No. 5838:

The proposed finding is incomplete and misleading. Mr. Qadan testified that "some of the data that could be generated outside the U.S. might impact the U.S. around clinical utility." (Qadan (Illumina) Tr. 4277.) Other witnesses also testified to the impact of international acceleration on the U.S. Dr. Aravanis testified that "with offering that test in many countries in the world, that will generate a significant amount of testing data. We know that that testing datea will be useful in payer discussions around the questions they'll have around clinical utility. We also know that that data will be useful in creating future versions of the Galleri test. We also know that that data will be useful in discussions with the FDA around FDA approval." (Aravanis (Illumina) Tr. 1966-67.) Mr. deSouza testified that "by accessing a bigger market, you get a better test because the algorithms continue to get refined, and you get better and better accuracy in the test the more samples you run. This is especially true if the samples of genomically diverse. . . This is a special issue in genomics because the cohorts that are used here in the U.S. to develop genomic tests are predominantly Caucasian cohorts. What that means is if you are an African-American person in the U.S. or a number of other minorities, the genomic

tests just simply aren't as good for you as they are for Caucasians, and that's just a health inequity we're dealing with in the U.S. that we will be able to address more fully as we expand the cohorts to include cohorts from Africa and from Asia". (deSouza (Illumina) Tr. 273, 2376.)

Accelerating market access to the Galleri test internationally will also save additional lives outside of the U.S. which should not be discounted. Dr. Carlton has estimated that acceleration of one year will save over 10,000 lives in the U.S. through 2030. International acceleration will more than double that number. (RX6000 (Carlton Trial Dep. at 73-75); RX3864 (Carlton Expert Report ¶ 119 n. 291 ("With a one-year acceleration, an additional 10.4 million tests would be performed outside of the U.S. over the nine-year period 2022-2030. the lives saved by these tests are valued the same as lives saved in the U.S., then the total benefits from acceleration would be more than double what I calculate.").) As Mr. deSouza stated: "GRAIL, over the next five years, only has plans to launch this product in the U.S., the UK, and Canada. We just went through a period where we saw the tragedy that happens when we restrict life-saving technologies to a small set of wealthier markets. We will make this test available globally much faster than Illumina could, and so those 10,000 lives that could be saved will be a much bigger number when you think about us making this test available to people around the world. This has personal resonance and urgency for me because I have family in Africa, I have family in India. On its own, GRAIL will not get the test to Africa and India even over the next decade, and so we feel a sense of urgency, given what we know this test can do, to get this test out into the market. And so that's what -- you know, that's what this transaction represents." (deSouza (Illumina) Tr. 2412.)

5839. Illumina did not estimate a figure for how payer adoption outside the United States would impact market access in the United States. (Qadan (Illumina) Tr. 4278).

Response to Finding No. 5839:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5838 which Respondents incorporate herein.

5840. Dr. Carlton testified that he is not the source of any claim that Illumina will accelerate international testing and expansion of Galleri. (RX6000 (Carlton Trial Dep. at 130)).

Response to Finding No. 5840:

The proposed finding is incomplete and misleading. Dr. Carlton testified that while he relied on other witnesses and documents, he came to his own independent conclusion based on the evidence that the reunion of Illumina and GRAIL will generate substantial efficiencies and that he is the source for the opinions expressed in his report and in his direct examination. (Carlton Tr. 196–97.) Respondents also note that they have presented unrebutted evidence that the Transaction is estimated to result in international acceleration and expansion. (PFF ¶¶ 1168-73.)

5841. Dr. Carlton testified that he did not quantify the benefit of acceleration of international testing and expansion of Galleri in his report. (RX6000 (Carlton Trial Dep. at 130)).

Response to Finding No. 5841:

The proposed finding is incomplete and misleading. Dr. Carlton opined that if the impact of acceleration internationally was similar to the impact in the U.S. then the total benefits from U.S. and international acceleration combined would be more than double what he calculates for the U.S. (RX6000 (Carlton Trial Dep. at 73-75); RX3864 (Carlton Expert Report ¶ 119 n. 291 ("With a one-year acceleration, an additional 10.4 million tests would be performed outside of the U.S. over the nine-year period 2022-2030. the lives saved by these tests are valued the same as lives saved in the U.S., then the total benefits from acceleration would be more than double

what I calculate.").) Dr. Carlton calculated that U.S. acceleration would save 10,000 lives and result in at least $37 billion in efficiencies. (RX6000 (Carlton Trial Dep. at 73-75).)

5842. Dr. Carlton testified that he did not estimate any costs associated with Illumina and Grail trying to accelerate international testing and expansion of Galleri. (RX6000 (Carlton Trial Dep. at 130)).

Response to Finding No. 5842:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5841 which is incorporated herein. Given the enormous estimated benefits of international acceleration any costs would be minimal and would not affect the analysis.

b) Acceleration of Other Test Developers' FDA Approval Processes Is Not Verifiable or Merger Specific

5843. When Illumina previously decided to divest its interest in Grail, Illumina stated in internal Q&A bullets that divesting Grail would "accelerate the liquid biopsy market for all." (PX2406 (Illumina) at 005 (Email from J. Flatley, Illumina, to E. Endicott, et. al, Illumina, attaching Illumina/Grail Q&A, Jan. 2, 2017)).

Response to Finding No. 5843:

The proposed finding is incomplete and misleading. As cited document shows, the quote is in response to the hypothetical question: "By creating and unleashing GRAIL have you created a competitor for your customers." (PX2406 (Illumina) at 005.) In the document, the response to that question does not say, as Complaint Counsel suggests, that MCED test development would be accelerated just by virtue of the fact that Illumina was spinning off GRAIL. That is an incoherent suggestion that finds no support in the document, which talks about accelerating "liquid biopsy" more broadly as a result of Illumina both "creating and unleashing" Grail. Mr. Flatley, who drafted the language quoted by Complaint Counsel, directly refuted the inference Complaint Counsel hopes to draw from the document when he was asked about it at his deposition (which Complaint Counsel conveniently fails to cite). Mr. Flatley explained that what

he meant with this language is that "if GRAIL has the constraints taken off it in terms of field of use, the could now compete against customers where in the earlier format [before the spin-off] they could not have because the field was constrained." (PX7079 (Flatley (Illumina) Dep. at 174).) Mr. Flatley went on to explain that, prior to the spin-off, the question regarding the creation an entity that would compete with customers more broadly in liquid biopsy was not a consideration because GRAIL was constrained to developing only an MCED test, "there were no customers in the screening market" and "there was a market that didn't exist and still doesn't, so there are no customers in the screening market." (PX7079 (Flatley (Illumina) Dep. at 175).)

5844. Dr. Carlton testified that he did not quantify the efficiency related to acceleration of other test developers' FDA approval processes. (PX7134 (Carlton Dep. at 169-70).

Response to Finding No. 5844:

Respondents have no specific response except to note that Dr. Carlton's report does say that "Acceleration of GRAIL's and other test developers' timelines will lead to a large number of incremental tests, which directly benefits consumers who would not otherwise have been timely tested; this will result in additional lives saved". (RX3864 (Carlton Expert Report ¶ 97).) If the acceleration of other tests results in even a small fraction of the additional tests that Dr. Carlton predicts for Galleri, the result will be significant.

c) Claimed Machine Learning Efficiencies Are Not Verifiable or Merger Specific

5845. Dr. Carlton testified that he did not quantify the machine learning efficiency in his report. (PX7134 (Carlton Dep. at 167-68)).

Response to Finding No. 5845:

The proposed finding is incomplete and misleading. Dr. Carlton's actual response was "Not other than, you know, the numbers I am using in my report, but I didn't do a separate analysis of Item 5." (PX7134 (Carlton Dep. at 167-68).) Dr. Carlton's report states: "GRAIL's

Galleri test uses a machine learning algorithm to determine the existence and location of cancer based on the methylation patterns in a patient's DNA. This algorithm has been 'trained' on the data from GRAIL's clinical trials which contain the methylation patterns and cancer diagnoses for hundreds of thousands of patients. By analyzing the complex relationships between methylation patterns and cancer diagnoses in this training data, the algorithm is refined to a set of rules that can be used to predict whether new patients who are tested have cancer. As GRAIL accumulates data from the commercial sales of its tests, it will add to its training data set, allowing it to refine its algorithm. This will allow GRAIL to not only improve the accuracy of the assay, but also allow it to detect additional types of cancer. Any acceleration in the adoption of Galleri will therefore allow it to detect more cancers, with greater accuracy, sooner, resulting in additional lives saved". (RX3864 (Carlton Expert Report ¶ 97).) If machine learning leads to a more accurate assay or more cancers detected, more lives will be saved and the benefits will be significant.

5846. Dr. Carlton testified that he did not quantify how much the acceleration of Grail's sales may improve the accuracy of Grail's assay. (PX7134 (Carlton Dep. at 169)).

Response to Finding No. 5846:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5845, which Respondents incorporate herein. Respondents also note that Dr. Carlton's actual response was "I don't do a separate analysis of that no." (PX7134 (Carlton Dep. at 169).)

5847. Dr. Carlton testified that he did not identify which additional types of cancer may be detected through acceleration of Grail's sales. (PX7134 (Carlton Dep. at 169)).

Response to Finding No. 5847:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5845, which Respondents incorporate herein.

D. NON-MERGER ALTERNATIVES COULD REPLICATE ILLUMINA'S CLAIMED EFFICIENCIES

1. Grail Is Able to Raise Funds as an Independent Company

5848. Before Illumina acquired Grail, Grail funded its operations through "private financing rounds" that involved venture capital and strategic investors. (Freidin (Grail) Tr. 3011).

Response to Finding No. 5848:

The proposed finding is incomplete and misleading. Mr. Freidin further testified that "GRAIL consider[ed] continuing down that path and continuing to fund its operations through additional private financing" and determined that "going to Illumina and getting acquired by them was a faster path to creating value and saving lives" because not having to go "back out and kick off another financing round is a timesaver and puts capital to work fast". (Freidin (Grail) Tr. 3011-12.)

5849. In addition to Illumina, Grail was previously owned by "large pharmaceutical companies" as well as mutual funds and private investors. (Bishop (Grail) Tr. 1407-08).

Response to Finding No. 5849:

Respondents have no specific response.

5850. Grail raised approximately $2 billion through its four rounds of private financing. (Freidin (Grail) Tr. 3016).

Response to Finding No. 5850:

The proposed finding is ambiguous to the extent it states an "approximate" amount. Mr. Freidin testified that "I think it was about $2 billion". (Freidin (Grail) Tr. 3016.) Respondents further note that Mr. Freidin testified that the fundraising was not "easy. A couple of the rounds

took multiple months, close to a year, from initiation until final close." (Freidin (Grail) Tr. 3016.)

5851. As of September 2020, Grail had raised "$1.9 billion through a combination of leading venture capital and strategic partners." (PX4082 (Grail) at 086 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, et. al, Morgan Stanley, attaching Grail 2020 S-1/Amended, Sept. 2020); PX5023 (Illumina) at 003 (Project: GRAIL, Phil Febbo & Corporate Development, Mar. 2020); PX6049 at 107 (Grail Narrative Response to Second Request, Mar. 1, 2021)).

Response to Finding No. 5851:

Respondents have no specific response.

5852. Grail noted in its S-1 filing that as of June 30, 2020 it "had $685.6 million in cash, cash equivalents, and marketable securities" on hand. (PX4082 (Grail) at 032 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, et. al, Morgan Stanley, attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 5852:

Respondents have no specific response.

5853. When Grail was acquired by Illumina, Grail had over $600 million in cash. (Freidin (Grail) Tr. 3166-67).

Response to Finding No. 5853:

The proposed finding is incomplete and misleading. Mr. Freiden testified that the $600 million number proposed by Complaint Counsel "sounds about right", and clarified that that amount "would have been less than two years of cash using our '21 and projected '22 run rate". (Freidin (Grail) Tr. 3166-67.)

5854. [redacted] (Ofman (Grail) Tr. 3383 (*in camera*)).

Response to Finding No. 5854:

Respondents have no specific response except to note that other GRAIL witnesses explained that GRAIL needed additional funding and that the transaction eliminated that risk.

(Bishop (GRAIL) Tr. 1416; Freidin (GRAIL) Tr. 3012-13; [redacted].)

5855. Grail received investment from Jeff Bezos and Bill Gates as part of its initial Series A financing. (Freidin (Grail) Tr. 3161).

Response to Finding No. 5855:

Respondents have no specific response.

5856. In late 2016, Grail initiated its second round of financing, or Series B. (PX2552 (Illumina) at 033 (Email from A. Covington, Illumina, to F. deSouza, Illumina, attaching GRAIL Update at Illumina BoD 7-27-16 DRAFT v2, July 21, 2016)).

Response to Finding No. 5856:

Respondents have no specific response

5857. [redacted] (PX2553 (Illumina) at 066 (Board of Directors Meeting, Oct. 2016) (*in camera*); PX7107 (deSouza (Illumina) Dep. at 209) (*in camera*)).

Response to Finding No. 5857:

Respondents have no specific response

5858. Grail's Series B raised $1 billion between February and December of 2017 from "investors from all over the world." (Freidin (Grail) Tr. 3016-17).

Response to Finding No. 5858:

The proposed finding is incomplete and misleading. Mr. Freidin testified that for the Series B round, "we began talking to folks in – toward the end of 2016, and the round finally closed toward the end of 2017". (Freidin (Grail) Tr. 3016). Mr. Freidin explained that, when a round of financing takes several months to complete the significance to GRAIL is that "[i]t's more management time. It's a distraction from actually operating and running the business. And also it takes us longer to get the money and then for us to put it to work. So if it takes six months longer, that's six months longer it takes for us to actually deploy those dollars." (Freidin (Grail) Tr. 3017-18.)

5859. Grail successfully raised $300 million as part of an "oversubscribed" Series C financing round in May 2018, bringing its total equity raised to more than $1.5 billion. (PX0051 at 01 (Grail Announces $300 Million Raised in Oversubscribed Series C Financing, May 21, 2018)).

Response to Finding No. 5859:

Respondents have no specific response.

5860. Grail successfully raised $390 million as part of a Series D financing round in May 2020, bringing its total equity raised to more than $1.9 billion. (PX0052 at 01-02 (Grail Announces $390 Million Series D Financing, May 6, 2020)).

Response to Finding No. 5860:

Respondents have no specific response.

5861. Before accepting Illumina's acquisition offer, Grail considered pursuing additional funding through more private financing. (Freidin (Grail) Tr. 3011-12).

Response to Finding No. 5861:

The proposed finding is incomplete and misleading. Mr. Freidin also testified that GRAIL concluded that "going to Illumina and getting acquired by them was a faster path to creating value and saving lives", that "knowing that we're not going to have to go back out and kick off another financing round, whether it's private or public, is a timesaver and puts capital to work faster" and that [e]ven if we were to successfully raise more money, it wouldn't come with all of the expertise and infrastructure, and so on". (Freidin (GRAIL) Tr. 3011-12.) Mr. Bishop further testified there was a risk "that if things don't go to plan, we may need to raise additional money sooner than that 12-month forecast" and "if in the future we were unsuccessful in raising additional money, we wouldn't be able to run our business the way we wanted" but that the transaction "very significantly" eliminated that risk because GRAIL would "no longer [be] at the whims of the market". (Bishop (GRAIL) Tr. 1419.)

5862. [redacted]

(PX7108 (Freidin (Grail) Dep. at 247-48) (*in camera*); PX4212 (Grail) at 008 [redacted] (*in camera*); PX7066 (Freidin (Grail) IHT at 299-300) (*in camera*)).

Response to Finding No. 5862:

The proposed finding relies in part on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

5863. Morgan Stanley's Mr. Strom confirmed that there is significant investor interest in the cancer diagnostics space. (Strom (Morgan Stanley) Tr. 3478).

Response to Finding No. 5863:

The proposed finding is incomplete and misleading. Mr. Strom testified that, since the time the Transaction was announced in September 2020, Morgan Stanley has not seen investor interest in the space slow down at all, and "frankly, that a lot of investors have seen the exit opportunity that GRAIL's investors had as a positive and sort of a validating moment for this space." (Strom (Morgan Stanley) Tr. 3478.)

2. Grail's Potential IPO Provided Access to Immediate Proceeds and Access to the Public Markets

a) Grail Prepared to Go Public Prior to Acquisition

5864. Grail considered an initial public offering ("IPO") in 2020. (Bishop (Grail) Tr. 1325; Freidin (Grail) Tr. 3019).

Response to Finding No. 5864:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

5865. [redacted] (Freidin (Grail) Tr. 3070-71 (*in camera*); Bishop (Grail) Tr. 1407; PX7066 (Freidin (Grail) IHT at 80-81) (*in camera*)).

Response to Finding No. 5865:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.) The proposed finding is also incomplete and misleading. [redacted]

[redacted]

5866. [redacted] (Bishop (Grail) Tr. 1437 (*in camera*); Freidin (Grail) Tr. 3020; PX7108 (Freidin (Grail) Dep. at 54-55) (*in camera*); PX4137 (Grail) at 007-08 (The Roundtable, Sept. 30, 2020) (*in camera*)).

Response to Finding No. 5866:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

5867. [redacted] (PX7108 (Freidin (Grail) Dep. at 25-26) (*in camera*)).

Response to Finding No. 5867:

The proposed finding is incomplete and misleading. In fact, investors had significant concerns about GRAIL and its products. [redacted]

5868. Mr. Freidin testified at trial that Grail's IPO would have given Grail the capital to invest in commercialization, lab operations, and international expansion. (Freidin (Grail) Tr. 3021).

Response to Finding No. 5868:

The proposed finding is misleading and misstates the trial record. In fact, Mr. Freidin testified that "we needed to raise at least $2 billion until we got to breakeven. And that wasn't what we were going to be raising in the IPO, so we would have to go back to the markets, which again had all sorts of other risks with it around execution". (Freidin (GRAIL) Tr. 3020-21.) Mr. Freiden further testified that "with the bankers we never got to the point that we actually priced the deal or really concluded on how much we would raise in total", but that "none of those amounts that we would raise would or were equal to the $2 billion that we would need to get to breakeven." (Freidin (GRAIL) Tr. at 3021.)

5869. As part of Grail's pursuit of an IPO, Grail created and filed a Form S-1 with the Securities and Exchange Commission on September 9, 2020. (Bishop (Grail) Tr. 1326-27; PX0043 (Grail SEC Form S-1 Registration Statement, Sept. 9, 2020)).

Response to Finding No. 5869:

Respondents have no specific response.

5870. [redacted] (PX7066 (Freidin (Grail) IHT at 63) (*in camera*)).

Response to Finding No. 5870:

Respondents have no specific response, except to note that the proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

5871. Grail filed an Amended S-1 on September 17, 2020, after making its initial S-1 filing with the SEC. (Bishop (Grail) Tr. 1328; PX4082 (Grail) at 005 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 5871:

Respondents have no specific response.

5872. Grail hired bankers to facilitate its IPO. (Freidin (Grail) Tr. 3019).

Response to Finding No. 5872:

The proposed finding is incomplete and misleading. [redacted] (Strom (Morgan Stanley) Tr. 3495-97, 3510-21.) Mr. Strom of Morgan Stanley testified that [redacted]

[redacted] (Strom (Morgan Stanley) Tr. 3531–33, 3535–36.)

5873. In preparation for its IPO, Grail's executive team participated in a number of meetings with a range of potential investors over a couple months. (Bishop (Grail) Tr. 1325; Freidin (Grail) Tr. 3019).

Response to Finding No. 5873:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5871, which Respondents incorporate herein. Morgan Stanley further recognized that [redacted] (PX7078 (Strom (Morgan Stanley) Dep. at 107-08).)

5874. Grail's top executives, including Hans Bishop, Josh Ofman, Matthew Young, Aaron Freidin, and Arash Jamshidi participated in investor meetings leading up to its planned IPO. (Bishop (Grail) Tr. 1326).

Response to Finding No. 5874:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5871, which Respondents incorporate herein.

5875. [redacted] (PX7108 (Freidin (Grail) Dep. at 30) (*in camera*)).

Response to Finding No. 5875:

Respondents have no specific response.

5876. Grail participated in non-deal roadshow ("NDR") meetings with potential IPO investors. (Bishop (Grail) Tr. 1325).

Response to Finding No. 5876:

Respondents have no specific response, except to note that "potential IPO investors" also include [redacted] (PX7078 (Strom (Morgan Stanley) Dep. at 107-08).)

5877. After the NDR meetings, Grail participated in testing-the-waters ("TTW") meetings with potential IPO investors. (Bishop (Grail) Tr. 1325-26). The TTW meetings took place around July and August of 2020. (Bishop (Grail) Tr. 1326).

Response to Finding No. 5877:

Respondents have no specific response, except to incorporate herein Respondents' responses to CCFF ¶ 5875. Respondents also note that "potential IPO investors" also include [redacted] (PX7078 (Strom (Morgan Stanley) Dep. at 107-08).)

5878. Grail CEO Hans Bishop participated in many of Grail's NDR and TTW meetings with potential IPO investors. (Bishop (Grail) Tr. 1325-26).

Response to Finding No. 5878:

Respondents have no specific response, except to incorporate herein Respondents' responses to CCFF ¶ 5875. Respondents also note that "potential IPO investors" also include [redacted] (PX7078 (Strom (Morgan Stanley) Dep. at 107-08).)

5879. [redacted] (PX4234 (Grail) at 010 [redacted] (*in camera*); PX7108 (Freidin (Grail) Dep. at 119-20) (confirming PX4234 (Grail) captured Grail's IPO timeline)).

Response to Finding No. 5879:

Respondents have no specific response, except to note that several timelines were proposed. (*See, e.g.*, RX 2627 (Morgan Stanley presentation targeting a potential IPO launch on October 5, 2020).)

5880. [redacted] (PX4234 (Grail) at 010 [redacted] (*in camera*); PX7108 (Freidin (Grail) Dep. at 119) (testifying that if October 6 is the pricing date then Grail would "probably trade" on October 8)).

Response to Finding No. 5880:

Respondents have no specific response, except to highlight the extremely risky nature of an IPO as GRAIL's sole source of financial support and that Mr. Strom testified [redacted] (Strom (Morgan Stanley) Tr. 3546.)

5881. Mr. Bishop confirmed at trial that the choice Grail was facing in 2020 was either to be acquired by Illumina or proceed with an IPO. (Bishop (Grail) Tr. 1408; PX7069 (Bishop (Grail) IHT at 216)). Mr. Bishop testified that both options "were evaluated in parallel over several months." (Bishop (Grail) Tr. 1408; PX7066 (Freidin (Grail) IHT at 29-30) (testifying that the IPO and Illumina deal was a "dual-track process")).

Response to Finding No. 5881:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.) The proposed finding is further incomplete and misleading to the extent that it suggests that GRAIL explored only two financing options for the reasons explained in Respondents' responses to CCFF ¶ 5871, which Respondents incorporate herein.

5882. [redacted] (Freidin (Grail) Tr. 3071 (*in camera*)).

Response to Finding No. 5882:

Respondents have no specific response.

5883. Because Illumina and Grail entered into an acquisition agreement, Grail never went public. (PX7108 (Freidin (Grail) Dep. at 113)).

Response to Finding No. 5883:

The proposed finding is incomplete and misleading to the extent that it implies that the Illumina transaction was the sole reason GRAIL did not conduct an IPO. Mr. Freidin testified that an IPO was not a viable way to achieve long term funding because GRAIL's capital needs were great, they would have to go back to the markets later and there were all sorts of execution and market risks. (Freidin (GRAIL) Tr. 3020-21.) In fact, GRAIL had on several prior occasions explored potential IPOs, and on each occasion failed to achieve a successful IPO. As Mr. Strom of Morgan Stanley testified, [redacted]. (Strom (Morgan Stanley) Tr. 3495–97 (*in camera*).) Mr. Strom testified that [redacted] (Strom (Morgan Stanley) Tr. 3500–02, 3504–05.) [redacted] (Strom (Morgan Stanley) Tr. 3527–30.) In addition, Mr. Freidin testified that "even if we were to raise all the capital, we wouldn't have the expertise, the infrastructure, the capabilities that Illumina provides us" and GRAIL would not have been able to achieve the efficiencies Mr. Freidin identified. (Freidin (GRAIL) Tr. 3019-20.)

b) [redacted]

5884. [redacted] (Freidin (Grail) Tr. 3090 (*in camera*)).

Response to Finding No. 5884:

The proposed finding is misleading. [redacted] (Freidin (Grail) Tr. 3090.)

5885. [redacted] (Freidin (Grail) Tr. 3090 (*in camera*)).

Response to Finding No. 5885:

The proposed finding is misleading to the extent it implies that an IPO "would happen". [redacted] (Freidin (Grail) Tr. 3090.)

5886. [redacted] (Freidin (Grail) Tr. 3090-91 (*in camera*); PX7108 (Freidin (Grail) Dep. at 21) ("[T]he market was ripe. There were a lot of favorable IPOs that were happening. . . . And [comparable companies'] values and their IPOs and their performance were all positive.")).

Response to Finding No. 5886:

The proposed finding is incomplete and misleading to the extent that it implies all contemporary IPOs were "all positive". As Mr. Freidin testified, "There were a lot of IPOs. There were some that did really well, there were some that did marginal, there were some that went down . . . ." In addition, Mr. Freidin testified that the IPO process was uncertain, risky and did not account for all of GRAIL's capital needs. (Freidin (Grail) Tr. 3020-21; 3023-26.)

5887. [redacted] (Freidin (Grail) Tr. 3092 (*in camera*); PX7108 (Freidin (Grail) Dep. at 22) ("[The year 2020] was a good market for raising capital publicly.")).

Response to Finding No. 5887:

Respondents have no specific response except to note that Mr. Freidin also testified that the IPO process was uncertain, risky and did not account for all of GRAIL's capital needs. (Freidin (Grail) Tr. 3020-21; 3023-26.)

5888. [redacted] (Freidin (Grail) Tr. 3091 (*in camera*)).

Response to Finding No. 5888:

Respondents have no specific response, except to note that the phrase [redacted] is vague and ambiguous as to quantity and the type of IPO.

5889. [redacted] (Freidin (Grail) Tr. 3091-92 (*in camera*)).

Response to Finding No. 5889:

Respondents have no specific response, except to note that the cited testimony relates to [redacted] (Freidin (Grail) Tr. 3091-92) Mr. Freidin also testified that the IPO process was uncertain, risky and did not account for all of GRAIL's capital needs. (Freidin (Grail) Tr. 3020-21; 3023-26.)

5890. [redacted] (Freidin (Grail) Tr. 3092 (*in camera*)).

Response to Finding No. 5890:

Respondents have no specific response, except to note that [redacted] (Freidin (Grail) Tr. 3091-92.) Mr. Freidin also testified that the IPO process was uncertain, risky and did not account for all of GRAIL's capital needs. (Freidin (Grail) Tr. 3020-21; 3023-26.)

c) [redacted]

5891. [redacted] (PX7108 (Freidin (Grail) Dep. at 84-85); PX7066 (Freidin (Grail) IHT at 29-30) (*in camera*)).

Response to Finding No. 5891:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.) The proposed finding is misleading and misstates the evidence to the extent it suggests that [redacted]; Mr. Freidin testified at his deposition that IPO proceeds would be used to "support our . . . efforts for the next two or three years", and that the exact uses of the money would depend on "[w]hatever amount we ended up raising", but "[f]rom our [long range plan] we knew we needed another couple of billion dollars". (PX7108 (Freidin (Grail) Dep. at 84-85).) At trial, Mr. Freidin testified that "our 2020 LRP showed that we needed to raise at least $2 billion until we got to breakeven. And that wasn't what we were going to be raising in the IPO, so we would have to go back to the markets, which again had all sorts of other risks with it around execution and just -- and also just what happens in the world, market risk." (Freidin (GRAIL) Tr. 3020-21.) Mr. Strom of Morgan Stanley confirmed that; [redacted]

[redacted]

(Strom (Morgan Stanley) Tr. 3531–33, 3535–36.)

5892. [redacted] (PX7066 (Freidin (Grail) IHT at 30) (*in camera*)).

Response to Finding No. 5892:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.) The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶ 5871, which Respondents incorporate herein, as well as to the extent that it suggests that Mr. Freidin testified that raising additional capital was an equally viable way of funding GRAIL's business. Mr. Freidin testified that "seeking additional private capital was" not "a practical alternative to achieve the benefits" of the transaction. (Freidin (GRAIL) Tr. 3018.) Specifically, the transaction "accelerates the value creation for our shareholders, it accelerates the saving of lives, it accelerates the . . . funding, our ability to have all the capital that we need now to deploy it. It was a reat return for our shareholders. It kind of derisks our business going forward. It also reduces -- it also eliminates the royalty that we had in our supply agreement with Illumina". (Freidin (GRAIL) Tr. 2973; *see also* 3012-13.)

5893. [redacted] (PX7066 (Freidin (Grail) IHT at 88) (*in camera*)).

Response to Finding No. 5893:

The proposed finding relies entirely on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.) The proposed finding is also misleading to the extent that it suggests that

GRAIL had the binary choice whether to pursue public or private financing for the reasons explained in Respondents' responses to CCFF ¶ 5871, which Respondents incorporate herein. In fact, Mr. Strom of Morgan Stanley testified [redacted] (Strom (Morgan Stanley) Tr. 3500–02, 3504–05.)

d) Grail's S-1 Explains How Grail Intended to Use the Proceeds from Its IPO

5894. [redacted] (PX4137 (Grail) at 007 (The Roundtable, Sep. 30, 2020) (*in camera*); PX7066 (Freidin (Grail) IHT at 63) (*in camera*)).

Response to Finding No. 5894:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

5895. Grail's Amended Form S-1 lists the "principal purposes" of Grail's IPO as follows:

> The principal purposes of this offering are to obtain additional capital to fund our research and product development, create a public market for our common stock, facilitate our future access to the public equity markets, increase awareness of our company among potential partners, and improve our competitive position. We intend to use the net proceeds of this offering for development and commercialization of Galleri and DAC, development of additional products, scaling of our technology and laboratory operations, and general corporate purposes.
>
> We currently expect to use the net proceeds from this offering, together with our existing cash, cash equivalents, and marketable securities, as follows:
>
> - approximately $[blank] million to fund our clinical studies through the initial commercialization of Galleri and DAC as LDTs, and to fund ongoing and new clinical studies to validate and demonstrate the utility of our products, and support our reimbursement efforts;

- approximately $[blank] million for current and future product development, including expansion of our laboratory operations to support future growth;

- approximately $[blank] million for preparation for commercial launch and expansion of commercial operations, including the growth of our sales force within the United States; and

- any proceeds not applied to the foregoing for working capital and general corporate purposes.

(PX4082 (Grail) at 075 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

Response to Finding No. 5895:

Respondents have no specific response.

5896. The SEC sent Grail a letter on August 24, 2020 with comments to Grail's confidential S-1. (PX4099 (Grail) at 277 (Email attaching Grail 2020 S-1, Sept. 9, 2020)).

Response to Finding No. 5896:

Respondents have no specific response.

5897. The SEC provided the following comment to Grail's Use of Proceeds section of Grail's then-confidential Form S-1:

> Please revise to disclose an estimate of how far in your development and commercialization of Galleri and DAC and the development of additional products the proceeds from this offering will allow you to reach with respect to each product candidate, including specific phases of pre-clinical and clinical trials. Also, please disclose the total estimate cost of each of the specified purposes for which the net proceeds are intended to be used, and, if material amounts of other funds are necessary to accomplish the specified purposes, provide an estimate of the amounts of such other funds and the sources thereof.

(PX4099 (Grail) at 281 (Email attaching Grail 2020 S-1, Sept. 9, 2020)).

Response to Finding No. 5897:

Respondents have no specific response.

5898. In response to the SEC's comment to the "Use of Proceeds" section, Grail responded that it "does not anticipate that material amounts of other funds will be necessary to accomplish the specified purposes" in the "Use of Proceeds" section. (PX4099 (Grail) at 281 (Email attaching Grail 2020 S-1, Sept. 9, 2020)).

Response to Finding No. 5898:

The proposed finding is misleading to the extent that it implies that the funds raised by a potential IPO would be sufficient to support GRAIL's operations without additional financing for the reasons explained in Respondents' responses to CCFF ¶ 5871, which Respondents incorporate herein. Moreover, Mr. Freidin stated that it was likely that an IPO would not be a way of securing long-term funding because GRAIL's 2020 LRP showed that GRAIL needed to raise at least $2 billion until it got to breakeven and that wasn't what GRAIL was going to raise in the IPO. (Freidin (GRAIL) Tr. 3020-21.) Mr. Strom of Morgan Stanley testified [redacted] (Strom (Morgan Stanley) Tr. 3500–02, 3504–05.)

5899. When asked how Grail would use IPO proceeds that exceeded Grail's expectations, Mr. Freidin testified as Grail's 30(b)(6) designee that Grail would follow its LRP and "having extra cash is always good for – to be opportunistic" for "acquisitive-type transactions" outside Grail's three products. (PX7108 (Freidin (Grail) Dep. at 98-99)).

Response to Finding No. 5899:

The proposed finding misstates the testimony, which distinguished between the LRP, which Mr. Freidin explained is a "point-in-time document" that "doesn't consider things that happened after that", and clearly stated that "the LRP doesn't include any acquisitive type transactions", and the possibilities that "extra cash" would provide, including the chance to be "opportunistic". (PX7108 (Freidin (Grail) Dep. at 98-99).) The proposed finding is also misleading to the extent it implies that a GRAIL IPO could have generated "extra cash" exceeding the $2 billion required to get to profitability under GRAIL's long range plan. Mr.

Freidin testified that GRAIL would not be "going to be raising" $2 billion "in the IPO. (Freidin (GRAIL) Tr. 3020-21.) Mr. Strom of Morgan Stanley confirmed that [redacted] (Strom (Morgan Stanley) Tr. 3531–33, 3535–36.)

5900. At his deposition, Mr. Freidin testified that the S-1's "[U]se of [P]roceeds section was derived from the LRP." (PX7108 (Freidin (Grail) Dep. at 86)).

Response to Finding No. 5900:

The proposed finding is incomplete; Mr. Freidin testified that "The use of proceeds section was derived from the LRP in more general buckets." (PX7108 (Freidin (Grail) Dep. at 86).)

e) During the IPO Process, Morgan Stanley Was a Trusted Advisor to Grail's Board [redacted]

5901. [redacted] (Freidin (Grail) Tr. 3092 (*in camera*)).

Response to Finding No. 5901:

Respondents have no specific response.

5902. [redacted] (Bishop (Grail) Tr. 1449 (*in camera*)).

Response to Finding No. 5902:

Respondents have no specific response.

5903. [redacted] (Freidin (Grail) Tr. 3094 (*in camera*)).

Response to Finding No. 5903:

Respondents have no specific response.

5904. [redacted] (PX4137 (Grail) at 008 (The Roundtable, Sept. 30, 2020 (*in camera*)); PX7108 (Freidin (Grail) Dep. at 54-55) (*in camera*)).

Response to Finding No. 5904:

The proposed finding is incomplete and misleading. Mr. Freidin [redacted] (Freidin (Grail) Tr. 3095-96.)

5905. [redacted] (Freidin (Grail) Tr. 3095 (*in camera*)).

Response to Finding No. 5905:

Respondents have no specific response.

5906. [redacted] (Freidin (Grail) Tr. 3096 (*in camera*); *see, e.g.,* PX4047 (Grail) at 051 (Email from M. Song, Grail, to H. Bishop, Grail, et al., attaching "Morgan Stanley Discussion Materials: Project Valor," Sept. 16, 2020 (*in camera*)).

Response to Finding No. 5906:

Respondents have no specific response, except to note that Morgan Stanley understood that the IPO was inherently risky and GRAIL had previously explored three unsuccessful IPOs. As Mr. Strom of Morgan Stanley testified, [redacted]

[redacted]

[redacted]

[redacted]

[redacted]. (Strom (Morgan Stanley) Tr. 3495–97 (*in camera*).) Mr. Strom testified [redacted]

[redacted]

[redacted]

[redacted]

[redacted] (Strom (Morgan Stanley) Tr. 3500–02, 3504–05.) [redacted]

[redacted]

[redacted]

5907. [redacted]

(PX5046 (Grail) at 002 [redacted]

Response to Finding No. 5907:

Respondents have no specific response.

5908. [redacted] (PX5046 (Grail) at 002 [redacted]

Response to Finding No. 5908:

Respondents have no specific response.

5909. [redacted] (PX5046 (Grail) at 002 [redacted]

Response to Finding No. 5909:

The proposed finding is incomplete. The quoted sentence does not specify the likelihood of such entry or the timing. [redacted]

5910. [redacted] (Bishop (Grail) Tr. 1450-51 (*in camera*)).

Response to Finding No. 5910:

The proposed finding is incomplete to the extent it suggests that Mr. Bishop was testifying about his own beliefs or understandings. In fact, Complaint Counsel was walking through bullet points in a Morgan Stanley presentation and asking Mr. Bishop to construe the points when the following quoted exchange occurred: [redacted] (Bishop (Grail) Tr. 1450-51.)

5911. [redacted] (Bishop (Grail) Tr. 1451 (*in camera*)).

Response to Finding No. 5911:

The proposed finding is incomplete without the additional context explained in Respondents' responses to CCFF ¶¶ 5863, 5866, and 5871, which Respondents incorporate herein.

5912. [redacted] (Bishop (Grail) Tr. 1451 (*in camera*)).

Response to Finding No. 5912:

The proposed finding is incomplete for the reasons explained in Respondents' responses to CCFF ¶¶ 5863, 5866, and 5871, which Respondents incorporate herein.

5913. [redacted] (PX5046 (Grail) at 002 [redacted]

Response to Finding No. 5913:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5863, 5866, and 5871, which Respondents incorporate herein.

5914. [redacted] (Freidin (Grail) Tr. 3097 (*in camera*)).

Response to Finding No. 5914:

The proposed finding is misleading and misstates the trial evidence for the reasons explained in Respondents' responses to CCFF ¶¶ 5863, 5866, and 5871, which Respondents incorporate herein. In fact, Mr. Freidin testified as follows: [redacted] (Freidin (Grail) Tr. 3097.) Mr. Strom also testified [redacted]

[redacted] (Strom (Morgan Stanley) Tr. 3543.) In addition, he testified that he heard "pretty consistent concerns from investors around our ability to receive broad adoption and FDA approval" and those concerns were significant". (Freidin (GRAIL) Tr. 3024-25.)

f) [redacted]

5915. Grail's Chief Medical Officer, Dr. Josh Ofman, testified at trial that "the valuation of the company [Grail] that some of the investors and analysts were ascribing was quite high." (Ofman (Grail) Tr. 3283).

Response to Finding No. 5915:

The proposed finding is incomplete and misleading. Dr. Ofman's full response states: "Well, you know, it's -- you know, there's no certainty around that, but what -- the valuation of the company that some of the investors and analysts were ascribing was quite high. *And so, you know, even, you know, for me personally even if that was going to be a better financial outcome, it wouldn't have mattered because I think for GRAIL to achieve its aspirations, the much better move was to be acquired by Illumina*." (Ofman (GRAIL) Tr. 3283-84 (emphasis added).) In fact, Dr. Ofman testified that Illumina's acquisition of GRAIL is a "better move" than a GRAIL IPO even though an IPO might have been a more lucrative "financial outcome" for Dr. Ofman personally, because the Transaction "with Illumina would really enable our mission and our vision to be accelerated in terms of our ability to achieve it, because getting to scale quickly is going to be the most important thing. And we have this amazing sense of urgency to get this breakthrough technology into the hands of doctors and their patients on a global scale as soon as possible." (Ofman (Grail) Tr. 3283-84.)

5916. At trial, Dr. Ofman described Grail's IPO as "perhaps being a more lucrative venture" than being acquired by Illumina. (Ofman (Grail) Tr. 3283).

Response to Finding No. 5916:

The proposed finding is misleading and misstates the trial evidence. In context, it is clear that Dr. Ofman referred to a potential IPO as a "more lucrative venture" and "better financial outcome" only "*for me personally"*, and clearly stated that the Illumina Transaction was better for GRAIL because it will "really enable our mission and our vision to be accelerated in terms of our ability to achieve it, because getting to scale quickly is going to be the most important thing. And we have this amazing sense of urgency to get this breakthrough technology into the hands of doctors and their patients on a global scale as soon as possible." (Ofman (Grail) Tr. 3283-84 (emphasis added).)

5917. [redacted] (Bishop (Grail) Tr. 1457-58 (*in camera*): PX5045 (Grail) at 030 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5917:

Respondents have no specific response.

5918. [redacted] (Freidin (Grail) Tr. 3100 (*in camera*); PX4175 (Grail) (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5918:

Respondents have no specific response.

5919. [redacted] (Freidin (Grail) Tr. 3100 (*in camera*)).

Response to Finding No. 5919:

Respondents have no specific response.

5920. [redacted] (Freidin (Grail) Tr. 3100 (*in camera*)).

Response to Finding No. 5920:

Respondents have no specific response.

5921. [redacted] (PX5045 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5921:

Respondents have no specific response.

5922. [redacted] (PX5045 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5922:

Respondents have no specific response.

5923. [redacted] (PX7066 (Freidin (Grail) IHT at 68) (*in camera*)).

Response to Finding No. 5923:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

5924. [redacted] (PX7066 (Freidin (Grail) IHT at 68-69) (*in camera*)).

Response to Finding No. 5924:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

5925. Mr. Bishop testified at trial that "particular[] investors that had a long-term investment horizon . . . were really interested in our story. And I believe we had the potential of getting their support had we gone ahead with an IPO." (Bishop (Grail) Tr. 1410).

Response to Finding No. 5925:

The proposed finding is incomplete and misleading. In the same answer, Mr. Bishop testified that "there were investors that candidly were very skeptical, particularly about multicancer early detection rather than single-cancer liquid biopsy detection. And the group that was skeptical, you know, had several different reasons for their skepticism." (Bishop (GRAIL) Tr. 1410-11.)

5926. [redacted] (Bishop (Grail) Tr. 1458 (*in camera*): PX5045 (Grail) at 030 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5926:

Respondents have no specific response.

5927. [redacted] (PX5045 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*); PX7066 (Freidin (Grail) IHT at 66-67) (*in camera*) ([redacted]).

Response to Finding No. 5927:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

5928. [redacted] (PX5045 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5928:

Respondents have no specific response.

5929. [redacted]

[redacted] (PX7066 (Freidin (Grail) IHT at 68) (*in camera*)).

Response to Finding No. 5929:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

5930. [redacted] (PX5045 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5930:

Respondents have no specific response, except to highlight the extremely risky nature of an IPO and the insufficient nature of individual private placements as GRAIL's sources of financial support, as explained in Respondents' responses to CCFF ¶¶ 5863, 5866, and 5871, which Respondents incorporate herein.

5931. [redacted] (Bishop (Grail) Tr. 1457 (*in camera*): PX5045 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5931:

The proposed finding is incomplete and misleading because it ignores the many investor concerns raised, such as the concerns listed on the following page of PX5045, [redacted] (PX5045 (Grail) at 030.)

5932. [redacted] (PX5045 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5932:

Respondents have no specific response, except to highlight the extremely risky nature of an IPO and the insufficient nature of individual private placements as GRAIL's sources of financial support, as explained in Respondents' responses to CCFF ¶¶ 5863, 5866, and 5871, which Respondents incorporate herein.

5933. [redacted] (PX5045 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5933:

The proposed finding is misleading and misstates the evidence. [redacted] (PX5045 (Grail) at 029 (*in camera*).)

5934. [redacted] (Bishop (Grail) Tr. 1458-59 (*in camera*): PX5045 (Grail) at 030 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)). [redacted] (Bishop (Grail) Tr. 1459 (*in camera*)).

Response to Finding No. 5934:

Respondents have no specific response, except to note that, by this proposed finding, Complaint Counsel apparently admits that as of the time of the transaction there were no MCED

tests commercially available in the United States. (*See* Resps.' Post-Trial Br. at 20-85 (discussing Complaint Counsel failure to prove a relevant market).)

5935. [redacted] (PX5045 (Grail) at 030 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5935:

Respondents have no specific response, except to note that Mr. Strom testified [redacted] (Strom (Morgan Stanley) Tr. 3530-31.)

5936. In an email to Grail's General Counsel, Ms. Song, Mr. Freidin described Grail's non-deal roadshow and testing-the-waters meetings as "[s]uccessful." (PX4088 (Grail) (Email from A. Freidin, Grail, to M. Song, Grail, Nov. 10, 2020). Regarding this statement in PX4088, Mr. Freidin testified that, "Yeah, it says 'successful,' meaning we met with enough of the folks that we wanted to. We were able to get feedback back from them. The analysts day, we were able to educate across many meetings how they should be thinking about our business in the long term. So it's those distinct pieces of the IPO process were successful." (PX7066 (Freidin (Grail) IHT at 203)).

Response to Finding No. 5936:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.) The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5863, 5866, and 5871, which highlight the extremely risky nature of an IPO and the insufficient nature of individual private placements as GRAIL's sources of financial support, and which Respondents incorporate herein.

5937. [redacted] (Freidin (Grail) Tr. 3098 (*in camera*); PX4175 (Grail) at 031 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5937:

The proposed finding is misleading. [redacted] (PX4175 (Grail) at 031.) The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5863, 5866, and 5871, which highlight the extremely risky nature of an IPO and the insufficient nature of individual private placements as GRAIL's sources of financial support, and which Respondents incorporate herein.

5938. [redacted] (Freidin (Grail) Tr. 3098 (*in camera*)).

Response to Finding No. 5938:

Respondents have no specific response.

5939. [redacted] (PX7066 (Freidin (Grail) IHT at 69-70) (*in camera*); PX4175 (Grail) at 031 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5939:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.) The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5863, 5866, and 5871, which highlight the extremely risky nature of an IPO and the insufficient nature of individual private placements as GRAIL's sources of financial support, and which Respondents incorporate herein.

5940. [redacted] (Freidin (Grail) Tr. 3098-99 (*in camera*); PX4175 (Grail) at 031 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5940:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5863, 5866, and 5871, which highlight the extremely risky nature of an IPO and the insufficient nature of individual private placements as GRAIL's sources of financial support, and which Respondents incorporate herein. Moreover, [redacted] (PX4175 (Grail) at 031.) Further, Mr. Freidin testified that, per GRAIL's 2020 long-range plan, the company needed to raise at least $2 billion to breakeven. The proposed IPO was not going to raise that sum, and so GRAIL would have to go back to the markets, which would be a further risk going forward. (Freidin (GRAIL) Tr. 3020–21.)

5941. [redacted] (PX7066 (Freidin (Grail) IHT at 71-72) (*in camera*); PX4175 (Grail) at 031 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5941:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.) The proposed finding is also incomplete and misleading for the reasons explained in

Respondents' responses to CCFF ¶¶ 5863, 5866, and 5871, which highlight the extremely risky nature of an IPO and the insufficient nature of individual private placements as GRAIL's sources of financial support, and which Respondents incorporate herein. Further, Mr. Freidin testified that, per GRAIL's 2020 long-range plan, the company needed to raise at least $2 billion to breakeven. The proposed IPO was not going to raise that sum, and so GRAIL would have to go back to the markets, which would be a further risk going forward. (Freidin (GRAIL) Tr. 3020–21.)

5942. [redacted] (PX7066 (Freidin (Grail) IHT at 71-72) (*in camera*)).

Response to Finding No. 5942:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.) The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5863, 5866, and 5871, which highlight the extremely risky nature of an IPO and the insufficient nature of individual private placements as GRAIL's sources of financial support, and which Respondents incorporate herein. Further, Mr. Freidin testified that, per GRAIL's 2020 long-range plan, the company needed to raise at least $2 billion to breakeven. The proposed IPO was not going to raise that sum, and so GRAIL would have to go back to the markets, which would be a further risk going forward. (Freidin (GRAIL) Tr. 3020–21.)

5943. [redacted] (Freidin (Grail) Tr. 3099 (*in camera*); PX4175 (Grail) at 031 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5943:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5863, 5866, and 5871, which highlight the extremely risky nature of an IPO and the insufficient nature of individual private placements as GRAIL's sources of financial support, and which Respondents incorporate herein.

5944. [redacted] (Freidin (Grail) Tr. 3099 (*in camera*); PX4175 (Grail) at 031 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5944:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5863, 5866, and 5871, which highlight the extremely risky nature of an IPO and the insufficient nature of individual private placements as GRAIL's sources of financial support, and which Respondents incorporate herein.

5945. [redacted] (Freidin (Grail) Tr. 3099; PX4175 (Grail) at 031 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5945:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5863, 5866, and 5871, which highlight the extremely risky nature of an IPO and the insufficient nature of individual private placements as GRAIL's sources of financial support, and which Respondents incorporate herein.

5946. [redacted] (Freidin (Grail) Tr. 3099-100; PX4175 (Grail) at 032 (Grail Board Session Meeting Materials, Sept. 10, 2020)). (*in camera*)).

Response to Finding No. 5946:

The proposed finding is incomplete and misleading. The bullet point referenced in this proposed finding clearly relates to minimum allocation sizes by funds, not to any specific interest

in making an investment in GRAIL of that size. Notably, at trial, Mr. Freidin offered to provide context to explain this bullet point, but Complaint Counsel repeatedly interrupted Mr. Freidin and refused to let him provide context, instead indicating that Complaint Counsel was [redacted]. (Freidin (Grail) Tr. 3098-100 (*in camera*) ([redacted].)

5947. [redacted] (Freidin (Grail) Tr. 3100 (*in camera*); PX4175 (Grail) at 032 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5947:

The proposed finding is incomplete and misleading. The cited testimony was sought solely to confirm that certain words appeared on the cited page of PX4175, not for the truth of the matter. Complaint Counsel made clear that it was [redacted] (Freidin (Grail) Tr. 3098-100 (*in camera*) ([redacted]

[redacted].)

5948. [redacted] (Freidin (Grail) Tr. 3099 (*in camera*)); PX4175 (Grail) at 032 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5948:

The proposed finding is incomplete and misleading. The cited testimony was sought solely to confirm that certain words appeared on the cited page of PX4175, not for the truth of the matter. Complaint Counsel made clear that it was [redacted] (Freidin (Grail) Tr. 3098-100 (*in camera*) ([redacted].) [redacted] Moreover, Mr. Freidin testified that GRAIL would not be "going to be raising" $2 billion "in the IPO. (Freidin (GRAIL) Tr. 3020-21.)

5949. [redacted]

[redacted] (PX7066 (Freidin (Grail) IHT at 77) (*in camera*); PX4175 (Grail) at 032 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5949:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

[redacted] Moreover, Mr. Freidin testified that GRAIL would not be "going to be raising" $2 billion "in the IPO. (Freidin (GRAIL) Tr. 3020-21.)

5950. [redacted] (Freidin (Grail) Tr. 3099 (*in camera*); PX4175 (Grail) at 032 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

Response to Finding No. 5950:

The proposed finding is incomplete and misleading. [redacted]

[redacted]

5951. [redacted]

[redacted]

(PX7066 (Freidin (Grail) IHT at 77) (*in camera*)).

Response to Finding No. 5951:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.) Moreover, it appears from this proposed finding that Complaint Counsel is conceding that,

[redacted] Mr. Freidin also testified that dilution of existing shareholders was a serious concern in connection with the IPO. (Freidin (GRAIL) Tr. 3023-24 ("If a company doesn't execute and deliver after they go public, then, you know, their valuation decreases and their ability to raise capital cause investors greater dilution, if it can happen at all"; Q. And how does that affect your -- that ability to raise additional funds down the line if there's been that greater dilution? A. It makes it more challenging.").)

5952. [redacted]

(Freidin (Grail) Tr. 3096 (*in camera*); *see* PX7108 (Freidin (Grail) Dep. at 54-55) (testifying that Grail expected to raise between $500 and $750 million through its IPO)).

Response to Finding No. 5952:

The proposed finding is incomplete and misleading. [redacted]

[redacted] (Freidin (Grail) Tr. 3095-96.)

g) [redacted]

For evidence that Grail management has hit strategic targets without Illumina's assistance, see Section VIII.C.1.b.2.e.ix. (Grail Is Hitting Its Strategic Targets Toward the Commercialization of Galleri Without Illumina's Assistance).

5953. [redacted] (PX4213 (Grail) at 003 [redacted]

Response to Finding No. 5953:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5863, 5866, and 5871, which highlight the extremely risky nature of an IPO and the insufficient nature of individual private placements as GRAIL's sources of financial support, and which Respondents incorporate herein.

5954. [redacted] (PX4213 (Grail) at 011 [redacted] *see* PX4088 (Grail) (Email from A. Freidin, Grail, to M. Song, Grail, Nov. 10, 2020) (describing for the purposes of his performance review, "Ready to launch the most anticipated IPO in healthcare for 2020")).

Response to Finding No. 5954:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5863, 5866, and 5871, which highlight the extremely risky nature of an IPO as GRAIL's source of financial support, and which Respondents incorporate herein. Respondents also note that, as conceded by Complaint Counsel, the quoted statements reflect descriptions provided in the context of a performance review seeking bonus compensation. (PX4088 (Grail) [redacted] Further, Mr. Freidin testified that, per GRAIL's 2020 long-range plan, the company needed to raise at least $2 billion to breakeven. The proposed IPO was not going to raise that sum, and so GRAIL would have to go back to the markets, which would be a further risk going forward. (Freidin (GRAIL) Tr. 3020–21.)

5955. [redacted] (Freidin (Grail) Tr. 3102-103 (*in camera*)); PX4213 (Grail) at 011 [redacted]

Response to Finding No. 5955:

Respondents have no specific response, but note that [redacted] (PX4175 (Grail) at 031.)

5956. [redacted] (Freidin (Grail) Tr. 3103 (*in camera*)).

Response to Finding No. 5956:

Respondents have no specific response.

5957. [redacted] (PX4213 (Grail) at 011 [redacted]

Response to Finding No. 5957:

Respondents have no specific response, except to note that, as conceded by Complaint Counsel, the quoted statements reflect descriptions provided in the context of a performance review seeking bonus compensation.

5958. [redacted] (Freidin (Grail) Tr. 3102 (*in camera*)).

Response to Finding No. 5958:

Respondents have no specific response.

3. Investors Remained Interested in a Grail IPO and Grail Remained Ready for an IPO After the Illumina Acquisition Was Announced

5959. If the Illumina-Grail transaction is unwound, investors have expressed interest "in making a more significant investment in GRAIL should [GRAIL] choose to access the capital markets." (*See, e.g.,* PX4468 (Grail) at 002 (Email from N. Cornell, Bluewater Life Science Advisors, to J. Craighead, Grail, Apr. 13, 2021)).

Response to Finding No. 5959:

The proposed finding is vague and ambiguous and fails to quantify what a "more significant investment" would entail. Notably, PX4468 is an email exchange with a minority investor from GRAIL's early Series B round, and does not include any specific investment targeted by that historical investor. (PX4468.)

5960. Grail's Vice President of Investor Relations, John Craighead, told investors that Grail will be "well positioned for any outcome" with the Illumina transaction. (PX4468 (Grail) at 001 (Email from J. Craighead, Grail, to N. Cornell, Bluewater Life Science Advisors, Apr. 16, 2021)); *see* PX4467 (Grail) at 002 (Text message exchange between V. Demas, Grail,

and H. Kiarie, Grail, Mar. 31, 2021) (noting that "we can still IPO" if the Proposed Acquisition falls through).

Response to Finding No. 5960:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 5863, 5866, and 5871, which highlight the extremely risky nature of an IPO and the insufficient nature of individual private placements as GRAIL's sources of financial support, and which Respondents incorporate herein.

5961. Mr. Freidin testified that, even after signing the deal with Illumina, Grail did not withdraw its Form S-1 in case it needed to go public if the Illumina deal did not finalize. (PX7108 (Freidin (Grail) Dep. at 113-14)).

Response to Finding No. 5961:

Respondents have no specific response.

5962. Grail had not withdrawn its Form S-1 as of June 23, 2021 because "if we keep this version up that [the SEC has] already reviewed, there is a chance that [the SEC does not] take 30 days to review it the next time if the [Illumina] deal does not happen." (PX7108 (Freidin (Grail) Dep. at 114)).

Response to Finding No. 5962:

Respondents have no specific response.

4. [redacted]

5963. [redacted] (Freidin (Grail) Tr. 3072 (*in camera*)).

Response to Finding No. 5963:

The proposed finding is incomplete and misleading. Mr. Freidin testified [redacted] (Freidin (Grail) Tr. 3071-72.) [redacted]

[redacted]

5964. [redacted] (Freidin (Grail) Tr. 3072 (*in camera*)).

Response to Finding No. 5964:

The proposed finding is incomplete and misleading. [redacted]

[redacted] (Freidin (Grail) Tr. 3072.)

5965. [redacted] (Freidin (Grail) Tr. 3073-74 (*in camera*)).

Response to Finding No. 5965:

The proposed finding is incomplete and misleading. [redacted] (Freidin (Grail) Tr. 3074.)

5966. Grail did not approach any other life sciences companies that have successfully obtained PMA approval for IVD tests about partnering or merging with Grail. (Ofman (Grail) Tr. 3447-48).

Response to Finding No. 5966:

The proposed finding is incomplete and misleading. Dr. Ofman testified that he did not know how many companies other than Illumina have successfully obtained PMA approval for IVD tests. He then said that GRAIL had not approached a specific list of companies provided by Complaint Counsel. (Ofman (GRAIL) Tr. 3446-48.)

IX. APPENDIX A: WITNESS BACKGROUNDS

A. LAY WITNESSES WHO TESTIFIED AT TRIAL

1. Dr. Christoph Lengauer

5967. Dr. Christoph Lengauer is a co-founder of Thrive Earlier Detection, which is now owned by Exact Sciences. Dr. Lengauer is currently a partner at Third Rock Ventures, a venture fund that invests mainly in companies that the fund creates and builds themselves. (Lengauer (Third Rock Ventures) Tr. 155-57).

Response to Finding No. 5967:

Respondents have no specific response.

5968. Dr. Lengauer serves as a consultant to Exact Sciences and, in this role, oversees Thrive's strategy. As part of his responsibilities, he serves on Thrive's management leadership team and is involved in the development of the CancerSEEK test. (Lengauer (Third Rock Ventures) Tr. 156-57).

Response to Finding No. 5968:

Respondents have no specific response.

5969. Prior to the Thrive's acquisition by Exact Sciences, Dr. Lengauer was the Chief Innovation Officer of Thrive since the company was founded, overseeing the development of Thrive's CancerSEEK blood-based test and was involved in decision-making and regulatory strategy. (Lengauer (Third Rock Ventures) Tr. 157).

Response to Finding No. 5969:

Respondents have no specific response.

5970. Before serving as a partner of Third Rock Ventures, Dr. Lengauer was the Chief Scientific Officer at Blueprint Medicines, which is a biotech company focused on oncology drug discovery. Before that role, Dr. Lengauer was the Global Head of Oncology Research for Sanofi. (Lengauer (Third Rock Ventures) Tr. 158). Dr. Lengauer led the target identification and validation group of Novartis before transitioning to the role at Sanofi. (PX7051, Lengauer (Third Rock Ventures) IHT at 14).

Response to Finding No. 5970:

The proposed finding relies in part on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and to that extent should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

5971. Dr. Lengauer has a Ph.D. in biology from the University of Heidelberg (Germany) and has a Master of Business Administration degree from Johns Hopkins University. In addition, Dr. Lengauer currently is an adjunct associate professor at Johns Hopkins University. (Lengauer (Third Rock Ventures) Tr. 158).

Response to Finding No. 5971:

Respondents have no specific response.

5972. Dr. Lengauer completed postdoctoral training at Johns Hopkins University with the laboratory of Bert Vogelstein and Ken Kinzler. Following this training, Dr. Lengauer worked in this laboratory developing a greater understanding of the nature of genetics and cancer for approximately ten years. (PX7051 (Lengauer (Third Rock Ventures) IHT at 13-14)).

Response to Finding No. 5972:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

2. Dr. Matthew Rabinowitz

5973. Dr. Matthew Rabinowitz is the co-founder of Natera and is currently Executive Chairman of the company, serving in this role since 2019. (Rabinowitz (Natera) Tr. 284-86). As Executive Chairman of Natera, Dr. Rabinowitz oversees development and strategy related to Natera's technology and business development decisions. (Rabinowitz (Natera) Tr. 286). Further, as Executive Chairman, Dr. Rabinowitz oversees regulatory decisions and activities, but is less involved compared to when he was the Chief Executive Officer of the company. (Rabinowitz (Natera) Tr. 296). [redacted] (PX7054 (Rabinowitz (Natera) IHT at 20-21 (*in camera*))).

Response to Finding No. 5973:

The proposed finding relies in part on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and to that extent should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

5974. Prior to serving as Executive Chairman of Natera, Dr. Rabinowitz was the Chief Executive Officer of the company. (Rabinowitz (Natera) Tr. 285). As Natera's CEO, Dr. Rabinowitz was directly involved in the day-to-day operations of the company. (Rabinowitz (Natera) Tr. 286-87). [redacted] (PX7054 (Rabinowitz (Natera) IHT at 19 (*in camera*))). [redacted] (PX7054 (Rabinowitz (Natera) IHT at 19 (*in camera*))).

Response to Finding No. 5974:

The proposed finding relies in part on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and to that extent should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

5975. [redacted] (PX7054, Rabinowitz (Natera) IHT at 19 (*in camera*)).

Response to Finding No. 5975:

The proposed finding relies in part on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and to that extent should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

5976. Dr. Rabinowitz has a Ph.D. in electrical engineering from Stanford University, as well as a B.S. and M.S. in electrical engineering from Stanford. (Rabinowitz (Natera) Tr. 284). In addition, Dr. Rabinowitz was a consulting professor at Stanford for eight years in the School of Engineering. (Rabinowitz (Natera) Tr. 287). He was also a visiting faculty member at Harvard University in the Genetics Department. (Rabinowitz (Natera) Tr. 287; PX7113 (Rabinowitz Depo at 55)).

Response to Finding No. 5976:

The proposed finding is in part not supported by the cited evidence. Dr. Rabinowitz testified at trial that his undergraduate degree is in physics. (Rabinowitz (Natera) Tr. 284.)

3. Dr. William Cance

5977. Dr. William Cance is the Chief Medical and Scientific Officer of the American Cancer Society, serving in this role since October 2019. (Cance (American Cancer Society) Tr. 591-92).

Response to Finding No. 5977:

Respondents have no specific response.

5978. As the Chief Medical and Scientific Officer of ACS, Dr. Cance's responsibilities include overseeing the medical and scientific aspects of the ACS's mission programs, such as its efforts in discovery, research, the development of patient programs implementation science, as well as providing advice and oversight of programs across the ACS's mission pillars. (Cance (American Cancer Society) Tr. 592).

Response to Finding No. 5978:

Respondents have no specific response.

5979. Dr. Cance testified at trial that the ACS has three mission pillars: "advocacy, discovery, and patient support." (Cance (American Cancer Society) Tr. 592). Advocacy includes public policy; discovery includes research that the ACS does that the organization funds externally, and patient support includes providing rides, lodging, and work with health systems across the United States. (Cance (American Cancer Society) Tr. 592-93).

Response to Finding No. 5979:

Respondents have no specific response.

5980. Dr. Cance is a licensed physician with clinical expertise in surgical oncology. (Cance (American Cancer Society) Tr. 593). Dr. Cance has been a licensed physician since 1982. (Cance (American Cancer Society) Tr. 593).

Response to Finding No. 5980:

Respondents have no specific response.

5981. Prior to his role at ACS, Dr. Cance was the deputy director and interim director of the University of Arizona Cancer Center in Phoenix, Arizona, where he coordinated cancer efforts while the University of Arizona expanded from Tucson into Phoenix and also oversaw an active research laboratory at the University of Arizona College of Medicine. (Cance (American Cancer Society) Tr. 594). While at the University of Arizona, Dr. Cance taught surgery and supervised surgical residents at Dignity Health St. Joseph's Hospital and was a Professor of Interdisciplinary Oncology. (Cance (American Cancer Society) Tr. 594).

Response to Finding No. 5981:

Respondents have no specific response except to note that Dr. Cance also testified that he is not knowledgeable in how multicancer early detection tests are created, formed and practiced. (Cance (ACS) Tr. 635-636).

5982. Dr. Cance is not currently employed by or being compensated by any company that is developing an early cancer detection test. (Cance (American Cancer Society) Tr. 597).

Response to Finding No. 5982:

Respondents have no specific response except to note that Dr. Cance testified that neither he nor the American Cancer Society takes any position on the acquisition of GRAIL by Illumina. (Cance (ACS) Tr. 629-630).

5983. Dr. Cance received his M.D. from Duke University School of Medicine and completed his residency at Barnes-Jewish Hospital in St. Louis, Missouri. (Cance (American Cancer Society) Tr. 593). In addition he completed a fellowship in immunology at Washington University School of Medicine in St. Louis, which is the academic partner of Barnes-Jewish Hospital. (Cance (American Cancer Society) Tr. 593-94). Dr. Cance also completed a clinical fellowship in surgical oncology at Memorial Sloan Kettering Cancer Center in New York. (Cance (American Cancer Society) Tr. 594).

Response to Finding No. 5983:

Respondents have no specific response.

4. Dr. Kenneth Chahine

5984. Dr. Ken Chahine was the Chief Executive Officer of Helio Health, Inc. ("Helio") from January 2020 to June 2021. (Chahine (Helio) Tr. 999). As Helio's CEO, Dr. Chahine essentially ran "all operations at the company." (Chahine (Helio) Tr. 999-1000).

Response to Finding No. 5984:

Respondents have no specific response.

5985. Since departing as CEO in June 2021, Dr. Chahine is now a consulting advisor to Helio, including an advisor specifically to Helio's CEO and its Board of Directors, when requested. (Chahine (Helio) Tr. 999).

Response to Finding No. 5985:

Respondents have no specific response.

5986. Dr. Chahine received a Ph.D. in biological chemistry from the University of Michigan, in which the focus of his thesis was on genetics and molecular biology. (Chahine (Helio) Tr. 1008-09). Dr. Chahine earned a juris doctorate as well and is a registered patent attorney. (Chahine (Helio) Tr. 1009).

Response to Finding No. 5986:

Respondents have no specific response.

5. Dr. Darya Chudova

5987. Dr. Darya Chudova is the Senior Vice President of Technology at Guardant Health ("Guardant") and has been in this role for approximately three years. (Chudova (Guardant) Tr. 1136). Prior to this role, she served as a Vice President of Technology and Senior Director of Bioinformatics at Guardant. (Chudova (Guardant) Tr. 1136). Dr. Chudova began working at Guardant in 2015. (Chudova (Guardant) Tr. 1135).

Response to Finding No. 5987:

Respondents have no specific response.

5988. Dr. Chudova's responsibilities as Guardant's Senior Vice President of Technology include overseeing technology development projects, such as the development of clinical diagnostic tests for therapy selection and MRD. (Chudova (Guardant) Tr. 1137-38).

Response to Finding No. 5988:

Respondents have no specific response.

5989. Until shortly before she testified at trial, Dr. Chudova was responsible for the entire technology staff at Guardant. (Chudova (Guardant) Tr. 1137).

Response to Finding No. 5989:

Respondents have no specific response.

5990. Dr. Chudova is currently focused on the development of Guardant's cancer screening applications. (Chudova (Guardant) Tr. 1137).

Response to Finding No. 5990:

Respondents have no specific response.

5991. Dr. Chudova testified at trial that she has been "very intrinsically involved" with the R&D teams at Guardant during her time at the company, including ensuring the "next-generation sequencing component" of its clinical diagnostic tests work and are "fit[ ] for the purpose of what [Guardant is] developing." (Chudova (Guardant) Tr. 1138-40). Each of Guardant's clinical tests in development uses NGS sequencing in its workflow. (Chudova (Guardant) Tr. 1140).

Response to Finding No. 5991:

Respondents have no specific response.

5992. Dr. Chudova was involved in the process of obtaining FDA approval for Guardant's Guardant360 therapy selection test. (Chudova (Guardant) Tr. 1149). Dr. Chudova testified at trial that she was "intimately involved in both the internal development work, as well as validation work leading up to the submission and [Guardant's] defense of the regulatory filing" with the FDA for the Guardant360 test. (Chudova (Guardant) Tr. 1149).

Response to Finding No. 5992:

Respondents have no specific response.

5993. Prior to her work at Guardant, Dr. Chudova served from 2008 to 2013 as a data analysis computational science contributor at Veracyte, which is a clinical diagnostic company focused on developing technologies related to thyroid cancer. (Chudova (Guardant) Tr. 1142-43). Dr. Chudova's work at Veracyte involved the use of micro-array technology. (Chudova (Guardant) Tr. 1142-43).

Response to Finding No. 5993:

Respondents have no specific response.

5994. Starting in early 2013, Dr. Chudova began working at Verinata, a company that was developing NIPT products reliant on NGS technology and was acquired by Illumina soon after she began working there. (Chudova (Guardant) Tr. 1143-44). After the acquisition, Dr. Chudova served as Associate Director of Bioinformatics at Illumina. (Chudova (Guardant) Tr. 1144).

Response to Finding No. 5994:

Respondents have no specific response.

5995. Dr. Chudova served as Associate Director of Bioinformatics at Illumina from early 2013 to 2015, where she focused on NIPT products. (Chudova (Guardant) Tr. 1144-45). While at Illumina, Dr. Chudova helped publish articles related to NIPT and the potential use of the technology for the early detection of cancer. (Chudova (Guardant) Tr. 1145-46).

Response to Finding No. 5995:

Respondents have no specific response.

5996. Dr. Chudova testified at trial that she left Illumina for Guardant in 2015 because she "was excited to find a company that was focused on applying" liquid biopsy technologies "that would be helpful for cancer patients." (Chudova (Guardant) Tr. 1146).

Response to Finding No. 5996:

Respondents have no specific response.

5997. Dr. Chudova received a master's degree in applied mathematics in Russia. (Chudova (Guardant) Tr. 1141). Dr. Chudova received a Ph.D. in computer science in the United States in 2007, which included three years of study in a joint program between the computer science and molecular biology departments to obtain a specialty in bioinformatics. (Chudova (Guardant) Tr. 1141-42).

Response to Finding No. 5997:

Respondents have no specific response.

6. Kevin Conroy

5998. Kevin Conroy is the Chairman and Chief Executive Officer of Exact Sciences ("Exact") and has worked at the company for over twelve years. (Conroy (Exact) Tr. 1526). Mr. Conroy joined the company on April 2, 2009, and at that time, there were only three employees including himself. (Conroy (Exact) Tr. 1532).

Response to Finding No. 5998:

Respondents have no specific response.

5999. Mr. Conroy testified at trial that when he joined the company, they had the "idea" to "develop two things, a colon cancer screening test that allows you to accurately detect colon cancer through a sample collected in the privacy of your own home[;] [a]nd then secondly, long-term was to develop what then we called a pan-cancer screening test or a universal cancer screening test from a single blood draw." (Conroy (Exact) Tr. 1532).

Response to Finding No. 5999:

The proposed finding is inaccurate. Page 1532, line 23 of the trial transcript reads "screening test from a simple blood draw." (Conroy (Exact) Tr. 1532 (emphasis added).) For the reasons explained in Respondents' response to CCFF ¶ 1908 which Respondents incorporate herein, there is no such thing as a "pan-cancer" test because there is no such thing as a universal cancer biomarker.

6000. Under Mr. Conroy's leadership, Exact has grown from a small, pre-commercial company into having approximately 6,000 employees and offering a range of different tests that are now sold to physicians and patients; as Mr. Conroy testified at trial, Exact is a "commercial company in that we have teams of people who educate healthcare providers about the tests that we offer, and we provide clinical testing services." (Conroy (Exact) Tr. 1532-33).

Response to Finding No. 6000:

Respondents have no specific response.

6001. As Chairman and CEO of Exact, Mr. Conroy's responsibilities include setting the agenda of the board of directors and general responsibility for the operations of the company. (Conroy (Exact) Tr. 1527).

Response to Finding No. 6001:

Respondents have no specific response.

6002. As CEO, Mr. Conroy has responsibility for strategic planning for the company, including the annual planning process, the three-year plan, the five-year plan, and more generally, "planning for how you can screen more people to detect cancer early and all of the investments and people that you need to make that happen." (Conroy (Exact) Tr. 1527). As part of the strategic planning process, Mr. Conroy assesses "internal and external threats" that could affect the company's "ability to make that long-term plan become real." (Conroy (Exact) Tr. 1527-28).

Response to Finding No. 6002:

Respondents have no specific response.

6003. As Chairman and CEO of Exact, Mr. Conroy has responsibilities relating to the merger and acquisition strategy of the company. (Conroy (Exact) Tr. 1528).

Response to Finding No. 6003:

Respondents have no specific response.

6004. Mr. Conroy is responsible for the overall commercialization of Exact's products, including ensuring that Exact brings their tests to physicians, healthcare providers, and ultimately to patients. (Conroy (Exact) Tr. 1529).

Response to Finding No. 6004:

Respondents have no specific response.

6005. Mr. Conroy is generally familiar with the commercialization planning for Exact's cancer tests. (Conroy (Exact) Tr. 1529).

Response to Finding No. 6005:

Respondents have no specific response.

6006. As Chairman and CEO of Exact, Mr. Conroy typically is not involved in negotiating supply contracts, but has been involved in "a very limited number of cases, including involved to a certain extent in negotiating or having conversations with Illumina because of the critical nature of next-generation sequencing as part of our long-term plan." (Conroy (Exact) Tr. 1528-29).

Response to Finding No. 6006:

Respondents have no specific response except to incorporate Respondents' response to

CCFF ¶ 1089 herein.

6007. Mr. Conroy consults Dr. Lengauer of Thrive when he has questions about CancerSEEK's technical specifications. (Conroy (Exact) Tr. 1553-54).

Response to Finding No. 6007:

Respondents have no specific response.

6008. Mr. Conroy received a juris doctorate from the University of Michigan in 1991. (Conroy (Exact) Tr. 1530). Mr. Conroy practiced intellectual property law for approximately nine

years in private practice and then in-house counsel for several years after that. (Conroy (Exact) Tr. 1530). Mr. Conroy was a member of the patent bar. (Conroy (Exact) Tr. 1530).

Response to Finding No. 6008:

Respondents have no specific response.

7. Dr. Andy Felton

6009. Dr. Andy Felton is the Vice President of Product Management, Platform Research, and Applied Markets at Thermo Fisher Scientific ("Thermo") and has served in this role for approximately seven years and with the legacy business for ten years. (Felton (Thermo Fisher) Tr. 1978-79).

Response to Finding No. 6009:

Respondents have no specific response.

6010. As the Vice President of Product Management, Platform Research, and Applied Markets at Thermo, Dr. Felton is responsible for the company's next-generation sequencing platforms (e.g., Ion Torrent), reagents, and software within the Clinical Sequencing Division as well as applications in research and applied markets. (Felton (Thermo Fisher) Tr. 1979).

Response to Finding No. 6010:

Respondents have no specific response.

6011. As part of his responsibilities, Dr. Felton monitors Thermo's competitors in the next-generation sequencing market and he understands the technology of their competitors as well as the requirements of the company's customers. (Felton (Thermo Fisher) Tr. 1980).

Response to Finding No. 6011:

Respondents have no specific response except to note that Dr. Felton also testified that

[redacted] (Felton (Thermo Fisher) Tr. 2016.)

6012. Prior to his current position at the company, Dr. Felton was the Senior Director of Product Management for Thermo's Next-Gen Sequencing Division from 2010 to 2014. (Felton (Thermo Fisher) Tr. 1980). In this role, Dr. Felton had very similar responsibilities to his current role in that he oversaw the next-generation sequencing platforms of the company as well as the core reagents. (Felton (Thermo Fisher) Tr. 1980).

Response to Finding No. 6012:

Respondents have no specific response.

6013. Before working at Thermo, Dr. Felton was the Director of Product Management for the capillary electrophoresis sequencing business at Applied Biosciences. (Felton (Thermo Fisher) Tr. 1980-81). In that role, Dr. Felton was responsible for platforms and core reagents of the capillary sequencing business, which was a precursor technology to next-generation sequencing. (Felton (Thermo Fisher) Tr. 1981). At Applied Biosciences, Dr. Felton was also involved in product management for the real-time PCR, sample preparation, and DNA synthesis businesses. (Felton (Thermo Fisher) Tr. 1981). Dr. Felton started at Applied Biosciences in 1994 and worked there until joining Thermo. (Felton (Thermo Fisher) Tr. 1981).

Response to Finding No. 6013:

Respondents have no specific response.

6014. Dr. Felton has a B.S. in chemistry from John Moores University as well as a Ph.D. in peptide protein chemistry from Oxford Brooks University. (Felton (Thermo Fisher) Tr. 1981).

Response to Finding No. 6014:

Respondents have no specific response.

8. William John Tolan Getty, III

6015. William Getty is the Senior Vice President of Commercial for the Screening Division at Guardant Health ("Guardant"). (Getty (Guardant) Tr. 2482). Mr. Getty has been in this role since January 2021. (Getty (Guardant) Tr. 2482-83).

Response to Finding No. 6015:

Respondents have no specific response.

6016. As SVP of Commercial for Guardant's Screening Division, Mr. Getty's responsibilities include "lead[ing] the commercialization of [Guardant's] screening product in development," the LUNAR-2, which "encompasses sales, marketing, medical affairs, commercial development, [and] all manners of activities that will support the commercialization of the product." (Getty (Guardant) Tr. 2483).

Response to Finding No. 6016:

Respondents have no specific response.

6017. In this role as SVP of Commercial, Mr. Getty "interact[s] with the broader organization on a strategic basis" regarding the development of Guardant's cancer screening tests. (Getty (Guardant) Tr. 2483-84). Mr. Getty reports to the Co-CEO, AmirAli Talasaz, and spends "a lot of time talking about strategic planning" with him; Mr. Getty is also a member of the executive management team where "those discussions are happening across the broader portfolio." (Getty (Guardant) Tr. 2484-85).

Response to Finding No. 6017:

Respondents have no specific response.

6018. Mr. Getty has responsibilities relating to Guardant's competitive assessments, testifying that "pretty much everyday [in] commercialization discussions, we are thinking about what our competition is doing, and . . . constantly staying abreast of what we can in terms of the competitive environment, how they are moving, and what that means for us as an organization, either to compete, or what it frankly means about the market longer term." (Getty (Guardant) Tr. 2485-86).

Response to Finding No. 6018:

Respondents have no specific response.

6019. After Guardant commercializes its screening test, Mr. Getty "will be responsible for overseeing the execution and [Guardant's] performance relative to the uptake of the test and . . . the responsibilities around revenue generation and making sure that we are moving forward." (Getty (Guardant) Tr. 2486). In this role, it will be Mr. Getty's responsibility to ensure physician adoption of the test, that the company is meeting internal forecasts, and ensuring that Guardant has a profitable business doing these activities. (Getty (Guardant) Tr. 2486-87).

Response to Finding No. 6019:

Respondents have no specific response.

6020. Guardant's executive management team, on which Mr .Getty serves, is "made up of senior leaders within the organization," as well as the co-CEOs. (Getty (Guardant) Tr. 2487). The executive management team has the "responsibility of guiding the organization on a strategic basis," which includes decisions about mergers and acquisitions, competitive threats, as well as things affecting the broader organization. (Getty (Guardant) Tr. 2487).

Response to Finding No. 6020:

Respondents have no specific response.

6021. Mr. Getty interacts with Dr. Darya Chudova, who also is part of the executive management team, and "spend[s] a lot of time talking about technical development, clinical

development, and . . . more broadly about the program overall." (Getty (Guardant) Tr. 2487-88).

Response to Finding No. 6021:

Respondents have no specific response.

6022. When Mr. Getty first joined Guardant, he was the Vice President of Marketing of the Oncology Division. (Getty (Guardant) Tr. 2481-82). He served in this role until becoming the SVP of Commercial for the Screening Division at Guardant. (Getty (Guardant) Tr. 2482-83).

Response to Finding No. 6022:

Respondents have no specific response.

6023. Prior to joining Guardant, Mr. Getty worked in the life sciences industry for many years, including working at Pfizer, Medivation (which was purchased by Pfizer), as well as Exelixis. (Getty (Guardant) Tr. 2481).

Response to Finding No. 6023:

Respondents have no specific response.

6024. Mr. Getty has a B.S. in biology from the University of Massachusetts at Amherst, and a Master of Business Administration from Fairleigh Dickinson University. (PX7040, Getty IHT at 13).

Response to Finding No. 6024:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

9. Michael Nolan

6025. Michael Nolan is the Chief Executive Officer at Freenome and has been in this role since April 2021. (Nolan (Freenome) Tr. 2695). Prior to becoming CEO, Mr. Nolan was the Chief Business Officer at Freenome from April 2019 until April 2021. (Nolan (Freenome) Tr. 2695).

Response to Finding No. 6025:

Respondents have no specific response.

6026. As Freenome's CEO, Mr. Nolan's responsibilities include managing "all functions" of the company, including product development, strategic planning, as well as the commercialization of Freenome's products. (Nolan (Freenome) Tr. 2698-701).

Response to Finding No. 6026:

Respondents have no specific response.

6027. Mr. Nolan testified that Freenome has a "technical assessment team," whose function is to "help [Freenome] evaluate different solutions [the company] might be considering, first of all starting with what are the science or the research questions that [Freenome] need[s] to be able to answer with that technology or … how [Freenome] might need to apply that technology for purposes of advancing in product development." (Nolan (Freenome) Tr. 2738-39). One area that the technical assessment team provides assessments on are NGS sequencers. (Nolan (Freenome) Tr. 2739).

Response to Finding No. 6027:

Respondents have no specific response.

6028. While serving as Freenome's Chief Business Officer, Mr. Nolan's responsibilities included various functions, such as "clinical development, market development, business development, corporate development, marketing, also IP strategy, and then additionally with the responsibility to look forward to additional functions that we'll have with sales, client services, [and] payer relations." (Nolan (Freenome) Tr. 2695-96). As part of his responsibilities with business development, Mr. Nolan was involved with the team that focuses on developing collaborations or partnerships. (Nolan (Freenome) Tr. 2696). As part of his responsibilities with market development, Mr. Nolan was involved with "forming relationships with key opinion leaders" as well as sites that assist Freenome with their ongoing clinical trial. (Nolan (Freenome) Tr. 2696-97).

Response to Finding No. 6028:

Respondents have no specific response.

6029. Prior to serving as Freenome's Chief Business Officer, Mr. Nolan was Freenome's Chief Commercial Officer. (Nolan (Freenome) Tr. 2697). In this role, Mr. Nolan's responsibilities involved "defining the customer requirements and then establishing the product requirements for [Freenome] to use in setting product specifications for the work that [they] would do to develop a test that would be brought to market." (Nolan (Freenome) Tr. 2697).

Response to Finding No. 6029:

Respondents have no specific response.

6030. Mr. Nolan "started in the industry in 1992," and "held a number of different roles through that process of increasing responsibility across various functions, including sales, marketing, market development, business development, general management, ranging from companies like Abbott Diagnostics to Roche Molecular Diagnostics to Life Technologies, Thermo Fisher, Luminex, [and] Foundation Medicine." (Nolan (Freenome) Tr. 2701).

Response to Finding No. 6030:

Respondents have no specific response.

6031. Mr. Nolan worked at Thermo Fisher from 2012 to 2015 as the Vice President and General Manager for Global Oncology. (Nolan (Freenome) Tr. 2701-02). In this role, Mr. Nolan's responsibilities included "taking the assets that the company had," such as their various instruments and platforms along with the consumables and service models oriented towards research use, and "bringing those to the category of oncology." (Nolan (Freenome) Tr. 2702). While at Thermo Fisher, Mr. Nolan worked with the PGM Dx next-generation sequencer. (Nolan (Freenome) Tr. 2702-03).

Response to Finding No. 6031:

The proposed finding is inaccurate, incomplete and misleading without additional context. Mr. Nolan testified at trial that "somewhere around 2012 is when [he] joined Life Technologies and maybe 2013 for Thermo Fisher." (Nolan (Freenome) Tr. 2701.)

6032. Mr. Nolan has a B.S. in biological sciences and secondary education, as well as a Master of Business Administration from the University of Wyoming. (PX0042 at 003 (Michael Nolan, LinkedIn Profile)).

Response to Finding No. 6032:

Respondents have no specific response.

10. Dr. Gary Gao

6033. Dr. Gary Gao is a founder and Chief Executive Officer of Med Data Quest, which is part of Singlera Genomics ("Singlera"). (Gao (Singlera) Tr. 2860). Dr. Gao is a board member, co-founder, and scientific advisor of Singlera. (Gao (Singlera) Tr. 2860).

Response to Finding No. 6033:

Respondents have no specific response.

6034. When Dr. Gao co-founded Singlera, he was the chairman of the board, scientific advisor, and the president of U.S. operations. (Gao (Singlera) Tr. 2870-71). Dr. Gao's

responsibilities included organizing the team, overseeing the laboratory, hiring people, raising capital, etc. (Gao (Singlera) Tr. 2871). Dr. Gao served as chairman of the board of Singlera from July 2014 until June 2020. (Gao (Singlera) Tr. 2871-72).

Response to Finding No. 6034:

Respondents have no specific response.

6035. Since June 2020, Dr. Gao has remained a board member and scientific advisor of Singlera. (Gao (Singlera) Tr. 2872). In these roles, Dr. Gao is involved in "any technology discussion with investors" as well as giving lectures, attending meetings to provide scientific input, and publishing papers. (Gao (Singlera) Tr. 2872).

Response to Finding No. 6035:

Respondents have no specific response.

6036. With respect to the development of Singlera's products, Dr. Gao is currently a scientific advisor and "heavily involved in the research part"; Dr. Gao meets weekly with Singlera's Chief Technology Officer Dr. Rui Lui as well as Professor Kun Zhang, who is another co-founder and scientific advisor of Singlera. (Gao (Singlera) Tr. 2871). In these discussions, Dr. Gao testified that they discuss the "research direction and also evaluate the research, and then [they] provide papers and publish results." (Gao (Singlera) Tr. 2871).

Response to Finding No. 6036:

Respondents have no specific response except to note that Dr. Gao testified that

Singlera's PanSeer test can be run using Thermo fisher equipment. (Gao (Singlera) Tr. 2928.)

6037. Dr. Gao obtained his bachelor's degree in biology from Beijing University in 1992, and then obtained a master's degree in biochemistry at the University of Tennessee Medical Center. (Gao (Singlera) Tr. 2860). Following this, Dr. Gao received a Ph.D. in computer science from the University of Memphis, and then conducted four years of Ph.D. research at IBM T.J. Watson Research in New York City. (Gao (Singlera) Tr. 2860).

Response to Finding No. 6037:

Respondents have no specific response.

6038. In 2006, Dr. Gao became an assistant professor at Virginia Commonwealth University in computer science, genomics, and life sciences. (Gao (Singlera) Tr. 2860-62). As an assistant professor at VCU, Dr. Gao conducted research at one of the first independent laboratories to purchase a Solexa next-generation sequencer before Illumina acquired Solexa. (Gao (Singlera) Tr. 2863).

Response to Finding No. 6038:

Respondents have no specific response.

6039. After four years as an assistant professor at VCU, Dr. Gao became an associate professor at the Lieber Institute of Brain Development at Johns Hopkins Biomedical Engineering department. (Gao (Singlera) Tr. 2860-61).

Response to Finding No. 6039:

Respondents have no specific response.

6040. In 2013, Dr. Gao left his employment as an associate professor at The Johns Hopkins University to start Med Data Quest under Singlera Genomics. (Gao (Singlera) Tr. 2861).

Response to Finding No. 6040:

Respondents have no specific response.

6041. Prior to his work at Singlera, Dr. Gao had experience with cell-free DNA. (Gao (Singlera) Tr. 2863-64). Dr. Gao's "earliest introduction into cell-free DNA work was through cooperation with Professor Dennis Lo from Chinese University of Hong Kong in 2007." (Gao (Singlera) Tr. 2863-64). Dr. Gao testified that "Professor Lo identified [him] as a collaborator" and Dr. Gao developed a protocol to process pregnant mother's blood to analyze cell-free DNA to identify whether or not the fetus had Down syndrome. (Gao (Singlera) Tr. 2864). From this research, Dr. Gao and Professor Lo published a paper in Proceedings of National Academy of Science in 2008, which described the use of cell-free DNA for non-invasive prenatal testing. (Gao (Singlera) Tr. 2864).

Response to Finding No. 6041:

The proposed finding is inaccurate and misleading for the reasons explained in

Respondents' response to CCFF ¶ 354, which is incorporated herein.

6042. After working with Professor Lo, Dr. Gao "figure[d] the same thing can be applied to detecting cancer." (Gao (Singlera) Tr. 2864). Dr. Gao spoke with Professor Kun Zhang at UCSD concerning this and together they started Singlera Genomics in July 2013 to use cell-free DNA to detect cancer early. (Gao (Singlera) Tr. 2864).

Response to Finding No. 6042:

The proposed finding is inaccurate and misleading for the reasons explained in

Respondents' response to CCFF ¶ 354, which is incorporated herein.

6043. Dr. Gao testified at trial that while he was performing research related to early cancer detection, Singlera Genomics was "way ahead of Grail," as Singlera was incorporated in July 2014 and Grail was "started as a spinoff from Illumina in 2015." (Gao (Singlera) Tr. 2869).

Response to Finding No. 6043:

The proposed finding is inaccurate, incomplete, and misleading to the extent it suggests that Singlera's PanSeer test is ahead of Grail's Galleri test in its stage of development or commercialization. Dr. Gao testified that Singlera is "far, far away" from launching its PanSeer test. (PX7102 (Gao (Singlera) Dep. at 118-119).) He testified that Singlera is not currently in talks with the FDA, that is will "take at least seven to ten years of time for [the current PanSeer] development to be able to go to FDA. (Gao (Singlera) Tr. 2891.) Dr. Gao testified that for the PanSeer test to be able detect 50 or 100 types of cancer, "it would take maybe 50 years." (Gao (Singlera) Tr. 2883.)

11. Dr. Alex Aravanis

6044. Dr. Alex Aravanis is the Chief Technology Officer at Illumina and has been in this role since June 2020. (Aravanis (Illumina) Tr. 1809-10).

Response to Finding No. 6044:

Respondents have no specific response.

6045. As Illumina's Chief Technology Officer, Dr. Aravanis is responsible for research and product development programs, develops strategies in those areas, and participates as a member of the executive team representing research and development. (Aravanis (Illumina) Tr. 1809-10).

Response to Finding No. 6045:

Respondents have no specific response.

6046. Dr. Aravanis is a co-founder of Grail and was involved in the early research and development of the technology relevant to Grail. (Aravanis (Illumina) Tr. 1772). Dr. Aravanis was also involved in preparing the business plan for Grail and the operational aspects of creating Grail as an independent company. (Aravanis (Illumina) Tr. 1772-73). Dr. Aravanis joined Grail in 2016 as Vice President of Research and Development. (Aravanis (Illumina) Tr. 1778). In this role, Dr. Aravanis developed the research and

development program at Grail, as well as built and managed the research and development team. (Aravanis (Illumina) Tr. 1817).

Response to Finding No. 6046:

Respondents have no specific response.

6047. Dr. Aravanis was promoted to Chief Scientific Officer at Grail, which included all of his responsibilities as Vice President of Research and Development, as well as laboratory operations and clinical development. (Aravanis (Illumina) Tr. 1818). Dr. Aravanis left Grail in May 2020 to join Illumina as Chief Technology Officer. (Aravanis (Illumina) Tr. 1819).

Response to Finding No. 6047:

Respondents have no specific response.

12. Hans Bishop

6048. Hans Bishop is the former Chief Executive Officer of Grail and became CEO in 2019. (Bishop (Grail) Tr. 1316; PX0405, (Illumina Appoints Ragusa as Chief Executive Officer (CEO) of GRAIL, Oct. 14, 2021, https://www.illumina.com/company/news-center/press-releases/press-release-details.html?newsid=2e72344d-ceaf-4453-868a-423516a4ba49 (last visited Oct. 25, 2021)). Mr. Bishop joined Grail's board of directors approximately one year before becoming CEO; he continued to serve on Grail's board of directors after becoming CEO. (Bishop (Grail) Tr. 1316).

Response to Finding No. 6048:

Respondents have no specific response.

6049. As CEO of Grail, Mr. Bishop was responsible to the board of directors and overseeing the leadership team at Grail. (Bishop (Grail) Tr. 1316-17). Further, as CEO of Grail, Mr. Bishop was responsible for proposing the company's overall strategy to the board, which would ultimately agree or reject such proposals. (Bishop (Grail) Tr. 1317). Moreover, Mr. Bishop's responsibilities included, *inter alia*, hiring and leading the management team, working with the management team to develop Grail's scientific product plans, working to finance the company, as well as report to the board of directors. (Bishop (Grail) Tr. 1317-18).

Response to Finding No. 6049:

Respondents have no specific response.

6050. As a member of Grail's board of directors, Mr. Bishop's responsibilities included, *inter alia*, ensuring that shareholders' interests were represented, that there was good discipline and processes regarding how Grail was run and controlled, and oversaw the quality of the

management of the company. (Bishop (Grail) Tr. 1316). In addition, Mr. Bishop presented various aspects of Grail's business to the board of directors, including, company strategy, results from R&D and product development efforts, financials, as well as strategy to serve customers. (PX7069 (Bishop (Grail) IHT at 26-27)).

Response to Finding No. 6050:

Respondents have no specific response.

6051. When Mr. Bishop was the CEO of Grail, his management team included, among others, Joshua Ofman, Matt Young, Marissa Song, Alice Chen, and Uplaksh Kumar. (PX7069 (Bishop (Grail) IHT at 26)).

Response to Finding No. 6051:

Respondents have no specific response.

6052. Mr. Bishop was involved in Grail's potential initial public offering in 2020. (Bishop (Grail) Tr. 1325).

Response to Finding No. 6052:

Respondents have no specific response.

6053. As part of exploring an IPO, Grail engaged in a number of meetings in July and August of 2020 with a range of potential investors, and Mr. Bishop participated in a "great many of them." (Bishop (Grail) Tr. 1325-26). After engaging in these non-deal roadshow meetings, Grail engaged in a second set of meetings with possible investors called "testing the waters" meetings. (Bishop (Grail) Tr. 1325-26). As Grail's CEO, Mr. Bishop presented and "participated in many of them," as did Dr. Josh Ofman, Matthew Young, Aaron Freiden, and Arash Jamshidi. (Bishop (Grail) Tr. 1326).

Response to Finding No. 6053:

Respondents have no specific response.

6054. As part of the IPO process, Mr. Bishop testified that the process to create the Form S-1 document was "rigorous," "reviewed by internal experts at Grail," "reviewed by both finance and legal at Grail," "reviewed by external experts," and Mr. Bishop was personally involved in preparing and reviewing the S-1. (Bishop (Grail) Tr. 1327). Mr. Bishop tried to ensure that the information contained in the S-1 was accurate, as Grail has an obligation to be truthful in the S-1. (Bishop (Grail) Tr. 1327-28).

Response to Finding No. 6054:

Respondents have no specific response.

6055. [redacted] (Bishop (Grail) Tr. 1438-39) (*in camera*)).

Response to Finding No. 6055:

6056. [redacted] (Bishop (Grail) Tr. 1501-02 (*in camera*)).

Response to Finding No. 6056:

The proposed finding relates to irrelevant subject matter because the proposed finding does not relate to any fact that is of consequence in determining this action.

6057. [redacted] (Bishop (Grail) Tr. 1501-02 (*in camera*)).

Response to Finding No. 6057:

The proposed finding relates to irrelevant subject matter because the proposed finding does not relate to any fact that is of consequence in determining this action.

6058. [redacted] (PX4473 (Grail) at 003 (Core Team, Apr. 15, 2021) (*in camera*)).

Response to Finding No. 6058:

The proposed finding relates to irrelevant subject matter because the proposed finding does not relate to any fact that is of consequence in determining this action.

6059. [redacted] (PX4473 (Grail) at 010 (Core Team, Apr. 15, 2021) (*in camera*)).

Response to Finding No. 6059:

The proposed finding relates to irrelevant subject matter because the proposed finding does not relate to any fact that is of consequence in determining this action.

13. Nicole Berry

6060. Nicole Berry is Illumina's Senior Vice President and General Manager of the Americas commercial region and has been in this role since January 2020. (Berry (Illumina) Tr. 642). Prior to this role, Ms. Berry served as the Vice President of the Americas sales team. (Berry (Illumina) Tr. 642). She has been employed at Illumina since 2009. (Berry (Illumina) Tr. 642).

Response to Finding No. 6060:

Respondents have no specific response.

6061. In her role as Illumina's Senior Vice President and General Manager of the Americas commercial region, Ms. Berry is responsible for Illumina's customer-facing functions in the United States, Canada, and Latin America, which includes sales, service and support, and the commercial operations team. (Berry (Illumina) Tr. 643).

Response to Finding No. 6061:

Respondents have no specific response.

6062. The service and support function includes the installation of Illumina's equipment into laboratories, servicing Illumina's equipment, as well as technical support. (Berry (Illumina) Tr. 646).

Response to Finding No. 6062:

Respondents have no specific response.

6063. Ms. Berry testified at trial that Illumina instruments are not "plug-and-play"; Illumina conducts a "check to ensure that the [customer's] operating environment is compatible," which includes "everything from the physical space, size, ventilation, humidity temperature, you know, HVAC, all those things are compatible with the operating requirements of the specific instrumentation." (Berry (Illumina) Tr. 672-73). After the Illumina instrument arrives, Illumina uncrates the equipment, as it is "a sensitive piece of instrumentation," and "essentially fire it up, you know, we do the – a little bit of on-site assembly, fire it up, and then we need to make sure that … it hasn't been damaged in transit, for example." (Berry (Illumina) Tr. 673). Illumina's service and support teams then "run control samples to validate that the instrument is performing to the specifications that exist for the instrument." (Berry (Illumina) Tr. 673). The whole process takes "three or four days to do[;] so it's not like plugging in a refrigerator and sticking your stuff in the fridge." (Berry (Illumina) Tr. 673-74).

Response to Finding No. 6063:

Respondents have no specific response except to note that Ms. Berry also testified that, in light of the Open Offer, customers will have access to the same support services that they had access to before the Transaction. Specifically, Ms. Berry testified that "if Illumina deliberately delayed or even refused to service an instrument that belonged to a test developer who signed the open offer", "we'd be in breach of the agreement." (Berry (Illumina) Tr. 871.) She also testified that "the open offer obligates Illumina to provide access to a customer to not only the same [product and support] services for which the customer had before the transaction but also any [product and support] services . . . that GRAIL has so that there will be absolutely no disadvantage to a customer signing this agreement on what they can access as relates to services". (Berry (Illumina) Tr. 865–66.)

6064. The commercial operations function includes administering price quotes to customers, business analytics (i.e., the collection of activities that relate to analyzing various business metrics and "how they may give [Illumina] the ability to, for example, forecast future business, provide information to other Illumina groups that is important for them to understand so that we can together work to meet the needs of our customers"). (Berry (Illumina) Tr. 646-47). In addition, Ms. Berry is responsible for the oversight of the sales leaders, the development of Illumina's sales plans and strategies, and meeting Illumina's revenue targets. (Berry (Illumina) Tr. 643).

Response to Finding No. 6064:

The proposed finding is inaccurate and incomplete. Page 647, line 7 of the trial transcript reads "needs of our – the future needs of our customers." (Berry (Illumina) Tr. 647.)

6065. Ms. Berry's team keeps track of every product that a customer orders, the service that customers receive, and also maintain a database that includes the prices that customers pay. (Berry (Illumina) Tr. 647). Ms. Berry testified that "customer-specific information related to sales, order history, service and support" is all "confidential information." (Berry (Illumina) Tr. 647).

Response to Finding No. 6065:

Respondents have no specific response except to note that, as Ms. Berry testified, Illumina takes extensive precautions to protect any customer confidential information and the Open Offer provides even greater confidentiality protections in the form of a firewall between Illumina and GRAIL. (*See, e.g.*, RRFF ¶¶ 2612, 2617–21.)

6066. Grail was one customer that was under Ms. Berry's responsibilities until Illumina consummated the acquisition of Grail on August 18, 2021. (Berry (Illumina) Tr. 649-50). Ms. Berry testified at trial that Illumina has "recently transitioned sales responsibility to Grail to an individual within Illumina who has no other customer responsibilities related to the oncology testing space." (Berry (Illumina) Tr. 650). When Grail was separate from Illumina prior to the acquisition, Ms. Berry had access to the prices Grail paid as well as the products that Grail purchased. (Berry (Illumina) Tr. 650).

Response to Finding No. 6066:

Respondents have no specific response.

6067. Ms. Berry testified that all customers that have shipment locations in the United States falls under her responsibilities, including Exact Sciences, Guardant Health, Natera, Freenome, Singlera, Foundation Medicine. (Berry (Illumina) Tr. 650-51).

Response to Finding No. 6067:

Respondents have no specific response.

6068. Ms. Berry has responsibilities relating to Illumina's supply agreements, testifying that she "oftentimes am called in to supply agreement discussions with customers as it relates to the terms that a customer may be seeking and our ability to accommodate those terms." (Berry (Illumina) Tr. 653). In addition, Ms. Berry provides input into the business terms of supply agreements, working closely with Illumina's legal team to translate customers' business requests into contract language. (Berry (Illumina) Tr. 653). Ms. Berry testified that she has "participated in many, many meetings prior to signature" where customers have questions on the terms of the supply agreements during the "negotiation or supply agreement development phase." (Berry (Illumina) Tr. 654).

Response to Finding No. 6068:

Respondents have no specific response.

6069. Ms. Berry testified at trial that she is familiar with the open offer that Illumina posted on its website, which is a standardized long-term supply agreement offered to Illumina's oncology customers that includes "key terms related to assuring the customer of continued

access to products, access to service, continuity, and access to commercial terms that they may have experienced prior to the acquisition." (Berry (Illumina) Tr. 688-89). In addition, Ms. Berry is "familiar with the essence of many of the negotiations" with oncology customers regarding the open offer and Ms. Berry is the signatory of the open offer, as she is the Senior Vice President responsible for the commercial business within the United States. (Berry (Illumina) Tr. 689-90).

Response to Finding No. 6069:

Respondents have no specific response.

6070. [redacted] (Berry (Illumina) Tr. 750-51 (*in camera*)).

Response to Finding No. 6070:

The proposed finding is incomplete and misleading. In the portion of Ms. Berry's testimony cited here, Ms. Berry testified that [redacted]

6071. [redacted] (Berry (Illumina) Tr. 774 (*in camera*)).

Response to Finding No. 6071:

Respondents have no specific response except to note that, as Ms. Berry testified, under the Open Offer, any discounts offered by Illumina to its oncology customers are standardized through a universal pricing grid. (*See, e.g.*, RRFF ¶¶ 2630, 2633–37.)

6072. In a text message between Ms. Berry and Kathy Davy, Illumina's former Vice President of Marketing for Clinical Genomics, Ms. Berry responded to a question about [redacted] (PX2283 (Illumina) at 001 (Mobile text chain between N. Berry, Illumina, and K. Davy, Illumina, June 4, 2020) (*in camera*); Berry (Illumina) Tr. 737-38 (*in camera*)).

Response to Finding No. 6072:

The proposed finding is incomplete and misleading for the reasons identified in Respondents' responses to CCFF ¶¶ 4222–25, which Respondents incorporate herein.

6073. In a text message dated September 16, 2020, four days prior to the announcement of Illumina's proposed acquisition of Grail, [redacted] (PX2158 (Illumina) at 001 (Mobile text chain between N. Berry, Illumina, and J. Preston, Illumina, Sept. 16, 2020) (*in camera*); (Berry (Illumina) Tr. 743-44 (*in camera*)).

Response to Finding No. 6073:

The proposed finding is incomplete and misleading without additional context. Ms. Berry further testified at trial with respect to PX2158 that [redacted] (Berry (Illumina) Tr. 744 (*in camera*).) Respondents further incorporate their responses to CCFF ¶¶ 2701 and 4222–25 herein.

14. Chris Della Porta

6074. Chris Della Porta is Grail's Director of Growth Strategy and has been in this role since September 2020. (Della Porta (Grail) Tr. 453-54).

Response to Finding No. 6074:

Respondents have no specific response.

6075. Mr. Della Porta founded Grail's growth strategy team, which he currently leads and is involved with planning for this team. (Della Porta (Grail) Tr. 455). In his role as Director

of Growth Strategy, he oversees the development of commercial forecasts for all products for long range planning and IPO efforts, as well as managing direct reports to successfully execute on model development. (PX4271 (Grail) at 001 (Della Porta Resume)).

Response to Finding No. 6075:

The proposed finding is inaccurate. [redacted] (Della Porta (Grail) Tr. 518.)

6076. One purpose of the growth strategy team is to develop new channels for the sale of Grail's Galleri test, which includes strategically evaluating potential customers for Galleri and approaching potential partners for the sale of Galleri. (Della Porta (Grail) Tr. 455-56). These potential customers include physicians groups, health systems, and employers. (Della Porta (Grail) Tr. 456-57). In addition, [redacted] (Della Porta (Grail) Tr. 527-28 (*in camera*)).

Response to Finding No. 6076:

Respondents have no specific response, except to note that Mr. Della Porta testified that [redacted]

6077. Grail's growth strategy team was involved with tasks relating to the launch of Galleri, including securing initial concierge physician customers. (Della Porta (Grail) Tr. 461-62).

Response to Finding No. 6077:

Respondents have no specific response, except to note that Mr. Della Porta testified that [redacted]

6078. As Grail's Director of Growth Strategy, Mr. Della Porta reports to Grail's Chief Commercial Officer Mr. Gautam Kollu. (Della Porta (Grail) Tr. 454-55).

Response to Finding No. 6078:

Respondents have no specific response.

6079. Mr. Della Porta is the Diagnostic Aid for Cancer product lead, progressing the DAC product concept to approved product program. In addition, Mr. Della Porta is the commercial lead on the new MRD concept team, responsible for commercial strategy and the business case. (PX4271 (Grail) at 001 (Della Porta Resume)).

Response to Finding No. 6079:

Respondents have no specific response.

6080. Mr. Della Porta was involved in founding Grail's competitive intelligence team, which had approximately ten people in the beginning of 2021. (Della Porta (Grail) Tr. 467). The competitive intelligence team's role included monitoring industry developments that were relevant to Grail. (Della Porta (Grail) Tr. 467). While Mr. Della Porta was the co-lead of the competitive intelligence team, it produced various work product, which included presentations and reports of particular companies and technologies of interest, and this was shared internally among Grail's executives and the board of directors. (Della Porta (Grail) Tr. 468-69). Mr. Della Porta was involved in collecting commercial information during his time on the competitive intelligence team. (Della Porta (Grail) Tr. 466).

Response to Finding No. 6080:

The proposed finding is misleading. Mr. Della Porta testified that he did not have any personal experience of the competitive intelligence team's slides being shared with GRAIL's board of directors. (Della Porta (GRAIL) Tr. 469.) He also did not have experience with the finance teams using the work product or how they used it. (Della Porta (GRAIL) Tr. 469.) The cited testimony does not support the proposition that the work product was "shared internally among Grail's executives." (Della Porta (GRAIL) Tr. 469.)

6081. Before transitioning to the Director of Growth Strategy position, Mr. Della Porta served Grail as the Associate Director of Product Marketing. (Della Porta (Grail) Tr. 454).

Response to Finding No. 6081:

Respondents have no specific response.

6082. Mr. Della Porta joined Grail as the Product Marketing Manager in 2016. (Della Porta (Grail) Tr. 454). Mr. Della Porta transitioned to the Senior Manager of Product Marketing role before assuming the role of Associate Director of Product Marketing at Grail. (Della Porta (Grail) Tr. 454).

Response to Finding No. 6082:

Respondents have no specific response.

15. Francis deSouza

6083. Francis deSouza is Illumina's Chief Executive Officer and has been in this role since July 2016. (deSouza (Illumina) Tr. 2190).

Response to Finding No. 6083:

Respondents have no specific response.

6084. As the CEO of Illumina, Mr. deSouza has responsibilities over numerous functions at the company, including strategy, corporate development, finance, legal, and human resources. (deSouza (Illumina) Tr. 2190-91). Mr. deSouza testified at trial that in his role as CEO, his responsibilities include "setting the long-term strategy and vision for the company," "managing the operations of the company to execute against that vision," and that he is the "key point person to manage our relationship with key stakeholders, members of our board, investors, [and] key opinion leaders in the industry." (deSouza (Illumina) Tr. 2306).

Response to Finding No. 6084:

Respondents have no specific response.

6085. Some of Mr. deSouza's direct reports include Susan Tousi, Illumina's Chief Commercial Officer, Dr. Alex Aravanis, Illumina's Chief Technology Officer, Sam Samad, Illumina's Chief Financial Officer, Chuck Dadswell, Illumina's General Counsel, and Joydeep Goswami, Illumina's SVP of Corporate Development and Strategy. (deSouza (Illumina) Tr. 2191-92).

Response to Finding No. 6085:

Respondents have no specific response.

6086. As Illumina's CEO, Mr. deSouza owes a fiduciary duty to shareholders, including creating long-term value for shareholders and increasing the value of the company. (deSouza (Illumina) Tr. 2193).

Response to Finding No. 6086:

The proposed finding is inaccurate and misleading without additional context. On page 2193 of the trial transcript, Mr. deSouza was asked if "Illumina also owes a fiduciary duty to [its] shareholders", if, "having a fiduciary duty, things are happening to create long-term value for

shareholders", and if "this fiduciary duty [i.e., Illumina's fiduciary duty] requires you to try and increase the value of the company", to each of which Mr. deSouza responded, "That's right." (deSouza (Illumina) Tr. 2193 (emphases added).)

6087. [redacted] (deSouza (Illumina) Tr. 2242-43 (*in camera*)).

Response to Finding No. 6087:

Respondents have no specific response.

6088. [redacted] (deSouza (Illumina) Tr. 2243 (*in camera*)).

Response to Finding No. 6088:

Respondents have no specific response.

6089. Mr. deSouza's receives an annual compensation bonus based on meeting certain performance metrics, including certain revenue targets and earnings-per-share targets. (deSouza (Illumina) Tr. 2193-94).

Response to Finding No. 6089:

Respondents have no specific response.

6090. [redacted] (deSouza (Illumina) Tr. 2281 (*in camera*)).

Response to Finding No. 6090:

Respondents have no specific response.

6091. [redacted] (deSouza (Illumina) Tr. 2281 (*in camera*)).

Response to Finding No. 6091:

Respondents have no specific response.

6092. [redacted] (deSouza (Illumina) Tr. 2281 (*in camera*)).

Response to Finding No. 6092:

The proposed finding is incomplete and misleading without additional context. Mr. deSouza testified at trial that he would [redacted] (deSouza (Illumina) Tr. 2281 (*in camera*).)

6093. Mr. deSouza joined Illumina in November 2013 as President and member of the Board. (deSouza (Illumina) Tr. 2194, 2308). Mr. deSouza reported to Jay Flatley, Illumina's CEO at the time. (deSouza (Illumina) Tr. 2194). Mr. deSouza is still the president of Illumina, but also assumed the role of CEO in 2016. (deSouza (Illumina) Tr. 2309).

Response to Finding No. 6093:

Respondents have no specific response.

6094. In his role as President at Illumina, Mr. deSouza was primarily responsible for running the "teams that build the products, so it was the product development and engineering teams, the manufacturing teams and quality teams." (deSouza (Illumina) Tr. 2308-09). Mr. deSouza was responsible for the "entire portfolio," which included the range of sequencers, but also included library prep kits, as well as IVDs and software products. (deSouza (Illumina) Tr. 2309).

Response to Finding No. 6094:

Respondents have no specific response.

16. Dr. John Leite

6095. Dr. Leite is the Chief Business Officer of InterVenn and has served in this role since November 2020. (Leite (Illumina) Tr. 2166). In this role, Dr. Leite is responsible for major partnership transactions, corporate strategy and development, as well as commercial activities. (Leite (Illumina) Tr. 2166-67).

Response to Finding No. 6095:

Respondents have no specific response.

6096. Prior to InterVenn, Dr. Leite was employed at Illumina for approximately six and a half years. (Leite (Illumina) Tr. 2073). When he first joined Illumina, Dr. Leite was the Vice President of Clinical Business Development; in this role, he was "responsible for major partnership transactions with either other IVD providers or with pharmaceutical companies across the clinical space." (Leite (Illumina) Tr. 2073). Partnership transactions, in Dr. Leite's testimony, include "transactions that stem outside the normal commercial function

and are partnerships, codevelopment agreements, [and] strategic partnerships." (Leite (Illumina) Tr. 2073-74).

Response to Finding No. 6096:

Respondents have no specific response.

6097. When Dr. Leite first joined Illumina, he was responsible for marketing within the Oncology Division, which included the "design of new diagnostic products for what was then a fairly nascent division of Illumina, which was the Oncology Business Unit." (Leite (Illumina) Tr. 2074). In this role, Dr. Leite and the team were "tasked with developing product specifications and product requirements for a whole new generation of diagnostic tests that relied on the Illumina platform," including the TST-170 and TSO-500 oncology selection tests. (Leite (Illumina) Tr. 2074-75).

Response to Finding No. 6097:

Respondents have no specific response.

6098. As part of Dr. Leite's marketing responsibilities early in his employment at Illumina, he was responsible for the TST-170, TSO-500, and a test called Praxis. (Leite (Illumina) Tr. 2076). With respect to the TSO-500, Dr. Leite was responsible for "designing or setting the specifications for the test, securing feedback from physicians who would likely be willing to use our tests, to get a sense for customer requirements, and then to work with the development team to ensure that those requirements were being met, and if any compromises in developments had to be made, how those could be achieved and what impact it would have." (Leite (Illumina) Tr. 2076). Dr. Leite was also responsible for the commercialization strategy. (Leite (Illumina) Tr. 2076).

Response to Finding No. 6098:

Respondents have no specific response.

6099. As part of his work related to the TSO-500, Dr. Leite had to know "pretty much everything" about the test, "including its expected performance, how it differentiates from other similar tests in the market, how it differentiates from the alternative if one were not to use a next-generation sequencing platform, and most importantly, how a physician is likely to make treatment decisions based on the test." (Leite (Illumina) Tr. 2076-77).

Response to Finding No. 6099:

Respondents have no specific response.

6100. Dr. Leite changed positions at Illumina and moved to the Business Development Group, where he had various titles, including Vice President of Strategic Partnerships and Vice President of Clinical Business Development. (Leite (Illumina) Tr. 2079-2080). In his role as Vice President of Clinical Business Development, Dr. Leite's responsibilities "shifted

from marketing of the Oncology Division products to the securing of collaborations and partnerships with industry partners, including other IVD companies and pharmaceutical companies." (Leite (Illumina) Tr. 2080).

Response to Finding No. 6100:

Respondents have no specific response.

6101. As part of securing those collaborations and partnerships, Dr. Leite's responsibilities included negotiations collaboration agreements, research activities, co-development agreements, as well as assisting in the development of companion diagnostic tests. (Leite (Illumina) Tr. 2080-81). Moreover, Dr. Leite was responsible for negotiating co-development or collaboration agreements with IVD companies that were focused on the development of in vitro diagnostics that were sold to hospitals and physicians directly. (Leite (Illumina) Tr. 2081). With these agreements, Illumina provided "access to [Illumina's] IVD sequencing instruments and those companies then validat[ed] their assays on [Illumina's] instruments, as well as securing quality agreements" and "supply agreements that continue to supply them during their development period"; these are commonly referred to as "IVD agreements" at Illumina. (Leite (Illumina) Tr. 2081).

Response to Finding No. 6101:

Respondents have no specific response.

6102. [redacted] (Leite (Illumina) Tr. 2097-98 (*in camera*)).

Response to Finding No. 6102:

Respondents have no specific response.

6103. John Leite was a business development lead for Illumina's PGDx partnership. (PX7093 (Young (Illumina) Dep. at 29)).

Response to Finding No. 6103:

Respondents have no specific response.

6104. Mr. Leite interacted with PGDx on Illumina's PGDx partnership. (PX7093, Young (Illumina) Dep. at 29-30).

Response to Finding No. 6104:

Respondents have no specific response except to note that Dr. Leite's title is "Dr.".

6105. Mr. Leite was the lead for Illumina's IVD partnership with Roche. (PX7093, Young (Illumina) Dep. at 26).

Response to Finding No. 6105:

Respondents have no specific response except to note that Dr. Leite's title is "Dr.".

6106. When negotiating with oncology therapy selection test developers, Dr. Leite testified at trial that "the ability to maximize penetration into the oncology market was always a consideration. As part of our strategy, we considered the value of inclusion of partners that were developing solutions close to ours. We considered a term called 'cannibalization' – in other words, what would be the sales of Illumina TSO-500 in the absence of these partners versus the presence of these partners – to try and decide at least a framework for summing up what the value of that partnership should be." (Leite (Illumina) Tr. 2084-85).

Response to Finding No. 6106:

Respondents have no specific response.

B. EXPERT WITNESSES WHO TESTIFIED IN TRIAL DEPOSITIONS

1. Dr. Fiona Scott Morton

6107. Dr. Fiona Scott Morton has been a professor at the Yale School of Management for approximately twenty years. (PX7138 (Scott Morton Trial Dep. at 8-10)).

Response to Finding No. 6107:

Respondents have no specific response.

6108. Dr. Scott Morton is a senior consultant with Charles River Associates and has held this position since 2013. (PX7138 (Scott Morton Trial Dep. at 8, 11-12)).

Response to Finding No. 6108:

Respondents have no specific response.

6109. Dr. Scott Morton earned a B.A. in economics from Yale College and a Ph.D. in economics from the Massachusetts Institute of Technology. (PX7138 (Scott Morton Trial Dep. at 9)).

Response to Finding No. 6109:

Respondents have no specific response.

6110. Dr. Scott Morton's primary field of academic research is industrial organization and is an empirical economist that uses data to study firms, markets, and competition. (PX7138 (Scott Morton Trial Dep. at 9)).

Response to Finding No. 6110:

Respondents have no specific response.

6111. Dr. Scott Morton has been a professor at the Stanford Graduate School of Business, University of Chicago Booth School of Business, and Yale School of Management. (PX7138 (Scott Morton Trial Dep. at 9-10)).

Response to Finding No. 6111:

Respondents have no specific response.

6112. Dr. Scott Morton was the chief economist in the Department of Justice Antitrust Division, where she supervised approximately fifty Ph.D. economists on antitrust matters and oversaw "many dozens" of merger matters requiring some analysis. (PX7138 (Scott Morton Trial Dep. at 10-11)).

Response to Finding No. 6112:

Respondents have no specific response.

6113. As a senior consultant with Charles River Associates, Dr. Scott Morton has engaged in matters involving healthcare industries, such as pharmaceuticals, biologics, insurance, as well as some telecommunications and digital work. (PX7138 (Scott Morton Trial Dep. at 12)).

Response to Finding No. 6113:

Respondents have no specific response, except to note that Dr. Scott Morton is not an expert in MCED tests, clinical trials, any field of chemistry or biological studies, cancer screening technologies, regulatory approval, payor reimbursement, commercial contracts, auditing or law. (PFF ¶¶ 2058–2063.)

6114. During her time at DOJ and Charles River Associates, Dr. Scott Morton has evaluated mergers that she concluded would not raise competition concerns as well as those that she concluded would raise competition concerns. (PX7138 (Scott Morton Trial Dep. at 12-13)).

Response to Finding No. 6114:

Respondents have no specific response.

6115. Dr. Scott Morton has been accepted as an economic expert witness in previous matters and has testified approximately half a dozen times at trial. (PX7138 (Scott Morton Trial Dep. at 13)).

Response to Finding No. 6115:

Respondents have no specific response.

6116. Dr. Scott Morton belongs to the American Economic Association, as well as the National Bureau of Economic Research. (PX7138 (Scott Morton Trial Dep. at 14)).

Response to Finding No. 6116:

Respondents have no specific response.

2. Dr. Dov Rothman

6117. [redacted] (PX7140 (Rothman Trial Dep. at 7-8); PX6092 (Rothman Rebuttal Report) ¶1 (*in camera*)).

Response to Finding No. 6117:

Respondents have no specific response.

6118. [redacted] (PX7140 (Rothman Trial Dep. at 7); PX6092 (Rothman Rebuttal Report) ¶1 (*in camera*)).

Response to Finding No. 6118:

Respondents have no specific response.

6119. [redacted] (PX6092 (Rothman Rebuttal Report) ¶2 (*in camera*)).

Response to Finding No. 6119:

Respondents have no specific response except to note that Dr. Rothman testified that he does not have any prior experience analyzing the efficiencies of vertical mergers (PX7140 (Rothman Trial Dep. at 42.) Dr. Rothman is not an expert in FDA approval, (PX7140 (Rothman Trial Dep. at 42–43); payer reimbursement, (PX7140 (Rothman Trial Dep. at 45); medical

technology risksharing agreements, (PX7140 (Rothman Trial Dep. at 45–46); medical device collaborations, (PX7140 (Rothman Trial Dep. at 46); [redacted]

6120. [redacted] (PX6092 (Rothman Rebuttal Report) ¶2 (*in camera*)).

Response to Finding No. 6120:

The proposed finding is inaccurate and misleading without additional context. Dr. Rothman testified that he had only previously served as a testifying expert in three merger litigation matters, none of which involved a healthcare merger or a vertical merger. (PX7140 (Rothman Trial Dep. at 41-42).)

6121. Dr. Rothman has previously served as an expert in other antitrust matters "involving mergers, joint conduct, [and] unilateral conduct." (PX7140 (Rothman Trial Dep. at 9)). As an expert in previous matters, Dr. Rothman "evaluated competitive effects as well as efficiencies." (PX7140 (Rothman Trial Dep. at 9)).

Response to Finding No. 6121:

The proposed finding is inaccurate and misleading without additional context. Dr. Rothman testified he had only previously served as a testifying expert in three merger litigation matters, which all involved the chemicals and consumer product industries, and that he has never testified in a healthcare merger case. (Rothman Trial Dep. at 10, 41) Dr. Rothman testified that he has never testified in any merger litigation where the transaction being challenged was a vertical acquisition or merger. (PX7140 (Rothman Trial Dep. at 42.)

In the past, Dr. Rothman has offered opinions for which he lacks the requisite expertise, which has led courts, including this court, to find his economic analysis to be flawed. *See, e.g.,* Initial Decision at 91, *In re Altria Group, Inc. & JUUL Labs, Inc.*, No. 9393 (F.T.C. Feb. 23, 2022) ("Dr. Rothman's post-Transaction HHI calculations are not economically sound"); *Aya*

Healthcare Servs., Inc. v. AMN Healthcare, Inc., 2020 WL 3414662, at *4 (S.D. Cal. June 22, 2020) ("Dr. Rothman's study allegedly showing supracompetitive prices is seriously flawed," based on a "bare assertion," and devoid of any "economic analysis"); *Aya Healthcare Sers., Inc. v. AMN Healthcare, Inc.*, 2020 WL 2553181, at *18 (S.D. Cal. May 20, 2020) (Dr. Rothman's analysis is "unreliable under the *Daubert* standard and of marginal relevance"), *aff'd* 9 F.4th 1102 (9th Cir. 2021); *Evonik*, 436 F. Supp. 3d at 319 & n.33 (Dr. Rothman's product and geographic markets are "ill-conceived" and his calculation of a GUPPI is "unreliable" and inapplicable to the industry at issue).

6122. Dr. Rothman has "served as an expert on a number of matters in the healthcare industry, matters involving commercial health insurers, hospitals, physicians, [and] pharmaceuticals." (PX7140 (Rothman Trial Dep. at 9)). Outside of healthcare, Dr. Rothman has served as an expert in antitrust matters involving the "agriculture, high-tech, [and] consumer electronics" industries. (PX7140 (Rothman Trial Dep. at 9)).

Response to Finding No. 6122:

The proposed finding is inaccurate and misleading without additional context. Dr. Rothman testified he had only previously served as a testifying expert in three merger litigation cases, all of which involved the chemicals and consumer product industries, and that he has never testified in a healthcare merger case. (Rothman Trial Dep. at 10, 41.) Dr. Rothman testified that he has never testified in any merger litigation where the transaction being challenged was a vertical acquisition or merger. (Rothman Trial Dep. at 42.) Dr. Rothman is not an expert in FDA approval, (PX7140 (Rothman Trial Dep. at 42–43); payer reimbursement, (PX7140 (Rothman Trial Dep. at 45); medical technology risksharing agreements, (PX7140 (Rothman Trial Dep. at 45–46); medical device collaborations, (PX7140 (Rothman Trial Dep. at 46); [redacted]

In the past, Dr. Rothman has offered opinions for which he lacks the requisite expertise, which has led courts, including this court, to find his economic analysis to be flawed. *See, e.g.,* Initial Decision at 91, *In re Altria Group, Inc. & JUUL Labs, Inc.*, No. 9393 (F.T.C. Feb. 23, 2022) ("Dr. Rothman's post-Transaction HHI calculations are not economically sound"); *Aya Healthcare Servs., Inc. v. AMN Healthcare, Inc.*, 2020 WL 3414662, at *4 (S.D. Cal. June 22, 2020) ("Dr. Rothman's study allegedly showing supracompetitive prices is seriously flawed," based on a "bare assertion," and devoid of any "economic analysis"); *Aya Healthcare Sers., Inc. v. AMN Healthcare, Inc.*, 2020 WL 2553181, at *18 (S.D. Cal. May 20, 2020) (Dr. Rothman's analysis is "unreliable under the *Daubert* standard and of marginal relevance"), *aff'd* 9 F.4th 1102 (9th Cir. 2021); *Evonik*, 436 F. Supp. 3d at 319 & n.33 (Dr. Rothman's product and geographic markets are "ill-conceived" and his calculation of a GUPPI is "unreliable" and inapplicable to the industry at issue).

6123. [redacted] (PX7140 (Rothman Trial Dep. at 9-10); PX6092 (Rothman Rebuttal Report) ¶2 (*in camera*)).

Response to Finding No. 6123:

Respondents have no specific response except to note that Dr. Rothman testified that he had only previously served as a testifying expert in three merger litigation matters, none of which involved a healthcare merger or a vertical merger. (PX7140 (Rothman Trial Dep. at 41-42.)

In the past, Dr. Rothman has offered opinions for which he lacks the requisite expertise, which has led courts, including this court, to find his economic analysis to be flawed. *See, e.g.,* Initial Decision at 91, *In re Altria Group, Inc. & JUUL Labs, Inc.*, No. 9393 (F.T.C. Feb. 23, 2022) ("Dr. Rothman's post-Transaction HHI calculations are not economically sound"); *Aya Healthcare Servs., Inc. v. AMN Healthcare, Inc.*, 2020 WL 3414662, at *4 (S.D. Cal. June 22,

2020) ("Dr. Rothman's study allegedly showing supracompetitive prices is seriously flawed," based on a "bare assertion," and devoid of any "economic analysis"); *Aya Healthcare Sers., Inc. v. AMN Healthcare, Inc.*, 2020 WL 2553181, at *18 (S.D. Cal. May 20, 2020) (Dr. Rothman's analysis is "unreliable under the *Daubert* standard and of marginal relevance"), *aff'd* 9 F.4th 1102 (9th Cir. 2021); *Evonik*, 436 F. Supp. 3d at 319 & n.33 (Dr. Rothman's product and geographic markets are "ill-conceived" and his calculation of a GUPPI is "unreliable" and inapplicable to the industry at issue).

6124. Dr. Rothman has previously served as an expert evaluating efficiencies in antitrust matters and testified about efficiencies in three antitrust matters in the chemical and consumer products industries. (PX7140 (Rothman Trial Dep. at 10)).

Response to Finding No. 6124:

Respondents have no specific response except to note that Dr. Rothman testified that he has never served as a testifying expert in a healthcare merger case or in a case involving a vertical acquisition or merger. (PX7140 (Rothman Trial Dep. at 41-42.)

In the past, Dr. Rothman has offered opinions for which he lacks the requisite expertise, which has led courts, including this court, to find his economic analysis to be flawed. *See, e.g.,* Initial Decision at 91, *In re Altria Group, Inc. & JUUL Labs, Inc.*, No. 9393 (F.T.C. Feb. 23, 2022) ("Dr. Rothman's post-Transaction HHI calculations are not economically sound"); *Aya Healthcare Servs., Inc. v. AMN Healthcare, Inc.*, 2020 WL 3414662, at *4 (S.D. Cal. June 22, 2020) ("Dr. Rothman's study allegedly showing supracompetitive prices is seriously flawed," based on a "bare assertion," and devoid of any "economic analysis"); *Aya Healthcare Sers., Inc. v. AMN Healthcare, Inc.*, 2020 WL 2553181, at *18 (S.D. Cal. May 20, 2020) (Dr. Rothman's analysis is "unreliable under the *Daubert* standard and of marginal relevance"), *aff'd* 9 F.4th 1102 (9th Cir. 2021); *Evonik*, 436 F. Supp. 3d at 319 & n.33 (Dr. Rothman's product and

geographic markets are "ill-conceived" and his calculation of a GUPPI is "unreliable" and inapplicable to the industry at issue).

6125. As an assistant professor at Columbia University, Dr. Rothman taught a course on quantitative research methods as well as a course on healthcare financial management. (PX7140 (Rothman Trial Dep. at 8)). In addition, Dr. Rothman taught at Harvard University, including a course on the economics of merger analysis. (PX7140 (Rothman Trial Dep. at 8-9)).

Response to Finding No. 6125:

Respondents have no specific response except to note that Dr. Rothman testified that he has never taught any courses about the FDA approval process. (PX7140 (Rothman Trial Dep. at 43.)

6126. Dr. Rothman has published work in various journals, including *Antitrust Law Journal*, *Journal of Competition Law & Economics*, *Journal of Health Economics*, among others. (PX7140 (Rothman Trial Dep. at 10-11); *see also* PX6092 (Rothman Rebuttal Report) ¶3 (*in camera*)). In addition, Dr. Rothman serves as a senior editor of the Antitrust Law Journal. (PX7140 (Rothman Trial Dep. at 11)).

Response to Finding No. 6126:

Respondents have no specific response except to note that Dr. Rothman testified that he has never published anything in any peer-reviewed publications about the assessment of efficiencies in vertical mergers. (PX7140 (Rothman Trial Dep. at 42.)

6127. In addition to his work as an expert, Dr. Rothman has "worked as a consultant on a range of matters on behalf of the DOJ, the FTC, as well as private parties." (PX7140 (Rothman Trial Dep. at 11)).

Response to Finding No. 6127:

The proposed fact is misleading without additional context. Dr. Rothman testified that he has never served as a testifying expert in a healthcare merger case or in a case involving a vertical acquisition or merger. (PX7140 (Rothman Trial Dep. at 41-42.)

3. Dr. Amol Navathe

6128. Dr. Amol Navathe is a faculty member at the University of Pennsylvania School of Medicine and at The Wharton School as well as a staff physician and core investigator at the Philadelphia VA Medical Center. (PX7139 (Navathe Trial Dep. at 7)). Dr Navathe is an affiliate of the Analysis Group, where he does expert witness work in conjunction with the organization. (PX7139 (Navathe Trial Dep. at 13)).

Response to Finding No. 6128:

Respondents have no specific response.

6129. As part of his employment at the University of Pennsylvania School of Medicine and the Wharton School, Dr. Navathe has teaching responsibilities, including teaching courses in healthcare reform, evaluating healthcare programs and policies, as well as a number of clinical responsibilities teaching medical residents and students on the clinical wards. (PX7139 (Navathe Trial Dep. at 7-8)). Dr. Navathe has taught courses that cover material relating to the FDA approval process, the evidentiary requirements for FDA approval, reimbursement by public and private payers. (PX7139 (Navathe Trial Dep. at 8)).

Response to Finding No. 6129:

Respondents have no specific response except to note that Dr. Navathe is not an expert on FDA evaluation of MCED tests, lacks experience on subjects relevant to concluding that the Transaction will not accelerate payor reimbursement and approval of Galleri, does not have any experience in obtaining FDA approval for any product, has never built a team to seek payor coverage for a medical device or analyzed a company's ability to get payor coverage and does not have any experience with entering into risk sharing agreements with regard to a medical diagnostic test. (PFF ¶¶ 2140-48.)

6130. Dr. Navathe's field of academic research is focused on health economics, including "three core domains": (1) "the impact of healthcare programs and policies on patient outcomes, access to care, access to technologies, patient outcomes, healthcare costs, and a number of other outcomes"; (2) working "collaboratively with health systems and health insurance companies, particularly private insurers, to design new interventions that are used to influence clinical decision-making"; and (3) utilizing "machine learning and predictive analytic techniques to study clinical decision-making" as well as studying new technologies that use these types of machine learning types of algorithms and their impact in clinical decision-making. (PX7139 (Navathe Trial Dep. at 8-9)).

Response to Finding No. 6130:

Respondents have no specific response except to note that Dr. Navathe is not an expert on FDA evaluation of MCED tests, lacks experience on subjects relevant to concluding that the Transaction will not accelerate payor reimbursement and approval of Galleri, does not have any experience in obtaining FDA approval for any product, has never built a team to seek payor coverage for a medical device or analyzed a company's ability to get payor coverage and does not have any experience with entering into risk sharing agreements with regard to a medical diagnostic tests. (PFF ¶¶ 2140-48.)

6131. Some of Dr. Navathe's research has related to value-based payment models, which are payments models involving the "final payment amount in reference to the value, in other words, in terms of the patient outcome, the quality, the patient experience or a number of other measures that are intended to assess the quality and the value of the service or product delivered." (PX7139 (Navathe Trial Dep. at 9-10)).

Response to Finding No. 6131:

Respondents have no specific response.

6132. Some of Dr. Navathe's research has related to reimbursement for medical devices by public payers. (PX7139 (Navathe Trial Dep. at 10-11)). Dr. Navathe's research has "examined the implications of the vast amounts of new types of data that have become available to algorithms, including detailed clinical data . . . that's available, for example, in an electronic health record, and the implications for devices that use machine learning algorithms to interpret this data" as well as providing input to clinicians regarding making healthcare decisions that ultimately affect patients. (PX7139 (Navathe Trial Dep. at 11-12).

Response to Finding No. 6132:

Respondents have no specific response except to note that Dr. Navathe is not an expert on FDA evaluation of MCED tests, lacks experience on subjects relevant to concluding that the Transaction will not accelerate payor reimbursement and approval of Galleri, does not have any experience in obtaining FDA approval for any product, has never built a team to seek payor coverage for a medical device or analyzed a company's ability to get payor coverage and does

not have any experience with entering into risk sharing agreements with regard to a medical diagnostic tests. (PFF ¶¶ 2140-48.)

6133. Dr Navathe's research has considered the type of evidence that the FDA may consider in approving medical diagnostics. (PX7139 (Navathe Trial Dep. at 12).

Response to Finding No. 6133:

Respondents have no specific response except to note that Dr. Navathe is not an expert on FDA evaluation of MCED tests, lacks experience on subjects relevant to concluding that the Transaction will not accelerate payor reimbursement and approval of Galleri, does not have any experience in obtaining FDA approval for any product, has never built a team to seek payor coverage for a medical device or analyzed a company's ability to get payor coverage and does not have any experience with entering into risk sharing agreements with regard to a medical diagnostic tests. (PFF ¶¶ 2140-48.)

6134. Dr. Navathe has published over one hundred peer-reviewed articles, including articles published in Science, "which is widely considered to be the top science journal," the New England Journal of Medicine, the Journal of the American Medical Association, the British Medical Journal, the Annals of Internal Medicine, as well as Health Affairs, "which is the top health policy journal." (PX7139 (Navathe Trial Dep. at 12-13)).

Response to Finding No. 6134:

Respondents have no specific response.

6135. Dr. Navathe is the cofounder of a healthcare technology company called Embedded Healthcare, which uses insights from behavioral science and behavioral economics and psychology to design interventions that health insurance companies and health systems can use at the point of care to improve clinical decision-making. (PX7139 (Navathe Trial Dep. at 13)).

Response to Finding No. 6135:

Respondents have no specific response.

6136. Dr. Navathe is a commissioner of the Medicare Payment Advisory Commission (MedPAC) and has served in this role since 2018. (PX7139 (Navathe Trial Dep. at 14)). MedPAC is a nonpartisan agency of the U.S. Congress that works directly with the Senate Finance Committee, the House Ways and Means Committee, and the House Energy and Commerce

Committee on all aspects of Medicare policy, providing neutral recommendations from a political perspective based on data analysis and the best available evidence to Congress as well as providing recommendations directly to the CMS. (PX7139 (Navathe Trial Dep. at 14).

Response to Finding No. 6136:

Respondents have no specific response.

6137. Dr. Navathe has consulting experience related to seeking reimbursement for medical products. (PX7139 (Navathe Trial Dep at 15)). Dr. Navathe "worked extensively with manufacturers to help develop market access plans and strategies" to approach payers, including private payers, "to secure reimbursement" as well as to "structure a variety of different types of value-based or outcome-based or risk-based types of contracts." (PX7139 (Navathe Trial Dep. at 16)).

Response to Finding No. 6137:

Respondents have no specific response except to note that Dr. Navathe does not have any experience in obtaining FDA approval for any product, has never built a team to seek payor coverage for a medical device or analyzed a company's ability to get payor coverage and does not have any experience with entering into risk sharing agreements with regard to a medical diagnostic tests. (PFF ¶¶ 2140-48.)

6138. Dr. Navathe has professional experience working with the FDA. (PX7139 (Navathe Trial Dep. at 16-17). Dr. Navathe was a senior program manager and medical officer at the Department of Health and Human Services in the Office of the Secretary from 2009 to 2011, including leading a $1.1 billion comparative effectiveness research program that was funded through the Recovery Act. (PX7139 (Navathe Trial Dep. at 17)). In that work, Dr. Navathe testified that he "worked extensively with the FDA on the development and direct investment of the federal government in data infrastructure to support comparative effectiveness and to also support real-world evidence research that could be utilized by the FDA." (PX7139 (Navathe Trial Dep. at 17)). Further, Dr. Navathe "worked collaboratively with the FDA on a project called the Mini-Sentinel project" in which HHS worked directly with private payers to set up a multipayer claims database to support the type of post-market surveillance after FDA approval of medical products. (PX7139 (Navathe Trial Dep. at 17)).

Response to Finding No. 6138:

Respondents have no specific response except to note that Dr. Navathe is not an expert on FDA evaluation of MCED tests, he lacks expertise on subjects relevant to concluding that the

Transaction will not accelerate payer reimbursement and approval of Galleri, he does not have any experience in obtaining FDA approval for any product, including building and supervising a team seeking FDA approval or analyzing a company's capability to get FDA approval and he does not have any experience in seeking premarket authorization from the FDA for any product. (PFF ¶¶ 2140-43.)

6139. Dr Navathe's work at HHS related to the evidentiary requirements for premarket approval from the FDA. (PX7139 (Navathe Trial Dep. at 17-18)).

Response to Finding No. 6139:

Respondents have no specific response except to note that Dr. Navathe does not have any experience in seeking premarket authorization from the FDA for any product.

6140. Dr. Navathe has a bachelor's of science in electrical engineering and economic systems from Stanford University, a medical doctorate degree from the University of Pennsylvania School of Medicine; and a Ph.D. in healthcare management and economics from The Wharton School at the University of Pennsylvania. (PX7139 (Navathe Trial Dep. at 6-7)).

Response to Finding No. 6140:

Respondents have no specific response.

C. SELECT WITNESSES WHO TESTIFIED BY DEPOSITION AND/OR INVESTIGATIONAL HEARING ONLY

1. Brian Blanchett

6141. Mr. Brian Blanchett is a Senior Director of Finance at Illumina and has been in this role since joining the company in July 2019. (PX7067 (Blanchett (Illumina) IHT at 5, 15)).

Response to Finding No. 6141:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

6142. As the Senior Director of Finance at Illumina, Mr. Blanchett's responsibilities include "assist[-ing] the corporate and business development organization in doing financial analysis" as well as rolling up the consolidated financial results of the company and reporting those to executives. (PX7067 (Blanchett (Illumina) IHT at 19)).

Response to Finding No. 6142:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (See Resps.' Post-Trial Br. at 275–76.)

2. David Daly

6143. Mr. David Daly is the President and Chief Operating Officer of Singular Genomics ("Singular"), which he joined in the Spring of 2021. (PX7109 (Daly (Singular Genomics) Dep. at 9, 13)).

Response to Finding No. 6143:

The proposed finding is not supported by the cited evidence. The cited pages of Mr. Daly's deposition transcript do not specify when in 2021 Mr. Daly joined Singular Genomics. (PX7109 (Daly (Singular Genomics) Dep. at 9, 13).)

6144. As Singular's President and COO, Mr. Daly is responsible for the build-out of the company's commercial organization and overall operations. (PX7109, Daly (Singular Genomics) Dep. at 13)).

Response to Finding No. 6144:

Respondents have no specific response.

6145. Prior to his role as President and COO of Singular Genomics, Mr. Daly was the CEO and board member of Thrive Earlier Detection ("Thrive"). (PX7109, Daly (Singular Genomics) Dep. at 13-14).

Response to Finding No. 6145:

Respondents have no specific response.

6146. Mr. Daly was the CEO of Thrive between August 2019 and January 2021. (PX7109, Daly (Singular Genomics) Dep. at 14).

Response to Finding No. 6146:

The proposed finding is not supported by the cited evidence. Pages 9 and 15 of Mr. Daly's deposition transcript, however, appear to support the proposed finding. (PX7109 (Daly (Singular Genomics) Dep. at 9, 15).)

6147. As Thrive's CEO, Mr. Daly's responsibilities include running the company, interfacing with the development team to see the CancerSEEK test through its various stages of development, and he was "directly involved" with the acquisition process of Thrive by Exact Sciences. (PX7109, Daly (Singular Genomics) Dep. at 14).

Response to Finding No. 6147:

The proposed finding is inaccurate and misleading without additional context. The proposed finding is phrased in the present tense even though Mr. Daly testified (and Complaint Counsel has proposed in Findings 6143 and 6146) that he is no longer Thrive's CEO, but instead Singular Genomics' President and CEO. (PX7109, Daly (Singular Genomics) Dep. at 9, 13-14).)

6148. Prior to working at Thrive, Mr. Daly was the Senior Vice President and General Manager of the Americas business unit at Illumina. (PX7109, Daly (Singular Genomics) Dep. at 15).

Response to Finding No. 6148:

Respondents have no specific response.

6149. As Illumina's SVP and General Manager of the Americas business unit, Mr. Daly was responsible for overseeing all commercial operations, including sales, marketing, customer service, and field service support. (PX7109, Daly (Singular Genomics) Dep. at 15).

Response to Finding No. 6149:

The proposed finding is inaccurate, incomplete and misleading without additional context. Mr. Daly testified that his position as "senior vice president and general manager of the Americas business unit" at Illumina entailed "[o]verseeing all commercial operations **for the Americas region**." (PX7109, Daly (Singular Genomics) Dep. at 15) (emphasis added).)

6150. Mr. Daly worked at Illumina between November 2017 and August 2019, and at all times was serving in the role of SVP and General Manager of the Americas business unit. (PX7109 (PX7109, Daly (Singular Genomics) Dep. at 15).

Response to Finding No. 6150:

Respondents have no specific response.

6151. [redacted]

[redacted] (PX7109, Daly (Singular Genomics) Dep. at 107) (*in camera*)).

Response to Finding No. 6151:

The proposed finding is incomplete and misleading. [redacted]

6152. [redacted] (PX7109, Daly (Singular Genomics) Dep. at 99-100) (*in camera*).

Response to Finding No. 6152:

The proposed finding is incomplete and misleading for the reasons identified in Respondents' responses to CCFF ¶ 6151, which Respondents incorporate herein.

6153. [redacted] (PX7109, Daly (Singular Genomics) Dep. at 101) (*in camera*) (emphasis added)).

Response to Finding No. 6153:

The proposed finding is incomplete and misleading without additional context. Immediately prior to the quoted testimony, Mr. Daly testified that he [redacted] and, when asked, [redacted] responded, [redacted] (PX7109, Daly (Singular Genomics) Dep. at 100-01) (*in camera*).) Immediately after the quoted testimony, Mr. Daly testified, [redacted] (PX7109, Daly (Singular Genomics) Dep. at 102) (*in camera*).)

3. John Fesko

6154. Mr. John Fesko currently serves as Natera's Chief Business Officer and has been in this role since 2019. (PX7053, Fesko (Natera) IHT at 5-6, 15).

Response to Finding No. 6154:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6155. As Chief Business Officer, Mr. Fesko has responsibilities relating to Natera's sales, pricing, and strategic planning. (PX7053, Fesko (Natera) IHT at 16). In addition, Mr. Fesko manages reimbursement, payer contracting, pharma services efforts, and Natera's international business. (PX7053, Fesko (Natera) IHT at 15-16). Furthermore, Mr. Fesko oversees Natera's "partnerships, several of which are focused on research developments, and the acquisition of new technologies, either, you know, outright or through licensing, or partnership also involves research and development. So I work closely with the R&D group at Natera." (PX7053, Fesko (Natera) IHT at 15-16).

Response to Finding No. 6155:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6156. Mr. Fesko joined Natera at the beginning of 2014 as Director of Business Development. (PX7053, Fesko (Natera) IHT at 14-15).

Response to Finding No. 6156:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6157. As Natera's Director of Business Development, Mr. Fesko "was responsible for most aspects of the company's partnering with third parties." Mr. Fesko would "set up partnerships, evaluate partnerships, [and] negotiate partnerships across the organization." (PX7053, Fesko (Natera) IHT at 15).

Response to Finding No. 6157:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6158. Immediately prior to Natera, Mr. Fesko worked for Roche as the Director of Business Development. (PX7053, Fesko (Natera) IHT at 12).

Response to Finding No. 6158:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6159. At Roche, Mr. Fesko was responsible for technology evaluation, strategy, and partnership deals with pharmaceutical companies working specifically with molecular diagnostic groups. (PX7053, Fesko (Natera) IHT at 13).

Response to Finding No. 6159:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-

Trial Br. at 275–76.) The proposed finding also relies on testimony that appears not only page 13, but also page 12 of Mr. Fesko's IH transcript. (PX7053, Fesko (Natera) IHT at 12-13).)

6160. Prior to working at Roche, Mr. Fesko held positions at Novartis, NPM Capital, and an oncology diagnostics company called Invivoscribe. (PX7053, Fesko (Natera) IHT at 12).

Response to Finding No. 6160:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6161. At Invivoscribe, Mr. Fesko worked on partnerships, sales, ran diagnostic tests within their lab, conducted research, and manufactured oncology kits. (PX7053, Fesko (Natera) IHT at 13).

Response to Finding No. 6161:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6162. Mr. Fesko studied biochemistry during his undergraduate degree and has an M.B.A. (PX7053, Fesko (Natera) IHT at 11-12).

Response to Finding No. 6162:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

4. Neil Gunn

6163. Mr. Neil Gunn was the President of Roche Sequencing Solutions from January 2016 to March 2021. (PX7043, Gunn (Roche) IHT at 4, 21-22).

Response to Finding No. 6163:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6164. In January 2016, Mr. Gunn became the President of Roche Sequencing. In this role, Mr. Gunn "was responsible for all of the activities from research [] to the commercialization of the products. That would include the quality programs, the regulatory programs, the clinical activities. The products were manufactured by a different part of Roche, and the products were sold by a different part of Roche, so operations and commercial sales activities was not [Mr. Gunn's] responsibility." (PX7043, Gunn (Roche) IHT at 22).

Response to Finding No. 6164:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6165. Mr. Gunn joined Roche Molecular Systems in October 2008 as Head of Business for Roche Molecular Diagnostics. (PX7043, Gunn (Roche) IHT at 18).

Response to Finding No. 6165:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6166. In September 2015, Mr. Gunn transitioned out of the Head of Business for Roche Molecular Diagnostics and into the role of Chief Commercial Officer for Roche Sequencing. (PX7043, Gunn (Roche) IHT at 21).

Response to Finding No. 6166:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6167. As Chief Commercial Officer, Mr. Gunn was "responsible for the lifecycle teams, for the development, [and] the clinical programs." (PX7043, Gunn (Roche) IHT at 21).

Response to Finding No. 6167:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6168. Prior to joining Roche, Mr. Gunn worked at Pall Corporation in a "scientific marketing role and then rose to the position of marketing director[.]" (PX7043, Gunn (Roche) IHT at 13-14).

Response to Finding No. 6168:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6169. Mr. Gunn's specialty role in filtration at Pall Corporation had applications in the clinical oncology space as "the transfusion of blood is a very frequent process in oncology patients, particularly in leukemias, but in all oncology, transfusion of blood is not an unusual practice." (PX7043, Gunn (Roche) IHT at 14-15).

Response to Finding No. 6169:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6170. Mr. Gunn worked at Pall Corporation for 14 years before relocating to San Francisco, California to become the senior director of global marketing for Chiron. (PX7043 (Gunn (Roche) IHT at 15)).

Response to Finding No. 6170:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6171. Mr. Gunn has an undergraduate degree in biology, a master's degree in science, and a Ph.D. in microbiology from the University of Portsmouth. (PX7043, Gunn (Roche) IHT at 13).

Response to Finding No. 6171:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

5. Dr. Nicholas Naclerio

6172. Dr. Nicholas Naclerio is a founding and managing partner of Illumina Ventures, which he joined in 2016. (PX7060, Naclerio (Illumina) IHT at 13-14)).

Response to Finding No. 6172:

The proposed finding is not supported by the cited evidence. Pages 13 and 14 of Dr. Naclerio's **deposition** transcript, however, appear to support the proposed finding. (PX7089 (Naclerio (Illumina) Dep. at 13-14).)

6173. Dr. Naclerio joined Illumina in 2010 by assisting the company in "set[-ting] up a corporate venture fund for them" and then "took on a number of other responsibilities in corporate development [and] corporate strategy." (PX7060, Naclerio (Illumina) IHT at 15)). Dr. Naclerio was the general manager of Illumina's enterprise informatics business unit. (PX7060, Naclerio (Illumina) IHT at 15)). He left Illumina to join Illumina Ventures in 2016. (PX7060, Naclerio (Illumina) IHT at 15-16)).

Response to Finding No. 6173:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6174. When Dr. Naclerio first joined Illumina, his title was Senior Vice President of Corporate and Venture Development. (PX7060, Naclerio (Illumina) IHT at 16)). In this role, Dr. Naclerio managed between a "dozen and two dozen people over time," with one part of the team managing "Illumina's strategic planning process," another part of the team handling "routine business development" such as in-licensing, out-licensing, and supply agreements, and another part of the team was "work[-ing] on venture investments and other corporate transactions." (PX7060, Naclerio (Illumina) IHT at 16)).

Response to Finding No. 6174:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6175. Dr. Naclerio was a "primary person" involved in Illumina's mergers and acquisitions activities, indicating that he and his team "would be the ones to work with lawyers, bankers, accountants" to "effect the transaction, to negotiate the merger agreements," and ensure that due diligence was properly done. (PX7060, Naclerio (Illumina) IHT at 17)).

Response to Finding No. 6175:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6176. Dr. Naclerio "worked with people in R&D and marketing and other parts of the company to put together the strategic planning, you know, strategic plan documents, which would include competitive analysis, so in that regard, we were I would say part of the process of competitive analysis." (PX7060, Naclerio (Illumina) IHT at 19)).

Response to Finding No. 6176:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6177. Dr. Naclerio was involved in Illumina's decision to start Grail, including being involved in "general discussions" as well as "involved in the more specific tactical implementation" of the transaction. (PX7060, Naclerio (Illumina) IHT at 23-24)).

Response to Finding No. 6177:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6178. As a "member of the senior management team," Dr. Naclerio was involved in the decision to spin Grail out of Illumina. (PX7060, Naclerio (Illumina) IHT at 28)).

Response to Finding No. 6178:

The proposed finding relies on IH testimony which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

The proposed finding also is inaccurate, incomplete and misleading without additional context. Dr. Naclerio testified with respect to "the decision to spin GRAIL out" that "it was something that was extensively discussed and debated. I mean, **it wasn't ultimately my decision**, but yes, I was -- I was involved in the discussions." (PX7060, Naclerio (Illumina) IHT at 28) (emphasis added).)

6. Cynthia Perettie

6179. Ms. Cynthia Perettie joined FMI as CEO in 2019 when Roche purchased FMI. (PX7068, Perettie (FMI) IHT at 14, 17-18).

Response to Finding No. 6179:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6180. As CEO of FMI, Ms. Perettie "over[saw] all of the operations within the company. And that includes everything from research through commercialization and anything in between. So all aspects of quality, regulatory, all of that." (PX7068, Perettie (FMI) IHT at 14-15).

Response to Finding No. 6180:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6181. Ms. Perettie joined Roche in May 2017 as Senior Vice President of Global Product Strategy of Oncology and served in that role for two years. (PX7068, Perettie (FMI) IHT at 14).

Response to Finding No. 6181:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6182. As Senior Vice President, Ms. Perettie was responsible for "overseeing the oncology pipeline for Roche [and] all of the associated tasks, from drug development through commercialization for those products around the globe." (PX7068, Perettie (FMI) IHT at 14).

Response to Finding No. 6182:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6183. Immediately prior to joining Roche, Ms. Perettie worked at Genentech as a "project team leader and life cycle leader for Avastin," before becoming the head of Genentech's breast cancer franchise in the U.S. sales and marketing operation; she then would become Genentech's head of oncology globally. (PX7068, Perettie (FMI) IHT at 13).

Response to Finding No. 6183:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6184. At Chiron, Ms. Perettie "did research on antisense, the small genes, small DNA and RNA fragments targeting KDR inflict." (PX7068, Perettie (FMI) IHT at 12).

Response to Finding No. 6184:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6185. After leaving Johns Hopkins, Ms. Perettie worked in the research department at Chiron Corporation before moving over to their marketing team. (PX7068, Perettie (FMI) IHT at 12).

Response to Finding No. 6185:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6186. Ms. Perettie worked at Johns Hopkins University as a research assistant. (PX7068 (Perettie (FMI-Roche) IHT at 11)). As a research assistant, Ms. Perettie was tasked with the "creation of small fragments of DNA that were used as potential therapeutics in ocular and oncology disorders." (PX7068, Perettie (FMI) IHT at 11).

Response to Finding No. 6186:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6187. Ms. Perettie has a bachelor's degree in biochemistry from the State University of New York at Potsdam and an MBA from St. Mary's College of California. (PX7068, Perettie (FMI) IHT at 10-11).

Response to Finding No. 6187:

The proposed finding relies on IH testimony which is hearsay and which Respondents had no opportunity to cross examine and should therefore be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

7. Dr. Bert Vogelstein

6188. Dr. Bert Vogelstein is the Clayton Professor of Oncology and Co-Director of the Ludwig Center for Cancer, Genetics and Therapeutics at the Sidney Kimmel Comprehensive Cancer Center of Johns Hopkins University School of Medicine. (PX7101, Vogelstein (Johns Hopkins University) Dep. at 63-64).

Response to Finding No. 6188:

Respondents have no specific response.

6189. Dr. Vogelstein holds a joint appointment in molecular biology and genetics at the Johns Hopkins University and as an investigator at the Howard Hughes Medical Institute. (PX7101, Vogelstein (Johns Hopkins University) Dep. at 64)).

Response to Finding No. 6189:

Respondents have no specific response.

6190. Dr. Vogelstein previously served as an Assistant Professor of Oncology at Johns Hopkins University. (PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶ 1)).

Response to Finding No. 6190:

Respondents have no specific response.

6191. Dr. Vogelstein submitted a declaration to the FTC dated March 24, 2021. (*See* PX8400 (Vogelstein (Johns Hopkins University) Decl.)).

Response to Finding No. 6191:

Respondents have no specific response except to note that Dr. Vogelstein testified that it was not his purpose in submitting a declaration to take a position on the acquisition of GRAIL by Illumina. (PX7101, Vogelstein (Johns Hopkins University) Dep. at 22.) Dr. Vogelstein also testified that he knows very little about the GRAIL/Illumina transaction. (PX7101, Vogelstein (Johns Hopkins University) Dep. at 23.)

6192. Dr. Vogelstein has devoted his career to researching and understanding the role of genetic alterations in human cancer and he, along with his team, has been credited with a number of scientific breakthroughs in this area. (PX7101, Vogelstein (Johns Hopkins University) Dep. at 64; PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶ 2).

Response to Finding No. 6192:

Respondents have no specific response.

6193. Alongside teams of researchers, Dr. Vogelstein helped discover that "a relatively small number of genes" play a major role in most human cancer types. (PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶ 2).

Response to Finding No. 6193:

Respondents have no specific response except to incorporate their response to CCFF ¶ 362 herein.

6194. Dr. Vogelstein and the group of researchers with whom he works was awarded the international prize from the American Association of Cancer Research for "pioneering the

development of liquid biopsies." (PX7101, Vogelstein (Johns Hopkins University) Dep. at 78-79).

Response to Finding No. 6194:

Respondents have no specific response.

6195. Dr. Vogelstein's lab is currently working on using the genetic alterations responsible for cancer to develop new diagnostic tests to identify cancers earlier and new therapies to treat patients with advanced disease. (PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶ 4).

Response to Finding No. 6195:

Respondents have no specific response.

6196. Dr. Vogelstein's lab is currently developing tests that rely on NGS to find cancer DNA in a small amount of blood or bodily fluids and can be used to detect cancer in asymptomatic individuals, personalize therapies to combat the unique genetic alterations within a tumor, and to monitor cancer's response to treatment. (PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶¶ 4, 6).

Response to Finding No. 6196:

Respondents have no specific response.

6197. Dr. Vogelstein testified in his deposition that his lab "published the first description of cancer genomes, what we called cancer genome landscapes, using an Illumina instrument" in approximately 2009 or 2010. (PX7101 (Vogelstein (Johns Hopkins University) Dep. 61).

Response to Finding No. 6197:

Respondents have no specific response.

6198. Dr. Vogelstein is a co-founder of Thrive Earlier Detection Corp. (PX7101, Vogelstein (Johns Hopkins University) Dep. at 27).

Response to Finding No. 6198:

Respondents have no specific response except to note that Dr. Vogelstein testified that he does not has and has not ever worked for Thrive and that as a consultant for Thrive, he only advised Thrive about scientific issues related to developing a test and that he knows "nothing about the business." (PX7101, Vogelstein (Johns Hopkins University) Dep. at 30.)

6199. Thrive was formed after it acquired a company Dr. Bert Vogelstein co-founded named PapGene. (PX7101, Vogelstein (Johns Hopkins University) Dep. at 28).

Response to Finding No. 6199:

Respondents have no specific response except to note that Dr. Vogelstein testified that he does not has and has not ever worked for Thrive and that as a consultant for Thrive, he only advised Thrive about scientific issues related to developing a test and that he knows "nothing about the business." (PX7101, Vogelstein (Johns Hopkins University) Dep. at 30.)

6200. Thrive has a collaboration agreement with Johns Hopkins University and Howard Hughes Medical Institute that involves sharing research between the organizations. (PX7101, Vogelstein (Johns Hopkins University) Dep. at 37-38).

Response to Finding No. 6200:

Respondents have no specific response.

6201. Thrive's predecessor in the development of the CancerSEEK test, PapGene, first described the screening test in Science magazine in approximately 2016 or 2017. (PX7101, Vogelstein (Johns Hopkins University) Dep. at 40, 46).

Response to Finding No. 6201:

Respondents have no specific response except to note that Dr. Vogelstein also testified, immediately after the source provided, that CancerSEEK is still under development, is not commercially available today, and that he "does not have a good idea" of when it would become commercially available." (PX7101, Vogelstein (Johns Hopkins University) Dep. at 41.)

6202. Dr. Vogelstein testified that his lab has "published so much on liquid biopsies that [they] receive requests from numerous [NGS] companies weekly to try to sell [them] instruments that could be used for liquid biopsies." (PX7101, Vogelstein (Johns Hopkins University) Dep. at 78-79).

Response to Finding No. 6202:

Respondents have no specific response except to note that Dr. Vogelstein also testified that he does not know which individual technique to analyzing blood will be best or adequate for

clinical use for screening for cancer. (PX7101, Vogelstein (Johns Hopkins University) Dep. at 81.)

6203. Dr. Vogelstein testified that "it's to [NGS manufacturer] companies' benefit to contact [them] whenever they have an instrument that they think would be of interest to" Dr. Vogelstein's lab and his lab "would definitely be interested in evaluating such instruments if they met the several criteria" they will need for their research. (PX7101, Vogelstein (Johns Hopkins University) Dep. at 79).

Response to Finding No. 6203:

Respondents have no specific response.

6204. Dr. Vogelstein completed a post-doctorate fellowship at the National Cancer Institute, where he focused on new technologies in molecular biology. (PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶ 1).

Response to Finding No. 6204:

Respondents have no specific response.

6205. Dr. Vogelstein received his undergraduate degree from the University of Pennsylvania, where he graduated *summa cum laude* with distinction in mathematics, and his medical degree from Johns Hopkins University of Medicine. (PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶ 1).

Response to Finding No. 6205:

Respondents have no specific response.

X. APPENDIX B: GALLERI HAS NOT BEEN CLINICALLY SHOWN TO PROVIDE EARLY DETECTION OF MORE THAN 50 CANCERS IN AN ASYMPTOMATIC POPULATION

6206. On the first page of their Pretrial Brief, Respondents claim that "GRAIL has developed an early screening test, Galleri, that can simultaneously screen for more than 50 cancers in asymptomatic patients who have no signs of cancer." (*See* Respondents' Pretrial Brief at 1, Aug. 18, 2021) (Respondents provide no citation for this claim)).

Response to Finding No. 6206:

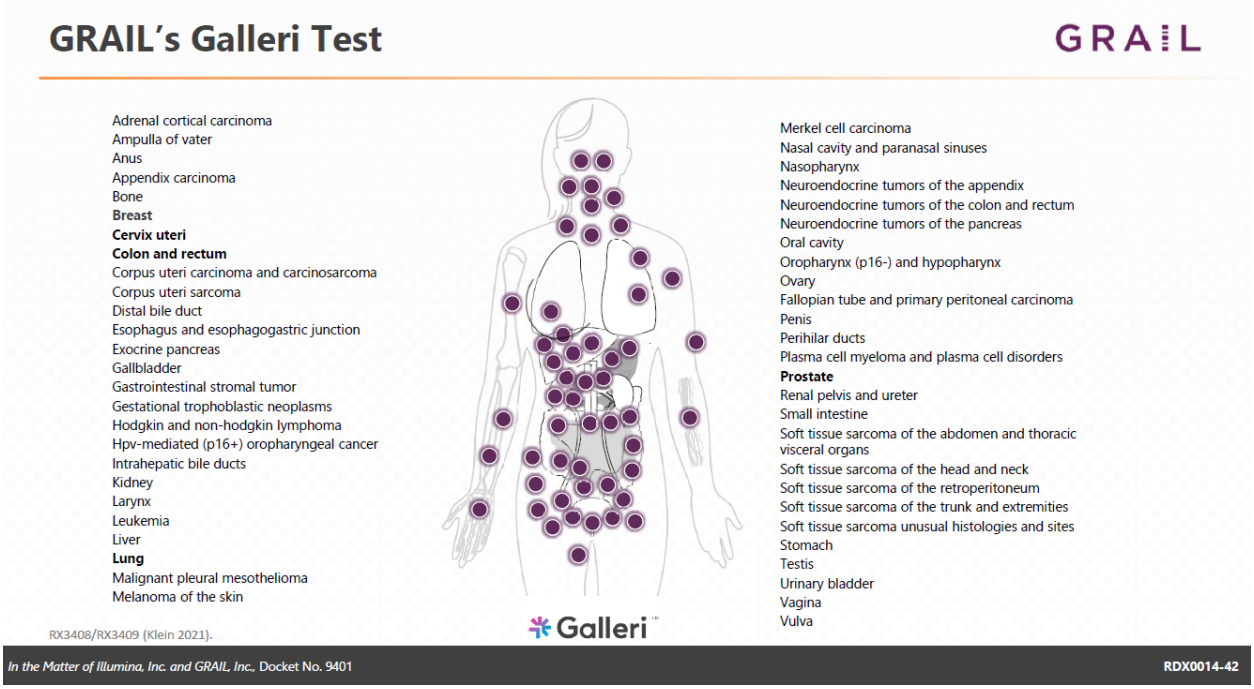
The proposed finding is misleading because of the use of the term "claim". GRAIL has demonstrated that the Galleri test can detect and screen for over 50 types of cancers, over 45 of

which lack recommended screenings. (PFF ¶ 61 (PX0043 (GRAIL) at 97, 5; Ofman (GRAIL) Tr. 3312).)

6207. Galleri has not been clinically shown to be able to detect more than 50 cancers in an asymptomatic population. (*See infra* Section X.B.2 (Grail's CCGA Study Involved Participants Who Had Already Been Diagnosed with Cancer) and Section X.E. (Grail Publicly Claims Only that Galleri Can "Detect a Cancer Signal" for Over Fifty Cancer Types on the Basis of CCGA, Not that Galleri Can "Screen" for Fifty Types of Early-Stage Cancer)).

Response to Finding No. 6207:

The proposed finding is incomplete and misleading. There is ample evidence from multiple clinical trials that the Galleri test can detect many more than seven types of early stage cancers in asymptomatic screening populations. In clinical studies, Galleri has detected over 50 types of cancers, of which 45 do not currently have a recommended screening procedure in the US. (PFF ¶¶ 39, 343, 1296; Bishop (GRAIL) Tr. 1373, 1391; RX3285 (GRAIL) at 1; RX3286 (GRAIL) at 2; RX3287 (GRAIL) at 1; Aravanis (Illumina) Tr. 1894–95, 1902; Cote Tr. 3791). Specifically, the results of the CCGA2 study, published in Annals of Oncology in March 2020, showed that Galleri was capable of detecting more than 50 cancer types at a specificity of 99.3% and a false-positive rate of less than 1% across the more than 50 cancer types. (PFF ¶ 388; RX3430 (Liu et al., 2020) at 1, 10.) Similarly, CCGA3 ultimately reported that GRAIL's Galleri v2 test achieved a specificity of 99.5% across more than 50 cancer types, a false-positive rate of 0.5%, sensitivity of 51.5% for all cancers, and a signal of origin prediction accuracy of 88.7%. (PFF ¶ 392; RX3408 (Klein et al., 2021) at 10; RX3869 (Cote Expert Report) ¶ 144.)



(RDX0014-42.)

Independent analysts and external observers have also concluded that Galleri has been clinically shown to detect 50 types of cancers. For instance, a report on the liquid biopsy market from Cowen notes that GRAIL has "conducted systematic clinical studies" and that Galleri "has been shown to be capable of identifying >50 types of cancers by scanning methylation patterns". (PFF ¶ 717.1; PX2022 (Cowen) at 27).) In addition, one of Complaint Counsel's witnesses, Dr. Cance of the American Cancer Society, testified that Galleri can detect 50 types of cancer. (Cance (ACS) Tr. 633.)

To the extent Complaint Counsel relies on its Proposed Findings in Section X.B.2 and Section X.E (CCFF ¶¶ 6238–46, 6276–82), Respondents also incorporate their responses to those Proposed Findings herein. Respondents further incorporate their responses to CCFF ¶ 133 herein.

6208. Galleri has not been clinically shown to be able to provide "early detection" of more than 50 cancers – even when assessed in a non-screening setting including symptomatic cancer patients. (*See infra* Section X.H. (Grail Has Not Presented Clinical Evidence That Galleri

Can Provide "Early Detection" of More Than 50 Cancer Types, Even in a Non-Screening Setting)).

Response to Finding No. 6208:

The proposed finding is inaccurate, incomplete and misleading. Respondents incorporate their responses to CCFF ¶¶ 133 and 6207 herein. To the extent Complaint Counsel relies on its Proposed Findings in Section X.H (CCFF ¶¶ 6299–344), Respondents also incorporate their responses to those Proposed Findings herein.

6209. [redacted]

Response to Finding No. 6209:

The proposed finding is misleading to the extent the term "claim" is a term of art with respect to FDA approval. GRAIL has demonstrated that the Galleri test can detect and screen for over 50 types of cancers, over 45 of which lack recommended screenings. (PFF ¶ 61 (PX0043 (GRAIL) at 97, 5; Ofman (GRAIL) Tr. 3312).) Respondents incorporate their responses to CCFF ¶¶ 133 and 6207 herein.

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

A. DEFINITIONS & BACKGROUND

1. Cancer Staging

6210. "Stage describes the extent or spread of cancer at the time of diagnosis." (RX3030 at 011 (American Cancer Society, Cancer Facts and Figures 2019)).

Response to Finding No. 6210:

Respondents have no specific response except to note that some cancers do not have a Stage IV and other cancers have alternative staging systems. (RX3030 at 011 (American Cancer Society, Cancer Facts & Figures 2019).) Respondents also incorporate their responses to CCFF ¶¶ 250 and 254 herein.

6211. Cancer is considered to be localized in Stages I-II. (PX0086 at 001 (Grail Press Release: GRAIL Presents Interventional PATHFINDER Study Data at 2021 ASCO Annual Meeting and Introduces Galleri, a Groundbreaking Multi-Cancer Early Detection Blood Test, June 4, 2021) (defining "localized" cancers as "stage I-II").

Response to Finding No. 6211:

Respondents have no specific response except to note that the cited document observes that Galleri has demonstrated the ability to detect more than 50 types of cancer in an observational study. (PX0086 at 001.) Respondents also incorporate their responses to CCFF ¶¶ 250 and 6210 herein.

6212. Cancer is local if it is "confined entirely to the organ or origin." (RX3030 at 023, Table 8 (American Cancer Society, Cancer Facts & Figures 2019)).

Response to Finding No. 6212:

Respondents have no specific response.

6213. By Stage IV, cancer is considered to be distant. (PX0086 at 001 (Grail Press Release: GRAIL Presents Interventional PATHFINDER Study Data at 2021 ASCO Annual Meeting and Introduces Galleri, a Groundbreaking Multi-Cancer Early Detection Blood Test, June 4, 2021) (defining the stages "before distant metastases" as "stage[s] I-III").

Response to Finding No. 6213:

Respondents have no specific response except to note that the cited document observes that Galleri has demonstrated the ability to detect more than 50 types of cancer in an observational study of prospectively collected samples. (PX0086 at 001.) Respondents also incorporate their responses to CCFF ¶¶ 250 and 6210 herein.

6214. Cancer is distant if it "has spread to parts of the body remote from the primary tumor either by direct extension or by discontinuous metastasis to distant organs, tissues, or via the lymphatic system to distant lymph nodes." (RX3030 at 023, Table 8 (American Cancer Society, Cancer Facts & Figures 2019)).

Response to Finding No. 6214:

Respondents have no specific response.

6215. Stage IV cancer is not early-stage cancer. (Ofman (Grail) Tr. 3430).

Response to Finding No. 6215:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 250 and 6210 herein.

6216. "While Stage IV cancer may be treated (resulting in prolongation of life), it is almost always incurable and will eventually result in the death of the patient." (RX3869 (Cote Rebuttal Report) ¶ 31).

Response to Finding No. 6216:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 250 and 6210 herein.

6217. Late-stage cancers are generally easier to detect than early-stage cancers. (Bishop (Grail) Tr. 1429-1430).

Response to Finding No. 6217:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 250 and 6210 herein.

6218. A November 2019 Grail Board of Directors presentation identified [redacted] (PX4172 (Grail) at 050 (Grail, Board of Directors Presentation, Nov. 21, 2019) (*in camera*)).

Response to Finding No. 6218:

The proposed finding is incomplete and misleading to the extent that it suggests that GRAIL refers to both Stages III and IV as "late stage" cancer in all circumstances. The cited Board of Directors presentation [redacted] (PX4172 (Grail) at 050 (Grail Board of Directors Meeting, Nov. 21, 2019) (*in camera*).) Thus, the presentation [redacted] (PX4172 (Grail) at 050 (Grail Board of Directors Meeting, Nov. 21, 2019 (in camera)).) Respondents also note that not all stage three cancers are the same: each stage has subdivisions that "have prognostic importance", and thus "even within a stage, . . . the patients can be subdivided". (Cote Tr. 3732.)

Further, Complaint Counsel chose not to discuss this document at trial, (CC Exhibit Index at 39), or in any deposition, and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents also refer to PFF ¶¶ 89-89.5. Respondents also incorporate their responses to CCFF ¶ 254 herein.

6219. In June 2021, Grail publicly described "clinical stages I-III" as "early [cancer] stages." (RX3041 at 006 (Interim Results of Pathfinder, June 4, 2021)).

Response to Finding No. 6219:

Respondents have no specific response, except to note that the interim PATHFINDER results displayed in RX3041 at 0005 indicated that Galleri detected 13 cancers in clinical stages I-III and 5 cancers with unknown cancer stage or where cancer stage is inapplicable. (RX3041 at 006.) Respondents also incorporate their responses to CCFF ¶¶ 250 and 6210 herein.

2. Early Detection

6220. [redacted] (Rabinowitz (Natera) Tr. 353-4 (*in camera*)).

Response to Finding No. 6220:

Respondents have no specific response.

6221. Early detection of cancer means detecting cancer at earlier stages. (Ofman (Grail) Tr. 3430).

Response to Finding No. 6221:

Respondents have no specific response except to note that Dr. Ofman testified in the cited testimony that GRAIL has demonstrated that the Galleri test can detect and screen for over 50 types of cancers, over 45 of which lack recommended screenings. (Ofman (GRAIL) Tr. 3312.)

6222. One of the most important attributes of a screening test is the ability to detect cancers at relatively early stages. (Conroy (Exact) Tr. 1701; *see also* PX4178 (Grail) at 009, Nephron Healthcare Investment Research, "Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly," Nov. 9, 2020 ("The goal of screening is to find cancers early, before they metastasize and become a bigger problem.").

Response to Finding No. 6222:

Respondents have no specific response except to note that the cited analyst presentation also notes that "There is always room to improve upon the *standard of care* for cancer screening". (PX4178 at 009) (emphasis added).)

6223. Detecting Stage IV cancer is not an instance of early cancer detection. (Ofman (Grail) Tr. 3431).

Response to Finding No. 6223:

The proposed finding is incomplete and misleading. Dr. Ofman agreed with the following question from Complaint Counsel: "And would you agree that to the extent an MCED test detects Stage 4 cancer in a patient *who has already been diagnosed with cancer*, that is not an instance of early cancer detection?" (Ofman (GRAIL) Tr. 3431 (emphasis added).)

3. MCED Tests Are Screening Tests to Detect Cancer in Asymptomatic Populations

6224. "Screening actually implies an asymptomatic person." (Abrams, Tr. 3620).

Response to Finding No. 6224:

The proposed finding is incomplete and misleading. Dr. Abrams testified that "most of the time there are no symptoms" when performing various screening tests, but "sometimes" a patient does have symptoms. (Abrams, Tr. 3620.)

6225. [redacted]

Response to Finding No. 6225:

Respondents have no specific response.

6226. During trial, Respondents' counsel referred to Galleri as a "multicancer screening test for asymptomatic patients":

> Q. Okay. So besides the Galleri test, Mr. Conroy, no other multicancer test is yet on the market. True?
>
> A. What do you mean by "multicancer test"?
>
> Q. No other multicancer screening test for asymptomatic patients is on the market, right?

(Conroy (Exact) Tr. 1709).

Response to Finding No. 6226:

Respondents have no specific response.

4. Background on Grail's Clinical Study Publications

6227. Grail had released results from two clinical studies as of trial: the Circulating Cell-free Genome Atlas ("CCGA") study and the PATHFINDER study. (Aravanis (Illumina) Tr. 1891-92; Cote, Tr. 3993).

Response to Finding No. 6227:

The proposed finding is incomplete and misleading. At the time of trial, GRAIL had released results from three separate CCGA substudies (CCGA 1, 2 and 3) and interim results from the PATHFINDER study. In February 2021, GRAIL released interim PATHFINDER results that were positive and largely confirmed the previous studies. (Ofman (GRAIL) Tr. 3293; [redacted] At the time of trial, GRAIL expected to complete the PATHFINDER study in January 2022. (RX3044 (GRAIL) at 2; RX3869 (Cote Expert Report) ¶ 147.)

6228. The CCGA study comprises three substudies: CCGA-1, CCGA-2, and CCGA-3. (PX7069 (Bishop (Grail) IHT at 79)).

Response to Finding No. 6228:

Respondents have no specific response.

6229. Grail used CCGA-1 and CCGA-2 to develop Galleri. (PX7069 (Bishop (Grail) IHT at 79-80); *see* PX6049 (Grail) at 015-16 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*) [redacted]).

Response to Finding No. 6229:

The proposed finding is incomplete and misleading. CCGA-1 was designed to discover and differentiate cancer biomarkers, to determine the most effective way to identify multiple cancers and their signal of origin, and train GRAIL's machine learning algorithms to detect those biomarkers. (Ofman (GRAIL) Tr. 3291–94; RX3410 (Liu 2018) at 1; RX3869 (Cote Expert

Report) ¶ 140.) Through the CCGA-1 sub-study, GRAIL concluded that interrogating genome-wide methylation patterns using bisulfite sequencing outperformed targeted sequencing and whole-genome sequencing approaches to detect cancer-derived mutations or chromosome alterations. (Ofman (GRAIL) Tr. 3291–92; RX3430 (Liu 2020) at 3, 9; RX3410 (Liu 2018) at 1.)

CCGA-2 was designed to perform further analysis, training, and validation of v1 of the Galleri test: specifically, to discover methylation patterns of identified cancer biomarkers associated with known cancer types, and then train and validate a machine-learning classifier to differentiate methylation patterns associated with cancer vs. non-cancer as well as predict the origin of the cancer signal. (Ofman (GRAIL) Tr. 3292; RX3430 (Liu 2020) at 3; RX3869 (Cote Expert Report) ¶ 141.) The results of the CCGA-2 study, published in Annals of Oncology in March 2020, showed that Galleri was capable of detecting more than 50 cancer types at a specificity of 99.3% and a false-positive rate of less than 1% across the more than 50 cancer types. (RX3430 (Liu 2020) at 1, 10; *see also* PFF ¶¶ 369–390.)

6230. The authors of the CCGA-3 substudy stated that the CCGA-2 substudy was used to "refine[]" Grail's assay and to "develop[]" machine learning classifiers, whereas the CCGA-3 substudy "is a large clinical validation study of [the Galleri] MCED test." (RX3409 at 002 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

Response to Finding No. 6230:

The proposed finding is incomplete and misleading. The authors of the CCGA-3 substudy stated that the "CCGA was divided into three pre-specified substudies: (i) discovery; (ii) training and validation with the selected and updated assay and classifiers, and (iii) clinical validation with an independent validation set with a further refined assay and classifiers optimized for screening." (RX3409 (Klein 2021) at 002.) CCGA-2 which was designed to

perform further analysis, training, and validation of v1 of the Galleri test: specifically, to discover methylation patterns of identified cancer biomarkers associated with known cancer types, and then train and validate a machine-learning classifier to differentiate methylation patterns associated with cancer vs. non-cancer as well as predict the origin of the cancer signal. (Ofman (GRAIL) Tr. 3292; RX3430 (Liu 2020) at 3 (noting that the second CCGA substudy was aimed at "further analysis (training/validation) with the selected assay."); RX3869 (Cote Expert Report) ¶ 141.) This training and validation was to demonstrate the feasibility of detecting cancer and predicting signal of origin with minimal false positives. (RX3430 (Liu 2020) at 3; RX0744 (GRAIL) at slide 46; RX3869 (Cote Expert Report) ¶ 141.) The results of the CCGA-2 study, published in Annals of Oncology in March 2020, showed that Galleri was capable of detecting more than 50 cancer types at a specificity of 99.3% and a false-positive rate of less than 1% across the more than 50 cancer types. (RX3430 (Liu 2020) at 1, 10.) CCGA-3 was designed to further validate the assay for multi-cancer detection and the identification of the cancer signal of origin. (Ofman (GRAIL) Tr. 3292–93; RX3408 (Klein 2021) at 6; RX3869 (Cote Expert Report) ¶ 141; *see also* PFF ¶¶ 369–390.)

6231. [redacted] (PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 6231:

Respondents have no specific response.

6232. CCGA-3 used the current version of Galleri, which Grail subsequently launched as an LDT in 2021. (PX7092 (Ofman (Grail) Dep. at 252); PX6049 (Grail) at 016 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

Response to Finding No. 6232:

Respondents have no specific response.

6233. Grail published selected results from its CCGA-2 substudy in 2020. (RX3430 at 001 (M.C. Liu at al., *Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA*, Annals of Oncology (2020)).

Response to Finding No. 6233:

The proposed finding is misleading to the extent of the use of the term "selected".

GRAIL published the results of its CCGA-2 substudy in 2020. (RX3430 (Liu 2000) at 001.)

6234. Grail published selected results from its CCGA-3 substudy in 2021. (RX3409 at 001 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

Response to Finding No. 6234:

The proposed finding is misleading to the extent of the use of the term "selected".

GRAIL published the results of its CCGA-3 substudy in 2021. (RX3409 (Klein 2001) at 001.)

6235. Grail published selected results from its PATHFINDER substudy in 2021. (RX3041 at 001 (Interim Results of Pathfinder, June 4, 2021)).

Response to Finding No. 6235:

The proposed finding is misleading to the extent of the use of the term "selected" and inaccurate because PATHFINDER is not a substudy. In February 2021, GRAIL released interim PATHFINDER results that were positive and largely confirmed the previous studies. (Ofman (GRAIL) Tr. 3293; [redacted] At the time of trial, GRAIL expected to complete the PATHFINDER study in January 2022. (RX3044 (GRAIL) at 2; RX3869 (Cote Expert Report) ¶ 147.)

B. GRAIL'S CCGA STUDY DID NOT ASSESS GALLERI'S PERFORMANCE IN THE INTENDED USE POPULATION (ASYMPTOMATIC SCREENING POPULATION)

1. Galleri Is Intended for Use as a Screening Test in Asymptomatic Populations

6236. [redacted] (Conroy (Exact) Tr. 1562 (*in camera*)).

Response to Finding No. 6236:

The proposed finding is incomplete and misleading because Mr. Conroy [redacted] (Conroy (Exact) Tr. 1734 (*in camera*)).

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

6237. Galleri is intended for use as a screening test in asymptomatic populations. (Ofman (Grail) Tr. 3431).

Response to Finding No. 6237:

The proposed finding is misleading to the extent "intended for use" is a term of art in the FDA context.

2. Grail's CCGA Study Involved Participants Who Had Already Been Diagnosed with Cancer

6238. Grail's Circulating Cell-free Genome Atlas ("CCGA") study assessed Galleri's ability to detect cancer signals in individuals who already had been diagnosed with cancer. (Cote, Tr. 3994; Ofman (Grail) Tr. 3435).

Response to Finding No. 6238:

The proposed finding is incomplete and misleading. Dr. Ofman testified that the CCGA-3 study included individuals who had been newly diagnosed with cancer. (Ofman (Grail) Tr. 3435–38.) Dr. Cote testified that the CCGA study is reflective of how Galleri would perform in a screening population. (Cote, Tr. 3994–95.)

6239. Dr. Ofman testified that CCGA is "what we call a case-control study, so the cases are newly diagnosed cancer patients." (Ofman (Grail) Tr. 3294-95; *see also* Cote, Tr. 3993).

Response to Finding No. 6239:

Respondents have no specific response except to note that CCGA is a prospective, multicenter (142 sites), case-control, observational study with longitudinal follow-up of 15,254 participants. (RX3430 (Liu 2000) at 003; Cote, Tr. 3789–90; RX3869 (Cote Expert Report) ¶ 139.) It is believed to be the largest case-control study that there has ever been for early detection. (Ofman (GRAIL) Tr. 3291.) The study was unique because the samples were prospectively collected. As Dr. Cote explained: "[The] case-control trial was actually prospectively collected, and it was done under a strict protocol for the collection of all of these samples. That makes it unique in terms of the case-control study, and . . . it was designed that way to provide sample collection under circumstances that would be similar to an actual clinical collection of samples." (Cote Tr. 3794–95.)

6240. "Participants eligible for the cancer arm [of the CCGA study] included individuals diagnosed with cancer and/or who were scheduled to undergo biopsy and/or surgical resection for known or highly suspected malignancy." (RX3409 at 002 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

Response to Finding No. 6240:

Respondents have no specific response.

6241. The CCGA study included symptomatic cancer participants. (RX3430 at 010 (M.C. Liu at al., *Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA*, Annals of Oncology (2020)); RX3409 at 006 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

Response to Finding No. 6241:

Respondents have no specific response.

6242. Dr. Claire Fiala and Eleftherios Diamandis, two researchers affiliated with Mount Sinai Hospital in Toronto, observed in a comment published in the Annals of Oncology (the same journal used by Grail) that the CCGA study compares healthy patients against patients who have already been diagnosed with cancer: "Consequently, the true sensitivity [of Galleri]

will likely be significantly lower when used as a screening tool." (PX4178 (Grail) at 024, (Email from S. Alag, Grail, to A. Chen, Grail, attaching "Nephron Healthcare Investment Research, Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly," Nov. 9, 2020)).

Response to Finding No. 6242:

The proposed finding improperly relies on expert testimony to support a purported fact. Dr. Claire Fiala and Eleftherios Diamandis were never disclosed as experts in this proceeding and therefore their opinions must be excluded. "[A]llowing the admission of expert evidence at this late stage of proceedings would render the Scheduling Order a mere suggestion rather than a strict timetable to ensure an orderly, efficient trial." Order on Admissibility of Evidence, at 5 (Mar. 10, 2022) (excluding Nephron Research on Illumina).

The proposed finding is based on double hearsay, is inaccurate, misleading, incomplete, and contradicted by the weight of the evidence. The proposed finding relies on an analyst report which does not include the full text of the purported "comment published in the Annals of Oncology" (*see* (PX4178 (Nephron) at 024), and that comment was never entered into evidence in this proceeding.

Respondents note that the analyst report cited in PX4178 observes that Illumina expects to increase investment in GRAIL to include "investments in R&D, in commercial teams to hire sales reps, and to scale G&A and marketing to support growth" and that "Illumina will need to invest significant resources behind GRAIL to support the commercial launch." (PX4178 (Nephron) at 031, 033.)

6243. Nephron Healthcare Investment Research explained that Grail's "CCGA Study Design Compares Enriched Cohort vs a Healthy Control," a feature that "increases the relative sensitivity since individuals with known cancer are enriched." (PX4178 (Grail) at 025, Email from S. Alag, Grail, to A. Chen, Grail, attaching "Nephron Healthcare Investment Research, Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly," Nov. 9, 2020)) (further stating that Nephron "expect[s] there will be

a sensitivity drop off in PATHFINDER" for Galleri relative to Grail's reported CCGA results).

Response to Finding No. 6243:

The proposed finding is based hearsay, is inaccurate, misleading, incomplete, and contradicted by the weight of the evidence. The proposed finding improperly relies on expert testimony and improper lay opinion testimony to support a purported fact. Nephron Healthcare Investment Research was never disclosed as an expert in this proceeding, and therefore its opinions must be excluded. "[A]llowing the admission of expert evidence at this late stage of proceedings would render the Scheduling Order a mere suggestion rather than a strict timetable to ensure an orderly, efficient trial." Order on Admissibility of Evidence, at 5 (Mar. 10, 2022) (excluding Nephron Research on Illumina).

a) Most Cancers in the CCGA Study Were Previously Identified by "Clinical Presentation"

6244. The majority of participants with cancer in the CCGA-3 substudy were identified by clinical presentation: 72.1 percent of cancers were "identified by clinical presentation," whereas 27.9 percent of cancers were "identified by [other] screening test[s]." (RX3409 at 006 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

Response to Finding No. 6244:

This proposed finding is irrelevant and misleading because it does not relate to cancers identified by the Galleri test in the CCGA-3 substudy. Respondents also note that "identify" in this context means that participants were identified for inclusion in the substudy. (RX3409 (Klein 2021) at 006.)

6245. The majority of participants with cancer in the CCGA-2 substudy were also identified by clinical presentation: 76 percent of cancers were diagnosed by "clinical presentation" whereas 24 percent of cancers were diagnosed by "screening." (RX3773 at 025, Table S1 ("Participant demographics and baseline characteristics") (Liu et al., Supplementary Information to Klein et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set (2021) (*see* notes to

Table S1 stating that the data presented "[r]epresents second CCGA sub-study and STRIVE study . . . primary analysis populations").

Response to Finding No. 6245:

This proposed finding is irrelevant and misleading because it does not relate to cancers identified by the Galleri test in the CCGA-2 substudy. Respondents also note that "identify" in this context means that participants were identified for inclusion in the substudy. (RX3773 (Supplementary Information to Klein 2021) at 025, Table S1.)

b) Galleri Performed Substantially Worse at Detecting Cancers Identified by Other Screening Tests in the CCGA-3 Substudy Than at Identifying Cancers Previously Identified by "Clinical Presentation"

6246. The authors of the CCGA-3 substudy noted that "overall sensitivity in cancers identified by clinical presentation [63.9% (61.8% - 66.0%)] was higher than that in cancers identified by screening tests [18.0% (15.5% - 20.8%)]." (RX3409 at 005 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

Response to Finding No. 6246:

The proposed finding is incomplete and misleading. As the cited article points out, this difference between sensitivities was "likely due to a preponderance of early-stage prostate and breast cancers in the screen-detected cancer classes." (RX3409 (Klein 2021) at 005.) Early-stage prostate cancer in particular "shed[s] less and [is] thus less detectable" by a cfDNA detection approach. (RX3409 (Klein 2021) at 009.)

Respondents also note that there is typically a tradeoff between specificity and sensitivity. (PFF ¶ 180 (RX3869 (Cote Expert Report) ¶ 95); *see also* [redacted].) Current standard of care screening modalities such as breast cancer screening (mammography) and prostate cancer screening are single cancer screening tests that prioritize sensitivity over specificity. This is different from the approach of Galleri, an MCED test. As the FDA has recognized, multi-cancer screening tests must prioritize specificity over sensitivity,

preferably specificities of at least 99%. [redacted] By contrast, the standard of care screening methods such as mammography have very low specificities and correspondingly high false positive rates. The current standard of care screening for breast cancer, mammography, has a PPV (positive predictive value) of only 4%, meaning that only 4 out of 100 positive tests actually identify breast cancer. (PFF ¶ 180.3 (RX3079 (Breast Cancer Surveillance Consortium) at 1; RX3442 (Marcus 2019) at 4).) This means that most patients with a "positive" mammography result will have to undergo further invasive testing, but will end up with a negative cancer diagnosis. (PFF ¶ 180.4 (RX3079 (Breast Cancer Surveillance Consortium) at 1; RX3442 (Marcus 2019) at 6).)

Given the same conditions, a test applying cutoff thresholds that minimizes false positives, *i.e.*, higher specificity, may often have a lower sensitivity than a test that results in a higher false positive rate. (PFF ¶ 180 (RX3869 (Cote Expert Report) ¶ 95).)

3. CCGA Included Stage IV Cancer Cases

6247. The cancer arm of the CCGA study included individuals diagnosed with Stage IV cancer. (Cote, Tr. 3994; RX3409 at 006, Table 1 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

Response to Finding No. 6247:

The proposed finding is misleading to the extent it suggests that Galleri is not capable of detecting cancers at earlier stages because some of the individuals included in the CCGA study

had stage IV cancer. However, as discussed by Dr. Aravanis at trial, given the rarity of many of the cancer types studied in the CCGA study, it was inevitable that a subset of the study would include individuals with stage IV cancer.

By way of background, the Circulating Cell-Free Genome Atlas Study ("CCGA"), started in August 2016, is GRAIL's foundational study. (PFF ¶ 369; Ofman (GRAIL) Tr. 3291–92; RX3287 (GRAIL) at 2; RX0867 (GRAIL) at 3; [redacted]; RX3869 (Cote Expert Report) ¶ 139.) It is a prospective, multicenter (142 sites), case-control, observational study with longitudinal follow-up. (PFF ¶ 371; RX3430 (Liu et al., 2020) at 1; Ofman (GRAIL) Tr. 3291–95; [redacted] RX0744 (GRAIL) at 47–48.) CCGA is believed to be the largest case-control study that has ever been performed for the early detection of cancer. (Ofman (GRAIL) Tr. 3291.)

As Dr. Aravanis testified, "for cancers where there is no existing screening methodology, those cancers tend to present very late stage in disease, so finding . . . patients with early-stage cancers is very hard and very rare." (Aravanis (Illumina) Tr. 1917–18.) To accomplish this daunting task, GRAIL had to set up 142 trial sites to find rare examples of individuals with these unscreened cancers at early-stage disease. (Aravanis (Illumina) Tr. 1918.) It was "unprecedented in scale and complexity and cost to do that." (Aravanis (Illumina) Tr. 1918.) However, given the rarity of certain cancers, it was inevitable that at least some of the individuals in the cancer arm would have stage IV cancer. Of the 15,254 participants in CCGA, 44% did not have a known cancer diagnosis while 56% had a newly diagnosed cancer ranging in all four stages (Stage I-IV). (RX3430 (Liu et al., 2020) at 3; RX3869 (Cote Expert Report) ¶ 139.)

Respondents also incorporate their responses to CCFF ¶¶ 250 and 6210 herein.

a) 21.9% of the Cancer Cases in CCGA-3 Were Stage IV Cancers

6248. Over 600 of the 2,823 participants in the cancer arm of the CCGA-3 substudy had been previously diagnosed with Stage IV cancer. (RX3409 at 009, Table 2 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

Response to Finding No. 6248:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶ 6247, which Respondents incorporate herein. Respondents also note that in a case control study, it is useful to have a full range of stages in order to understand the sensitivity and specificity of the proposed assay. Respondents also note that in the DETECT-A study, out of the 26 cancer samples the CancerSEEK workflow detected, more than a third (34.6%) or 9 cancer samples are from stage IV. (*See* (Lennon 2020) at 6-7, Table 1.) Respondents further note that Guardant's and Freenome's case control studies for their single-cancer tests (colorectal cancer) also included stage IV cancer samples. (*See* RX3405 (Kim 2019) at 2; RX3592 (Putcha 2020).) Respondents also incorporate their responses to CCFF ¶¶ 250 and 6210 herein.

6249. Individuals with previously diagnosed Stage IV cancer accounted for 21.9% of the individuals in the cancer arm of the CCGA-3 substudy. (RX3409 at 006, Table 1 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

Response to Finding No. 6249:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 6247–48, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶¶ 250 and 6210 herein.

6250. Individuals with previously diagnosed Stage IV cancer accounted for between 23% and 24% of the individuals in the cancer arm of the CCGA-2 substudy. (RX3773 at 025, Table S1 ("Participant demographics and baseline characteristics") (Liu et al., Supplementary Information to Klein et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set (2021).

Response to Finding No. 6250:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 6247–48, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶¶ 250 and 6210 herein.

b) 38.3% of the Cancer Cases for Which Galleri Detected a Signal in CCGA-3 Were Stage IV Cancers

6251. Over 550 of the 1,453 participants in the CCGA-3 substudy for which Galleri detected a cancer signal had been previously diagnosed with Stage IV cancer. (RX3409 at 009, Table 2 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

Response to Finding No. 6251:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 6247–48, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶¶ 250 and 6210 herein.

6252. Individuals with previously diagnosed Stave IV cancer accounted for 38.3% of the true positive results returned by the Galleri test in the CCGA-3 substudy. (RX3409 at 009, Table 2 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021)) (557 / 1453 = 38.3%)).

Response to Finding No. 6252:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 6247–48, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶¶ 250 and 6210 herein.

c) Galleri Performed Substantially Worse at Detecting Earlier Stage Cancers in the CCGA-3 Substudy Than at Identifying Stage IV Cancers

6253. The authors of the CCGA-3 substudy reported that Galleri's "overall sensitivity across cancer classes and stages was 51.5%." (RX3409 at 005 (E. A. Klein et al., *Clinical*

Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021))).

Response to Finding No. 6253:

The proposed finding is incomplete and misleading in that it suggests that the "performance" of the Galleri is reflected in the sensitivity of the Galleri test alone. Not so. As noted above in RRFF ¶ 6246, it is critical for a test like Galleri to maintain a very high level of specificity, even at the expense of sensitivity. [redacted] Complaint Counsel, however, persists in mischaracterizing a "low" sensitivity as a poor performance. The appropriate metric is the specificity and positive predictive value (PPV) of the tests. Given the same conditions, a test applying cutoff thresholds that minimizes false positives, *i.e.*, higher specificity, may often have a lower sensitivity than a test that results in a higher false positive rate. (PFF ¶ 180 (RX3869 (Cote Expert Report) ¶ 95).) For example, the standard of care screening methods such as mammography have very low specificities and correspondingly low PPV of only 4%, meaning that only 4 out of 100 positive tests actually identify breast cancer. (PFF ¶ 180.3 (RX3079 (Breast Cancer Surveillance Consortium) at 1; RX3442 (Marcus 2019) at 4).) This means that most patients with a "positive" mammography result will have to undergo further invasive testing, but will end up with a negative cancer diagnosis. (PFF ¶ 180.4 (RX3079 (Breast Cancer Surveillance Consortium) at 1; RX3442 (Marcus 2019) at 6).)

Respondents also note that the authors of the CCGA-3 substudy also reported that Galleri's sensitivity in the group of twelve cancers "that contribute to a large proportion of cancer deaths . . . most of which currently lack screening tests, was higher than that observed in all cancers." (RX3409 (Klein 2021) at 008-9.) Sensitivity for those twelve cancers was 76.3%. (RX3409 (Klein 2021) at 007.) Moreover, as the CCGA-3 substudy authors noted, "[t]here are

limitations to using sensitivity to measure performance of an MCED test in that the absolute number of cancers detected increases with each additional cancer class, even if the average sensitivity over all cancer classes decreases. In other words, overall sensitivity of 51.5% would represent more absolute cancer cases detected than the 76.3% sensitivity in the restricted pre-specified set of 12 cancer classes. These observations reinforce the limitation of the sensitivity metric, which may not reflect the total clinical utility of an MCED test. Thus, PPV may be a more clinically relevant metric." (RX3409 (Klein 2021) at 007.) The extrapolated PPV reported in CCGA-3 was 44.4%, significantly higher than that of currently recommended screening tests. (RX3409 (Klein 2021) at 007.) For comparison, Exact's CancerSEEK test obtained PPV of only 5.9% with its single baseline blood test. (RX3419 (Lennon 2020) at 8 & Table 2; Lengauer (Exact/Thrive) Tr. 257–59; RX3869 (Cote Expert Report) ¶ 178.) Respondents also incorporate their responses to CCFF ¶¶ 250, 6207, 6246–48 and 6253 herein.

6254. The Galleri test detected a cancer signal for 90.1% of individuals with Stage IV cancer in the CCGA-3 substudy. (RX3409 at 009, Table 2 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

Response to Finding No. 6254:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 6246–48 and 6253, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶¶ 250 and 6207 herein.

6255. For participants in the CCGA-3 substudy with previously diagnosed Stage I-III cancers, however, the sensitivity of the Galleri test was 40.7%. (RX3409 at 009, Table 2 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

Response to Finding No. 6255:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 6246–48 and 6253, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶¶ 250 and 6207 herein. Respondents also note that to the extent Complaint Counsel suggests that Galleri's performance is somehow wanting because it has a higher sensitivity for stage IV cancers than for stage I-III cancers, this purported shortcoming is nonsensical. *Every* cancer screening test will have a higher sensitivity for stage IV cancers than for earlier stage cancers, because stage IV cancers will shed more ctDNA into the blood than earlier stage cancers. (*See*, *e.g.*, PFF ¶ 263.1 (RX3773 (Klein et al., 2021); RX3867 (Deverka Expert Report) ¶ 97).)

6256. The Galleri test failed to detect a cancer signal for 59.3% of individuals previously diagnosed with Stage I-III cancers in the CCGA-3 substudy. (RX3409 at 009, Table 2 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

Response to Finding No. 6256:

The proposed finding is incomplete and misleading in that it suggests that the "performance" of the Galleri is reflected in the sensitivity of the Galleri test alone. Not so. As noted above in RRFF ¶ 6246, it is critical for a test like Galleri to maintain a very high level of specificity, even at the expense of sensitivity. [redacted]

[redacted] Complaint Counsel, however, persists in mischaracterizing a "low" sensitivity as a poor performance.

As noted, Galleri "was designed to maintain a high specificity while detecting common signals across many cancer types." (RX3409 (Klein 2021) at 007.) Galleri's specificity for v2 of its test is 99.5%. (PFF ¶ 357 (RX3409 (Klein 2021) at 5; RX3408 (Klein 2021 AACR

Presentation) at 10; RX0872 (GRAIL) at 9, 13; RX3869 (Cote Expert Report) ¶ 136).) There is typically a tradeoff between specificity and sensitivity in cancer screening tests. (RX3869 (Cote Expert Report) ¶ 95.) Given the same conditions, a test applying cutoff thresholds that minimizes false positives, *i.e.*, higher specificity, may often have a lower sensitivity than a test that results in a higher false positive rate. (RX3869 (Cote Expert Report) ¶ 95; *see also* Nolan (Freenome) 2827 [redacted] A test developer focusing on a cancer screening test for a large number of cancer types must focus on attaining a very high specificity rate, and a high PPV, which will often result in correspondingly lower sensitivity rates. (Cote Tr. 3778–81; RX3869 (Cote Expert Report) ¶ 95.) This is because when screening the general population of individuals over age 50, or those with a family history of cancer, it is critical that the morbidity and expense of following up on a false positive test is minimized. (RX3869 (Cote Expert Report) ¶ 95.)

Respondents further note that Galleri was able to detect 40.7% of Stage I–III cancers—including 16.8% of Stage I and 40.4% of Stage II cancers, which are often curable, and 77.0% of Stage III cancers, which are also potentially curable—most of which would have been undetectable until they reached incurable stage. (RX3409 (Klein et al 2021) at 1.)

Respondents also incorporate their responses to CCFF ¶¶ 250, 6207, 6246 and 6253 herein.

6257. For participants in the CCGA-3 substudy with previously diagnosed Stage I-II cancers, the sensitivity of the Galleri test was 27.5%. (RX3409 at 009, Table 2 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

Response to Finding No. 6257:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 6246–48, 6253 and 6256, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶¶ 250 and 6207 herein.

6258. The Galleri test failed to detect a cancer signal for 72.5% of individuals previously diagnosed with Stage I-II cancers in the CCGA-3 substudy. (RX3409 at 009, Table 2 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

Response to Finding No. 6258:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 250, 6207, 6246–48, 6253 and 6256 herein. Respondents also note that to the extent Complaint Counsel suggests that Galleri's performance is somehow wanting because it has a higher sensitivity for stage IV cancers than for stage I-III cancers, this purported shortcoming is nonsensical. *Every* cancer screening test will have a higher sensitivity for stage IV cancers than for earlier stage cancers, because stage IV cancers will shed more ctDNA into the blood than earlier stage cancers. (*See*, *e.g.*, PFF ¶ 263.1 (RX3773 (Klein et al., 2021); RX3867 (Deverka Expert Report) ¶ 97).)

4. Grail's CCGA Study Did Not Involve the Intended Use Population for Galleri (Asymptomatic Screening Population)

6259. Dr. Ofman testified that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95).

Response to Finding No. 6259:

The proposed finding is incomplete and misleading. Dr. Ofman testified that Galleri was clinically validated in 2019 and 2020. (Ofman (Grail) Tr. 3294.) GRAIL undertook the SUMMIT and STRIVE studies to study the assay in the intended use populations of "screening-

eligible women undergoing mammograms" and "smokers", even though GRAIL did not need the results of STRIVE and SUMMIT to prove that Galleri worked. (Ofman (Grail) Tr. 3295.)

6260. Dr. Ofman testified that Grail undertook the SUMMIT and STRIVE studies because, after the CCGA study, "we needed to also study our assay in what we call the intended use population." (Ofman (Grail) Tr. 3294-95).

Response to Finding No. 6260:

The proposed finding is incomplete and misleading. Dr. Ofman testified that Galleri was clinically validated in 2019 and 2020. (Ofman (Grail) Tr. 3294.) GRAIL undertook the SUMMIT and STRIVE studies to study the assay in the intended use populations of "screening-eligible women undergoing mammograms" and "smokers". (Ofman (Grail) Tr. at 3295.) GRAIL did not need the results of STRIVE and SUMMIT to prove that Galleri worked. (Ofman (Grail) Tr. at 3295.)

6261. As of trial, Grail had not analyzed the data from either the SUMMIT or STRIVE studies. (Ofman (Grail) Tr. 3294-95 ("[W]e haven't analyzed those data yet because we're reserving them for our FDA submission on the next version of our test.")).

Response to Finding No. 6261:

The proposed finding is incomplete and misleading. Dr. Ofman testified that GRAIL felt that "PATHFINDER, which was an actual return of results study, interventional, in actual clinical practice, would be a more powerful way to add to our clinical validation than those cohort studies." (Ofman (Grail) Tr. 3296.) GRAIL did not need the results of STRIVE and SUMMIT to prove that Galleri worked. (Ofman (Grail) Tr. at 3295.)

With respect to Dr. Ofman's reference to "the next version of our test", Respondents note that GRAIL has locked version 2 of Galleri, which is the version currently on the market, and is working on an updated version of Galleri that meets current performance standards while sequencing fewer regions of the genome, thereby reducing the cost of the test. (PFF ¶ 1607

(Ofman (GRAIL) Tr. 3301–03.) GRAIL does not intend to modify the biomarkers used in the Galleri test at this time. (Ofman (GRAIL) Tr. 3303–04.)

C. GRAIL'S CCGA STUDY DOES NOT REFLECT HOW GALLERI WOULD PERFORM IN THE INTENDED USE POPULATION (ASYMPTOMATIC SCREENING POPULATION)

6262. [redacted] (PX4609 (Grail) at 016 [redacted] (*in camera*)).

Response to Finding No. 6262:

The proposed finding is incomplete and misleading. Respondents incorporate their responses to CCFF ¶¶ 6253 and 6256 herein.

6263. Results from early studies or trials are not necessarily predictive of future clinical trial results. (Conroy (Exact) Tr. 1712).

Response to Finding No. 6263:

The proposed finding is incomplete and misleading.

Dr. Ofman testified with respect to GRAIL's PATHFINDER study that "It was really remarkable that [Galleri] performed pretty close to as we predicted it would, and the PPV that we've seen thus far on the interim seems to be very well-aligned with what we've seen in prior studies. And that's really important because in this field, you know, it's littered with companies that do these small, underpowered studies, case-control studies -- I have lots of examples -- where they put it into actual clinical care and the tests don't work. And so, you know, there's a lot of skepticism about that, and so it was really important for us to show that the robust CCGA study was able to replicate itself under real-world conditions." (Ofman (GRAIL) Tr. 3296–97.)

The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony.

(*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

6264. Mr. Conroy, CEO and Chairman of Exact, testified about the limitations of a case control study versus a "true screening setting," in response to questions from Mr. Marriott:

> Q. And the Cohen study, it had several limitations. Is that fair to say?
>
> A. I think that is fair to say.
>
> Q. And, in fact, they're acknowledged by the authors, that the patient cohort in the study was comprised of individuals with known cancers, most diagnosed on the basis of symptoms of disease. Fair to say?
>
> A. Yes. That's a limitation.
>
> Q. Okay. And moreover, most individuals in a true screening setting would have less advanced disease, right?
>
> A. Yes.
>
> Q. And another limitation here was that the study's controls were limited to healthy individuals, right?
>
> A. Well, that's what this says. You know, I'm not an expert on the actual study.
>
> Q. Okay. Buy you understand that a true cancer screening – that in a true cancer screening setting, some individuals might have inflammatory or other diseases which could result in a greater proportion of false-positive results than observed in the study, right?
>
> A. I – I agree with that statement, yes.
>
> . . .
>
> Q. And the proportion of cancers of each type in the cohort was not representative of those in the United States as a whole. Fair to say?
>
> A. That's usually the case with case-control studies, and it appears to be the case here.

(Conroy (Exact) Tr. 1701-02 (discussing RX3142 (Joshua Cohen, et al., Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test, 359 Science 926 (2018)); *see* PX7058 (Conroy (Exact) IHT at 106-107) (*in camera*) ([redacted])

[redacted]).

Response to Finding No. 6264:

The proposed finding is incomplete and misleading. To date, CancerSEEK has been studied in two trials: Cohen, a case-control study conducted by Thrive's founders at Johns Hopkins University involving 1817 participants (1005 cancer patients and 812 healthy individuals), and Lennon, the prospective, interventional DETECT-A (Detecting cancers Earlier Through Elective mutation-based blood Collection and Testing) study conducted by Thrive involving 10,006 female participants. (RX3142 (Cohen 2018) at 1; RX3419 (Lennon 2020) at 2); [redacted]

DETECT-A Did Not Detect All Cancer Types. Although all cancer types (with some exclusions) were purportedly included in the DETECT-A study, in fact the nature of the assay (focusing on 16 genes and 9 protein biomarkers) was such that it was clearly designed to focus on only a few cancers that might be detected in a liquid biopsy screening test using those limited markers, specifically, epithelial cancers. (RX3419 (Lennon 2020) at 2–4; Cote Tr. 3810–11.) The study only detected cancers of 10 organs: lymphoma, colorectal, appendix, uterine, thyroid, kidney, lung, breast, ovary and cancer of unknown primary. (RX3419 (Lennon 2020) at 4, 6–7, 9; Lengauer (Exact/Thrive) Tr. 243, 260–61.)

DETECT-A Missed Cancers Detected by Galleri. Although the cancers were present in the population studied by CancerSEEK, CancerSEEK was unable to detect several cancer types that Galleri has detected. (*Compare* RX3419 (Lennon 2020) at 1, 6–7, 9 *with* (RX3409 (Klein 2021) at 1, 5; Lengauer (Exact/Thrive) Tr. 261–62; [redacted].) Based on these results and the assay design itself, the evidence does not support the proposition that CancerSEEK currently detects the same number of cancer types as GRAIL's Galleri test. (RX3869 (Cote

Expert Report) ¶ 177.) [redacted]

[redacted] In contrast, GRAIL has demonstrated that the Galleri test can detect and screen for over 50 types of cancers, over 45 of which lack recommended screenings. (PFF ¶ 61 (PX0043 (GRAIL) at 97, 5; Ofman (GRAIL) Tr. 3312).)

Improper Lay Opinion Testimony. The proposed finding is also based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

The proposed finding relies in part on IH testimony which Respondents had no opportunity to cross examine and therefore the cited testimony should be given no weight. (*See* Resps.' Post-Trial Br. at 275–76.)

6265. The authors of Grail's CCGA-2 substudy acknowledge that CCGA does not enable an understanding of how Galleri would perform in an asymptomatic screening population: "[T]he [CCGA] study has limitations. Participants with cancer were not all asymptomatic; to understand performance in an asymptomatic screening population will require additional studies, which are ongoing." (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020))).

Response to Finding No. 6265:

The proposed finding is incomplete and misleading to the extent it suggests that GRAIL does not have an understanding of how Galleri will perform in an asymptomatic screening limitations. GRAIL's PATHFINDER study is a prospective, interventional study of 6,662 participants over the age of 50 with a cohort with additional risk of a positive cancer result (3695; ~55% of total enrollment), and another cohort containing participants without any

heightened risk (2934). (PFF ¶¶ 394 (RX3044 (GRAIL) at 1–2), 399 (Ofman (GRAIL) Tr. 3293; RX0744 (GRAIL) at 73), 1290 (Aravanis (Illumina) Tr. 1891–92).)

In February 2021, GRAIL released interim prospective interventional study (PATHFINDER) results that were positive and largely confirmed the previous studies, including CCGA. (Ofman (GRAIL) Tr. 3293; [redacted]

There was no concern that Galleri found 13 different types of cancer rather than 50 in PATHFINDER. Given the background incidence of cancer in the population (*see* PFF ¶ 321 (RX3501 (National Cancer Institute) at 2; RX3869 (Cote Expert Report) ¶ 118)), it would not be expected that 50 types of cancer would even develop in a group of 6,000 or so participants. To find "all 50 cancers, you know, in a real-world population is going to require hundreds of thousands of people, so PATHFINDER was not designed to do that. PATHFINDER was really designed to understand the specificity of the test and its positive predictive value. So no, we were -- we were thrilled that there was such a diversity of cancers that were found in PATHFINDER." (Ofman (GRAIL) Tr. 3298; Cote Tr. 3806 (In a "prospective study of 6600 patients, there would be no way to find all of those 50 incident cancers.").) Respondents also incorporate their responses to CCFF ¶¶ 133 and 6207 herein.

6266. The authors of Grail's CCGA-3 substudy identify as a "limitation" of CCGA "that CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021))).

Response to Finding No. 6266:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 6265, which Respondents incorporate herein.

6267. The authors of Grail's CCGA-3 substudy further identify as a "limitation" of CCGA "that the blood samples collected from participants with cancer after biopsies had been carried out could increase the possibility that the tumor cfDNA fraction may increase relative to before the biopsy." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021))).

Response to Finding No. 6267:

The proposed finding is incomplete and misleading. The authors of the CCGA-3 substudy concluded that "[t]aken together, these results demonstrate that this targeted methylation-based MCED test has high specificity that is generalizable across study populations, detects cancer signals across a broad range of cancer types with diverse biologic features (including those that currently lack screening tests), and provides accurate CSO prediction that may inform patient management. These results support that this blood-based MCED test may complement existing single-cancer screening tests and result in reduced cancer mortality." (RX3409 (Klein 2021) at 010.)

6268. The Galleri CCGA study excluded individuals with "[p]oor health status" or "[a]cute exacerbation or flare of an inflammatory condition requiring escalation in medical therapy within 14 days prior to blood draw." (RX3773 at 032 , Table S1 ("Participant Inclusion and Exclusion Criteria") (M.C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 2021)).

Response to Finding No. 6268:

Respondents have no specific response.

6269. [redacted]

[redacted] (Conroy (Exact) Tr. 1571 (*in camera*)).

Response to Finding No. 6269:

The proposed finding is incomplete and misleading. The CancerSEEK assay is only designed to detect 10 cancer types, not the over 50 types of cancers by Galleri. (RX3869 (Cote Expert Report) ¶ 174.) [redacted] Although the cancers were present in the population studied in the DETECT-A trial, CancerSEEK was unable to detect several cancer types that Galleri has detected. (*Compare* RX3419 (Lennon 2020) at 1, 6–7, 9 *with* (RX3409 (Klein 2021) at 1, 5; Lengauer (Exact/Thrive) Tr. 261–62; [redacted].)

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation, and also relies on improper lay opinion. Respondents incorporate their responses to CCFF ¶ 6264 herein.

6270. [redacted] (Lengauer (Third Rock Ventures) Tr. 192-93 (*in camera*)).

Response to Finding No. 6270:

The proposed finding is inaccurate, incomplete and misleading. The proposed finding is inaccurate, incomplete and misleading to the extent it suggests that [redacted] (RX3142 (Cohen 2018) at 2 ("We then used

CancerSEEK to study 1005 patients *who had been diagnosed* with stage I to III cancers of the ovary, liver, stomach, pancreas, esophagus, colorectum, lung, or breast.") (emphasis added); PFF ¶¶ 426.1, 427.) By contrast, GRAIL's CCGA study is a *prospective*, multi-center, case-control, observational study with longitudinal follow-up of 15,254 participants. (PFF ¶ 370 (RX3409 (Klein 2021) at 2; (RX3430 (Liu 2020) at 1; Ofman (GRAIL) Tr. 3291–95; [redacted] [redacted] RX0744 (GRAIL) at 47–48).) It is believed to be the largest case-control study that there has ever been for early detection. (Ofman (GRAIL) Tr. 3291.)

The CCGA study was unique because the samples were prospectively collected from consented participants for the purpose of the CCGA study. As Dr. Cote explained: "[The] case-control trial was actually prospectively collected, and it was done under a strict protocol for the collection of all of these samples. That makes it unique in terms of the case-control study, and . . . it was designed that way to provide sample collection under circumstances that would be similar to an actual clinical collection of samples." (Cote Tr. 3794–95.)

Respondents note that GRAIL's PATHFINDER study is a prospective, interventional study of 6,662 participants over the age of 50 with a cohort with additional risk of a positive cancer result (3695; ~55% of total enrollment), and another cohort containing participants without any heightened risk (2934). (PFF ¶¶ 394 (RX3044 (GRAIL) at 1–2), 399 (Ofman (GRAIL) Tr. 3293; RX0744 (GRAIL) at 73), 1290 (Aravanis (Illumina) Tr. 1891–92).) In February 2021, GRAIL released interim prospective interventional study (PATHFINDER) results that were positive and largely confirmed the previous studies. (Ofman (GRAIL) Tr. 3293; [redacted] [redacted] [redacted] The PATHFINDER interim results also show that

Galleri detected three cancer types for which stage designation is not applicable (lymphoid leukemia, plasma cell neoplasm, and Waldenstrom macroglobulinemia), one recurrent cancer type at the "local" stage (prostate), and one cancer for which the stage was unknown (colon or rectum). (RX3041 (Beer 2021) at 005.) Galleri has been shown to detect the largest number of cancer types in a prospective clinical trial.

Respondents further note that GRAIL's STRIVE study is a prospective, observational, longitudinal study of approximately 100,000 women undergoing mammography (PFF ¶ 403 (Ofman (GRAIL) Tr. 3293–95; RX0744 (GRAIL) at 71), GRAIL's SUMMIT study is a prospective, observational study of approximately 13,000 participants between the ages of 50–77 with a substantial smoking history (PFF ¶¶ 407–409 (RX3291 (GRAIL) at 1; RX0744 (GRAIL) at 46–47, 72), and [redacted] and a prospective, real-world, pragmatic, randomized clinical study in the U.K. with the NHS in 140,000 screening-eligible individuals (PFF ¶¶ 1603 (Ofman (GRAIL) Tr. 3291–300), 1648 (Freidin (GRAIL) Tr. 3008)). Respondents also incorporate their responses to CCFF ¶¶ 1938–39 and 2089 herein.

6271. [redacted] (PX4609 (Grail) at 021 [redacted] (*in camera*); *see also* Ofman (Grail) Tr. 3407-08 (*in camera*)).

Response to Finding No. 6271:

The proposed finding is incomplete and misleading. [redacted]

[redacted] STRIVE is a prospective, observational, longitudinal, cohort study of approximately 100,000 women undergoing mammography for screening indications and associated medical care, whose samples were taken around the time of a screening mammogram appointment. (Cote Tr. 3804; Ofman (GRAIL) Tr. 3293–95; RX0744 (GRAIL) at 71; RX3869 (Cote Expert Report) ¶ 148.) The goals of the STRIVE study are to confirm the performance of Galleri in a population with no known active cancer diagnosis, validate Galleri's ability to detect breast cancer and to evaluate Galleri's test performance and sensitivity in the clinically meaningful subgroup of breast cancer patients. (Ofman (GRAIL) Tr. 3293–95; Cote Tr. 3804–05; RX0744 (GRAIL) at 71; RX3869 (Cote Expert Report) ¶ 148.) [redacted] In comparison, as the DETECT-A study result shows, the CancerSEEK workflow combining complete both blood tests and PET-CT imaging had an overall sensitivity of only 15.6%. (PFF ¶ 431 (RX3419 (Lennon et al., 2020) at 8 & Table 2).)

D. GRAIL'S CCGA STUDY DOES NOT CONSTITUTE CLINICAL VALIDATION OF GALLERI AS A MULTI-CANCER EARLY DETECTION SCREENING TEST FOR AN ASYMPTOMATIC POPULATION

6272. At trial, Grail Chief Medical Officer, Dr. Josh Ofman, defined "clinical validation" as "does the test perform as predicted in the intended use population, a population that the test will actually be used in." (Ofman (Grail) Tr. 3284-85).

Response to Finding No. 6272:

The proposed finding is incomplete and misleading to the extent that it suggests that Galleri was not clinically validated. Dr. Ofman testified that Galleri was clinically validated in

2019 and 2020 in the CCGA-2 and CCGA-3 studies. (Ofman (Grail) Tr. 3294.) Dr. Ofman also testified that Galleri is analytically and clinically validated to satisfy the requirements to sell the test as an LDT in a single laboratory and is CAP/CLIA-certified. (Ofman (Grail) Tr. 3317–18.) Respondents also incorporate their responses to CCFF ¶ 6259 herein.

6273. Dr. Gary Gao, co-founder of Singlera, testified that "the evidence from a case-control study cannot be expansive to a[n] asymptomatic population for early cancer screening." (Gao (Singlera) Tr. 2933-34).

Response to Finding No. 6273:

The proposed finding is inaccurate, incomplete and misleading to the extent it suggests that GRAIL has not demonstrated the ability of the Galleri test to screen for 50 cancer types. Unlike PanSeer, where an earlier version has been studied in a small retrospective study (*see* RRFF ¶¶ 2406, 2416–17 and 2421), Galleri has been studied in several, large prospective trials.

GRAIL's CCGA study is a *prospective*, multi-center, case-control, observational study with longitudinal follow-up of 15,254 participants. (PFF ¶ 370 (RX3409 (Klein 2021) at 2; (RX3430 (Liu 2020) at 1; Ofman (GRAIL) Tr. 3291–95; [redacted] RX0744 (GRAIL) at 47–48).) It is believed to be the largest case-control study that there has ever been for early detection. (Ofman (GRAIL) Tr. 3291.) The study was unique because the samples were prospectively collected. As Dr. Cote explained: "[The] case-control trial was actually prospectively collected, and it was done under a strict protocol for the collection of all of these samples. That makes it unique in terms of the case-control study, and . . . it was designed that way to provide sample collection under circumstances that would be similar to an actual clinical collection of samples." (Cote Tr. 3794–95.)

Respondents note that GRAIL's PATHFINDER study is a prospective, interventional study of 6,662 participants over the age of 50 with a cohort with additional risk of a positive

cancer result (3695; ~55% of total enrollment), and another cohort containing participants without any heightened risk (2934). (PFF ¶¶ 394 (RX3044 (GRAIL) at 1–2), 399 (Ofman (GRAIL) Tr. 3293; RX0744 (GRAIL) at 73), 1290 (Aravanis (Illumina) Tr. 1891–92).) In February 2021, GRAIL released interim prospective interventional study (PATHFINDER) results that were positive and largely confirmed the previous studies. (Ofman (GRAIL) Tr. 3293; [redacted] The PATHFINDER interim results also show that Galleri detected three cancer types for which stage designation is not applicable (lymphoid leukemia, plasma cell neoplasm, and Waldenstrom macroglobulinemia), one recurrent cancer type at the "local" stage (prostate), and one cancer for which the stage was unknown (colon or rectum). (RX3041 (Beer 2021) at 005.) Galleri has been shown to detect the largest number of cancer types of in a prospective clinical trial.

The proposed finding is incomplete and misleading, and based on testimony for which the witnesses lack personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

6274. Dr. Gao testified that the FDA "usually require[s] a randomized clinical trial, [what] we call a pivotal – prospective pivotal trial. So that means you follow a healthy population with no symptoms from today, while you start your trial over hundreds of sites." (Gao (Singlera) Tr. 2886-87).

Response to Finding No. 6274:

Respondents note that GRAIL has been in communication with the FDA regarding the Galleri test, and Galleri has received breakthrough device designation from the FDA in 2018 as well as investigational device exemption (IDE). (Ofman (GRAIL) Tr. 3305–06.)

Respondents also note that [redacted]

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation, and also relies on improper lay opinion. Respondents incorporate their responses to CCFF ¶ 6273 herein.

6275. Dr. Ofman testified that "there should be robust analytical and clinical validation at population scale to support [an MCED] test's deployment in the population." (Ofman (Grail) Tr. 3291).

Response to Finding No. 6275:

Respondents have no specific response.

E. GRAIL PUBLICLY CLAIMS ONLY THAT GALLERI CAN "DETECT A CANCER SIGNAL" FOR OVER FIFTY CANCER TYPES ON THE BASIS OF CCGA, NOT THAT GALLERI CAN "SCREEN" FOR FIFTY TYPES OF EARLY-STAGE CANCER

6276. The fifty-plus cancers that Grail claims Galleri can detect are listed on RX2770, which is a poster presented at the American Society of Clinical Oncology ("ASCO") in June 2021, based on the CCGA study. (Bishop (Grail) Tr. 1374-75; RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6276:

The proposed finding is incomplete and misleading to the extent it suggests that Galleri cannot, in fact, screen for the cancer types listed on RX2770. GRAIL has demonstrated that the Galleri test can detect and screen for over 50 types of cancers, over 45 of which lack

recommended screening procedures. (PX0043 (GRAIL) at 97, 5; *see also* Ofman (GRAIL) Tr. 3312.) Respondents also incorporate their responses to CCFF ¶¶ 133 and 6207 herein.

6277. The ASCO Poster for CCGA claims that Galleri can provide "Detection of a Cancer Signal for over 50 AJCC Cancer Types." (RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6277:

The proposed finding is incomplete and misleading to the extent it suggests that Galleri cannot, in fact, screen for the cancer types listed on RX2770. GRAIL has demonstrated that the Galleri test can detect and screen for over 50 types of cancers, over 45 of which lack recommended screening procedures. (PX0043 (GRAIL) at 97, 5; *see also* Ofman (GRAIL) Tr. 3312.) Respondents also incorporate their responses to CCFF ¶¶ 133 and 6207 herein.

6278. Grail uses definitions from the American Joint Committee on Cancer ("AJCC") to identify cancer types. (RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6278:

Respondents have no specific response except to note that the American Joint Committee on Cancer ("AJCC") is "a committee of experts in their various fields, so, you know, one can think of renal diseases, cancers and breast cancers, et cetera, who undertake on a regular basis a reevaluation of data and oftentimes make changes in the cancer staging nomenclature to reflect advances in disease." (Cote Tr. 3796–97.) The AJCC "publishes both […] cancer classifications and staging for cancers that is widely used throughout the world." (Cote Tr. 3733.) Dr. Cote further testified: "The cancer types that the Galleri test used fundamentally were the AJCC classification – the American Joint Commission on Cancer – cancer classification. So these are the standard way that we, as clinicians dealing with cancer, would subclassify cancer. This is not only true in the United States; it's true worldwide." (Cote Tr. at 3796.)

6279. For instance, Grail breaks down colon and rectum cancer into multiple different AAJC cancer types for counting purposes. (Ofman (Grail) Tr. 3433).

Response to Finding No. 6279:

Respondents have no specific response except to note that as Dr. Cote explained in response to a question regarding the AJCC cancer types that fall within the colon and rectum class at trial that:

> So when we think about cancers of the colon and rectum, what we commonly think about are the adenocarcinomas of the colon. These are cancers that are -- derive from the lining cells of the -- of the intestine, what are known as the luminal epithelium of the intestine. And in the subgroupings that you are referring to, these would be listed as colon and rectum. Those are the adenocarcinomas of the colon and rectum, but in addition to that, there were several other cancers that were identified that are not adenocarcinomas of the colon and rectum. These include the appendiceal adenocarcinomas and then neuroendocrine tumors of the appendix and neuro-endocrine tumors of the colon and rectum. Neuroendocrine tumors are derived from a different cell in the intestine, neuroendocrine cells. These are not part of the lining of the cells, and they would not be seen by standard colonoscopy. In addition, appendiceal adenocarcinomas also wouldn't be seen by a colonoscopy." (Cote Tr. 3798–99).

Respondents also incorporate their responses to CCFF ¶ 6278 herein.

6280. Dr. Cote testified that AJCC types are the standard way that clinicians would "subclassify" cancer. (Cote Tr. 3796).

Response to Finding No. 6280:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 6279 herein.

6281. The CCGA poster presented at ASCO in June 2021 lists 51 AJCC cancer types as having been "detected" by Galleri (excluding repeated entries):

1) Anus
2) Urinary bladder
3) Breast
4) Cervix uteri
5) Appendix carcinoma
6) Colon and rectum
7) Neuroendocrine tumors of the appendix
8) Neuroendocrine tumors of the colon and rectum
9) Esophagus and esophagogastric junction
10) Distal bile duct
11) Gallbladder
12) Perihilar ducts
13) HPV-mediated (p16+) oropharyngeal cancer
14) Larynx
15) Nasal cavity and paranasal sinuses
16) Nasopharynx
17) Oral cavity
18) Oropharynx (p16-) and hypopharynx
19) Kidney
20) Intrahepatic bile ducts
21) Liver
22) Lung
23) Hodgkin and non-Hodgkin lymphoma
24) Melanoma of the skin
25) Leukemia
26) Ovary, fallopian tube and primary peritoneal carcinoma
27) Exocrine pancreas
28) Neuroendocrine tumors of the pancreas
29) Plasma cell myeloma and plasma cell disorders
30) Prostate
31) Bone
32) Corpus uteri sarcoma
33) Gastrointestinal stromal tumor
34) Soft tissue sarcoma of the abdomen and thoracic visceral organs
35) Soft tissue sarcoma of the head and neck
36) Soft tissue sarcoma of the retroperitoneum
37) Soft tissue sarcoma of the trunk and extremities

38) Soft tissue sarcoma unusual histologies and sites
39) Stomach
40) Renal pelvis and ureter
41) Corpus uteri carcinoma and carcinosarcoma
42) Adrenal cortical carcinoma
43) Ampulla of vater
44) Gestational trophoblastic neoplasms
45) Malignant pleural mesothelioma
46) Merkel cell carcinoma
47) Penis
48) Small intestine
49) Testis
40) Vagina
51) Vulva

(RX2770 at 001 (Habte Ylmer, et al., Detection of Cancer Signal for Over 50 AJCC Cancer Types with a Multi-Cancer Early Detection Test, 2021)).

Response to Finding No. 6281:

The proposed finding is incomplete and misleading to the extent it suggests that Galleri cannot, in fact, screen for the cancer types listed on RX2770. GRAIL has demonstrated that the Galleri test can screen for over 50 types of cancers, over 45 of which lack recommended screening procedures in the United States. (PX0043 (GRAIL) at 97, 5; *see also* Ofman (GRAIL) Tr. 3312.) Respondents also incorporate their responses to CCFF ¶¶ 133 and 6207 herein.

6282. The CCGA poster presented at ASCO in June 2021 lists the "results" from Grail's "third CCGA substudy" as the basis for the data and claims on the poster. (RX2770 at 001 (2021 ASCO CCGA Poster) (*see* "Conclusions" box of poster)).

Response to Finding No. 6282:

The proposed finding is incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 6281 and 6288, which Respondents incorporate herein.

F. GRAIL'S PATHFINDER STUDY PROVIDES CLINICAL EVIDENCE THAT GALLERI CAN IDENTIFY SEVEN TYPES OF EARLY-STAGE CANCER IN A SCREENING POPULATION

6283. Dr. Ofman explained that Grail's PATHFINDER study is "an interventional study, which is what we call a real-world clinical practice study," of 6,600 patients from the screening eligible population with no suspicion of cancer. (Ofman (Grail) Tr. 3293).

Response to Finding No. 6283:

Respondents have no specific response.

6284. According to Dr. Ofman, Grail felt that PATHFINDER, "which was an actual return of results study, interventional, in actual clinical practice, would be a more powerful way to add to our clinical validation than [STRIVE and SUMMIT]." (Ofman (Grail) Tr. 3296).

Response to Finding No. 6284:

Respondents have no specific response.

6285. As part of PATHFINDER, patients received results from their test and were tracked for one year. (Ofman (Grail) Tr. 3293, 3296).

Response to Finding No. 6285:

Respondents have no specific response.

6286. Grail publicly reported the interim results from its PATHFINDER study. (Ofman (Grail) Tr. 3293).

Response to Finding No. 6286:

Respondents have no specific response.

6287. At trial, Dr. Ofman summarized the interim results from PATHFINDER, including that Galleri detected 13 cancer types, not 50: "In the PATHFINDER study, [Grail] found 29 cancers, 13 different types of cancer, and some in their early stages." (Ofman (Grail) Tr. 3297-98).

Response to Finding No. 6287:

The proposed finding is incomplete and misleading. Dr. Ofman testified that in the PATHFINDER study, Galleri was able to find cancer in patients who had no idea that they had it. (Ofman (Grail) Tr. 3297–98.) As Dr. Ofman explained, "[i]n the PATHFINDER study, we found 29 cancers, 13 different types of cancer, and some in their early stages. We found early pancreatic cancer. We found early liver cancer. We found early head and neck cancer. We found a lot of hematologic malignancies. So it was almost like you were standing on the street corner watching healthy 50-year-olds walk by that had no idea they had cancer and seeing the

cancers just light up as they walked by. It was really remarkable." (Ofman (Grail) Tr. 3297–98.)

Respondents also incorporate their responses to CCFF ¶ 6265 herein.

6288. Based on the PATHFINDER study, the Galleri test has been shown to detect seven types of Stage I-III cancer in an asymptomatic screening population. (Cote Tr. 4000-01; RX3041 at 005 (Thomasz Beer, Interim Results of Pathfinder, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, June 4, 2021) (showing seven cancers as being detected in stages one through three: head and neck, liver/bile duct, lung, lymphoma, ovary, pancreas, and small intestine)).

Response to Finding No. 6288:

The proposed finding is incomplete and misleading to the extent it suggests that Galleri cannot, in fact, detect and screen for over 50 types of cancers, 45 of which lack recommended screening procedures in the United States. (PX0043 (GRAIL) at 97, 5; *see also* Ofman (GRAIL) Tr. 3312.) The PATHFINDER interim results also show that Galleri detected three cancer types for which stage designation is not applicable (lymphoid leukemia, plasma cell neoplasm, and Waldenstrom macroglobulinemia), one recurrent cancer type at the "local" stage (prostate), and one cancer for which the stage was unknown (colon or rectum). (RX3041 (Beer 2021) at 005.)

Galleri's data has been reviewed by multiple regulatory health authorities. (Ofman (GRAIL) Tr. 3306, 3318, 3440.) In particular, the New York State Department of Health has reviewed the validation data supporting Galleri and has approved Galleri as an LDT to be offered to New York state residents; Galleri is the only MCED test with approval from New York State Department of Health, which is considered the highest state regulatory bar for a laboratory developed test. (Ofman (GRAIL) Tr. 3440; Qadan (Illumina) Tr. at 4279; [redacted].) In addition, Galleri was reviewed by the FDA as part of two investigational device exemption applications for the conduct of PATHFINDER and PATHFINDER 2, and in both cases, FDA allowed GRAIL to report out all cancer type information generated by Galleri. (Ofman (GRAIL) Tr. 3306, 3318.)

The proposed finding is also incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 133, 250, 6207, 6210 and 6287, which Respondents incorporate herein.

6289. The PATHFINDER study does not provide clinical evidence of Galleri's ability to screen for more than 50 types of cancer in an asymptomatic screening population. (Cote Tr. 4000-02; Ofman (Grail) Tr. 3298).

Response to Finding No. 6289:

The proposed finding is incomplete and misleading. As Dr. Cote testified at trial, PATHFINDER was never intended to provide clinical evidence of Galleri's ability to screen for more than 50 types of cancer in an asymptomatic population. (Cote Tr. 4001). PATHFINDER was not designed to show that GRAIL could detect 50 cancer types in a real-world population, because to do so a study would require enrollment of hundreds of thousands of people. (Ofman (Grail) Tr. 3298.) PATHFINDER was designed to understand the specificity and positive predictive value of Galleri. (Ofman (Grail) Tr. 3298.) Nevertheless, Dr. Ofman testified that GRAIL was "thrilled that there was such a diversity of cancers that were found in PATHFINDER." (Ofman (Grail) Tr. 3298.) Respondents also incorporate their responses to CCFF ¶¶ 133 and 6207 herein.

6290. According to Dr. Ofman, Grail was not concerned that PATHFINDER didn't find 50 cancer types, because to do so "in a real-world population is going to require hundreds of thousands of people, so PATHFINDER was not designed to do that." (Ofman (Grail) Tr. 3298).

Response to Finding No. 6290:

The proposed finding is incomplete and misleading to the extent it suggests that Galleri cannot, in fact, screen for over 50 types of cancers, 45 of which lack recommended screening procedures in the United States. (PX0043 (GRAIL) at 97, 5; *see also* Ofman (GRAIL) Tr. 3312.) The proposed finding is also incomplete, and misleading for the reasons explained in

Respondents' responses to CCFF ¶¶ 133, 250, 6207, 6210, 6287 and 6289, which Respondents incorporate herein.

6291. [redacted] (Ofman (Grail) Tr. 3323-24 (*in camera*)).

Response to Finding No. 6291:

The proposed finding is incomplete and misleading to the extent it suggests that Galleri cannot, in fact, screen for over 50 types of cancers, 45 of which lack recommended screening procedures in the United States. (PX0043 (GRAIL) at 97, 5; *see also* Ofman (GRAIL) Tr. 3312.) Respondents also note that Dr. Ofman testified that [redacted] The proposed finding is also incomplete and misleading for the reasons explained in Respondents' responses to CCFF ¶¶ 133, 250, 6207, 6210, 6287 and 6289, which Respondents incorporate herein.

6292. Seventy percent of positive Galleri results were falsely positive for asymptomatic normal-risk participants in PATHFINDER, according to the interim results reported by Grail. (RX3041 at 004 (Thomasz Beer, Interim Results of Pathfinder, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, June 4, 2021) (Fraction calculated based on all participants "without additional risk" for whom Grail reported diagnostic resolution. Galleri generated 9 true positives and 21 false positives for participants "without additional risk." An additional 6 patients tested positive but are listed as having "no current diagnostic resolution.")).

Response to Finding No. 6292:

The proposed finding improperly attempts to characterize and interpret the results of the PATHFINDER study without any expert testimony by characterizing the "without additional

risk" column of RX3041-4 as "asymptomatic normal-risk participants." This is not the correct way of calculating the false positive rate of the PATHFINDER trial. Contary to Complaint Counsel's unproven contention, the interim PATHFINDER results reported an estimated Positive Predictive Value ("PPV") of 45%. (RX3041 (Beer 2021) at 004.) Respondents note that specificity, or the true negative rate, measures the proportion of actual negative samples that are correctly identified as such, or how often a test correctly generates a negative result for people not having the condition for which they are being tested (PFF ¶ 173 (Cote Tr. 3778–3781; RX3869 (Cote Expert Report) ¶ 93)), while PPV is the percentage of patients with a positive test who actually have cancer. (PFF ¶ 174 (Cote Tr. 3778–81; RX3869 (Cote Expert Report) ¶ 93).) PPV represent the probability a patient has cancer when the test result is positive, and is a particularly important metric for cancer screening tests. (PFF ¶ 174.1 (Cote Tr. 3779; RX3869 (Cote Expert Report) ¶ 93).)

G. GRAIL HAS NOT PRESENTED CLINICAL EVIDENCE THAT GALLERI CAN PROVIDE "EARLY DETECTION" OF MORE THAN 50 CANCER TYPES

1. Grail's CCGA Study Does Not Provide Clinical Evidence of Galleri's Ability to Detect Cancer Early in a Screening Population

6293. *See* Sections X.B. (Grail's CCGA Study Did Not Assess Galleri's Performance in the Intended Use Population (Asymptomatic Screening Population)) through X.E. (Grail Publicly Claims Only that Galleri Can "Detect a Cancer Signal" for Over Fifty Cancer Types on the Basis of CCGA, Not that Galleri Can "Screen" for Fifty Types of Early-Stage Cancer)).

Response to Finding No. 6293:

The proposed finding is improper because it treats Complaint Counsel's inaccurate, misleading and argumentative headers as purported facts. To the extent Complaint Counsel relies on its Proposed Findings in Sections X.B through X.E. (CCFF ¶¶ 6236–82), Respondents incorporate their responses to those Proposed Findings herein.

2. Grail's PATHFINDER Study Provides Clinical Evidence of Galleri's Ability to Detect Only Seven Types of Stage I-III Cancer in an Asymptomatic Population

6294. *See* Complaint Counsel's Proposed Finding of Fact ¶ 6288.

Response to Finding No. 6294:

The proposed finding is improper because it treats Complaint Counsel's misleading and argumentative headers as purported facts. To the extent Complaint Counsel relies on its Proposed Findings in CCFF ¶ 6288, Respondents incorporate their responses to that Proposed Findings herein.

3. Dr. Cote Conceded That Galleri Has Been Clinically Shown to Detect Only Seven Types of Stage I-III Cancer in an Asymptomatic Population

6295. In his report, Dr. Cote wrote that "GRAIL has developed a multicancer screening test, Galleri, that simultaneously screens for over 50 different types of cancer from a single blood sample." (RX3869 (Cote Rebuttal Report) ¶ 133).

Response to Finding No. 6295:

Respondents have no specific response.

6296. Dr. Cote testified that his use of the term "screening" in paragraph 133 of his report "refer[s] to the ability to detect cancers at early stage specifically." (Cote Tr. 3992).

Response to Finding No. 6296:

Respondents have no specific response.

6297. Dr. Cote testified that the only clinical trials of Galleri for which results have been released as of trial were the CCGA study and the PATHFINDER study. (Cote Tr. 3993).

Response to Finding No. 6297:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 6239 and 6265 herein.

6298. At trial, Dr. Cote conceded that Galleri has been clinically shown to detect only seven types of Stage I through Stage III cancer in an asymptomatic screening population. (Cote Tr. 3994, 4000-01).

Response to Finding No. 6298:

The proposed finding is incomplete and misleading. In the portion of Dr.Cote's testimony cited here, Dr. Cote was responding only to Complaint Counsel's questions regarding the PATHFINDER study, whereas he had testified about the clinical results of the other trials studying Galleri in other testimony, such as that about CCGA. (Cote Tr. 3994, 4000–01.) Dr. Cote later explained that "the issue with cancer --circulating cancer biomarkers is that at earlier stages of disease, they are at low levels. So one of the primary issues with an early cancer screening test is whether or not it can detect the target cancers at early enough stages to be potentially curable. *The Galleri test has shown that and has shown that for 50 cancers*." (Cote Tr. 4008 (emphasis added).) Dr. Cote further explained that "the CCGA study was a very special, almost unique sort of case-control study, because it was a prospective -- prospectively collected case-control study. It was with a very large number of individuals, including the target cancers at relevant stages and also normal controls. It was designed in such a way as to replicate the conditions under which a sample might be taken in a clinical screening situation. So this was very different from other case-control studies, for example, that have been done in this area." (Cote Tr. 4009.) Complaint Counsel presented no scientific expert at trial and Dr. Cote's testimony is unrebutted.

In addition to Dr. Cote's testimony, there is ample evidence from multiple clinical trials that the Galleri test can detect many more than seven types of early stage cancers in asymptomatic screening populations. In clinical studies, Galleri has detected over 50 types of cancers, of which 45 do not currently have a recommended screening procedure in the US. (PFF ¶¶ 39, 343, 1296; Bishop (GRAIL) Tr. 1373, 1391; RX3285 (GRAIL) at 1; RX3286 (GRAIL) at 2; RX3287 (GRAIL) at 1; Aravanis (Illumina) Tr. 1894–95, 1902; Cote Tr. 3791). Specifically,

the results of the CCGA2 study, published in Annals of Oncology in March 2020, showed that Galleri was capable of detecting more than 50 cancer types at a specificity of 99.3% and a false-positive rate of less than 1% across the more than 50 cancer types. (PFF ¶ 388; RX3430 (Liu et al., 2020) at 1, 10.) Similarly, CCGA3 ultimately reported that GRAIL's Galleri v2 test achieved a specificity of 99.5% across more than 50 cancer types, a false-positive rate of 0.5%, sensitivity of 51.5% for all cancers, and a signal of origin prediction accuracy of 88.7%. (PFF ¶ 392; RX3408 (Klein et al., 2021) at 10; RX3869 (Cote Expert Report) ¶ 144.)

Respondents also incorporate their responses to CCFF ¶¶ 133, 6207, and 6288 herein.

H. GRAIL HAS NOT PRESENTED CLINICAL EVIDENCE THAT GALLERI CAN PROVIDE "EARLY DETECTION" OF MORE THAN 50 CANCER TYPES, EVEN IN A NON-SCREENING SETTING

1. Grail's CCGA-3 Substudy Presents Individual Staging Results for Only 14 of the 51 AJCC Cancer Types Grail Claims Galleri Can Detect

6299. Dr. Ofman testified that the CCGA-3 substudy reported sensitivity by broad cancer classes, but that he could not recall if the CCGA-3 substudy reported sensitivity by cancer stage for each of the individual cancer types for which Grail claims Galleri can detect a signal: "I can't recall if whether the appendix of the CCGA3 paper contained all of that, but certainly we report out, you know, all the cancer classes . . . ." (Ofman (Grail) Tr. 3439).

Response to Finding No. 6299:

Respondents have no specific response.

6300. Dr. Ofman testified that he did not know whether Grail's CCGA-3 substudy counted Galleri as having detected a particular cancer type even if Galleri only detected a cancer signal in subjects with Stage IV cancer. (Ofman (Grail) Tr. 3435-36).

Response to Finding No. 6300:

Respondents have no specific response.

6301. The CCGA-3 substudy reports sensitivity data by clinical cancer stage for cancer classes, not for individual AJCC cancer types. (RX3773 at 038-41, Table S5 (M.C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 2021)).

Response to Finding No. 6301:

The proposed finding is incomplete and misleading. Contrary to Complaint Counsel's unproven contention, Table S6 in RX3773 provides sensitivities for cancer classes *and* AJCC Cancer Types. (RX3773 (Supplementary Information to Klein 2021) at 042–44, Table S6.) Complaint Counsel presented no expert testimony or other admissible evidence to explain to the Court why the distinction between Table S5's report of sensitivity by clinical cancer stage for cancer classes and not for individual AJCC cancer types is relevant (and it is not), and as a result this finding deserves no weight.

6302. The CCGA-3 substudy provides individual staging information for the following 14 AJCC cancer types only (the 14 AJCC cancer types that are coterminous with reported "cancer classes"):

AJCC Cancer "Type"	**Coterminous Cancer "Class" (Staging Info Provided)**
Anus	Anus
Urinary bladder	Bladder
Breast	Breast
Cervix uteri	Cervix
Esophagus and esophagogastric junction	Esophagus
Kidney	Kidney
Lung	Lung
Hodgkin and non-Hodgkin lymphoma	Lymphoma
Melanoma of the skin	Melanoma
Ovary, fallopian tube and primary peritoneal carcinoma	Ovary
Plasma cell myeloma and plasma cell disorders	Plasma cell neoplasm
Prostate	Prostate
Renal pelvis and ureter	Urothelial tract
Corpus uteri carcinoma and carcinosarcoma	Uterus

(RX3773 at 038-44, Tables S5 & S6 (M.C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 2021)).

Response to Finding No. 6302:

The proposed finding is incomplete and misleading. The chart included in this proposed finding does not appear in RX3773 and Complaint Counsel did not produce it as part of discovery.

Further, given that Complaint Counsel did not produce this chart as part of discovery, Complaint Counsel also chose not to discuss this chart at trial, or in any deposition, and therefore, the chart should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (and it is not), and as a result this finding deserves no weight.

a) Galleri Failed to Identify Any Instances of Early-Stage Melanoma in the CCGA-3 Substudy

6303. Melanoma is one of the AJCC cancer types for which Grail claims Galleri can detect a signal. (Ofman (Grail) Tr. 3436; RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6303:

The proposed finding is misleading. Galleri has in fact been demonstrated to detect melanoma. (RX3773 (Supplementary Information to Klein 2021) at 043 (reporting detection of melanoma).)

6304. At trial, Dr. Ofman stated that he did not know whether Galleri detected a cancer signal for any of the CCGA-3 participants with Stage I to Stage III melanoma. (Ofman (Grail) Tr. 3435-37).

Response to Finding No. 6304:

Respondents have no specific response except incorporate their responses to CCFF ¶ 6303 herein.

6305. Galleri detected a cancer signal for 0 of 7 participants in the CCGA-3 substudy with Stage I-III melanoma. (RX3773 at 039, Table S5 (M.C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 2021)).

Response to Finding No. 6305:

The proposed finding is misleading. Respondents note that RX3773 also observes that Galleri detected 6 out of 6 participants in the CCGA-3 substudy with Stage IV melanoma. (RX3773 (Supplementary Information to Klein 2021) at 039, Table S5.) Moreover, Dr. Ofman testified, "[W]hen you order Galleri as a physician, you're not suspecting any particular type of cancer. That's why you order Galleri." (Ofman (GRAIL) Tr. 3312.) No other putative MCED test developer has published any data showing that its test can detect melanoma at any stage, or [redacted], therefore Galleri's ability to do so is extremely valuable.

6306. The only instances of melanoma that Galleri detected in the CCGA-3 substudy were Stage IV melanoma. (RX3773 at 039, Table S5 (M.C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 2021)).

Response to Finding No. 6306:

The proposed finding is incomplete, and misleading for the reasons explained in Respondents' responses to CCFF ¶ 6305, which Respondents incorporate herein.

b) Galleri Failed to Identify Any Instances of Early-Stage Urothelial Tract Cancer in the CCGA-3 Substudy

6307. Urothelial tract cancer is one of the AJCC cancer types for which Grail claims Galleri can detect a signal. (Ofman (Grail) Tr. 3437; RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6307:

The proposed finding is misleading. Galleri has in fact been demonstrated to detect urothelial tract cancer. (RX3773 (Supplementary Information to Klein 2021) at 043 (reporting detection of urothelial tract cancer).)

6308. Galleri detected a cancer signal for 0 of 2 participants in the CCGA-3 substudy with Stage I-III urothelial tract cancer. (RX3773 at 040, Table S5 (M.C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 2021)).

Response to Finding No. 6308:

The proposed finding is misleading. Respondents note that RX3773 observes that Galleri detected all 8 out of 8 participants in the CCGA-3 substudy with Stage IV urothelial tract cancer. (RX3773 (Supplementary Information to Klein 2021) at 039, Table S5.) Respondents also note that there were no participants with Stage II or III urotherial tract cancer in the CCGA-3 substudy. (RX3773 (Supplementary Information to Klein 2021) at 040, Table S5.) Moreover, as Dr. Ofman testified, "[W]hen you order Galleri as a physician, you're not suspecting any particular type of cancer. That's why you order Galleri." (Ofman (GRAIL) Tr. 3312).) No other purported MCED test developer has published any data showing that its test can detect urothelial tract cancer at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6309. The only instances of urothelial tract cancer that Galleri detected in the CCGA-3 substudy were Stage IV urothelial tract cancer. (RX3773 at 040, Table S5 (M.C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 2021)).

Response to Finding No. 6309:

The proposed finding is misleading for the reasons explained in Respondents' responses to CCFF ¶ 6308, which Respondents incorporate herein.

2. CCGA-3 Does Not Provide Staging Information for 37 of the 51 AJCC Cancer Types that Grail Claims Galleri Can Detect

a) CCGA-3 Provides No Staging Information to Indicate Whether the Single Instance of Cancer Detected for 11 AJCC Cancer Types Was Early-Stage Cancer

6310. Grail claims that Galleri can detect a signal for each of the 11 AJCC cancer types listed in Complaint Counsel's Proposed Findings of Fact ¶ 6311, below. (RX2770 (2021 ASCO CCGA Poster); Bishop (Grail) Tr. 1374-75)).

Response to Finding No. 6310:

The proposed finding is misleading. Galleri has in fact been demonstrated to detect a cancer signal for each of the 11 AJCC cancer types listed in CCFF ¶ 6311. (RX3773 (Supplementary Information to Klein 2021) at 043 (reporting detection of cancer for cancer types listed in CCFF ¶ 6311).)

6311. Galleri identified a single instance of cancer in the CCGA-3 substudy for each of the 11 AJCC cancer types listed below; no staging information about these specific cancer types is provided in the CCGA-3 substudy, supplemental materials published with the CCGA-3 substudy, or the 2021 CCGA ASCO Poster.

AJCC Cancer "Type"	Instances Detected	Stage I-III Instances Detected
Appendix carcinoma	1	Unknown / Not reported
Neuroendocrine tumors of the appendix	1	Unknown / Not reported
Perihilar ducts	1	Unknown / Not reported
Nasal cavity and paranasal sinuses	1	Unknown / Not reported
Adrenal cortical carcinoma	1	Unknown / Not reported
Ampulla of vater	1	Unknown / Not reported
Penis	1	Unknown / Not reported
Bone	1	Unknown / Not reported
Gestational trophoblastic neoplasms	1	Unknown / Not reported
Gastrointestinal stromal tumors	1	Unknown / Not reported
Soft tissue sarcoma of the head and neck	1	Unknown / Not reported

(RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038-41 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6311:

The proposed finding is incomplete and misleading. The chart included in this proposed finding does not appear in RX3773 and Complaint Counsel did not produce it as part of discovery.

Galleri has in fact been demonstrated to detect a cancer signal for each of the 11 AJCC cancer types listed in the chart. (RX3773 (Supplementary Information to Klein 2021) at 043 (reporting detection of cancer for cancer types listed in the chart.) No other purported MCED test developer has published any data showing that its test can detect these types of cancer at any stage.

With respect to the statements regarding staging, as Dr. Cote explained at trial, the cancer stages are a continuum, and not all cancers for each stage are the same. "A stage -- each stage does have subdivisions, and these subdivisions have prognostic importance. So even within a stage, this is – the patients can be subdivided. I should also mention that these stages are being -- are constantly updated. They are part of what is known as the American Joint Commission on Cancer, or the AJCC, that publishes the -- both the cancer classification and the staging for cancers that is widely used throughout the world."

Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight.

Further, given that Complaint Counsel did not produce this chart as part of discovery, Complaint Counsel also chose not to discuss this chart at trial, or in any deposition, and therefore, the chart should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it.

6312. The data presented in the CCGA-3 substudy do not indicate whether the single instance of appendix carcinoma that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038, 042 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of colon/rectum, but not for appendix carcinoma specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6312:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for appendix carcinoma. (RX3773 (Supplementary Information to Klein 2021) at 043.) No other purported MCED test developer has published any data showing that its test can detect appendix carcinoma at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6313. The data presented in the CCGA-3 substudy do not indicate whether the single instance of neuroendocrine tumors of the appendix that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038, 042 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of colon/rectum, but not for neuroendocrine tumors of the appendix specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6313:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in

fact been demonstrated to detect a cancer signal for neuroendocrine tumors of the appendix. (RX3773 (Supplementary Information to Klein 2021) at 043.) No other purported MCED test developer has published any data showing that its test can detect neuroendocrine tumors of the appendix at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6314. The data presented in the CCGA-3 substudy do not indicate whether the single instance of cancer of the perihilar ducts that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038, 042 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of gallbladder, but not for cancer of the perihilar ducts specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6314:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for cancer of the perihilar ducts. (RX3773 (Supplementary Information to Klein 2021) at 043.) No other purported MCED test developer has published any data showing that its test can detect cancer of the perihilar ducts at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6315. The data presented in the CCGA-3 substudy do not indicate whether the single instance of nasal cavity and paranasal sinus cancer that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038-39, 042 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging

information for the broader cancer "class" of head and neck, but not for nasal cavity and paranasal sinus cancer specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6315:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for nasal cavity and paranasal sinus cancer. (RX3773 (Supplementary Information to Klein 2021) at 043.) No other purported MCED test developer has published any data showing that its test can detect nasal cavity and paranasal sinus cancer at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6316. The data presented in the CCGA-3 substudy do not indicate whether the single instance of adrenal cortical carcinoma that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040-41, 043 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of "other," but not for adrenal cortical carcinoma specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6316:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for adrenal cortical carcinoma. (RX3773 (Supplementary Information to Klein 2021) at 043.) No other purported MCED test developer has published any data showing that its test can detect adrenal cortical carcinoma at any stage, [redacted]

[redacted], therefore Galleri's ability to do so is extremely valuable.

6317. The data presented in the CCGA-3 substudy do not indicate whether the single instance of ampulla of vater that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040-41, 043 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of "other," but not for ampulla of vater specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6317:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for ampulla of vater. (RX3773 (Supplementary Information to Klein 2021) at 043.) No other purported MCED test developer has published any data showing that its test can detect cancer of the ampulla of vater at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6318. The data presented in the CCGA-3 substudy do not indicate whether the single instance of penile cancer that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040-41, 043 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of "other," but not for penile cancer specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6318:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this

information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for penile cancer. (RX3773 (Supplementary Information to Klein 2021) at 043.) No other purported MCED test developer has published any data showing that its test can detect penile cancer at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6319. The data presented in the CCGA-3 substudy do not indicate whether the single instance of bone cancer that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040, 044 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of sarcoma, but not for bone cancer specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6319:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for bone cancer. (RX3773 (Supplementary Information to Klein 2021) at 043.) No other purported MCED test developer has published any data showing that its test can detect this bone cancer at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

In addition, as Dr. Cote testified at trial, there is value in detecting bone cancer: "Bone cancer is a lethal disease, and while not a major killer, kills substantial numbers of patients in the United States." (Cote Tr. 3795–96.)

6320. The data presented in the CCGA-3 substudy do not indicate whether the single instance of gestational trophoblastic neoplasms that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent

Validation Set, Annals of Oncology (2021)); RX3773 at 040-41, 043 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of "other," but not for gestational trophoblastic neoplasms specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6320:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for gestational trophoblastic neoplasms. (RX3773 (Supplementary Information to Klein 2021) at 043.) No other purported MCED test developer has published any data showing that its test can detect gestational trophoblastic neoplasms at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6321. The data presented in the CCGA-3 substudy do not indicate whether the single instance of gastrointestinal stromal tumors that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040, 044 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of sarcoma, but not for gastrointestinal stromal tumors specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6321:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for gastrointestinal stromal tumors. (RX3773 (Supplementary Information to Klein 2021) at 043.) No other purported MCED test developer

has published any data showing that its test can detect gastrointestinal stromal tumors at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6322. The data presented in the CCGA-3 substudy do not indicate whether the single instance of soft tissue sarcoma of the head and neck that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038, 044 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of sarcoma, but not for soft tissue sarcoma of the head and neck specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6322:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for soft tissue sarcoma of the head and neck. (RX3773 (Supplementary Information to Klein 2021) at 043.) No other purported MCED test developer has published any data showing that its test can detect soft tissue sarcoma of the head and neck any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

b) CCGA-3 Provides No Staging Information to Indicate Whether the Five or Fewer Instances of Cancer Detected for a Further 16 AJCC Cancer Types Were Early-Stage Cancers

6323. Grail claims that Galleri can detect a signal for each of the 16 AJCC cancer types listed in Complaint Counsel's Proposed Findings of Fact ¶ 6324, below. (RX2770 at 001 (2021 ASCO CCGA Poster); Bishop (Grail) Tr. 1374-75).

Response to Finding No. 6323:

The proposed finding is incomplete and misleading to the extent it suggests that Galleri cannot, in fact, detect the cancer types listed on RX2770. GRAIL has demonstrated that the

Galleri test can detect over 50 types of cancers, over 45 of which lack recommended screenings, including each of the 16 AJCC cancer types listed in CCFF ¶ 6324. (PX0043 (GRAIL) at 97, 5; *see also* Ofman (GRAIL) Tr. 3312; RX3773 (Supplementary Information to Klein 2021) at 043).

6324. Galleri identified five or fewer instances of cancer in the CCGA-3 substudy for each of the 16 AJCC cancer types listed below; no staging information about these specific cancer types is provided in the CCGA-3 substudy, supplemental materials published with the CCGA-3 substudy, or the 2021 CCGA ASCO Poster.

AJCC Cancer "Type"	**Instances Detected**	**Stage I-III Instances Detected**
Neuroendocrine tumors of the colon and rectum	3	Unknown / Not reported
Distal bile duct	3	Unknown / Not reported
Nasopharynx	3	Unknown / Not reported
Oral cavity	3	Unknown / Not reported
Leukemia	2	Cancer Not Staged
Malignant pleural mesothelioma	3	Unknown / Not reported
Merkel cell carcinoma	2	Unknown / Not reported
Small intestine	3	Unknown / Not reported
Testis	5	Unknown / Not reported
Vagina	2	Unknown / Not reported
Vulva	4	Unknown / Not reported
Neuroendocrine tumors of the pancreas	3	Unknown / Not reported
Corpus uteri sarcoma	3	Unknown / Not reported
Soft tissue sarcoma of the abdomen and thoracic visceral organs	2	Unknown / Not reported
Soft tissue sarcoma of the retroperitoneum	2	Unknown / Not reported
Soft tissue sarcoma unusual histologies and sites	2	Unknown / Not reported

(*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038-41, Table S5 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6324:

The proposed finding is incomplete and misleading. The chart included in this proposed finding does not appear in RX3773 and Complaint Counsel did not produce it as part of discovery.

Galleri has in fact been demonstrated to detect a cancer signal for each of the 16 AJCC cancer types listed in the chart, some of the patients of these types of cancer could have been at stages I–III. (RX3773 (Supplementary Information to Klein 2021) at 043; PFF ¶ 61 (PX0043 (GRAIL) at 97, 5; Ofman (GRAIL) Tr. 3312).) No other purported MCED test developer has published any data showing that its test can detect these cancers at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight.

6325. The data presented in the CCGA-3 substudy do not indicate whether the three instances of neuroendocrine tumors of the colon and rectum that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038 (Table S5), 042 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of colon/rectum, but not for neuroendocrine tumors of the colon and rectum specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6325:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for neuroendocrine tumors of the colon and

rectum. (RX3773 (Supplementary Information to Klein 2021) at 043.) No other purported MCED test developer has published any data showing that its test can detect neuroendocrine tumors of the colon and rectum at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

As Dr. Cote testified at trial, "neuroendocrine tumors are derived from a different cell in the intestine, neuroendocrine cells. These are not part of the lining of the cells, and they would not be seen by standard colonoscopy." (Cote Tr. 3798–99.)

6326. The data presented in the CCGA-3 substudy do not indicate whether the three instances of distal bile duct cancer that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038 (Table S5), 042 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of gallbladder, but not for distal bile duct cancer specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6326:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for distal bile duct cancer. (RX3773 (Supplementary Information to Klein 2021) at 043.) No other purported MCED test developer has published any data showing that its test can detect distal bile duct cancer at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

As Dr. Cote testified at trial, there is value in detecting bile duct cancer because "while bile duct cancer is not a particularly prevalent cancer, it is a cancer that is almost always found at late stages, and, therefore, when it is found, it is deadly." (Cote Tr. 3796.)

6327. The data presented in the CCGA-3 substudy do not indicate whether the three instances of nasopharyngeal cancer that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038-39 (Table S5), 042 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of head and neck, but not for nasopharyngeal cancer specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6327:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for nasopharyngeal cancer. (RX3773 (Supplementary Information to Klein 2021) at 043.) No other purported MCED test developer has published any data showing that its test can detect nasopharyngeal cancer at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6328. The data presented in the CCGA-3 substudy do not indicate whether the three instances of oral cavity cancer that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038-39 (Table S5), 042 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of head and neck, but not for oral cavity cancer specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6328:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for oral cavity cancer. (RX3773 (Supplementary Information to Klein 2021) at 043.) No other purported MCED test developer has published any data showing that its test can detect oral cavity cancer at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6329. The data presented in the CCGA-3 substudy do not indicate whether the two instances of leukemia that Galleri identified in CCGA-3 included any Stage I through III cancers specifically, or "early stage" cancers more generally. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 039, 041 (Table S5), 043 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (the CCGA-3 substudy does not provide staging information for the broader cancer "class" of myeloid neoplasm (with which the cancer type of leukemia is coterminous), stating instead that myeloid neoplasm is "[n]ot expected to be staged."); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6329:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for leukemia. (RX3773 (Supplementary Information to Klein 2021) at 043.) It is in fact well-accepted that leukemia is a cancer for which common stage designation is not applicable. No other purported MCED test developer

has published any data showing that its test can detect leukemia at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6330. The data presented in the CCGA-3 substudy do not indicate whether the three instances of malignant pleural mesothelioma that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040-41 (Table S5), 043 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of "other," but not for malignant pleural mesothelioma specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6330:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for malignant pleural mesothelioma. (RX3773 (Supplementary Information to Klein 2021) at 043.) No other purported MCED test developer has published any data showing that its test can detect this cancer at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6331. The data presented in the CCGA-3 substudy do not indicate whether the two instances of Merkel cell carcinoma that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040-41 (Table S5), 043 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of "other," but not for Merkel cell carcinoma specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6331:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this

information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for Merkel cell carcinoma. (RX3773 (Supplementary Information to Klein 2021) at 043.) No other purported MCED test developer has published any data showing that its test can detect this cancer at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6332. The data presented in the CCGA-3 substudy do not indicate whether the three instances of small intestine cancer that Grail identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040-41 (Table S5), 043 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of "other," but not for small intestine cancer specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6332:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for small intestine cancer. (RX3773 (Supplementary Information to Klein 2021) at 043.) No other purported MCED test developer has published any data showing that its test can detect small intestine cancer at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6333. The data presented in the CCGA-3 substudy do not indicate whether the five instances of testicular cancer that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040-41 (Table S5), 043 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021))

(listing staging information for the broader cancer "class" of "other," but not for testicular cancer specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6333:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for testicular cancer. (RX3773 (Supplementary Information to Klein 2021) at 043.) No other purported MCED test developer has published any data showing that its test can detect testicular cancer at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6334. The data presented in the CCGA-3 substudy do not indicate whether the two instances of vaginal cancer that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040-41 (Table S5), 043-44 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of "other," but not for vaginal cancer specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6334:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for vaginal cancer. (RX3773 (Supplementary Information to Klein 2021) at 044.) No other purported MCED test developer has published any data showing that its test can detect vaginal cancer at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6335. The data presented in the CCGA-3 substudy do not indicate whether the four instances of vulvar cancer that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040-41 (Table S5), 043-44 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of "other," but not for vulvar cancer specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6335:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for vulvar cancer. (RX3773 (Supplementary Information to Klein 2021) at 044.) No other purported MCED test developer has published any data showing that its test can detect vulvar cancer at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6336. The data presented in the CCGA-3 substudy do not indicate whether the three instances of neuroendocrine tumors of the pancreas that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 039-40 (Table S5), 044 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of pancreas, but not for neuroendocrine tumors of the pancreas specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6336:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for neuroendocrine tumors of the pancreas.

(RX3773 (Supplementary Information to Klein 2021) at 044.) No other purported MCED test developer has published any data showing that its test can detect this cancer at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6337. The data presented in the CCGA-3 substudy do not indicate whether the three instances of corpus uteri sarcoma that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040 (Table S5), 044 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of sarcoma, but not for corpus uteri sarcoma specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6337:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for corpus uteri sarcoma. (RX3773 (Supplementary Information to Klein 2021) at 044.) No other purported MCED test developer has published any data showing that its test can detect corpus uteri sarcoma at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6338. The data presented in the CCGA-3 substudy do not indicate whether the two instances of soft tissue sarcoma of the abdomen and thoracic visceral organs that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040 (Table S5), 044 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of sarcoma, but not for soft tissue sarcoma of

the abdomen and thoracic visceral organs specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6338:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for soft tissue sarcoma of the abdomen and thoracic visceral organs. (RX3773 (Supplementary Information to Klein 2021) at 044.) No other purported MCED test developer has published any data showing that its test can soft tissue sarcoma of the abdomen and thoracic visceral organs at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6339. The data presented in the CCGA-3 substudy do not indicate whether the two instances of soft tissue sarcoma of the retroperitoneum that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040 (Table S5), 044 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of sarcoma, but not for soft tissue sarcoma of the retroperitoneum specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6339:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for soft tissue sarcoma of the retroperitoneum. (RX3773 (Supplementary Information to Klein 2021) at 044.) No other purported MCED test developer has published any data showing that its test can detect soft tissue sarcoma of the

retroperitoneum at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6340. The data presented in the CCGA-3 substudy do not indicate whether the two instances of soft tissue sarcoma with unusual histologies and sites that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040 (Table S5), 044 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of sarcoma, but not for soft tissue sarcoma with unusual histologies and sites specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6340:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for soft tissue sarcoma with unusual histologies and sites. (RX3773 (Supplementary Information to Klein 2021) at 044.) No other purported MCED test developer has published any data showing that its test can detect this cancer at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

c) CCGA-3 Provides No Staging Information to Indicate Whether the Six or More Instances of Cancer Detected for a Further 10 AJCC Cancer Types Were Early-Stage Cancers

6341. Grail claims that Galleri can detect a signal for the AJCC cancer types: colon and rectum, gallbladder, HPV-mediated (p16+) oropharyngeal cancer, larynx, oropharynx (p16-) and hypopharynx, intrahepatic bile ducts, liver, exocrine pancreas, soft tissue sarcoma of the trunk and extremities, and stomach. (RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6341:

The proposed finding is incomplete and misleading to the extent it suggests that Galleri cannot, in fact, detect the cancer types listed on RX2770. GRAIL has demonstrated that the

Galleri test can detect over 50 types of cancers, over 45 of which lack recommended screenings, including the AJCC cancer types: colon and rectum, gallbladder, HPV-mediated (p16+) oropharyngeal cancer, larynx, oropharynx (p16-) and hypopharynx, intrahepatic bile ducts, liver, exocrine pancreas, soft tissue sarcoma of the trunk and extremities, and stomach. (PX0043 (GRAIL) at 97, 5; *see also* Ofman (GRAIL) Tr. 3312; RX3773 (Supplementary Information to Klein 2021) at 042-044).

6342. The CCGA-3 substudy provides staging information for the broader cancer "classes" of which the AJCC cancer types are subtypes: colon and rectum, gallbladder, HPV-mediated (p16+) oropharyngeal cancer, larynx, oropharynx (p16-) and hypopharynx, intrahepatic bile ducts, liver, exocrine pancreas, soft tissue sarcoma of the trunk and extremities, and stomach. (RX3773 at 038-40 (Table S5), 042-44 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021))).

Response to Finding No. 6342:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for the AJCC cancer types: colon and rectum, gallbladder, HPV-mediated (p16+) oropharyngeal cancer, larynx, oropharynx (p16-) and hypopharynx, intrahepatic bile ducts, liver, exocrine pancreas, soft tissue sarcoma of the trunk and extremities, and stomach. (RX3773 (Supplementary Information to Klein 2021) at 042-044.) No other purported MCED test developer has published any data showing that its test can detect all these cancers at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6343. The CCGA-3 substudy does not provide staging information specifically for AJCC cancer types: colon and rectum, gallbladder, HPV-mediated (p16+) oropharyngeal cancer, larynx, oropharynx (p16-) and hypopharynx, intrahepatic bile ducts, liver, exocrine pancreas, soft tissue sarcoma of the trunk and extremities, and stomach. (*See* RX3773 at 038-40 (Table

S5), 042-44 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021))).

Response to Finding No. 6343:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for the AJCC cancer types: colon and rectum, gallbladder, HPV-mediated (p16+) oropharyngeal cancer, larynx, oropharynx (p16-) and hypopharynx, intrahepatic bile ducts, liver, exocrine pancreas, soft tissue sarcoma of the trunk and extremities, and stomach. (RX3773 (Supplementary Information to Klein 2021) at 042-044.) No other purported MCED test developer has published any data showing that its test can detect all these cancers at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6344. The data presented in the CCGA-3 substudy do not indicate the number of Stage I through III cancers that Galleri identified in CCGA-3 specifically for AJCC cancer types: colon and rectum, gallbladder, HPV-mediated (p16+) oropharyngeal cancer, larynx, oropharynx (p16-) and hypopharynx, intrahepatic bile ducts, liver, exocrine pancreas, soft tissue sarcoma of the trunk and extremities, and stomach. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038-40 (Table S5), 042-44 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021))).

Response to Finding No. 6344:

The proposed finding is incomplete and misleading. Additionally, Complaint Counsel has presented no expert testimony or other admissible evidence to explain to the Court why this information is relevant (it is not), and as a result this finding deserves no weight. Galleri has in fact been demonstrated to detect a cancer signal for the AJCC cancer types: colon and rectum,

gallbladder, HPV-mediated (p16+) oropharyngeal cancer, larynx, oropharynx (p16-) and hypopharynx, intrahepatic bile ducts, liver, exocrine pancreas, soft tissue sarcoma of the trunk and extremities, and stomach. (RX3773 (Supplementary Information to Klein 2021) at 042-044.) No other purported MCED test developer has published any data showing that its test can detect all these cancers at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

I. GALLERI'S SENSITIVITY AT DETECTING STAGE I-III CANCERS FOR INDIVIDUAL AJCC CANCER TYPES IN THE CCGA STUDY WAS LOW AND/OR UNREPORTED ACROSS MULTIPLE CANCER TYPES FOR WHICH GRAIL CLAIMS THAT GALLERI CAN DETECT A SIGNAL

6345. Grail designed CCGA to determine how many types of cancer Galleri could detect. (Ofman (Grail) Tr. 3298-99).

Response to Finding No. 6345:

The proposed finding is incomplete and misleading. Dr. Ofman testified that through the CCGA study, GRAIL "collected an enormous number of different cancer types at all stages, all newly diagnosed, untreated, and –and our test was subjected to that to see if those cancers could be detected. And subsequently, in the U.K. study that we are doing with 140,000 individuals, that's powered as well to find, you know, many of the less common cancers." (Ofman (Grail) Tr. 3298-99.) Respondents also incorporate their responses to CCFF ¶¶ 6229–6230 herein.

6346. There was no minimum sensitivity threshold for Grail to report signal detection for particular cancer types in the CCGA-3 substudy. (Ofman (Grail) Tr. 3437-39).

Response to Finding No. 6346:

The proposed finding is incomplete and misleading. Dr. Ofman testified that there was no minimum sensitivity threshold for GRAIL to count a particular cancer type as being detected in the CCGA-3 study because "[t]he idea was to set the specificity level, fix that, and let sensitivity vary by cancer type, because that's related to how much DNA is being shed into the

blood." (Ofman (Grail) Tr. 3437–38.) Respondents also incorporate their responses to CCFF ¶ 6256 herein.

6347. A negative Galleri test "doesn't preclude that there's cancer there." (Ofman (Grail) Tr. 3309-10).

Response to Finding No. 6347:

Respondents have no specific response except to note that this proposed finding is true for all cancer screening tests, including standard of care screening tests. (Ofman (Grail) Tr. 3309–10.) Respondents also incorporate their responses to CCFF ¶ 6256 herein.

6348. Dr. Ofman testified that, "if you have a negative Galleri test, you still want to encourage the individual to get their single-cancer screening tests." (Ofman (Grail) Tr. 3309-10).

Response to Finding No. 6348:

Respondents have no specific response except to note that at this time, Galleri is not meant as an alternative or replacement to standard cancer screening procedures, but rather as a complement to recommended screenings, designed to detect more cancers earlier while minimizing the harms that may come from a false positive result. (PFF ¶ 358 (RX0744 (GRAIL) at 76–90; [redacted] RX0867 (Clinical Overview Deck) at 15; PX7086 (Cance (ACS) Dep. at 50–53); [redacted]; RX3869 (Cote Expert Report) ¶ 136.)

6349. Mr. Bishop testified that doctors make the decision about whether it is appropriate to prescribe Galleri for patients. (Bishop (Grail) Tr. 1375).

Response to Finding No. 6349:

Respondents have no specific response.

6350. [redacted] (Della Porta (Grail) Tr. 531-32 (*in camera*)).

Response to Finding No. 6350:

The proposed finding is incomplete and misleading. Respondents also their responses to CCFF ¶¶ 6256 and 6346 herein.

6351. [redacted] (Ofman (Grail) Tr. 3415 (*in camera*); PX4609 (Grail) at 017 [redacted] (*in camera*)).

Response to Finding No. 6351:

The proposed finding is incomplete and misleading. In the cited testimony, Dr. Ofman testified only that PX4069 contained the language cited in the proposed finding: [redacted].

Complaint Counsel did not elicit any other testimony regarding this proposed finding and therefore, the document should be accorded little weight and Complaint Counsel should not be permitted to rely on any inferences from it. Respondents further note that the cited section of PX4609 states that [redacted] **(PX4609 (Grail) at 017** [redacted] **(*in camera*)**). Respondents also incorporate their responses to CCFF ¶¶ 6246, 6256 and 6346 herein.

6352. The Annals of Oncology (the same journal used by Grail) published a comment on CCGA-2 by Dr. Claire Fiala and Eleftherios Diamandis, two researchers affiliated with Mount Sinai Hospital in Toronto, stating: "Initially, the achieved specificity [of Galleri in CCGA-2] looks remarkable . . . [In practice,] the sensitivity for late stage cancers is irrelevant as they are likely detectable by symptoms." (PX4178 (Grail) at 024 (Email from S. Alag, Grail, to A. Chen, Grail, attaching Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly, Nov. 12, 2020)).

Response to Finding No. 6352:

The proposed finding improperly relies on expert testimony to support a purported fact. Dr. Claire Fiala and Eleftherios Diamandis were never disclosed as experts in this proceeding and therefore their opinions should be excluded and given no weight. "[A]llowing the admission of expert evidence at this late stage of proceedings would render the Scheduling Order a mere suggestion rather than a strict timetable to ensure an orderly, efficient trial." Order on Admissibility of Evidence, at 5 (Mar. 10, 2022) (excluding Nephron Research on Illumina).

The proposed finding is based on double hearsay, inaccurate, misleading, incomplete, and contradicted by the weight of the evidence. The proposed finding relies on an analyst report which does not include the full text of the purported "comment published in the Annals of Oncology" (*see* (PX4178 (GRAIL) at 024), and that comment was never entered into evidence in this proceeding.

Respondents note that the analyst report cited in PX4178 observes that Illumina expects to increase investment in GRAIL to include "investments in R&D, in commercial teams to hire sales reps, and to scale G&A and marketing to support growth" and that "Illumina will need to invest significant resources behind GRAIL to support the commercial launch." (PX4178 (GRAIL) at 031, 033.) Respondents also incorporate their responses to CCFF ¶ 6242 herein.

6353. A November 2020 investment research report produced by Grail identifies the "relatively low sensitivity of Galleri in early stage cancers" as reported in CCGA-2 as a "[p]otential [i]ssue" for Grail: "The potential value proposition in early cancer detection is just that – in detecting cancers early, where intervention can save lives. As such, the relatively low sensitivity of Galleri in early stage cancers raises concerns for its ultimate commercial prospects." (PX4178 (Grail) at 019 (Email from S. Alag, Grail, to A. Chen, Grail, attaching Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly, Nov. 12, 2020)).

Response to Finding No. 6353:

The proposed finding improperly relies on expert testimony and improper lay opinion testimony to support a purported fact. Nephron Healthcare Investment Research was never disclosed as an expert in this proceeding, and therefore its opinions must be excluded. Respondents incorporate their responses to CCFF ¶¶ 6243, 6246, 6256 and 6346 herein.

The proposed finding is based on inadmissible hearsay, is inaccurate, misleading, incomplete, and contradicted by the weight of the evidence. The Nephron report noted that in the CCGA-2 substudy, Galleri's Stage I sensitivity was 18% overall, and 39% in pre-specified cancer types. (PX4178 (Nephron) at 019.) Stage II showed improved results, with sensitivity of 43% in all cancers and 69% in pre-specified cancers. (PX4178 (Nephron) at 019.) Nephron also observed with respect to Thrive's CancerSEEK test that "[o]verall sensitivity was weak at 27%, and only 10% for Stage 1 cancer." (PX4178 (Nephron) at 049.)

6354. Nephron Healthcare Investment Research observed that Galleri's "Stage 1 sensitivity for Breast, Esophagus, Kidney, and Prostate Cancer was essentially 0%" in CCGA-2. (PX4178 (Grail) at 020 (Email from S. Alag, Grail, to A. Chen, Grail, attaching Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly, Nov. 12, 2020)).

Response to Finding No. 6354:

The proposed finding improperly relies on expert testimony and improper lay opinion testimony to support a purported fact. Nephron Healthcare Investment Research was never disclosed as an expert in this proceeding, and therefore its opinions must be excluded. Respondents incorporate their responses to CCFF ¶¶ 6243, 6246, 6256, 6346 and 6353 herein.

The proposed finding is based on inadmissible hearsay, is inaccurate, misleading, incomplete, and contradicted by the weight of the evidence. The Nephron report also observed with respect to Thrive's CancerSEEK test that "despite being a female-only population,

CancerSEEK did not perform well for women with breast cancer. CancerSEEK detected 1 case, although another 26 were caught by other means." (PX4178 (Nephron) at 049.)

6355. Galleri's reported sensitivity at detecting Stage 1 and Stage 2 colon/rectum cancer [in CCGA-2] "would not meet CMS' recent proposed NCD criteria of >74% sensitivity and >90% specificity." (PX4178 (Grail) at 020 (Email from S. Alag, Grail, to A. Chen, Grail, attaching Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly, Nov. 12, 2020)).

Response to Finding No. 6355:

The proposed finding improperly relies on expert testimony and improper lay opinion testimony to support a purported fact. Nephron Healthcare Investment Research was never disclosed as an expert in this proceeding, and therefore its opinions must be excluded. Respondents incorporate their responses to CCFF ¶¶ 6243, 6246, 6256, 6346 and 6353 herein.

The proposed finding is based on inadmissible hearsay, is inaccurate, misleading, incomplete, and contradicted by the weight of the evidence. Galleri is not intended for use as a single-cancer screening test or as a replacement for standard of care screenings. As Dr. Ofman testified, "when you order Galleri as a physician, you're not suspecting any particular type of cancer. That's why you order Galleri." (Ofman (GRAIL) Tr. 3312.)

6356. The CCGA-3 substudy provided data on Galleri's sensitivity at detecting Stage I-III cancers specifically for only 14 of the 51 AJCC cancer types for which Grail claims Galleri can detect a signal. (RX3773 at 038-41, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA)).

Response to Finding No. 6356:

The proposed finding is incomplete and misleading to the extent it suggests that Galleri cannot, in fact, detect the 51 AJCC cancer types listed in RX3773. Galleri has in fact been demonstrated to detect a cancer signal for 51 AJCC cancer types. (RX3773 (Supplementary Information to Klein 2021) at 038-41, Table S5.) The CCGA-3 substudy also reports sensitivity for cancer types that are not expected to be staged, and sensitivity for cancer types where stage

information was missing. (RX3773 (Supplementary Information to Klein 2021) at 038–41, Table S5.) Respondents also incorporate their responses to CCFF ¶¶ 6255–6256 herein.

1. Melanoma

6357. Melanoma is one of the cancer types for which Grail claims Galleri can detect a signal. (*See* Bishop (Grail) Tr. 1374-75; RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6357:

The proposed finding is incomplete and misleading. Galleri has been shown to detect melanoma. (RX2770 (2021 ASCO CCGA Poster) at 001.) No other purported MCED test developer has published any data showing that its test can detect melanoma at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6358. The CCGA-3 substudy reports Galleri's overall sensitivity in detecting melanoma as 46.2 percent. (Ofman (Grail) Tr. 3436; RX3409 at 007, Figure 3 (Klein, et al., Clinical validation of a targeted methylation-based multi-cancer early detection test using an independent validation set, 2021); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6358:

Respondents have no specific response.

6359. Galleri's sensitivity for Stage I-III melanoma in the CCGA-3 substudy was 0.0%. (*See* RX3773 at 039, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA) (Zero test positives for Stage I-III melanoma out of 7 participants in the substudy with Stage I-III melanoma)).

Response to Finding No. 6359:

The proposed finding is misleading. Respondents note that Galleri detected 100% of melanoma cases in Stage IV. (RX3773 (Supplementary Information to Klein 2021) at 039, Table S5.) Respondents also incorporate their responses to CCFF ¶ 6305 herein.

6360. Galleri failed to detect 100% of early-stage melanoma cases in the CCGA-3 substudy. (Ofman (Grail) Tr. 3430, 3436-37; *see* RX3773 at 039, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-

free DNA) (Zero test positives for Stage I-III melanoma out of 7 participants in the substudy with Stage I-III melanoma)).

Response to Finding No. 6360:

The proposed finding is misleading. Respondents note that Galleri detected 100% of melanoma cases in Stage IV. (RX3773 (Supplementary Information to Klein 2021) at 039, Table S5.) Respondents note that while Galleri detects melanoma with a sensitivity of 46.2% (RX3773 (Supplementary Information to Klein 2021) at 039, Table S5), no other putative MCED test developer has published any data showing that its test can detect melanoma at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable. Respondents also incorporate their responses to CCFF ¶ 6305 herein.

6361. Melanoma is estimated to be the fifth leading site for new cancer cases for both men and women in the United States. (RX3030 at 012, Figure 3 (American Cancer Society, Cancer Facts & Figures 2019)).

Response to Finding No. 6361:

Respondents have no specific response except to incorporate their responses to CCFF ¶ 6305 herein. Respondents note that while Galleri detects melanoma with a sensitivity of 46.2% (RX3773 (Supplementary Information to Klein 2021) at 039, Table S5), no other putative MCED test developer has published any data showing that its test can detect melanoma at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6362. The five-year survival rate for melanoma diagnosed when it is local is 98 percent. (RX3030 at 023, Table 8 (American Cancer Society, Cancer Facts & Figures 2019); *see* PX0086 at 001 (GRAIL Presents Interventional PATHFINDER Study Data at 2021 ASCO Annual Meeting and Introduces Galleri, a Groundbreaking Multi-Cancer Early Detection Blood Test, June 4, 2021) (defining "localized" cancers as "stage I-II")).

Response to Finding No. 6362:

The proposed finding is misleading to the extent it suggests that all local melanoma cases have the same survival rate. As Dr. Cote explained at trial, the cancer stages are a continuum, and not all cancers for each stage are the same. "A stage -- each stage does have subdivisions, and these subdivisions have prognostic importance. So even within a stage, this is – the patients can be subdivided. I should also mention that these stages are being -- are constantly updated. They are part of what is known as the American Joint Commission on Cancer, or the AJCC, that publishes the -- both the cancer classification and the staging for cancers that is widely used throughout the world."

Respondents note that while Galleri detects melanoma with a sensitivity of 46.2% (RX3773 (Supplementary Information to Klein 2021) at 039, Table S5), no other putative MCED test developer has published any data showing that its test can detect melanoma at any stage, [redacted]. Given the inability of any other putative MCED test developer to diagnose melanoma at any stage, Galleri's ability to do so, is extremely valuable.

Respondents also incorporate their responses to CCFF ¶ 6305 herein.

6363. The five-year survival rate for melanoma diagnosed when it is distant is 23 percent. (RX3030 at 023, Table 8 (American Cancer Society, Cancer Facts & Figures 2019); *see* PX0086 at 001 (GRAIL Presents Interventional PATHFINDER Study Data at 2021 ASCO Annual Meeting and Introduces Galleri, a Groundbreaking Multi-Cancer Early Detection Blood Test, June 4, 2021) (defining "stage[s] I-III" as the stages "before distant metastases")).

Response to Finding No. 6363:

The proposed finding is misleading to the extent it suggests that all distant melanoma cases have the same survival rate. As Dr. Cote explained at trial, the cancer stages are a continuum, and not all cancers for each stage are the same. "A stage -- each stage does have

subdivisions, and these subdivisions have prognostic importance. So even within a stage, this is – the patients can be subdivided. I should also mention that these stages are being -- are constantly updated. They are part of what is known as the American Joint Commission on Cancer, or the AJCC, that publishes the -- both the cancer classification and the staging for cancers that is widely used throughout the world."

Respondents note that while Galleri detects melanoma with a sensitivity of 46.2% (RX3773 (Supplementary Information to Klein 2021) at 039, Table S5), no other putative MCED test developer has published any data showing that its test can detect melanoma at any stage, [redacted]. Given the inability of any other putative MCED test developer to diagnose melanoma at any stage, Galleri's ability to do so, is extremely valuable.

Respondents also incorporate their responses to CCFF ¶ 6305 herein.

2. Urothelial Tract Cancer

6364. Urothelial tract cancer is one of the cancer types for which Grail claims Galleri can detect a signal. (*See* Bishop (Grail) Tr. 1374-75; RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6364:

The proposed finding is misleading. Galleri has been shown to detect urothelial tract cancer. (RX2770 (2021 ASCO CCGA Poster) at 001.) No other purported MCED test developer has published any data showing that its test can detect urothelial tract cancer at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable.

6365. The CCGA-3 substudy reports Galleri's sensitivity in detecting urothelial tract cancer as 80.0 percent. (RX3409 at 007, Figure 3 (Klein, et al., Clinical validation of a targeted methylation-based multi-cancer early detection test using an independent validation set, 2021); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6365:

Respondents have no specific response.

6366. Galleri's sensitivity for Stage I-III urothelial tract cancer in the CCGA-3 substudy was 0.0%. (*See* RX3773 at 040, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA) (0 test positives for Stage I-III urothelial tract cancer out of 2 participants in the substudy with Stage I-III urothelial tract cancer)).

Response to Finding No. 6366:

The proposed finding is misleading. Galleri detected 100% of Stage IV urothelial tract cancer in the CCGA-3 substudy. (RX3773 (Supplementary Information to Klein 2021) at 040, Table S5). Respondents also incorporate their responses to CCFF ¶ 6308 herein.

6367. Galleri failed to detect 100% of early-stage urothelial tract cancers in the CCGA-3 substudy. (Ofman (Grail) Tr. 3437; *see* RX3773 at 040, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA) (0 test positives for Stage I-III urothelial tract cancer out of 2 participants in the substudy with Stage I-III urothelial tract cancer)); Ofman (Grail) Tr. 3430).

Response to Finding No. 6367:

The proposed finding is misleading. Galleri detected 100% of Stage IV urothelial tract cancer in the CCGA-3 substudy. (RX3773 (Supplementary Information to Klein 2021) at 040, Table S5). Given the rarity of urothelial cancer, Respondents note that there were no participants with Stage II or III urothelial cancer in the CCGA-3 substudy. Respondents note that while Galleri detects urothelial cancer with a sensitivity of 80.0% (RX3773 (Supplementary Information to Klein 2021) at 040, Table S5), no other putative MCED test developer has published any data showing that its test can detect urothelial at any stage, [redacted], therefore Galleri's ability to do so is extremely valuable. Respondents also incorporate their responses to CCFF ¶ 6308 herein.

3. Prostate Cancer

6368. Prostate cancer is one of the cancer types for which Grail claims Galleri can detect a signal. (*See* Bishop (Grail) Tr. 1374-75; RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6368:

The proposed finding is misleading. Galleri has been shown to detect prostate cancer.

(RX2770 (2021 ASCO CCGA Poster) at 001.)

6369. The CCGA-3 substudy reports Galleri's sensitivity in detecting prostate cancer as 11.2 percent. (RX3409 at 007, Figure 3 (Klein, et al., Clinical validation of a targeted methylation-based multi-cancer early detection test using an independent validation set, 2021); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6369:

Respondents have no specific response.

6370. Galleri detected a cancer signal for 22 of 388 participants in the CCGA-3 substudy with Stage I-III prostate cancer. (RX3773 at 040, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA)).

Response to Finding No. 6370:

Respondents have no specific response.

6371. Galleri's sensitivity for Stage I-III prostate cancer in the CCGA-3 substudy was 5.7%. (*See* RX3773 at 040, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA) (22 test positives for Stage I-III prostate cancer out of 388 participants in the substudy with Stage I-III prostate cancer)).

Response to Finding No. 6371:

The proposed finding is incomplete and misleading. As Dr. Ofman testified, "Prostate cancer is one of the cancers where the majority of them are encapsulated and slow-growing and do not shed a lot of DNA into the blood. However, our thinking about why we reported all these out is even when there are some cancers where we have low sensitivity because they don't shed a lot of DNA into the blood, any that we detect increases the cancer detection rate. And so our

strong preference is even for those cancers where we have low sensitivity, it's quite valuable to still report anything that we find, even among things like prostate, where we know they're largely encapsulated cancers that are slow-growing and not shedding a lot of DNA into the blood." (Ofman (Grail) Tr. 3438–39).

As the CCGA-3 study noted, early-stage prostate cancer in particular "shed[s] less and [is] thus less detectable" by a ctDNA detection approach. (RX3409 (Klein 2021) at 005.) This is a feature and not a bug, because "this suggests that [Galleri] has the potential to minimize overdiagnosis." (RX3409 (Klein 2021) at 9.) Indeed, the American Cancer Society observes that: "No organizations presently endorse routine prostate screening for men at average risk because of concerns about the *high risk of overdiagnosis* (detecting disease that would never have caused symptoms or harm), along with the high potential for serious side effects associated with prostate cancer treatment." (RX3030 (American Cancer Society, Cancer Facts & Figures 2019) at 025.)

Indeed, current screening modalities such as prostate cancer screening are single cancer screening tests that prioritize sensitivity over specificity. This is different from the approach of Galleri, an MCED test. As the FDA has recognized, multi-cancer screening tests must prioritize specificity over sensitivity, preferably specificities of at least 99%. [redacted]

Respondents also note that Galleri is designed to be a complement to recommended screenings, including prostate cancer screening, and is not meant as an alternative or replacement to standard cancer screening procedures. (PFF ¶ 358 (RX0744 (GRAIL) at 76–90; [redacted] RX0867 (Clinical Overview Deck) at 15; PX7086 (Cance (ACS) Dep. at 50–53); [redacted]; RX3869 (Cote Expert Report) ¶ 136).)

The proposed finding improperly attempts to interpret the results of the CCGA-3 substudy without any expert testimony by attempting to calculate the sensitivity for Stage I-III prostate cancer reported in the CCGA-3 substudy, and should be afforded no weight.

Respondents also incorporate their responses to CCFF ¶¶ 6246 and 6256 herein.

6372. Galleri failed to detect over 94% of instances of early-stage prostate cancer in the CCGA-3 substudy. (Ofman (Grail) Tr. 3438; *see* RX3773 (Supplementary Information to Klein 2021) at 040, Table S5 (22 test positives for Stage I-III prostate cancer out of 388 participants in the substudy with Stage I-III prostate cancer)).

Response to Finding No. 6372:

The proposed finding is incomplete and misleading, and improperly attempts to interpret the results of the CCGA-3 substudy without any expert testimony. Respondents incorporate their responses to CCFF ¶¶ 6246, 6256 and 6371 herein.

6373. Prostate cancer is estimated to be the number one site of new cancer cases for men in the United States. (RX3030 at 012, Figure 3 (American Cancer Society, Cancer Facts & Figures 2019).

Response to Finding No. 6373:

Respondents have no specific response except to note that the American Cancer Society observes that "[t]he majority (90%) of prostate cancers are discovered at a local or regional stage, for which the 5-year relative survival rate approaches 100%" and that death rate for prostate cancer has declined by 51%, which is attributed to earlier detection, through prostate-specific antigen ("PSA") testing, and advances in treatment. (RX3030 at 025-026, Figure 3

(American Cancer Society, Cancer Facts & Figures 2019.) Respondents also note that the American Cancer Society observes that: "No organizations presently endorse routine prostate screening for men at average risk because of concerns about the *high risk of overdiagnosis* (detecting disease that would never have caused symptoms or harm), along with the high potential for serious side effects associated with prostate cancer treatment." (RX3030 at 025) Respondents incorporate their responses to CCFF ¶¶ 6246, 6256 and 6371 herein.

6374. Prostate cancer is estimated to be the second leading cause of estimated cancer deaths for men in the United States. (RX3030 at 012, Figure 3 (American Cancer Society, Cancer Facts & Figures 2019).

Response to Finding No. 6374:

Respondents have no specific response except to incorporate their responses to CCFF ¶¶ 6246, 6256, 6371 and 6373 herein.

6375. The five-year survival rate for prostate cancer diagnosed when it is local is greater than 99 percent. (RX3030 at 023, Table 8 (American Cancer Society, Cancer Facts & Figures 2019); *see* PX0086 at 001 (GRAIL Presents Interventional PATHFINDER Study Data at 2021 ASCO Annual Meeting and Introduces Galleri, a Groundbreaking Multi-Cancer Early Detection Blood Test, June 4, 2021) (defining "localized" cancers as "stage I-II")).

Response to Finding No. 6375:

The proposed finding is misleading to the extent it suggests that all local prostate cancer cases have the same survival rate. As Dr. Cote explained at trial, the cancer stages are a continuum, and not all cancers for each stage are the same. "A stage -- each stage does have subdivisions, and these subdivisions have prognostic importance. So even within a stage, this is – the patients can be subdivided. I should also mention that these stages are being -- are constantly updated. They are part of what is known as the American Joint Commission on Cancer, or the AJCC, that publishes the -- both the cancer classification and the staging for cancers that is widely used throughout the world."

Respondents also incorporate their responses to CCFF ¶¶ 6246, 6256, 6371 and 6373 herein.

6376. The five-year survival rate for prostate cancer diagnosed when it is distant is 30 percent. (RX3030 at 023, Table 8 (American Cancer Society, Cancer Facts & Figures 2019); *see* PX0086 at 001 (GRAIL Presents Interventional PATHFINDER Study Data at 2021 ASCO Annual Meeting and Introduces Galleri, a Groundbreaking Multi-Cancer Early Detection Blood Test, June 4, 2021) (defining "stage[s] I-III" as the stages "before distant metastases")).

Response to Finding No. 6376:

The proposed finding is misleading to the extent it suggests that all local prostate cancer cases have the same survival rate. As Dr. Cote explained at trial, the cancer stages are a continuum, and not all cancers for each stage are the same. "A stage -- each stage does have subdivisions, and these subdivisions have prognostic importance. So even within a stage, this is – the patients can be subdivided. I should also mention that these stages are being -- are constantly updated. They are part of what is known as the American Joint Commission on Cancer, or the AJCC, that publishes the -- both the cancer classification and the staging for cancers that is widely used throughout the world."

Respondents also incorporate their responses to CCFF ¶¶ 6246, 6256, 6371 and 6373 herein.

4. Kidney Cancer

6377. Kidney cancer is one of the cancer types for which Grail claims Galleri can detect a signal. (*See* Bishop (Grail) Tr. 1374-75; RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6377:

The proposed finding is misleading. Galleri has been shown to detect kidney cancer. (RX2770 (2021 ASCO CCGA Poster) at 001.)

6378. The CCGA-3 substudy reports Galleri's sensitivity in detecting kidney cancer as 18.2 percent. (RX3409 at 007, Figure 3 (Klein, et al., Clinical validation of a targeted

methylation-based multi-cancer early detection test using an independent validation set, 2021); RX2770 at 001 (2021 ASCO CCGA Poster)).

Response to Finding No. 6378:

Respondents have no specific response.

6379. Galleri detected a cancer signal for 6 of 77 participants in the CCGA-3 substudy with Stage I-III kidney cancer. (RX3773 at 039, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA)).

Response to Finding No. 6379:

Respondents have no specific response.

6380. Galleri's sensitivity for Stage I-III kidney cancer in the CCGA-3 substudy was 7.8%. (*See* RX3773 at 039, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA) (6 test positives for Stage I-III kidney cancer out of 77 participants in the substudy with Stage I-III kidney cancer)).

Response to Finding No. 6380:

The proposed finding is incomplete and misleading. Galleri is not intended to be used as a single cancer test. (*See, e.g.*, RRFF ¶¶ 6246, 6256 and 6371). Instead, Galleri's goal is to maximize the number of cancers detected. (Bishop (GRAIL) Tr. 1389–93.) As Dr. Ofman testified at trial, "when you order Galleri as a physician, you're not suspecting any particular type of cancer. That's why you order Galleri." (Ofman Tr. 3312).)

The proposed finding improperly attempts to interpret the results of the CCGA-3 substudy without any admissible expert testimony, by attempting to calculate the sensitivity for Stage I-III kidney cancer reported in the CCGA-3 substudy, and should be afforded no weight.

6381. Galleri failed to detect 92.2% of instances of early-stage kidney cancer in the CCGA-3 substudy. (*See* RX3773 at 039, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA) (6 test positives for Stage I-III kidney cancer out of 77 participants in the substudy with Stage I-III kidney cancer); *see* Ofman (Grail) Tr. 3430)).

Response to Finding No. 6381:

The proposed finding is incomplete and misleading, and improperly attempts to interpret the results of the CCGA-3 substudy without any admissible expert testimony. Respondents incorporate their responses to CCFF ¶ 6380 herein.

6382. The five-year survival rate for kidney cancer diagnosed when it is local is 93 percent. (RX3030 at 023, Table 8 (American Cancer Society, Cancer Facts & Figures 2019); *see* PX0086 at 001 (GRAIL Presents Interventional PATHFINDER Study Data at 2021 ASCO Annual Meeting and Introduces Galleri, a Groundbreaking Multi-Cancer Early Detection Blood Test, June 4, 2021) (defining "localized" cancers as "stage I-II")).

Response to Finding No. 6382:

The proposed finding is misleading to the extent it suggests that all local kidney cancer cases have the same survival rate. As Dr. Cote explained at trial, the cancer stages are a continuum, and not all cancers for each stage are the same. "A stage -- each stage does have subdivisions, and these subdivisions have prognostic importance. So even within a stage, this is – the patients can be subdivided. I should also mention that these stages are being -- are constantly updated. They are part of what is known as the American Joint Commission on Cancer, or the AJCC, that publishes the -- both the cancer classification and the staging for cancers that is widely used throughout the world."

6383. The five-year survival rate for kidney cancer diagnosed when it is distant is 12 percent. (RX3030 at 023, Table 8 (American Cancer Society, Cancer Facts & Figures 2019); *see* PX0086 at 001 (Grail Press Release: GRAIL Presents Interventional PATHFINDER Study Data at 2021 ASCO Annual Meeting and Introduces Galleri, a Groundbreaking Multi-Cancer Early Detection Blood Test, June 4, 2021) (defining "stage[s] I-III" as the stages "before distant metastases")).

Response to Finding No. 6383:

The proposed finding is misleading to the extent it suggests that all distant kidney cancer cases have the same survival rate. As Dr. Cote explained at trial, the cancer stages are a continuum, and not all cancers for each stage are the same. "A stage -- each stage does have

subdivisions, and these subdivisions have prognostic importance. So even within a stage, this is – the patients can be subdivided. I should also mention that these stages are being -- are constantly updated. They are part of what is known as the American Joint Commission on Cancer, or the AJCC, that publishes the -- both the cancer classification and the staging for cancers that is widely used throughout the world."

5. The CCGA-3 Substudy Does Not Report Cancer Stages for 37 of 51 AJCC Cancer Types for Which Grail Claims Galleri Can Detect a Signal

6384. The CCGA-3 substudy does not report Galleri's sensitivity at detecting Stage I-III cancers for 37 of the 51 AJCC cancer types for which Grail claims that Galleri can detect a signal. (RX3773 at 038-41, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA)).

Response to Finding No. 6384:

The proposed finding is incomplete and misleading to the extent it suggests that Galleri cannot, in fact, detect the 51 AJCC cancer types listed in RX3773. Galleri has in fact been demonstrated to detect a cancer signal for 51 AJCC cancer types. (RX3773 (Supplementary Information to Klein 2021) at 038-41, Table S5.) The CCGA-3 substudy also reports sensitivity for cancer types that are not expected to be staged, and sensitivity for cancer types where stage information was missing. (RX3773 (Supplementary Information to Klein 2021) at 038–41, Table S5.) Respondents also incorporate their responses to CCFF ¶¶ 6246 and 6256 herein.

J. GRAIL HAS NOT GENERATED SUFFICIENT CLINICAL EVIDENCE TO SUPPORT A 50-CANCER DETECTION CLAIM BEFORE THE FDA

6385. [redacted] (Ofman (Grail) Tr. 3416 (*in camera*)).

Response to Finding No. 6385:

Respondents have no specific response.

6386. [redacted] (Ofman (Grail) Tr. 3416 (*in camera*)).

Response to Finding No. 6386:

Respondents have no specific response.

6387. A November 2020 investment research report produced by Grail explained that "None of GRAIL's studies represent a truly prospective, real-world study. 70% of PATHFINDER enrollment is from an 'elevated risk group.'" The report concluded that "GRAIL Might Need to Run a New Study to Submit a PMA for Asymptomatic Patients." (PX4178 (Grail) at 025, Nephron Healthcare Investment Research, "Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly," Nov. 9, 2020).

Response to Finding No. 6387:

The proposed finding improperly relies on expert testimony and improper lay opinion testimony to support a purported fact. Contrary to Complaint Counsel's statement, the described research report was not "produced by GRAIL". Nephron Healthcare Investment Research was never disclosed as an expert in this proceeding, and therefore its opinions must be excluded. The proposed finding is based on inadmissible hearsay, is inaccurate, misleading, incomplete, and contradicted by the weight of the evidence. Respondents incorporate their responses to CCFF ¶ 6243 herein.

6388. Hans Bishop, Grail's CEO, testified that "[t]here are some rare cancers that we [don't] yet have sufficient data on which to make performance claims," and that "there are cancers that we have insufficient data on which to say we can detect them today." (Bishop (Grail) Tr. 1375).

Response to Finding No. 6388:

Respondents have no specific response.

6389. [redacted] (Ofman (Grail) Tr. 3416-17 (*in camera*)).

Response to Finding No. 6389:

Respondents have no specific response.

6390. Kevin Conroy, Chairman and Chief Executive Officer ("CEO") of Exact Sciences, described [redacted]

[redacted]

(Conroy (Exact) Tr. 1578 (*in camera*)).

Response to Finding No. 6390:

The proposed finding is based on testimony for which the witness lacks personal knowledge or foundation. The proposed finding also relies on improper lay opinion testimony. (*See* Resps.' Motion *in Limine* to Exclude Improper Lay Witness Opinion Testimony (Aug. 5, 2021).)

6391. Dr. Ofman, Grail's CMO, testified [redacted]

[redacted]

(Ofman (Grail) Tr. 3333-34 (*in camera*)).

Response to Finding No. 6391:

Respondents have no specific response except to note that one of the efficiencies of the Transaction is that Illumina can aid GRAIL in the FDA approval process. Dr. Ofman testified that [redacted]

6392. Dr. Ofman testified at trial that Grail [redacted] (Ofman (Grail) Tr. 3416-17 (*in camera*)).

Response to Finding No. 6392:

Respondents have no specific response.

6393. Nephron Healthcare Investment Research conducted what it described as a "comprehensive review of clinical data for early detection tests for pan-cancer screening" and published a report on Grail's clinical data in 2020, concluding that "GRAIL's clinical data has shortcomings." (PX4178 (Grail) at 005 (Email from S. Alag, Grail, to A. Chen, Grail, attaching Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly, Nov. 12, 2020)).

Response to Finding No. 6393:

The proposed finding improperly relies on expert testimony and improper lay opinion testimony to support a purported fact. Nephron Healthcare Investment Research was never

disclosed as an expert in this proceeding, and therefore its opinions must be excluded. The proposed finding is based hearsay, is inaccurate, misleading, incomplete, and contradicted by the weight of the evidence. Respondents incorporate their responses to CCFF ¶ 6243 herein.

6394. [redacted] (Ofman (Grail) Tr. 3335-36 (*in camera*)).

Response to Finding No. 6394:

Respondents have no specific response except to note that one of the efficiencies of the Transaction is that Illumina can aid GRAIL in the FDA approval process. Respondents incorporate their responses to CCFF ¶ 6391 herein.

RESPONDENTS' REPLY CONCLUSIONS OF LAW

I. THE FEDERAL TRADE COMMISSION HAS JURISDICTION

1. The Federal Trade Commission ("FTC") has jurisdiction over the subject matter of this proceeding pursuant to Section 5 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45, and Section 7 of the Clayton Act, 15 U.S.C. §§ 18, 21(b).

Response to Proposed Conclusion of Law No. 1:

The proposed conclusion is incomplete. Although Respondents do not disagree that the cited legal authorities purport to provide the Commission with jurisdiction over this proceeding, the boundaries of the Commission's jurisdiction are unclear and arbitrary. The FTC and the Department of Justice ("DOJ") share responsibility for enforcing federal antitrust law, but the decision as to which agency will lead the investigation is devoid of public scrutiny, violating due-process and equal-protection guarantees. No one can seriously dispute that the parties to a merger challenged by the FTC are treated very differently from the parties to a merger challenged by DOJ. There is no rational basis for these differences, which can be outcome determinative. Treating parties differently based on whether their merger is reviewed by the FTC instead of DOJ is unrelated to any legitimate governmental purpose. The Equal Protection Clause of the Fifth Amendment commands that the government shall not "deny to any person within its jurisdiction the equal protection of the laws". U.S. Const. amend. V & XIV, § 1; *U.S. v. Windsor*, 570 U.S. 744, 774 (2013) ("The liberty protected by the Fifth Amendment's Due Process Clause contains within it the prohibition against denying to any person the equal protection of the laws.") (citing *Bolling v. Sharpe*, 347 U.S. 497, 499–50 (1954)). "The guaranty of 'equal protection of the laws is a pledge of the protection of equal laws'". *Romer v. Evans*, 517 U.S. 620, 633-34 (1996) (quoting *Skinner v. Oklahoma ex rel. Williamson*, 316 U.S. 535, 541 (1942)). Thus, the Equal Protection Clause protects against "arbitrary and irrational discrimination" by the Government, *Bankers Life & Cas. Co. v. Crenshaw*, 486 U.S. 71, 83

(1988), and demands that "all persons similarly situated should be treated alike", *Tennessee v. Lane*, 541 U.S. 509, 522 (2004) (quoting *Cleburne v. Cleburne Living Center, Inc.*, 473 U.S. 432, 439 (1985)). Any difference in treatment "run[s] afoul of the Equal Protection Clause" when there is no "rational relationship between the disparity of treatment and some legitimate governmental purpose". *Montgomery v. Louisiana*, 577 U.S. 190, 231 (2016).

The FTC's discretion over where to bring its antitrust actions also violates Article I of the Constitution. Congress gave the FTC the power to bring antitrust actions within the agency instead of in an Article III court whenever the FTC in its unfettered discretion decides to do so. *See* 15 U.S.C. §§ 45(b). That was a delegation of legislative power, as "the mode of determining" which cases are assigned to administrative tribunals "is completely within congressional control". *Crowell v. Benson*, 285 U.S. 22, 50 (1932) (quoting *Ex parte Bakelite Corp.*, 279 U.S. 438, 451 (1929)). However, Congress gave the FTC no guidance, much less an intelligible principle, with which to exercise that power. *See* 15 U.S.C. §§ 45(b), 53(b). Thus, Congress unconstitutionally delegated legislative power to the FTC. *See* U.S. Const. art. I, § 1.

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

2. The Commission has jurisdiction over Respondent Illumina, Inc. ("Illumina").

Response to Proposed Conclusion of Law No. 2:

The proposed conclusion is incomplete for the reasons explained in Respondents' responses to CCCoL ¶ 1, which Respondents incorporate herein.

3. Respondent Illumina, Inc. is, and at all times has been, a corporation as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and also a person as defined in Section 1 of the Clayton Act, 15 U.S.C. § 12, and in Section 7 of the Sherman Act, 15 U.S.C. § 7.

Response to Proposed Conclusion of Law No. 3:

Respondents have no specific response.

4. The Commission has jurisdiction over Respondent GRAIL, Inc. ("Grail").

Response to Proposed Conclusion of Law No. 4:

The proposed conclusion is incomplete for the reasons explained in Respondents' responses to CCCoL ¶ 1, which Respondents incorporate herein.

5. Respondent Grail is, and at all times has been, a corporation as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and also a person as defined in Section 1 of the Clayton Act, 15 U.S.C. § 12, and in Section 7 of the Sherman Act, 15 U.S.C. § 7.

Response to Proposed Conclusion of Law No. 5:

Respondents have no specific response.

6. The FTC is an administrative agency of the U.S. Government established, organized, and existing pursuant to the FTC Act, 15 U.S.C. § 41 *et seq* (2006). The FTC is vested with the authority and responsibility for enforcing, *inter alia*, Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45.

Response to Proposed Conclusion of Law No. 6:

The proposed conclusion is incomplete for the reasons explained in Respondents' responses to CCCoL ¶ 1, which Respondents incorporate herein.

7. Respondents, including their relevant operating subsidiaries, are, and at all relevant times have been, engaged in activities in or affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44 (2006), and Section 1 of the Clayton Act, 15 U.S.C. § 12 (2006).

Response to Proposed Conclusion of Law No. 7:

Respondents have no specific response.

II. THIS ACQUISITION VIOLATES SECTION 7 OF THE CLAYTON ACT

8. Section 7 of the Clayton Act avers that "[n]o person . . . shall acquire [stock or assets] . . . where in any line of commerce . . . in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly." 15 U.S.C. § 18 (2012).

Response to Proposed Conclusion of Law No. 8:

The Proposed Conclusion is inaccurate, incomplete, and misleading. Section 7 does require "making a prediction about the future", and deals with probabilities, *U.S. v. AT&T*

(AT&T I), 310 F. Supp. 3d 161, 189–91 (D.D.C. 2018), but it does not permit blocking a merger based on speculative "possibilities", *AT&T I* at 189–91, or "guesswork", and it does not permit ignoring the actual facts. *FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 311 (D.D.C. 2020) ("[A]ntitrust theory and speculation cannot trump facts, and even Section 13(b) cases must be resolved on the basis of the record evidence relating to the market and its probable future." (quoting *FTC v. Arch Coal*, 329 F. Supp. 2d 109, 116–17 (D.D.C. 2004))). Complaint Counsel must therefore prove that "the challenged acquisition [is] *likely* substantially to lessen competition." *Arch Coal*, 329 F. Supp. 2d at 115 (emphasis added); *see United States v. Marine Bancorp.*, 418 U.S. 602, 623 n.22 (1974) (alleged future harm to competition must be "sufficiently probable and imminent" to warrant relief); *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1109 (N.D. Cal. 2004) (rejecting merger challenge because government failed to prove the "merger will *likely* lead to a substantial lessening of competition") (emphasis added); *In re Altria Grp., Inc.*, FTC No. 9393, at 110 (Feb. 15, 2022) (citing *Mercantile Tex. Corp. v. Bd. of Governors of Fed. Rsrv. Sys*., 638 F. 2d 1255, 1272 (5th Cir. 1981) ("The competitive conditions of a market five years in the future cannot reliably be predicted."); *see also FTC v. Tenet Health Care Corp*., 186 F.3d 1045, 1051 (8th Cir. 1999) ("Section 7 deals in probabilities not ephemeral possibilities."). Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

9. Section 5 of the FTC Act proscribes "[u]nfair methods of competition in or affecting commerce . . . ." 15 U.S.C. § 45(a)(1).

Response to Proposed Conclusion of Law No. 9:

The proposed conclusion is inaccurate, incomplete, and misleading for the reasons explained in Respondents' response to CCCoL ¶ 8, which Respondents incorporate herein.

10. An acquisition that violates Section 7 of the Clayton Act, by definition, is a violation of Section 5 of the FTC Act. *See, e.g.*, *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454 (1986).

Response to Proposed Conclusion of Law No. 10:

The proposed conclusion is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCCoL ¶ 8, which Respondents incorporate herein .

11. Section 7 of the Clayton Act applies to all mergers, which "must be tested by the same standard, whether they are classified as horizontal, vertical, conglomerate, or other." *FTC v. Procter & Gamble Co.*, 386 U.S. 568, 577 (1967).

Response to Proposed Conclusion of Law No. 11:

The proposed conclusion is incomplete and misleading. The "same standard" referred to in *FTC v. Procter & Gamble Co.*, 386 U.S. 568, 577 (1967), is the "core question" of "whether a merger may substantially lessen competition", *Procter & Gamble* at 577. Because the Transaction is purely vertical (as opposed to horizontal), Complaint Counsel "cannot use a short cut to establish a presumption of anticompetitive effect"; rather, it must make a "fact-specific" showing that the Transaction is anticompetitive. *United States v. AT&T, Inc. (AT&T II)*, 916 F.3d 1029, 1032 (D.C. Cir. 2019); *see also Republic Tobacco Co. v. North Atl. Trading Co.*, 381 F.3d 717, 737 (7th Cir. 2004) ("As horizontal agreements are generally more suspect than vertical agreements, we must be cautious about importing relaxed standards of proof from horizontal agreement cases into vertical agreement cases. To do so might harm competition and frustrate the very goals that antitrust law seeks to achieve."). Complaint Counsel cannot prove that the merger is likely to substantially lessen competition absent a showing that it would likely result in anticompetitive harm that substantially outweighs the efficiencies reasonably likely to result from the Transaction. Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

12. "Economic arrangements between companies standing in a supplier-customer relationship are characterized as 'vertical.'" *Brown Shoe Co. v. United States*, 370 U.S 294, 323 (1962).

Response to Proposed Conclusion of Law No. 12:

Respondents have no specific response.

13. Courts and the Commission have traditionally analyzed Section 7 claims under a burden-shifting framework outlined in *Baker Hughes* and its progeny, *see United States v. Baker Hughes, Inc.*, 908 F.2d 981, 982-83 (D.C. Cir. 1990); *In re Otto Bock HealthCare N. Am., Inc.*, 2019 WL 5957363, at *11 (F.T.C. Nov. 1, 2019); *In re Polypore Int'l, Inc.*, Docket No. D-9327, 2010 WL 9549988, at *9 (F.T.C. Nov. 5, 2010), and the same burden-shifting framework applies to both horizontal and vertical mergers. *See United States v. AT&T, Inc.*, 310 F. Supp. 3d 161, 191 n.17 (D.D.C. 2018) (rejecting, "as a matter of law and logic," defendants' assertion that the Section 7 burden-shifting framework is inapplicable to vertical merger cases such that the Government "has the burden to account for all of defendants' proffered efficiencies as part of making its prima facie case").

Response to Proposed Conclusion of Law No. 13:

The proposed conclusion is incomplete.

First, Complaint Counsel bears "the burden on every element of their Section 7 challenge." *Arch Coal*, 329 F. Supp. 2d at 116. Complaint Counsel's "failure of proof in any respect will mean the transaction should not be enjoined." *Id.* at 116. To prove a violation of the Clayton Act, Complaint Counsel must show that, "notwithstanding the merger's [] procompetitive effects, [it] has met its burden of proof of establishing" that the merger of Illumina and GRAIL, "at this time and in this remarkably dynamic industry, is likely to substantially lessen competition in the manner it predicts." *AT&T I* at 194.

Second, while the burden shifting framework announced in *U.S. v. Baker Hughes Inc.*, 908 F.2d 981, 990 (D.C. Cir. 1990) may apply, it operates differently for vertical mergers than it does for horizontal mergers. In particular, a challenge to a vertical merger must be assessed in the light of the widespread recognition that, unlike horizontal mergers, "most vertical mergers are procompetitive." 4A Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law § 10A-1 (5th

ed. 2021); *see also Republic Tobacco Co. v. North Atl. Trading Co.*, 381 F.3d 717, 737 (7th Cir. 2004) ("As horizontal agreements are generally more suspect than vertical agreements, we must be cautious about importing relaxed standards of proof from horizontal agreement cases into vertical agreement cases. To do so might harm competition and frustrate the very goals that antitrust law seeks to achieve."). Complaint Counsel thus bears the burden to demonstrate that a vertical merger is anticompetitive when any resulting harm is balanced against any resulting efficiencies. The District Court of the District of Columbia applied this approach in *AT&T I*, the only vertical merger challenged by the DOJ in over four decades. In rejecting the DOJ's challenge to the vertical merger at issue, the court in *AT&T I* observed that there is "recognition among academics, courts, and antitrust enforcement authorities alike that many vertical mergers create vertical integration efficiencies between purchasers and sellers." *AT&T I* at 193. The court described the government's burden under the *Baker Hughes* framework, explaining: "I will discuss the conceded consumer benefits associated with the proposed merger. Mindful of those conceded benefits, and the need to balance them against the Government's allegations of consumer harm, I will then evaluate whether the Government has carried its burden to show a likelihood that the challenged merger will result in a substantial lessening of competition." *AT&T I* at 195. Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

14. Under this burden-shifting framework, "[f]irst, the government must establish a prima facie case that an acquisition is unlawful." *Polypore Int'l*, 2010 WL 9549988, at *9; *see also Baker Hughes,* 908 F.2d at 982.

Response to Proposed Conclusion of Law No. 14:

The proposed conclusion is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCCoL ¶ 13, which Respondents incorporate herein.

15. The Government's burden of production at this stage is low. The Government need only provide evidence "sufficient to raise an inference [of anticompetitive effect] to shift the burden to Respondent[s] for rebuttal." *In re Otto Bock HealthCare N. Am., Inc.*, 2019 WL 2118886, *27 n.25 (F.T.C. May 6, 2019) (Chappell, A.L.J.).

Response to Proposed Conclusion of Law No. 15:

The proposed conclusion is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCCoL ¶ 13, which Respondents incorporate herein.

16. "The burden of producing evidence to rebut [the *prima facie* case] then shifts to the defendant." *Baker Hughes*, 908 F.2d at 982.

Response to Proposed Conclusion of Law No. 16:

The proposed conclusion is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCCoL ¶ 13, which Respondents incorporate herein.

17. "If the defendant successfully rebuts the [*prima facie* case], the burden of producing additional evidence of anticompetitive effect shifts to the government, and merges with the ultimate burden of persuasion, which remains with the government at all times." *Baker Hughes*, 908 F.2d at 983.

Response to Proposed Conclusion of Law No. 17:

Respondents have no specific response.

18. Although Complaint Counsel has the ultimate burden in this case, Respondents bear the burden of proving their factual propositions. Initial Decision, *In re Altria Group, Inc. and Juul Labs, Inc.*, Docket No. 9393, at 5 (F.T.C. Feb. 15, 2022) ("[C]ounsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto.") (quoting 16 C.F.R. § 3.43(a)).

Response to Proposed Conclusion of Law No. 18:

The proposed conclusion is inaccurate, incomplete, and misleading for the reasons explained in Respondents' responses to CCCoL ¶ 13, which Respondents incorporate herein.

III. THE RESEARCH, DEVELOPMENT, AND COMMERCIALIZATION OF MCED TESTS IS A RELEVANT PRODUCT MARKET

19. The Supreme Court has recognized that Section 7 prohibits acquisitions that may "substantially lessen competition within the area of effective competition." *Brown Shoe*,

370 U.S. at 324 (quoting *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 593 (1957) (internal quotations omitted).

Response to Proposed Conclusion of Law No. 19:

Respondents have no specific response.

20. To determine the "area of effective competition," courts "reference . . . a product market (the 'line of commerce') and a geographic market (the 'section of the country')[.]" *Brown Shoe*, 370 U.S. at 324. "Often, the first steps in analyzing a merger's competitive effects are to define the geographic and product markets affected by it." *ProMedica Health Sys., Inc. v. F.T.C.*, 749 F.3d 559, 565 (6th Cir. 2014). Whether the transaction at issue is horizontal or vertical, courts use the same set of analytic tools to define the affected market. *See Brown Shoe*, 370 U.S. at 324-28.

Response to Proposed Conclusion of Law No. 20:

Respondents have no specific response. .

21. It is well settled that "the boundaries of the relevant market must be drawn with sufficient breadth to . . . recognize competition where, in fact, competition exists." *Brown Shoe*, 370 U.S. at 326.

Response to Proposed Conclusion of Law No. 21:

The proposed conclusion is incomplete. "Relevant market analysis is based on the 'narrowest market' principle", the analysis of which requires "examining the most narrowly-defined product or group of products sold . . . [that] constitutes a relevant market". *See Arch Coal*, 329 F. Supp. 2d at 120. To meet its burden, Complaint Counsel was required to adduce admissible evidence proving its alleged relevant market, not mere speculation. *See Reifert v. S. Cent. Wisconsin MLS Corp*., 450 F.3d 312, 318 (7th Cir. 2006) ("a conclusory assumption of competition where products or services appear to be similar is insufficient" to prove a relevant product market); *Arch Coal*, 329 F. Supp. 2d at 117 (D.D.C. 2004) ("[A]ntitrust theory and speculation cannot trump facts"). The fact that the hypothesized MCED market proposed by Complaint Counsel does not, in fact, exist is significant because courts have held that where a market does not exist, there can be no anticompetitive effects. *Kenney v. Am. Bd. of Internal*

Med., 412 F. Supp. 3d 530, 547 (E.D. Pa. 2019), aff'd, 847 F. App'x 137 (3d Cir. 2021) (holding that Defendant "cannot have a monopoly in a market that does not exist."); *Collins v. Associated Pathologists, Ltd*., 844 F.2d 473, 480 (7th Cir. 1988) ("It is impossible to monopolize a market that does not exist."); *Siva v. Am. Bd. of Radiology*, 418 F. Supp. 3d 264, 277 (N.D. Ill. 2019) (holding that a defendant cannot have or exploit a "monopoly in a market that does not exist."); *In re Altria Grp., Inc*., No. 9393, at 110 (Feb. 15, 2022) (citing *Mercantile Tex. Corp. v. Bd. of Governors of Fed. Rsrv. Sys*., 638 F.2d 1255, 1272 (5th Cir. 1981) ("The competitive conditions of a market five years in the future cannot reliably be predicted."). Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

22. A product market's "outer boundaries" are determined by the "reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *FTC v. Tronox Ltd.*, 332 F. Supp. 3d 187, 198 (D.D.C. 2018) (quoting *Brown Shoe*, 370 U.S. at 325).

Response to Proposed Conclusion of Law No. 22:

The proposed conclusion is incomplete. The test of reasonable interchangeability requires that courts "consider only substitutes that constrain pricing in the reasonably foreseeable future, and only products that can enter the market in a relatively short time can perform this function." *United States v. Microsoft Corp.*, 253 F.3d 34, 53-54 (D.C. Cir. 2001); *see also Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 218 (D.C. Cir. 1986) (citation omitted) (only substitutes that can enter the market "promptly" should be considered). The proposed conclusion is also incomplete for the reasons explained in Respondents' responses to CCFF ¶ 21 and the relevant discussion in their opening and reply post-trial briefs, which Respondents incorporate herein.

23. To make this determination, courts generally look to two types of evidence: "the 'practical indicia' set forth by the Supreme Court in *Brown Shoe*, and testimony from

experts in the field of economics." *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 27 (D.D.C. 2015).

Response to Proposed Conclusion of Law No. 23:

Respondents have no specific response.

24. In *Brown Shoe,* the Supreme Court identified a series of "practical indicia" courts should consider in determining the relevant product market. The indicia include "industry or public recognition of the [market] as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." *Brown Shoe*, 370 U.S. at 325; *see also Otto Bock*, 2019 WL 2118886, at *5 (Chappell, A.L.J.); *Sysco* 113 F. Supp. 3d at 27; *United States v. Aetna, Inc.*, 240 F. Supp. 3d 1, 21 (D.D.C. 2017); *United States v. H&R Block*, 833 F. Supp. 2d 36, 51 (D.D.C. 2011). Together, these practical indicia identify MCED tests as a distinct product market for purposes of assessing the Acquisition's competitive effects. *See* (CCFF ¶¶ 688-821).

Response to Proposed Conclusion of Law No. 24:

The proposed conclusion is incomplete. "While the 'practical indicia' named in *Brown Shoe* . . . are important considerations in defining a market, they were never intended to exclude economic analysis altogether". *Reifert v. S. Cent. Wisconsin MLS Corp.*, 450 F.3d 312, 320 (7th Cir. 2006).

Respondents object to the identified product market because Complaint Counsel has not carried its burden of establishing that all "MCED tests" comprise a relevant product market. Complaint Counsel argues that all "MCED tests", no matter their stage of development, constitute the relevant product market based on the *Brown Shoe* practical indicia and the hypothetical monopolist test. To show this, however, Complaint Counsel relies solely on a "negative" market definition—what MCED tests are not—and fails to answer the more fundamental question: what attributes determine whether a cancer screening test is an "MCED test" that is reasonably substitutable for Galleri in the "arena within which significant substitution in consumption or production" will occur? *See Am. Express Co.*, 138 S. Ct. at 2286 (quoting Areeda & Hovenkamp § 5.02). Whether the relevant market is labeled as a commercial

market or an innovation one, Complaint Counsel cannot ignore the attributes of the tests at issue, because the essential attributes of a market "provide[] the context against which to measure [] competitive effects". *Geneva Pharms. Tech. Corp. v. Barr Lab'ys Inc.*, 386 F.3d 485, 496 (2d Cir. 2004). As discussed in Respondents' Reply Br. § II.A, Complaint Counsel's alleged market (1) is out of step with the *Brown Shoe* factors; (2) flunks the Hypothetical Monopolist Test; (3) disregards reasonable interchangeability and cross-elasticity of demand; (4) is impermissibly speculative and simultaneously over- and under-inclusive; and (5) is not salvaged by labeling the market an innovation one.

Respondents also incorporate their responses to CCFF ¶¶ 688–821 and the relevant discussion in their opening and reply post-trial briefs.

25. Not all of *Brown Shoe*'s practical indicia are required to find a relevant market. *See Int'l T. & T. Corp. v. General T. & E. Corp.*, 518 F.2d 913, 932-33 (9th Cir. 1975) ("These indicia were listed with the intention of furnishing practical aids in identifying zones of actual or potential competition rather than with the view that their presence or absence would dispose, in talismanic fashion, of the submarket issue. Whether or not a court is justified in carving out a submarket depends ultimately on whether the factors which distinguish one purported submarket from another are 'economically significant' in terms of the alleged anticompetitive conduct.").

Response to Proposed Conclusion of Law No. 25:

Respondents have no specific response except to note that Complaint Counsel failed to address three of the seven factors at all. (CC Post-Trial Br. at 50–57.)

26. Along with the practical indicia set out in *Brown Shoe*, courts commonly use the hypothetical monopolist test to assess the relevant product market. *See FTC v. Advocate Health Care Network*, 841 F.3d 460, 468-69 (7th Cir. 2016) (applying the hypothetical monopolist test to define a relevant geographic market); *see also FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 338 (3d Cir. 2016); *In re ProMedica Health Sys., Inc.*, 2012 WL 1155392, at *14 (F.T.C. Mar. 28, 2012); *Sysco*, 113 F. Supp. 3d at 33; *H&R Block,* 833 F. Supp. 3d at 51-52; *Horizontal Merger Guidelines* § 4.1.1.

Response to Proposed Conclusion of Law No. 26:

Respondents have no specific response.

27. Under the hypothetical monopolist test, a candidate market constitutes a relevant antitrust market if a hypothetical monopolist could profitably impose a "small but significant and non-transitory increase in price" ("SSNIP"), or reduce quality or availability, on at least one product of the merging parties in the candidate market, or whether customers switching to alternative products would make such a price increase unprofitable. *See Horizontal Merger Guidelines* § 4.1.1; *see also Otto Bock*, 2019 WL 2118886, at *6 (Chappell, A.L.J.).

Response to Proposed Conclusion of Law No. 27:

Respondents have no specific response except to emphasize that Complaint Counsel's application of the hypothetical monopolist test does not support its proposed relevant market. Complaint Counsel cites no case accepting an application of the hypothetical monopolist test based entirely upon a *qualitative* assessment of the market, without any supporting *quantitative* economic analysis, and courts typically reject purely qualitative assessments. *In re Live Concert Antitrust Litig.*, 863 F. Supp. 2d 966, 985–86 (C.D. Cal. 2012); *see also Se. Mo. Hosp.*, 642 F.3d at 616 (rejecting plaintiff's expert's conclusion that a SSNIP in the relevant market would not cause customers to switch when there were "no market studies to support [the] claim" and the "assertion [was] without analytic or even anecdotal evidence."); *Reifert*, 450 F.3d at 318 (requiring that "a plaintiff prove that products are good substitutes *using economic evidence*; a conclusory assumption of competition where products or services appear to be similar is insufficient") (emphasis added).; *ABS Glob., Inc. v. Inguran, LLC*, No. 14-cv-503-wmc, 2016 WL 3963246, at *14 (W.D. Wis. July 21, 2016) ("[This] Circuit has repeatedly emphasized the need for both a quantitative and qualitative economic analysis in arriving at a market definition[.]"). Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

28. Products do not need to be identical to fall within the same product market. *See United States v. Energy Sols., Inc.*, 265 F. Supp. 3d 415, 436 (D. Del. 2017) (products comprising a relevant market "need not be identical, only reasonable substitutes"); *see also Hicks v. PGA Tour Inc.,* 897 F.3d 1109, 1122 (9th Cir. 2018) (holding that "claims

of increased effectiveness" of certain products does not "place" those products "in a distinct market"); *Humana Inc. v. Mallinckrodt ARD LLC*, CV 19-06926, 2020 WL 3041309, at *4, n.2 (C.D. Cal. Mar. 9, 2020) (explaining "it is wrong" to suggest that because two products "are not identical" they are not in the same relevant product market).

Response to Proposed Conclusion of Law No. 28:

The proposed conclusion is incomplete. While products need not be identical to occupy the same relevant product market, Complaint Counsel nonetheless bears the burden to specify and prove the boundaries of the "arena within which significant substitution in consumption or production" will occur. *See Am. Express Co.*, 138 S. Ct. at 2286. A relevant product market consists of "products that have reasonable interchangeability for the purposes for which they are produced—price, use and qualities considered." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 404 (1956). "The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *Brown Shoe*, 370 U.S. at 325; *see du Pont*, 351 U.S. at 395. The test of reasonable interchangeability requires that courts "consider only substitutes that constrain pricing in the reasonably foreseeable future, and only products that can enter the market in a relatively short time can perform this function." *U.S. v. Microsoft Corp.*, 253 F.3d 34, 53–54 (D.C. Cir. 2001); *see also Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 218 (D.C. Cir. 1986) (citation omitted) (only substitutes that can enter the market "promptly" should be considered). "Interchangeability of use and cross-elasticity of demand look to the availability of products that are similar in character or use to the product in question and the degree to which buyers are willing to substitute those similar products for the product." *FTC v. Swedish Match*, 131 F. Supp. 2d 151, 157 (D.D.C. 2000). Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

29. Instead, as the Supreme Court explained in *Brown Shoe*, "the boundaries of the relevant market must be drawn with sufficient breadth . . . to recognize competition where, in fact, competition exists." *Brown Shoe*, 370 U.S. at 326. This is because the relevant product market is meant to reflect actual "business reality [] of how the market is perceived by those who strive for profit in it," and of where the competitive concerns may arise. *FTC v. Cardinal Health, Inc.,* 12 F. Supp. 2d 34, 46 (D.D.C. 1998) (quoting *FTC v. Coca-Cola Co.*, 641 F. Supp. 1128, 1132 (D.D.C. 1986), *vacated as moot*, 829 F.2d 191 (D.C. Cir. 1987)).

Response to Proposed Conclusion of Law No. 29:

The proposed conclusion is incomplete for the reasons explained in Respondents' responses to CCCoL ¶¶ 21–27, which Respondents incorporate herein.

30. Here, all MCED test developers are pursuing the same goal of creating the best MCED test. Contrary to Respondents' claims, the evidence shows that MCED tests will ultimately be quite similar. But they are unlikely to be identical. In an innovative market, such as the MCED test market here, differentiation and new approaches are *attributes of competition*, not indicia of its absence. *See* (CCFF ¶¶ 1902-2606).

Response to Proposed Conclusion of Law No. 30:

The proposed conclusion is improper and should be disregarded because it is a proposed finding of fact couched as a proposed conclusion of law. In any event, the proposed conclusion is incorrect and unsupported by the record. As Respondents have explained, at present, there is no product in existence that is reasonably interchangeable with GRAIL's Galleri test. (*See* PFF ¶ 697, 700–708.) Even if the tests in development were on the market, or could be expected to launch in the near term, Complaint Counsel failed to prove that any of these tests will be reasonably interchangeable with Galleri if and when they are launched. (PFF ¶¶ 708–708.3.)

Further, to the extent it can be construed as a proposed conclusion of law, it is inaccurate and incomplete. *First*, market definition turns not on whether producers share the same general goal but on the reasonable interchangeability of use or the cross-elasticity of demand between the product and the substitutes for it. *Brown Shoe,* 370 U.S. at 325; *du Pont,* 351 U.S. at 395. Simply stating that products "need not be identical" (CC Post-Trial Br. at 59), to occupy the

same relevant product market or that "differentiation and new approaches are attributes of competition" (CCCoL ¶ 30) does not discharge Complaint Counsel of its burden to identify the attributes that would make a test part of the market it alleges—that is, to specify and prove whether a cancer screening test is an "MCED test" that is reasonably substitutable for Galleri in the "arena within which significant substitution in consumption or production" will occur. *See Am. Express Co.*, 138 S. Ct. at 2286 (quoting Areeda & Hovenkamp § 5.02). In labelling the relevant market an "innovative" one, the proposed finding attempts to ignore the attributes of the tests at issue; but it cannot: the essential attributes of a market "provide[] the context against which to measure [] competitive effects". *Geneva Pharms. Tech. Corp. v. Barr Lab'ys Inc.*, 386 F.3d 485, 496 (2d Cir. 2004).

Second, even if Complaint Counsel were correct that "the evidence shows that MCED test will *ultimately* be quite similar" (they are not), this nevertheless fails as a matter of law. The test of reasonable interchangeability requires that courts "consider only substitutes that constrain pricing in *the reasonably foreseeable future*, and only products that can enter the market in a relatively short time can perform this function." *United States v. Microsoft Corp.*, 253 F.3d 34, 53-54 (D.C. Cir. 2001) (emphasis added); *see also Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 218 (D.C. Cir. 1986) (citation omitted) (only substitutes that can enter the market "promptly" should be considered); *see also In re Altria Grp., Inc.*, FTC No. 9393, at 108–09 (Feb. 15, 2022) ("[T]o conclude that future products would likely . . . reach the market would require unacceptable and unfair speculation.") Courts have repeatedly rejected alleged markets defined to include products that are not yet in existence and whose features are highly uncertain, and have rejected the inclusion of undefined future products in a relevant market. *See SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1211 (2d. Cir. 1981) (overturning jury verdict in

plaintiffs' favor and holding that patent acquisitions did not violate Section 7 as a matter of law because the relevant product market did not exist at the time of the acquisitions and for another eight years following the acquisitions); *Fraser v. Major League Soccer, L.L.C.*, 97 F. Supp. 2d 130, 140 (D. Mass. 2000), *aff'd*, 284 F.3d 47 (1st Cir. 2002) ("The relevant test under § 7 looks to whether competition in existing markets has been reduced. Where there is no existing market, there can be no reduction in the level of competition. . . . Competition that does not exist cannot be decreased.")

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

31. Based on the hypothetical monopolist test, *see* (CCFF ¶¶ 822-30), and the *Brown Shoe* practical indicia, *see* (CCFF ¶¶ 688-821), the relevant product market is the research, development, and commercialization of MCED tests ("MCED test market").

Response to Proposed Conclusion of Law No. 31:

The proposed conclusion is inaccurate, incomplete, and misleading. (*See* COL ¶¶ 10–52.)

IV. THE UNITED STATES IS THE RELEVANT GEOGRAPHIC MARKET

32. The relevant market in which to assess the anticompetitive harms of the Acquisition necessarily includes the relevant geographic market, or the area of competition affected by the merger. *See Sysco*, 113 F. Supp. 3d at 48 ("[T]he proper question to be asked . . . [is] where, within the area of competitive overlap, the effect of the merger on competition will be direct and immediate.'" (quoting *United States v. Phila. Nat'l Bank*, 374 U.S. 321, 357 (1963)); *see also Advocate Health Care Network*, 841 F.3d at 476 (citing *Phila. Nat'l Bank*, 374 U.S. at 357); *see also Horizontal Merger Guidelines* § 4.2.

Response to Proposed Conclusion of Law No. 32:

Respondents do not dispute that the relevant geographic market is the United States.

33. Regulatory requirements are a well-recognized factor in determining the scope of geographic markets. *Horizontal Merger Guidelines* §4.2. When "customers in the United States must use products approved by U.S. regulators," then "[t]he geographic market is defined around U.S. customers." *Horizontal Merger Guidelines* §4.2.2; *see also Otto Bock*, 2019 WL 2118886, at *5-6 (Chappell, A.L.J.); Complaint, *In re Össur*

Hf., Össur Am. Holdings, Inc., and College Park Indus., Inc., Docket No. C-4712, at 2-3 (F.T.C. May 28, 2020) (defining the relevant geographic market for a medical device as the United States); Complaint, *In re Stryker Corp. and Wright Med. Grp. N.V.*, Docket No. C-4728, at 2 (F.T.C. Dec. 17, 2020) (same).

Response to Proposed Conclusion of Law No. 33:

Respondents do not dispute that the relevant geographic market is the United States.

34. The United States has unique regulatory, *see* (CCFF ¶¶ 831-50), and reimbursement, *see* (CCFF ¶¶ 851-77), realities that distinguish it from other areas in the world with respect to the sale of MCED tests. In the United States, the FDA is responsible for regulating and approving medical devices for their safety and effectiveness, as set forth in Section 201(h)(2) of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 321 (defining the term "device" to include "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals"); *see also Morgan v. Medtronic, Inc.,* 172 F. Supp. 3d 959, 965 (S.D. Tex. 2016) ("Congress enacted the [Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act 'MDA'] in 1976 and granted the FDA authority to regulate the safety and effectiveness of medical devices sold in the United States."). *See* (CCFF ¶¶ 510, 512, 831-50).

Response to Proposed Conclusion of Law No. 34:

Respondents do not dispute that the relevant geographic market is the United States.

35. Here, the United States is the relevant geographic market in which to analyze the effects of the Acquisition because the United States has unique regulatory requirements, *see* (CCFF ¶¶ 831-50), and American physicians and patients require tests that are approved by U.S. regulators. *See* (CCFF ¶¶ 831-85).

Response to Proposed Conclusion of Law No. 35:

Respondents do not dispute that the relevant geographic market is the United States.

V. ILLUMINA'S NGS INSTRUMENTS AND CONSUMABLES ARE RELATED PRODUCTS TO MCED TESTS

36. The Government need not prove that the related product constitutes a relevant antitrust market. *See Brown Shoe*, 370 U.S. at 325, 344 (finding a Section 7 violation when only a relevant product market was shown); *du Pont*, 353 U.S. at 593-95 (same); *AT&T*, 310 F. Supp. 3d at 195-97, 226–27 (D.D.C.) (scrutinizing the "measure of customer loss" underpinning the Government's "increased-leverage theory" without requiring proof of the upstream firm's "'market power' in the programming market").

Response to Proposed Conclusion of Law No. 36:

The proposed conclusion is incorrect, incomplete and misleading.

Complaint Counsel's burden to prove a related product market follows naturally from its burden to prove the Transaction will *substantially* lessen competition. *Arch Coal*, 329 F. Supp. 2d at 116 ("[P]laintiffs have the burden on every element of their Section 7 challenge, and a failure of proof in any respect will mean the transaction should not be enjoined."). Defining a cognizable related product market is a necessary element of making this showing because "[v]ertical restraints often pose no risk to competition unless the entity imposing them has market power, which cannot be evaluated unless the Court first defines the relevant market." *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2285, n.7 (2018); *see also Auburn News Co. v. Providence J. Co*., 659 F.2d 273, 278 (1st Cir. 1981) ("Where substantial market power is absent at any one product or distribution level, vertical integration will not have an anticompetitive effect."); *Fruehauf*, 603 F.2d at 353.

While the case law expressly addressing this issue is sparse, the requirement to prove a related product market can be inferred from prior decisions on vertical mergers. The *Fruehauf* Court held that in assessing the anticompetitive effect of a vertical merger, it is necessary to measure "the degree of market power that would be possessed by the merged enterprise and *the number and strength of competing suppliers and purchasers*". *Id.* at 353 (emphasis added).

Similarly, commentary on the Vertical Merger Guidelines states it is necessary to (1) "understand what inputs are included in the 'related product' category," (2) determine "whether price increases by the merging firm that produces the 'related product' will lead to accommodating price increases by its competitors" and (3) "measure the share of output accounted for by the related product." Jonathan B. Baker, Nancy L. Rose, Steven C. Salop &

Fiona Scott Morton, *Recommendations and Comments on the Draft Vertical Merger Guidelines* (Feb. 24, 2020) at 6–7.

Complaint Counsel's reliance on *Brown Shoe*, *du Pont* and *AT&T* is unavailing. The burden to prove a related product market was not at issue in those cases, and therefore cannot be fairly read to support Complaint Counsel's desired conclusion. In *Brown Shoe*, the Supreme Court held that the "relevant line[s] of commerce" were the markets for men's, women's and children's shoes. 370 U.S. at 326. The Court explicitly discussed both Brown Shoe's and Kinney's market power in the *manufacture and retail* of men's, women's and children's shoes, respectively. Brown was the fourth largest manufacturer and Kinney owned the largest chain of retail stores in the country. *Id.* at 332–33. Because of Kinney's market power in the related retail stores market, Brown could use its ownership of Kinney to force Brown shoes into Kinney stores, thereby foreclosing Brown's manufacturer competitors from access to Kinney's retail channel. *Id.* at 331–32. In *duPont*, the issue was that duPont's stake in General Motors enabled duPont to foreclose its competitors in the upstream market for automobile finishes and fabrics by preventing them from selling to General Motors. 353 U.S. at 595. Critical to such a finding was that General Motors was a "colossus of the giant automobile industry" that accounted for upwards of two fifths of the total sales of cars in the country. *duPont* at 595. In *AT&T I*, while defendants had not "meaningfully challenged the Government's proposed product market", 310 F. Supp. 3d at 195, "accepting the Government's proposed product market does not mean that Turner's position in the upstream programming market is irrelevant to evaluating the Government's theories of harm in this case". *AT&T I* at 196. Instead, the court found that "examining the importance of Turner's content to distributors in the upstream programming

market is a necessary (but not sufficient) step in evaluating the Government's increased-leverage theory". *AT&T I* at 196.

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

37. No court has held that the government must prove monopoly power in a related product market to prove that a merger violates the Clayton Act. Instead, the proper inquiry here is whether Illumina supplies related products on which Grail's rivals rely. *AT&T*, 310 F. Supp. 3d at 195-97 (D.D.C.) (finding relevant antitrust product market for downstream multichannel video distribution in which alleged harm from transaction would occur, but not defining a related antitrust product market around upstream programming).

Response to Proposed Conclusion of Law No. 37:

The proposed conclusion is incorrect and incomplete. As discussed in Respondents' response to CCCoL ¶ 36, there is legal authority for the proposition that Complaint Counsel must prove the related product market. Moreover, in *AT&T I*, the defendants had not "meaningfully challenged the Government's proposed product market", 310 F. Supp. 3d at 195, and the court wrote that "accepting the Government's proposed product market does not mean that Turner's position in the upstream programming market is irrelevant to evaluating the Government's theories of harm in this case". *AT&T I* at 196. Instead, the court found that "examining the importance of Turner's content to distributors in the upstream programming market is a necessary (but not sufficient) step in evaluating the Government's increased-leverage theory". *AT&T I* at 196.

In asking this Court to find that putative MCED test developers require NGS platforms that only Illumina can provide and for which there are no substitutes, Complaint Counsel effectively asks the Court to define a related product market without any real analysis. Complaint Counsel has not offered the evidence necessary to define the related product market as Illumina NGS instruments and consumables (or anything else). Complaint Counsel makes no

mention of the *Brown Shoe* factors—none—and did not conduct any hypothetical monopolist test (quantitative, qualitative or otherwise). Complaint Counsel simply declares that Illumina occupies 100% of what Complaint Counsel calls the related product. That is not analysis; it is unsupported assertion. But even if unsupported assertions were credited in the law (and they are not), they are no basis for killing a life-saving transaction.

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

38. Illumina's NGS instruments and consumables are related products to MCED tests, serving as critical inputs necessary to their development and commercialization. *See* (CCFF ¶¶ 925-1018).

Response to Proposed Conclusion of Law No. 38:

The proposed conclusion is inaccurate, incomplete, misleading, and unsupported by the record. In concluding that Illumina's NGS instruments and consumables comprise the related product market, Complaint Counsel did not conduct any detailed examination of "market data, figures or other relevant material adequately describing the nature, cost, usage or other features of competing products." *Grason Elec. Co.*, 571 F. Supp. at 1521 (citation omitted). Complaint Counsel did not undertake any effort to conduct a SSNIP test to determine whether the boundaries of the related product market were limited to Illumina's NGS systems, other NGS systems, or non-NGS systems. *See Sysco*, 113 F. Supp. 3d at 33. Rather, it simply asserted that the related product market consisted of Illumina's NGS instruments and consumables, and nothing else. Complaint Counsel's failure to properly define a related product market is fatal to its case, as proof of a related product market is an element of Complaint Counsel's case on which it bears the burden of proof. *See Arch Coal, Inc.*, 329 F. Supp. 2d at 116. Because the dynamics in the upstream market are critical to Complaint Counsel's theory of harm of foreclosure and

raising rivals' costs, without properly defining the related product market, it cannot show that the merger is likely to "substantially lessen competition in the manner it predicts." *AT&T I*, 310 F. Supp. 3d at 194. Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

VI. THE ACQUISITION HAS A REASONABLE PROBABILITY OF SUBSTANTIALLY LESSENING COMPETITION IN THE U.S. MCED TEST MARKET

39. The Acquisition has a reasonable probability of substantially lessening competition in the market for the research, development, and commercialization of MCED tests in the United States and cause harm to American consumers. *See* (CCFF ¶¶ 1019-1398, 2607-3569).

Response to Proposed Conclusion of Law No. 39:

The proposed conclusion is inaccurate, incomplete and misleading for the reasons explained in Respondents' Reply Br. § III and Respondents' COL ¶¶ 60–83, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶¶ 1019–1398, 2607–3569 herein.

40. As the Supreme Court has explained, "[t]he primary vice of a vertical merger . . . is that, by foreclosing the competitors of either party from a segment of the market otherwise open to them, the arrangement may act as a clog on competition, which deprives rivals of a fair opportunity to compete." *Brown Shoe Co*., 370 U.S. at 323-24 (internal quotations omitted).

Response to Proposed Conclusion of Law No. 40:

To the extent this proposed finding is meant to suggest that a vertical merger can be found based solely on upstream share, the proposed conclusion is incomplete and misleading. The Court in *Brown Shoe* required actual evidence of a probable foreclosure effect: one that, for example, could simultaneously "run afoul of the Sherman Act". *See Brown Shoe Co. v. United States*, 370 U.S. 294, 328, 332 (1962) (holding that it was "apparent both from past behavior of Brown and from the testimony of Brown's President, that Brown would use its ownership of

Kinney to force Brown shoes into Kinney stores. Thus, in operation this vertical arrangement would be quite analogous to one involving a tying clause"). The other vertical cases Complaint Counsel cites likewise required actual evidence of likely foreclosure effects. *See United States v. American Cyanamid Co.*, 719 F.2d 558, 566 (2d. Cir. 1983) (noting that courts in vertical cases require evidence as to "the *likelihood and size* of any market foreclosure"); *Fruehauf*, 603 F.2d at 352 ("The Supreme Court's insistence that each merger challenged under [Section] 7 be viewed . . . in the context of its particular industry, and that the Clayton Act protects Competition, not Competitors, contravenes the notion that a significant level of foreclosure is itself the proscribed effect" of Section 7 (internal citations and quotation marks omitted)); *In re Zinc Antitrust Litig.,* No. 14-cv-3728, 2016 WL 3167192, at *23 (S.D.N.Y. 2016) ("[T]he allegations in the [Complaint] do not even attempt to raise an inference that Glencore Ltd.'s acquisition of Pacorini foreclosed [competitors]" and "[t]here is no plausible allegation that competition was lessened or likely to be lessened in the relevant sense."). No modern court has ever held that the government can so easily condemn a vertical merger.

Further, Complaint Counsel's challenge to this vertical merger cannot rely on any presumptions of harm that may be available in a horizontal case. As the Court of Appeals in *AT&T II* recognized, "unlike horizontal mergers, the government cannot use a short cut to establish a presumption of anticompetitive effect through statistics about the change in market concentration, because vertical mergers produce no immediate change in the relevant market share." *AT&T II*, 916 F.3d at 1032. Further much more is required than "testimony from third-party competitors" that is "speculative, based on unproven assumptions, or unsupported." *AT&T II* 916 F.3d at 1038 (quoting *AT&T I*, 310 F. Supp. at 214). Rather, Complaint Counsel was required to bring forward substantial evidence that the Transaction likely will result in

competitive harm that outweighs the Transaction's procompetitive benefits. Complaint Counsel failed to carry its burden of proving likely competitive harm by a wide margin.

Complaint Counsel bears the burden to demonstrate that a vertical merger is anticompetitive when any resulting harm is balanced against any resulting efficiencies. The District Court of the District of Columbia applied this approach in *AT&T I*, the only vertical merger challenged by the DOJ in over four decades. 310 F. Supp. 3d 161. In rejecting the DOJ's challenge to the vertical merger at issue, the court in *AT&T I* observed that there is "recognition among academics, courts, and antitrust enforcement authorities alike that many vertical mergers create vertical integration efficiencies between purchasers and sellers." *AT&T I* at 193. The court described the government's burden under the *Baker Hughes* framework, explaining: "I will discuss the conceded consumer benefits associated with the proposed merger. Mindful of those conceded benefits, and the need to balance them against the Government's allegations of consumer harm, I will then evaluate whether the Government has carried its burden to show a likelihood that the challenged merger will result in a substantial lessening of competition." *AT&T I* at 195.

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

41. Foreclosure in the vertical merger context can mean either "foreclosing competitors of [one party] from access to a potential source of supply, or from access on competitive terms." *Yankees Entm't & Sports Network, LLC v. Cablevision Sys. Corp.*, 224 F. Supp. 2d 657, 673 (S.D.N.Y. 2002); *see also Sprint Nextel Corp. v. AT&T, Inc.*, 821 F. Supp. 2d 308, 330 (D.D.C. 2011) (explaining rivals "paying more to procure necessary inputs" is the type of injury "that the antitrust laws were designed to prevent").

Response to Proposed Conclusion of Law No. 41:

The proposed finding is incomplete and misleading as Complaint Counsel cannot sustain its burden merely by showing that the Transaction may disadvantage some of GRAIL's putative

rivals vis-à-vis GRAIL—for example, as a result of GRAIL becoming a more efficient competitor through vertical integration—because "[t]he antitrust laws . . . were enacted for the protection of competition not competitors." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977). Rather, Complaint Counsel must demonstrate that GRAIL rivals would be foreclosed "in a substantial share" of a well-defined relevant product market, enabling Illumina to suppress innovation and output, and raise prices. *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 595 (1957); *see also Fruehauf*, 603 F.2d at 352 n.9; *McWane Inc. v. FTC*, 783 F.3d 814, 838–39 (11th Cir. 2015). Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

42. Long-standing court precedent has set forth a framework for evaluating whether a vertical merger violates Section 7 of the Clayton Act. Case law and economic literature have looked to whether the merged firm has the ability and incentive to harm downstream rivals when evaluating the legality of a vertical combination. *See, e.g., AT&T*, 310 F. Supp. 3d at 243-45 (D.D.C.) (analyzing whether AT&T had ability and incentive to foreclose or restrict rival video programming distributors' access to Time Warner content); *In re* Union Carbide *Corp.*, 59 F.T.C. 614, 1961 WL 65409, at *19 (1961) (Lipscomb, A.L.J.) (finding anticompetitive harm where the merged firm "has the power to exclude" competing producers from a segment of the market).

Response to Proposed Conclusion of Law No. 42:

The proposed conclusion is incomplete, and misleading. Resulting harm from a merger must be balanced against resulting efficiencies. The District Court of the District of Columbia applied this approach in *AT&T I*, the only vertical merger challenged by the DOJ in over four decades. 310 F. Supp. 3d 161. In rejecting the DOJ's challenge to the vertical merger at issue, the court in AT&T I observed that there is "recognition among academics, courts, and antitrust enforcement authorities alike that many vertical mergers create vertical integration efficiencies between purchasers and sellers." *AT&T I* at 193. The court described the government's burden

under the Baker Hughes framework, explaining: "I will discuss the conceded consumer benefits associated with the proposed merger.

Mindful of those conceded benefits, and the need to balance them against the Government's allegations of consumer harm, I will then evaluate whether the Government has carried its burden to show a likelihood that the challenged merger will result in a substantial lessening of competition." *AT&T I* at 195. Further, Complaint Counsel misplaces reliance on *In re Union Carbide Corp.*, 59 F.T.C. 614, 1961 WL 65409, (1961), for the proposition that it need not prove Illumina would likely engage in conduct causing market foreclosure, so long as it shows that Illumina has the "power" to do so. (CC Post-Trial Br. at 81, 104). However, as a 61-year-old Commission decision, and a splintered one at that, *Union Carbide* does not control the standard to be applied here. Further, the Commissioners who voted to affirm the ALJ's ruling in that case were concerned that the merger there would compel other market participants to vertically integrate, and that such market-wide vertical integration would harm competition, and that such effects had already occurred as a result of the merger. Thus, contrary to Complaint Counsel's suggestion, the Commissioners in *Union Carbide* did not uphold the ALJ decision on the basis that the merged firm had a theoretical power to foreclose rivals but no incentive to do so. Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

43. While "it is the power [to harm competitors] that counts, not its exercise," *Union Carbide,* 1961 WL 65409, at *19 (Lipscomb, A.L.J.), courts may examine a merged firm's incentives to foreclose the relevant market when considering whether there is the potential for competitive harm. *See, e.g.*, *Ford Motor Co. v. United States*, 405 U.S. 562, 568-71 (1972) (Because Ford "made the acquisition in order to obtain a foothold" in the aftermarket spark plug market, "it would have every incentive to . . . maintain the virtually insurmountable barriers to entry" in that market through foreclosure.); *AT&T*, 310 F. Supp. 3d at 243-45 (D.D.C.) (analyzing whether AT&T had the ability and incentive to foreclose or restrict rival video programming distributors' access to Time Warner content).

Response to Proposed Conclusion of Law No. 43:

The proposed conclusion is incomplete, and misleading. It is not simply a party to a merger's incentives that must be considered: to demonstrate "the probable anticompetitive effect of the merger" Complaint Counsel must show that Illumina's likely incentives absent the transaction would be *different*, or else there could be no merger-specific "effect". *AT&T I*, 310 F. Supp. 3d at 190 (internal quotations omitted). In other words, Complaint Counsel must prove that the Transaction will change the *status quo* to a large enough extent to substantially lessen competition. Complaint Counsel's showing fails here as well. By electing not to conduct a proper analysis of Illumina's incentives absent the merger, Complaint Counsel failed to prove a "probable anticompetitive effect of the merger". *AT&T I*, 310 F. Supp. 3d at 190 (emphasis added). Further, unlike in *Ford Motor Co. v. United States*, 405 U.S. 562 (1972), in which Ford failed to proffer an effective conduct remedy, the Open Offer contractually obliges Illumina *not* to disadvantage and/or foreclosure its purported rivals, thus eliminating any concern regarding Illumina's alleged incentive to harm GRAIL's putative rivals. (*See* PFF ¶¶ 1000–57.) Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

44. Although Respondents claim that Illumina's "long-standing and core strategy is to catalyze development and expansion of sequencing," *see* Answer at 7, when Illumina is vertically integrated, this objective is weighed against the impact on Illumina's own downstream sales when it determines its strategy. By doing this, Illumina is simply acting as any standalone profit-maximizing firm would; it is only that Illumina is spurred to do this *through* acquisition that runs afoul of the law. *See, e.g.*, *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 768-69 (1984) (explaining, in a non-merger antitrust case, that when "two or more entities that previously pursued their own interests separately are combining to act as one for their common benefit" it "deprives the marketplace of the independent centers of decision making that competition assumes and demands").

Response to Proposed Conclusion of Law No. 44:

The proposed conclusion is also improper and should be disregarded because it is a proposed finding of fact couched as a proposed conclusion of law. In any event, the proposed conclusion is inaccurate, incomplete and misleading. Complaint Counsel bears the burden to demonstrate that a vertical merger is anticompetitive when any resulting harm is balanced against any resulting efficiencies. To meet this burden, Complaint Counsel had to present a model showing that the Transaction's purported anticompetitive effects outweighed its efficiencies. *See, e.g.*, *AT&T I*, 310 F. Supp. 3d at 237 (rejecting the government's challenge to the vertical merger for failure to meet "the Government's burden to adequately support its proffered [vertical theory of] harm"); *Fruehauf*, 603 F.2d at 355, 360 (rejecting the government's challenge to a vertical merger because its theories were based on "speculation rather than fact" with respect to one market and "too ephemeral" with respect to another market to prove that some degree of foreclosure would be sufficient to "significantly lessen" competition); *United States v. Hammermill Paper Co.*, 429 F. Supp. 1271, 1293–94 (W.D. Pa. 1977) (finding that "the United States has not carried its burden of proof that the effect of the [vertical] acquisition . . . may be substantially to lessen competition in the manufacture and sale of printing and fine paper in the United States" because "the possibility of foreclosure of access by manufacturers is barred by" a multitude of factors). Complaint Counsel and its expert, Dr. Scott Morton, did not offer a quantitative model that balances all the economic factors that arise. (PFF ¶ 808.) Respondents further incorporate their response to CCCoL ¶ 43 and the relevant discussion in their opening and reply post-trial briefs.

45. As the trial record demonstrates, the Acquisition fundamentally alters Illumina's incentives towards its MCED test developer customers, giving Illumina ample motivation to exercise its power to disadvantage Grail's rivals both prior to their launch and post-commercialization. *See* (CCFF ¶¶ 3079-569).

Response to Proposed Conclusion of Law No. 45:

The proposed conclusion should be disregarded because it violates the Court's Order on Post-Trial Filings (at 2) requiring that "[a]ll legal contentions, including, but not limited to, contentions regarding liability and the proposed remedy, shall be supported by applicable legal authority."

The proposed conclusion is also improper and should be disregarded because it is a proposed finding of fact couched as a proposed conclusion of law. In any event, the proposed conclusion is inaccurate, incomplete and misleading for the reasons explained in PFF ¶¶ 847–72 and Respondents' responses to CCFF ¶¶ 3079–569 , which Respondents incorporate herein. Even if Complaint Counsel had established that Illumina has the ability to foreclose GRAIL's putative rivals, it failed to show that the Transaction gives Illumina any incentive to do so. Complaint Counsel's incentive theory (1) ignores the Open Offer; (2) misreads the evidence concerning future MCED revenues and profits; and (3) relies on contrived assumptions divorced from reality. Complaint Counsel's contention regarding Illumina's prior behavior is likewise wanting; it proves exactly the opposite of what Complaint Counsel seeks to show, refuting its case. Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

46. MCED tests developers' expansive reliance on Illumina during research, development, and commercialization of MCED tests, as well as the many levers Illumina has to identify and disadvantage its rivals, provides Illumina with the ability to foreclose Grail's rivals. *See* (CCFF ¶¶ 2608-3078).

Response to Proposed Conclusion of Law No. 46:

The proposed conclusion should be disregarded because it violates the Court's Order on Post-Trial Filings (at 2) requiring that "[a]ll legal contentions, including, but not limited to,

contentions regarding liability and the proposed remedy, shall be supported by applicable legal authority."

The proposed conclusion is improper and should be disregarded because it is a proposed finding of fact couched as a proposed conclusion of law. In any event, the proposed conclusion is inaccurate, incomplete and unsupported by the record for the reasons explained in PFF ¶¶ 916–27 and 946–49 and Respondents' responses to CCFF ¶¶ 2608–3078. As Complaint Counsel acknowledges, "the proper timeframe for evaluating the effects of the merger on future competition must be 'functionally viewed, in the context of its particular industry.'" (CC Post-Trial Br. at 130 (citing *United States v. Aetna, Inc.,* 240 F. Supp. 3d 1, 79 (D.D.C. 2017) (internal citation omitted)). Thus, it was Complaint Counsel's burden to demonstrate that Illumina has the ability and incentive to foreclose *during the relevant timeframe*—when any MCED test in development emerges as a likely rival to GRAIL—which is, at best, far in the future. Complaint Counsel failed to meet that burden, because, among other things, its theory does not, and could not, account for the surge of impending entry and attendant investment in NGS.

Further, the Open Offer contractually obliges Illumina *not* to disadvantage and/or foreclosure its purported rivals. (*See* PFF ¶¶ 1000–57.) Complaint Counsel's assertion that it need not account for the Open Offer because it is merely a remedy is contrary to law. *AT&T II*, 916 F. 3d at 1046-47 (noting that "the government failed to meet its burden of proof" in part because DOJ's expert had not considered the effect of offers of arbitration agreements); *Arch Coal*, 329 F. Supp. 2d at 159 ("[T]his Court's task [is] . . . to review the entire transaction in question . . . [and] the Court is unwilling simply to ignore the fact" of the defendant's post-merger transaction commitment).

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

47. *Brown Shoe* and its progeny also provide that the determination of a merger's likely competitive effects may be based on an analysis of several specific factors. While only a subset of those factors may be relevant to the fact-specific inquiry of a given case, courts have held that "the Clayton Act will, of course, have been violated" when "the share of the market foreclosed is so large that it approaches monopoly proportions." *Brown Shoe*, 370 U.S. at 328-29; *United States v. American Cyanamid Co.*, 719 F.2d 558, 566 (2d. Cir. 1983); *Fruehauf Corp. v. FTC*, 603 F.2d 345, 352 (2d Cir.1979) (noting that there is no *per se* rule that potential foreclosure "amount[s] to a violation of § 7" without more, "except where the share of the market foreclosed reaches monopoly proportions"). A high degree of potential foreclosure, alone, could be sufficient to show a reasonable probability of competitive harm. *Id*. Here the Court does not have to rely on just that factor as it is corroborated by other factors such as "the nature and economic purpose of the arrangement" and escalating barriers to entry by new firms. *Brown Shoe*, 370 U.S. at 328-29, 333; *see also American Cyanamid*, 719 F.2d at 566; *Fruehauf*, 603 F.2d at 352-53; *U.S. Steel Corp. v. FTC*, 426 F.2d 592, 598-99 (6th Cir. 1970).

Response to Proposed Conclusion of Law No. 47:

The proposed conclusion is incorrect and incomplete.

First, while the Court in *Brown Shoe* noted that Section 7 may be violated where the "share of the market foreclosed is so large that it approaches monopoly proportions", 370 U.S. at 327, it *did not say* that foreclosure can be shown by high shares alone. To the contrary, it required actual evidence of a probable foreclosure effect: one that, for example, could simultaneously "run afoul of the Sherman Act". *See id.* at 328, 332 (holding that it was "apparent both from past behavior of Brown and from the testimony of Brown's President, that Brown would use its ownership of Kinney to force Brown shoes into Kinney stores. Thus, in operation this vertical arrangement would be quite analogous to one involving a tying clause"). The other vertical cases Complaint Counsel cites likewise required actual evidence of likely foreclosure effects. *See United States v. American Cyanamid Co.*, 719 F.2d 558, 566 (2d. Cir. 1983) (noting that courts in vertical cases require evidence as to "the *likelihood and size* of any

market foreclosure"); *Fruehauf*, 603 F.2d at 352 ("The Supreme Court's insistence that each merger challenged under [Section] 7 be viewed . . . in the context of its particular industry, and that the Clayton Act protects Competition, not Competitors, contravenes the notion that a significant level of foreclosure is itself the proscribed effect" of Section 7 (internal citations and quotation marks omitted)); *In re Zinc Antitrust Litig.,* No. 14-cv-3728, 2016 WL 3167192, at *23 (S.D.N.Y. 2016) ("[T]he allegations in the [Complaint] do not even attempt to raise an inference that Glencore Ltd.'s acquisition of Pacorini foreclosed [competitors]" and "[t]here is no plausible allegation that competition was lessened or likely to be lessened in the relevant sense."). No modern court has ever held that the government can so easily condemn a vertical merger.

Second, as to the "nature and purpose" of the Transaction, that factor cuts decisively against Complaint Counsel's case, not in favor of it. While Illumina obviously acquired the shares of GRAIL that it did not already own to improve Illumina's overall business and profitability in the long term, part and parcel of that was Illumina's determination that it can do for GRAIL what needs to be done to accelerate the widespread adoption of Galleri, save lives and accelerate the growth of a nascent use case for its NGS technology. That is not a reason to block the Transaction; it is a reason to celebrate it. And, the fact that Illumina believed that acquiring GRAIL will create value for shareholders is a far cry from showing that Illumina did so with an intent to foreclose its clinical customers.

While Complaint Counsel stresses the importance of intent, it points to no evidence that Illumina acquired GRAIL with the intent to foreclose any putative GRAIL rival. Rather, all internal documents and testimony from Illumina relating to its strategic rationale for the merger show that Illumina's intent was to accelerate consumer access to Galleri, help expand GRAIL's technology to other disease states, and, of course, profit from that acceleration and growth. (PFF

¶ 208.) There is nothing anticompetitive about Illumina's acquisition intent. *See United States v. Hammermill Paper Co.*, 429 F. Supp. 1271 (W.D. Pa. 1977) (rejecting the government's vertical theory, *inter alia*, because there was no evidence that the defendant's intent in consummating the acquisition was "to foreclose competing suppliers from access to the acquired paper merchant outlets", and "[t]he lack of evidence of intent to foreclose in the instant case is material.").

Third, there is no evidence the Transaction will erect any barriers to entry. Complaint Counsel's claim to the contrary is remarkably devoid of evidentiary support. In fact, there is abundant evidence that the Transaction has *spurred* investment in early cancer detection field, and in liquid biopsy more broadly, indicating that the Transaction has *lowered* entry barriers, not raised them.

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

48. Although today Illumina is the only supplier of NGS platforms to Grail and its rivals, the Clayton Act does not require that there be complete foreclosure to run afoul of antitrust laws. *See Brown Shoe*, 370 U.S. at 323 n.39 (citing S. Rep. No. 81-1775, at 4298 (1950)) (explaining that the goal of Section 7 is "to arrest restraints of trade in their incipiency and before they develop into full-fledged restrains violative of the Sherman Act."); *see also id.* at 328-29 ("[T]he tests for measuring the legality of any particular economic arrangement under the Clayton Act are to be less stringent than those used in applying the Sherman Act.").

Response to Proposed Conclusion of Law No. 48:

The proposed conclusion is incorrect, incomplete and/or misleading. The Court in *Brown* it required actual evidence of a probable foreclosure effect: one that, for example, could simultaneously "run afoul of the Sherman Act". *See Brown Shoe* at 328, 332 (holding that it was "apparent both from past behavior of Brown and from the testimony of Brown's President, that Brown would use its ownership of Kinney to force Brown shoes into Kinney stores. Thus, in operation this vertical arrangement would be quite analogous to one involving a tying clause").

The other vertical cases Complaint Counsel cites likewise required actual evidence of likely foreclosure effects. *See United States v. American Cyanamid Co.*, 719 F.2d 558, 566 (2d. Cir. 1983) (noting that courts in vertical cases require evidence as to "the *likelihood and size* of any market foreclosure"); *Fruehauf*, 603 F.2d at 352 ("The Supreme Court's insistence that each merger challenged under [Section] 7 be viewed . . . in the context of its particular industry, and that the Clayton Act protects Competition, not Competitors, contravenes the notion that a significant level of foreclosure is itself the proscribed effect" of Section 7 (internal citations and quotation marks omitted)); *In re Zinc Antitrust Litig.,* No. 14-cv-3728, 2016 WL 3167192, at *23 (S.D.N.Y. 2016) ("[T]he allegations in the [Complaint] do not even attempt to raise an inference that Glencore Ltd.'s acquisition of Pacorini foreclosed [competitors]" and "[t]here is no plausible allegation that competition was lessened or likely to be lessened in the relevant sense."). No modern court has ever held that the government can so easily condemn a vertical merger.

Complaint Counsel misplaces reliance on *In re Union Carbide Corp.*, 59 F.T.C. 614, 1961 WL 65409, (1961), for the proposition that it need not prove Illumina would likely engage in conduct causing market foreclosure, so long as it shows that Illumina has the "power" to do so. (CC Post-Trial Br. at 81, 104). However, as a 61-year-old Commission decision, and a splintered one at that, *Union Carbide* does not control the standard to be applied here. Further, the Commissioners who voted to affirm the ALJ's ruling in that case were concerned that the merger there would compel other market participants to vertically integrate, and that such market-wide vertical integration would harm competition, and that such effects had already occurred as a result of the merger. Thus, contrary to Complaint Counsel's suggestion, the Commissioners in *Union Carbide* did not uphold the ALJ decision on the basis that the merged firm had a theoretical power to foreclose rivals but no incentive to do so.

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

49. The Supreme Court recognized that "the very nature and purpose of the arrangement" was a factor to examine to determine the legality of a vertical merger. *Brown Shoe*, 370 U.S. at 329; *see also U.S. Steel*, 426 F.2d at 599; *Fruehauf*, 603 F.2d at 353. For example, in *Ford Motor Co. v. United States*, the Supreme Court held that Ford "made the acquisition in order to obtain a foothold in the aftermarket" spark plug market and "[o]nce [Ford] established [a foothold], it would have every incentive to . . . maintain the virtually insurmountable barriers to entry" in that market by foreclosing manufacturers from selling to Ford. 405 U.S. at 568-71.

Response to Proposed Conclusion of Law No. 49:

The proposed conclusion is incomplete. Regarding the "nature and purpose" of the Transaction, that factor cuts decisively against Complaint Counsel's case, not in favor of it. While Illumina obviously acquired the shares of GRAIL that it did not already own to improve Illumina's overall business and profitability in the long term, part and parcel of that was Illumina's determination that it can do for GRAIL what needs to be done to accelerate the widespread adoption of Galleri, save lives and accelerate the growth of a nascent use case for its NGS technology. That is not a reason to block the Transaction; it is a reason to celebrate it. And, the fact that Illumina believed that acquiring GRAIL will create value for shareholders is a far cry from showing that Illumina did so with an intent to foreclose its clinical customers.

While Complaint Counsel stresses the importance of intent, it points to no evidence that Illumina acquired GRAIL with the intent to foreclose any putative GRAIL rival. Rather, all internal documents and testimony from Illumina relating to its strategic rationale for the merger show that Illumina's intent was to accelerate consumer access to Galleri, help expand GRAIL's technology to other disease states, and, of course, profit from that acceleration and growth. (RRFF ¶ 208.) There is nothing anticompetitive about Illumina's acquisition intent. *See United States v. Hammermill Paper Co.*, 429 F. Supp. 1271 (W.D. Pa. 1977) (rejecting the government's

vertical theory, *inter alia*, because there was no evidence that the defendant's intent in consummating the acquisition was "to foreclose competing suppliers from access to the acquired paper merchant outlets", and "[t]he lack of evidence of intent to foreclose in the instant case is material.").

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

50. Courts have held that the creation or increase of entry barriers can militate in favor of prohibiting a vertical merger. *See U.S. Steel*, 426 F.2d at 605; *Ford Motor*, 405 U.S. at 568-71. As the Sixth Circuit explained in *U.S. Steel Corp. v. FTC*, such barriers can include "possible reliance on suppliers from a vertically integrated firm with whom [a new entrant in the relevant market] is also competing" and "the psychological 'fears' of smaller rivals competing with large integrated concerns." 426 F.2d at 605 (citing *Procter & Gamble*, 386 U.S. at 578).

Response to Proposed Conclusion of Law No. 50:

The proposed conclusion is incomplete. There is no evidence the Transaction will erect any barriers to entry. Complaint Counsel contends that the Transaction "has caused MCED test developers to reevaluate their appetites", but the only "evidence" Complaint Counsel cites is the bald assertion by [redacted] There is also abundant evidence that the Transaction has *spurred* investment in early cancer detection field, and in liquid biopsy more broadly, indicating that the Transaction has *lowered* entry barriers, not raised them. (*See* Resps. Reply Br. § III.D.)

Tellingly, Complaint Counsel also has not pointed to a single instance over the last four years when Illumina has disadvantaged any GRAIL rival, despite Illumina's partial ownership of GRAIL. Nor is there any such evidence since Illumina closed the Transaction. Thus, this case is unlike those that Complaint Counsel relies upon, where the evidence of foreclosure materialized

after the mergers at issue were consummated. *See Ford Motor Co. v. U.S.*, 405 U.S. 562, 568, 581 (1972) (finding that evidence following Ford's consummated acquisition of Autolite showed that the merger actually raised barriers to entry in the spark plug market); *Heatransfer Corp. v. Volkswagenwerk, A.G*, 553 F.2d 964, 982 (5th Cir. 1977) ("After the acquisition of Intercontinental Motors, sales of the VPC unit increased markedly . . . to the detriment of other suppliers", supporting the jury's finding of a Section 7 violation). Here, there is no such evidence, because Illumina has no incentive (nor ability) to harm the companies who claim to be competing with GRAIL.

Similarly, if Complaint Counsel had examined the competitive effects of Illumina's vertical integration in therapy selection, it would have discovered that the parade of horribles and innovation harms Complaint Counsel speculates will occur in the alleged MCED market as a result of the Transaction never materialized. (PFF ¶¶ 966–973.) Today, Illumina has collaboration agreements in place with Roche, PGDx and numerous other test developers in therapy selection pursuant to which these formidable competitors are developing IVD tests that will compete with Illumina's own therapy selection test. (PFF ¶ 966.)

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

51. Under the *Brown Shoe* framework, this Acquisition would substantially lessen competition in the market for the research, development, and commercialization of MCED tests in the United States and cause harm to American consumers. *See* (CCFF ¶¶ 1019-1398, 2607-3569).

Response to Proposed Conclusion of Law No. 51:

The proposed conclusion is inaccurate, incomplete, and misleading. (*See* COL ¶¶ 27–42.)

a. THE ACQUISITION WILL HARM INNOVATION IN THE MCED TEST MARKET

52. Anticompetitive harm under Section 7 includes harm to innovation. *See Otto Bock*, 2019 WL 5957363, at *2 (finding that the acquisition "is likely to cause future anticompetitive effects in the form of higher prices and less innovation"); Initial Decision, *Altria*, Docket No. 9393, at 97, 99-100 (analyzing harm to innovation competition, along with price and shelf space competition, as a potential effect of the investment agreement between the parties); *In re Polypore Int'l, Inc.*, 2010 WL 9434806, at *211 (F.T.C. Mar. 1, 2010) (Chappell, A.L.J.) (finding that in one market "innovation competition has been eliminated post-acquisition"); *In re R.R. Donnelley & Sons Co.*, No. 9243, 1995 WL 17012641, at *73 (F.T.C. July 21, 1995) (competitive harm under Section 7 may "include a prediction of adverse effects in competitive dimensions other than price—reductions in output, product quality, or innovation"); *see also Horizontal Merger Guidelines* § 6.4 (explaining that harm to innovation can be an anticompetitive effect of a merger). In fact, in *United States v. AT&T, Inc.*, the D.C. Circuit explained that it "does not hold that quantitative evidence of price increase is required in order to prevail on a Section 7 challenge. Vertical mergers can create harms beyond higher prices for consumers, including decreased product quality and reduced innovation." 916 F.3d 1029, 1045-46 (D.C. Cir. 2019).

Response to Proposed Conclusion of Law No. 52:

The proposed conclusion is incomplete and misleading to the extent it suggests a market can include products that do not yet exist, such that harm to innovation within that purported market can constitute an anticompetitive harm.

First, all of the cases Complaint Counsel cites in its proposed conclusion also found markets consisting of products already on the market. *See Otto Bock*, 2019 WL 5957363, at *1, 5 (defining the market as the sale of certain products currently sold); *Altria*, at 126, Docket No. 9393 (F.T.C. Feb. 15, 2022) (Initial Decision) (same); *In re Polypore Int'l, Inc.*, 2010 WL 9434806, at *30–*37 (F.T.C. Mar. 1, 2010) (same); *In re R.R. Donnelley & Sons Co.*, No. 9243, 1995 WL 17012641, at *123 (F.T.C. Jul. 21, 1995) (same); *United States v. AT&T Inc.*, 916 F.3d 1029, 1032–33 (D.C. Cir. 2019) (same). Thus, those cases do not support the assertion that anticompetitive harm includes harm to innovation in a market of products that do not yet exist.

Further, courts have repeatedly rejected alleged markets defined to include products that do not yet exist and whose features are highly uncertain, and have rejected the inclusion of

undefined future products in a relevant market. *See SCM Corp.*, 645 F.2d at 1211 (overturning jury verdict in plaintiffs' favor and holding that patent acquisitions did not violate Section 7 as a matter of law because the relevant product market did not exist at the time of the acquisitions and for another eight years following the acquisitions); *Fraser v. Major League Soccer, L.L.C.*, 97 F. Supp. 2d 130, 140 (D. Mass. 2000), *aff'd*, 284 F.3d 47 (1st Cir. 2002) ("The relevant test under § 7 looks to whether competition in *existing* markets has been reduced. Where there is no existing market, there can be no reduction in the level of competition. . . . Competition that does not exist cannot be decreased."); *Epic Games, Inc. v. Apple Inc.*, 2021 WL 4128925 at *56 (N.D. Cal. 2021) (excluding the offerings of certain gaming companies from the relevant product submarket because the record was limited as to those companies, and they were "too new for a determination of whether they should or should of undefined future products in a relevant market; *Apartment Source of Pa., L.P. v. Phila. Newspapers, Inc.*, No. CIV. A. 98-5472, 1999 WL 349938, at *22–24 (E.D. Pa. May 21, 1999) (finding in defendants' favor because plaintiffs' alleged market was at most an "emerging submarket" within an apparent broader market and was not a well-defined separate market); *Crucible, Inc. v. Stora Kopparbergs Bergslags AB*, 701 F. Supp 1157, 1161 (W.D. Pa. 1988) ("Regarding the 1966 acquisition of the Battelle patents, a finding of no relevant market in PM high speed steel products is mandated by the fact that commercial production and marketing of PM high speed steel products in the United States did not begin until 1971, four years after the patent acquisitions."). (*See* Resps.' Post-Trial Br. at 23–26.)

Second, courts have held that where a market does not exist, there can be no anticompetitive effects, harm to innovation or otherwise. *Kenney v. Am. Bd. of Internal Med.*, 412 F. Supp. 3d 530, 548 (E.D. Pa. 2019), *aff'd*, 847 F. App'x 137 (3d Cir. 2021) (holding that

Defendant "cannot have a monopoly in a market that does not exist"); *Collins v. Associated Pathologists, Ltd.*, 844 F.2d 473, 480 (7th Cir. 1988) ("It is impossible to monopolize a market that does not exist."); *Siva v. Am. Bd. of Radiology*, 418 F. Supp. 3d 264, 277 (N.D. Ill. 2019) (holding that a defendant cannot have or exploit a "monopoly in a market that does not exist"); *In re Altria Grp., Inc.*, No. 9393, at 110 (Feb. 15, 2022) (citing *Mercantile Tex. Corp. v. Bd. of Governors of Fed. Rsrv. Sys.*, 638 F.2d 1255, 1272 (5th Cir. 1981) ("The competitive conditions of a market five years in the future cannot reliably be predicted.").

Third, even if the purported MCED test did exist and included products that did not yet exist, Complaint Counsel failed to prove that the Transaction is likely to substantially lessen competition, such as by harming innovation. Complaint Counsel ignored the real world constraints on Illumina's ability to lessen competition, such as the Open Offer, failed to take into account intensifying upstream competition, and failed to show that Illumina has any incentive to foreclose GRAIL's putative rivals, and failed to note that Illumina's past vertical integrations undercuts Complaint Counsel's theory of harm.

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

53. Not only is the innovation competition in the MCED test market important to protect in and of itself, the Federal Trade Commission has recognized the special importance of protecting competition in emerging markets:

> While monopolies are to be abhorred wherever they appear, it is of particular importance that they be arrested in an infant industry which appears destined for far greater expansion and growth. Strong and vigorous competition is the catalyst of rapid economic progress. Any lessening of competition is therefore doubly harmful in a new industry since its inevitable effect is to slow down the growth rate of the industry.

Union Carbide, 1961 WL 65409, at *35.

Response to Proposed Conclusion of Law No. 53:

The proposed conclusion is incomplete and misleading for the reasons explained in Respondents' responses to CCCoL ¶ 52, which Respondents incorporate herein. Respondents also note that the relevant market in *Union Carbide* was an "infant" or "new" industry only insofar as "polyethylene is a relatively new product for which new uses and applications are discovered almost daily". 1961 WL 65409, at *35. Thus, Respondents' proposed conclusion wrongly uses *Union Carbide* to suggest that purported MCED tests that do not currently exist should constitute a relevant market.

Further, while Complaint Counsel insinuates in this proposed conclusion that there exists an emerging or innovation market of MCED tests, Complaint Counsel failed to prove an appropriate innovation market. While it is true that Galleri is a nascent product, that other putative MCED tests in development do not yet even exist and that there is limited economic evidence, none of this relieves Complaint Counsel of its burden to prove the relevant market and the attributes that define its boundaries. The law does not set a different standard for establishing a nascent market or an innovation one. *See OrthoAccel Techs., Inc. v. Propel Orthodontics, LLC*, No. 4:16-CV-00350-ALM, 2017 WL 1213629, at *3 (E.D. Tex. Apr. 3, 2017) (requiring plaintiff to "plead a relevant product market in precise economic terms" despite it being "difficult to assess cross-elasticity of demand for nascent products in a relatively new market"); *Golden Gate Pharmacy Servs., Inc. v. Pfizer, Inc.*, No. C-09-3854 MMC, 2010 WL 1541257, at *3 (N.D. Cal. Apr. 16, 2010), *aff'd*, 433 F. App'x 598 (9th Cir. 2011) (rejecting the plaintiffs' alleged product market because they failed to sufficiently allege interchangeability "both in the pharmaceutical product markets and in the innovation market for pharmaceutical products"). *See also, e.g.*, *Apartment Source*, 1999 WL 349938, at *1 (rejecting the plaintiffs' proposed market

because "[a]n emerging submarket that has not yet developed into a distinct and identifiable market by definition is not well-defined, and therefore does not constitute a relevant product market under Section 2 of the Sherman Act."); *Epic Games*, 2021 WL 4128925, at *56 , 2021 WL 4128925, at *56 (N.D. Cal. Sept. 10, 2021) (requiring all products in the mobile game apps market to be reasonably interchangeable and thus excluding certain gaming services from the product for being "too new" for the court to determine "whether consumes [sic] will or do consider these products reasonably interchangeable"). Complaint Counsel's lax approach would effectively relieve it of the burden of proof and substitute the FTC's subjective policy assessments for established law and objective evidence.

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

54. Grail and its MCED rivals are currently competing on the basis of innovation. *See* (CCFF ¶¶ 3639-68). This competition will benefit consumers in the form of more accurate and cost-effective MCED tests. *See, e.g.*, (CCFF ¶¶ 3644, 3650, 3652, 3658, 3661, 3665).

Response to Proposed Conclusion of Law No. 54:

The proposed conclusion should be disregarded because it violates the Court's Order on Post-Trial Filings (at 2) requiring that "[a]ll legal contentions, including, but not limited to, contentions regarding liability and the proposed remedy, shall be supported by applicable legal authority."

The proposed conclusion is also improper and should be disregarded because it is a proposed finding of fact couched as a proposed conclusion of law. In any event, the proposed conclusion is incorrect and unsupported by the record. The record shows that GRAIL is not competing with any other company (PFF ¶¶ 680.1, 684, 698, **Error! Reference source not found.**–**Error! Reference source not found.**), and the test of reasonable interchangeability

requires that courts "consider only substitutes that constrain pricing in *the reasonably foreseeable future*, and only products that can enter the market in a relatively short time can perform this function." *United States v. Microsoft Corp.*, 253 F.3d 34, 53-54 (D.C. Cir. 2001) (emphasis added); *see also Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 218 (D.C. Cir. 1986) (citation omitted) (only substitutes that can enter the market "promptly" should be considered).

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

55. This vertical merger has reasonable probability of harming innovation competition for MCED tests. *See* (CCFF ¶¶ 3570-668).

Response to Proposed Conclusion of Law No. 55:

The proposed conclusion should be disregarded because it violates the Court's Order on Post-Trial Filings (at 2) requiring that "[a]ll legal contentions, including, but not limited to, contentions regarding liability and the proposed remedy, shall be supported by applicable legal authority."

The proposed conclusion is improper and should be disregarded because it is a proposed finding of fact couched as a proposed conclusion of law. In any event, the Proposed Conclusion is incorrect and unsupported by the record. *First*, as explained in Respondents' response to CCCoL ¶ 54, there is no competition between GRAIL and any other company and thus, this vertical merger cannot harm any competition for MCED tests. (PFF ¶¶ 680.1, 684.) *Second*, Complaint Counsel failed to prove that the Transaction is likely to substantially lessen competition. Complaint Counsel's allegations that the Transaction harms innovation and commercial competition each fail on multiple grounds. They depend on claims as to Illumina's incentives that have no support in the record and are contradicted by Illumina's track record of

vertical integration. They depend on claims about putative GRAIL rivals that are divorced from reality. And they depend on claims about the Galleri test that are easily refuted. Complaint Counsel thus has failed to show that the Transaction will cause any harm to competition at all, much less an imminent, substantial lessening of competition.

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

b. THE ACQUISITION WILL HAMPER COMMERCIAL COMPETITION BETWEEN MCED TESTS

56. When analyzing the competitive harm to the commercialization of MCED tests, "the proper timeframe for evaluating the effects of the merger on future competition must be 'functionally viewed, in the context of its particular industry.'" *Aetna,* 240 F. Supp. 3d at 79 (internal citation omitted).

Response to Proposed Conclusion of Law No. 56:

The proposed conclusion is incomplete and thus misleading to the extent that it suggests that an MCED test market currently exists such that that market could suffer competitive harm. As stated by the court in *United States v. Aetna Inc.*, before "judging the probable anticompetitive effect of [a] merger" where "predictions too far in the future risk becoming mere 'ephemeral possibilities'", "[t]he first question in this case is about the proper boundaries of that 'particular market'" and "for competition to be lessened, there must necessarily be competition to begin with". 240 F. Supp. 3d 1, 18, 79 (quotations omitted). The court in *Aetna* did not support the Complaint Counsel's argument that companies whose products are not yet in existence can constitute a market, as the products at issue in *Aetna* were all already on the market. *Aetna* at 19. Since Complaint Counsel failed to allege a relevant market (*see* Resps.' Reply Br. § II.A.), Complaint Counsel failed to establish a market to which it could apply an analysis of any potential anticompetitive harm. Respondents also incorporate their responses to CCCoL ¶ 52 and the relevant discussion in their opening and reply post-trial briefs.

57. As this Court explained in *In re Altria Group, Inc. and Juul Labs, Inc.*, this means looking at whether competition "would have existed in the 'near future,'" where "near" is "defined in terms of the entry barriers and lead time necessary for entry in the particular industry." Initial Decision, *Altria*, Docket No. 9393, at 106, 111-12 (quoting *BOC Int'l, Ltd. v. FTC*, 557 F.2d 24, 29 (2d Cir. 1977)).

Response to Proposed Conclusion of Law No. 57:

The proposed conclusion is incomplete for the reasons explained in Respondents' response to CCCoL ¶ 56, which Respondents incorporate herein, and unsupportive of Complaint Counsel's case. Complaint Counsel failed to prove that the Transaction will be likely to substantially lessen competition. In *Altria*, the government argued that the merger between Altria and JUUL would be likely to substantially lessen competition by supposedly foreclosing the possibility of Altria "eventually [having] a product competing in [the relevant] market". Initial Decision, *Altria*, Docket No. 9393, at 112. The Court rejected this argument because the law requires a potential entry of a product to be in the "near future" because the "'degree of uncertainty' in any economic prediction as to future market conditions 'becomes unacceptably high as it is projected further and further into the future" and that "the evidence fail[ed] to prove a reasonable probability that Altria would have competed in the e-cigarette market in the near future." *Altria* at 107. Likewise, Complaint Counsel failed to prove a relevant market and thus that the Transaction may harm competition. The test of reasonable interchangeability requires that courts "consider only substitutes that constrain pricing in *the reasonably foreseeable future*, and only products that can enter the market in a relatively short time can perform this function." *United States v. Microsoft Corp.*, 253 F.3d 34, 53-54 (D.C. Cir. 2001) (emphasis added); *see also Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 218 (D.C. Cir. 1986) (citation omitted) (only substitutes that can enter the market "promptly" should be considered). At present, there is no product in existence that is reasonably interchangeable with Galleri; nor is

one expected to enter in the foreseeable future. (PFF ¶ 697.) Thus, like the potential entries of competitors in *Altria*, the alleged potential entries of these purported MCED developers are too uncertain for Complaint Counsel to prove harm to competition. Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

58. Grail and its rivals expect to compete vigorously on price, service, and performance once on the market. This commercial competition will ultimately lead to lower prices and improved products. This vertical merger has reasonable probability of harming this commercial competition. *See* (CCFF ¶¶ 3189-569).

Response to Proposed Conclusion of Law No. 58:

The proposed conclusion should be disregarded because it violates the Court's Order on Post-Trial Filings (at 2) requiring that "[a]ll legal contentions, including, but not limited to, contentions regarding liability and the proposed remedy, shall be supported by applicable legal authority."

The proposed conclusion is improper and should be disregarded because it is a proposed finding of fact couched as a proposed conclusion of law. In any event, the proposed conclusion is incorrect and unsupported by the record. The test of reasonable interchangeability requires that courts "consider only substitutes that constrain pricing in *the reasonably foreseeable future*, and only products that can enter the market in a relatively short time can perform this function." *United States v. Microsoft Corp.*, 253 F.3d 34, 53-54 (D.C. Cir. 2001) (emphasis added); *see also Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 218 (D.C. Cir. 1986) (citation omitted) (only substitutes that can enter the market "promptly" should be considered). As Respondents have explained, [redacted] (PFF ¶ 680.1), and most of the putative MCED developers identified by Complaint Counsel do not expect (and none can reasonably be

expected) to launch a screening test for more than one cancer for many years (PFF ¶ 700). Thus, at present, there is no product in existence that is reasonably interchangeable with Galleri; nor is one expected to enter in the foreseeable future. (PFF ¶ 697.)

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

59. Analysis of both Illumina's post-Acquisition ability and incentive and the *Brown Shoe* framework supports the same conclusion: Illumina's acquisition of Grail will likely result in harm both to current innovation competition in the MCED market and competition between the commercialized versions of Grail's Galleri and rival MCED tests. *See* (CCFF ¶¶ 1019-1398, 2607-3668).

Response to Proposed Conclusion of Law No. 59:

The proposed conclusion is incorrect. As Respondents have explained in their opening and reply briefs, Complaint Counsel failed to prove the Transaction is likely to substantially lessen competition. (*See* Resps.' Opening Br. § II; Resps.' Reply Br. § III.) Respondents also incorporate their responses to CCFF ¶¶ 1019–1398, 2607–3668 and their responses to COL ¶ 55 herein.

60. Once Complaint Counsel establishes its *prima facie* case, the burden shifts to Respondents to rebut Complaint Counsel's fact-specific showing of potential competitive harm. *Baker Hughes*, 908 F.2d at 982.

Response to Proposed Conclusion of Law No. 60:

The proposed conclusion is inaccurate and thus misleading to the extent that it suggests that the *Baker Hughes* burden-shifting framework applies precisely to a vertical case as it would in a horizontal case.

Although the *Baker Hughes* burden-shifting framework may apply to a vertical merger challenge, Complaint Counsel's contention that it applies precisely as it would in a horizontal case misstates the law. Complaint Counsel asserts that its "burden of production" for its *prima facie* case is extremely low, relying on the Court's observation in *Otto Bock* that the burden

shifts to Respondents once the FTC provides evidence "sufficient to raise an inference of anticompetitive effect". (CC Post-Trial Br. at 43.) But *Otto Bock* involved a horizontal merger, as to which "proof of market structure and direct competition between Ottobock and Freedom [was] sufficient to raise an inference of likely anticompetitive effects". *In re Otto Bock HealthCare N. Am., Inc.*, 2019 WL 2118886, *27 n.25 (F.T.C. May 6, 2019). Those presumptions do not apply here, in the vertical context.

"A vertical merger, unlike a horizontal one, does not eliminate a competing buyer or seller from the market". *Fruehauf*, 603 F.2d at 351; *AT&T I*, 310 F. Supp. 3d at 192. "Most instances of vertical integration, including those that result from mergers, are economically beneficial. As a result, the presumptions in favor of vertical mergers should be stronger than the presumptions favoring horizontal mergers." Areeda & Hovenkamp, *Antitrust Law*, ¶ 1020. "[I]t is widely conceded that as a general matter, vertical mergers are inherently more likely to create substantial efficiencies than horizontal mergers," David T. Scheffman & Richard S. Higgins, *Vertical Mergers: Theory and Policy*, 12 Geo. Mason L. Rev. 967 (2004), and that "vertical mergers generally raise fewer competitive concerns than do horizontal mergers." OECD Note at 10, ¶ 37; *id.* at ¶ 24 ("Vertical mergers have a stronger claim to being efficient than do horizontal mergers, given the fundamentally different effects of improved coordination between complements versus substitutes.")

Thus, "the familiar horizontal merger playbook is of little use", "there is no short-cut way to establish anticompetitive effects, as there is with horizontal mergers", and there is no "theoretical basis for dealing with vertical mergers" that is "comparable" to the "well-founded and rather generally accepted" "economic reason for limiting horizontal mergers". *AT&T*, 310 F. Supp. 3d at 161 (internal citations and quotation marks omitted). Therefore, contrary to

Complaint Counsel's assertion, in a vertical case, there is no "short cut to establish a presumption of anticompetitive effect". *AT&T II*, 916 F.3d at 1032. Rather, the law demands robust proof of probable anticompetitive effects "on the basis of the record evidence relating to the market and its probable future". *AT&T I*, 310 F. Supp. 3d at 190; *Fruehauf*, 603 F.2d at 352-53 (rejecting "that a significant level of foreclosure is itself the proscribed effect [of the Clayton Act]. . . . A showing of some probable anticompetitive impact is still essential".) Complaint Counsel failed to adduce such evidence here.

Respondents also incorporate their responses to CCCoL ¶ 16 and the relevant discussion in their opening and reply post-trial briefs.

VII. RESPONDENTS FAIL TO MEET THEIR BURDEN TO SHOW ENTRY WILL BE TIMELY, LIKELY, AND SUFFICIENT TO COUNTERACT THE COMPETITIVE HARM FROM THE ACQUISITION

61. Respondents bear the burden of providing evidence that "ease of entry" rebuts Complaint Counsel's *prima facie* case. *Otto Bock*, 2019 WL 5957363, at *12 (citing *FTC v. H.J. Heinz Co.*, 246 F.3d 708, 715 n.7 (D.C. Cir. 2001); *see also H&R Block*, 833 F. Supp. 2d at 73 (noting that defendants "carry the burden to show" that entry or expansion is sufficient "to fill the competitive void" that would result from the merger) (internal quotations omitted).

Response to Proposed Conclusion of Law No. 61:

The proposed conclusion is incorrect and incomplete. Because Complaint Counsel has failed to establish a *prima facie* case of competitive harm, for the reasons given in Respondents' Opening Br. §§ I–II and Respondents' Reply Br. §§ I–III, Respondents have no burden to rebut Complaint Counsel's Section 7 case. The proposed conclusion is also misleading to the extent that it suggests that Complaint Counsel's burden to prove its prima facie case in the same in both horizontal and vertical merger cases and misapplies Respondents' burden of proof to the alleged related market in this case rather than the relevant product market.

First, Complaint Counsel cites only horizontal merger cases. *See Otto Bock*, 2019 WL 5957363, at *12; *FTC v. H.J. Heinz Co.*, 246 F.3d at 711–12; *H&R Block*, 833 F. Supp. 2d at 45. However, unlike in a horizontal merger, in which "proof of market structure and direct competition between [two competitors] [was] sufficient to raise an inference of likely anticompetitive effect", *Otto Bock*, 2019 WL 2118886, at *27 n.25 (F.T.C. May 6, 2019), in a vertical case, there is no "short cut to establish a presumption of probable anticompetitive effect". *AT&T II*, 916 F.3d at 1032. This makes sense as by definition a vertical merger does not remove a competitor from the market and thus does not result in a "competitive void" that entry or expansion must fill. Respondents also incorporate their responses to CCCoL ¶ 60 herein.

Second, in *Otto Bock*, this Court was referring to the "ease of entry" of new competitors in the relevant product market that could rebut the government's prima facie case, while Complaint Counsel wrongly applies this principle to the related upstream market of NGS products rather than the purported relevant market of MCED tests. Thus, Complaint Counsel places the burden on Respondents to prove ease of entry of potential upstream competitors when it is Complaint Counsel's burden to prove that the Transaction would foreclose GRAIL's putative rivals because of a lack of competition in the upstream market.

Respondents further incorporate COL ¶ 65 and the relevant discussion in their opening and reply post-trial briefs.

62. "The mere existence of potential entrants does not by itself rebut the anti-competitive nature of an acquisition." *Chi. Bridge & Iron Co N.V. v. FTC*, 534 F.3d 410, 436 (5th Cir. 2008).

Response to Proposed Conclusion of Law No. 62:

The proposed conclusion is incomplete and misleading to the extent that it suggests that Respondents have the burden to prove potential entrants in the upstream NGS market. On the contrary, Complaint Counsel has the burden to prove a lack of potential entrants or competition in the upstream market in order to prove its foreclosure theory in its prima facie case. *See* CoL ¶ 65. As explained in Respondents' Reply Brief § III.E, Complaint Counsel failed to meet that burden.

Further, Respondents note that just as "the mere existence of potential entrants does not by itself rebut the anticompetitive nature of an acquisition" as it does not prove the existence of competition, the mere existence of putative potential MCED test developers does not by itself prove the existence of competition in Complaint Counsel's purported MCED market. *Chi. Bridge & Iron Co N.V. v. FTC*, 534 F.3d 410, 436 (5th Cir. 2008).

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

63. Entry or expansion must be "'timely, likely, and sufficient in its magnitude, character, and scope' to counteract a merger's anticompetitive effects." *United States v. Anthem, Inc.*, 236 F. Supp. 3d 171, 222 (D.D.C. 2017) (citations omitted).

Response to Proposed Conclusion of Law No. 63:

The proposed conclusion is incomplete and misleading to the extent that it suggests that Respondents have the burden to prove potential entrants in the upstream NGS market. On the contrary, Complaint Counsel has the burden to prove a lack of potential entrants or competition in the upstream market in order to prove its foreclosure theory in its prima facie case. *See* CoL ¶ 65. As explained in Respondents' Reply Brief § III.E, Complaint Counsel failed to meet that burden.

Further, Respondents note that just as "the mere existence of potential entrants does not by itself rebut the anticompetitive nature of an acquisition" as it does not prove the existence of competition, the mere existence of putative potential MCED test developers does not by itself prove the existence of competition in Complaint Counsel's purported MCED market, when those test developers' statements are unsubstantiated and implausible. *Chi. Bridge & Iron Co N.V. v. FTC*, 534 F.3d 410, 436 (5th Cir. 2008). If Complaint Counsel's claims had any basis in reality, there would be data (such as reports from clinical studies) [redacted] There would be documentation as to how many cancers the developer's test can detect, with what specificity and sensitivity, and with what tumor of origin accuracy. None of that is in the record, [redacted] (*See* PFF ¶¶ 703.8–703.13; RRFF ¶¶ 2185-2256.) Thus, Complaint Counsel hangs its entire case on the say-so of non-credible testimony of test developers whose own internal documents undermine their claims.

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

64. In assessing whether entry is likely, courts often look to the history of entry, including the "inability of new firms to gain traction," to assess "how difficult it is for new entrants to compete on the same playing field as the merged firm . . . ." *Anthem*, 236 F. Supp. 3d at 222-24 (dismissing Dr. Robert Willig's "breezy assurances" that developing a provider network is "not a big barrier to entry or expansion") (citations and quotations omitted).

Response to Proposed Conclusion of Law No. 64:

The proposed conclusion is incorrect and incomplete for the reasons explained in Respondents' responses to CCCoL ¶ 62, which Respondents incorporate herein.

65. Respondents have not shown that entry is timely, likely, and sufficient to satisfy the strict requirements for MCED tests, and thus, fail to demonstrate that it would counteract the competitive harm from the Acquisition. *See* (CCFF ¶¶ 1212-1398, 5013).

Response to Proposed Conclusion of Law No. 65:

The proposed conclusion is incorrect and incomplete for the reasons explained in Respondents' responses to CCCoL ¶ 63 herein, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶¶ 1212–1398, 5013.

VIII. RESPONDENTS FAIL TO MEET THEIR BURDEN TO DEMONSTRATE THAT THEIR PROPOSED EFFICIENCIES AND ANY OTHER ALLEGED PROCOMPETITIVE BENEFIT OFFSET THE COMPETITIVE HARM

66. The stronger the *prima facie* case "the greater [Respondents'] burden of production on rebuttal." *Polypore*, 2010 WL 9549988 at *9; *see also Heinz*, 246 F.3d at 725; *Baker Hughes*, 908 F.2d at 991.

Response to Proposed Conclusion of Law No. 66:

The proposed conclusion is incorrect and incomplete for the reasons explained in Respondents' responses to CCCoL ¶ 61 herein, which Respondents incorporate herein. In addition, Respondents note that *In re Polypore*, like *Heinz* and *Baker Hughes*, is also a horizontal merger case. Because the Transaction is purely vertical (as opposed to horizontal), Complaint Counsel "cannot use a short cut to establish a presumption of anticompetitive effect"; rather, it must make a "fact-specific" showing that the Transaction is anticompetitive. *United States v. AT&T, Inc. (AT&T II)*, 916 F.3d 1029, 1032 (D.C. Cir. 2019); *see also Republic Tobacco Co. v. North Atl. Trading Co.*, 381 F.3d 717, 737 (7th Cir. 2004) ("As horizontal agreements are generally more suspect than vertical agreements, we must be cautious about importing relaxed standards of proof from horizontal agreement cases into vertical agreement cases. To do so

might harm competition and frustrate the very goals that antitrust law seeks to achieve."). Complaint Counsel cannot prove that the merger is likely to substantially lessen competition absent a showing that it would likely result in anticompetitive harm that substantially outweighs the efficiencies reasonably likely to result from the Transaction. Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

67. Respondents bear the burden of producing "clear evidence showing that the merger will result in efficiencies that will *offset* the anticompetitive effects and ultimately benefit consumers." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *Penn State Hersey*, 838 F.3d at 350) (emphasis added); *see also Hackensack*, 2022 WL 840463, at *10; *accord* Initial Decision, *Altria Group*, Docket No. 9393, at 5 ("[C]ounsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto.") (quoting 16 C.F.R. § 3.43(a)). In assessing such efficiency claims, courts have applied strict standards in their review. *Heinz*, 246 F.3d at 720-21; *H&R Block*, 833 F. Supp. 2d at 890.

Response to Proposed Conclusion of Law No. 67:

The proposed conclusion is incomplete and thus misleading to the extent that it suggests that (1) Complaint Counsel can enjoy the same presumption of anticompetitive harm in a vertical case as it does in a horizontal case and (2) Complaint Counsel need not take any account of efficiencies in its case. As explained in Respondents' responses to CCCoL ¶ 61, Complaint Counsel cites only horizontal merger cases in which "proof of market structure and direct competition between [two competitors] is sufficient to raise an inference of likely anticompetitive effect", *Otto Bock*, 2019 WL 2118886, at *27 n.25 (F.T.C. May 6, 2019). However, in a vertical case, there is no "short cut to establish a presumption of probable anticompetitive effect". *AT&T II*, 916 F.3d at 1032.

Second, Complaint Counsel suggests that Respondents alone bear the burden of proving efficiencies. However, even under the horizontal framework, once Respondents prove verifiable, merger-specific efficiencies, the burden returns to Complaint Counsel to prove that the

efficiencies do not outweigh the alleged anticompetitive effects such that the Transaction is still likely to substantially lessen competition. *Fed. Trade Comm'n v. Wilh. Wilhelmsen Holding ASA*, 341 F. Supp. 3d 27, 45 (D.D.C. 2018) ("Where defendants successfully rebut the presumption of illegality, 'the burden of producing additional evidence of anticompetitive effect shifts to the government, and merges with the ultimate burden of persuasion, which remains with the government at all times.'") (citations omitted).

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

68. No court has held that EDM and efficiencies could immunize an otherwise anticompetitive merger. *See Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (observing that "[r]esearch does not reveal a case that permitted an otherwise unlawful transaction to proceed based on claimed efficiencies."); *see also Penn State Hershey*, 838 F.3d at 347-48 ("Contrary to endorsing [an efficiencies] defense, the Supreme Court has instead, on three occasions, cast doubt on its availability . . . . Based on [the Supreme Court's past statements] and on the Clayton Act's silence on the issue, we are skeptical that such an efficiencies defense even exists.") (citations omitted).

Response to Proposed Conclusion of Law No. 68:

The proposed conclusion is incomplete and thus misleading insofar as it suggests that no court has upheld a merger based on its efficiencies outweighing any alleged anticompetitive effects. Complaint Counsel fails to mention that in the same paragraph as the quoted language from *Penn State Hershey*, the court stated that "other courts of appeals have held that the efficiencies defense is cognizable", "still others have analyzed the efficiencies to determine whether they might overcome the presumption of illegality", and the "FTC's *Merger Guidelines* also recognize the [efficiencies] defense". 838 F.3d 327, 347–48 (3d Cir. 2016). In doing so, Complaint Counsel attempts to render efficiencies irrelevant when courts have repeatedly rejected challenges to mergers due to their efficiencies, including mergers generating much less substantial healthcare benefits (*see* COL ¶ 95), increasing consumer access to a product (*see*

COL ¶ 98), producing R&D efficiencies (*see* COL ¶ 100), resulting in cost savings (*see* COL ¶ 102), eliminating double marginalization (*see* COL ¶ 104), increasing supply chain and operational efficiencies (*see* COL ¶ 106), and accelerating international expansion (*see* COL ¶ 107).

Courts have repeatedly held that a transaction is lawful under Section 7 unless any anticompetitive effects outweigh any procompetitive effects. *See, e.g., New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 207 (S.D.N.Y. 2020); *FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1054–55 (8th Cir. 1999) (courts should consider "evidence of enhanced efficiency in the context of the competitive effects of the merger" since "the merged entity may well enhance competition"); *Saint Alphonsus Med. Ctr.-Nampa Inc. v. St. Luke's Health Sys., Ltd.*, 778 F.3d 775, 790 (9th Cir. 2015) ("[A] defendant can rebut a prima facie case with evidence that the proposed merger will create a more efficient combined entity and thus increase competition."); *FTC v. Univ. Health, Inc.*, 938 F.2d 1206, 1222 (11th Cir. 1991) ("[A] defendant may rebut the government's prima facie case with evidence showing that the intended merger would create significant efficiencies in the relevant market."); *AT&T I*, 310 F. Supp. 3d at 190 ("One way defendants may [contest the Government's case] is to offer evidence that 'post-merger efficiencies outweigh the merger's anticompetitive effects."). Cases cited by Complaint Counsel are not to the contrary. *See FTC v. H.J. Heinz Co.*, 246 F.3d 708, 720–21 (D.C. Cir. 2001); *United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 89 (D.D.C. 2011); *FTC v. Wilh. Wilhelmsen Holding ASA*, 341 F. Supp. 3d 27, 72 (D.D.C. 2018); *FTC v. CCC Holdings, Inc.*, 605 F. Supp. 2d 26. 72–73 (D.D.C. 2009).

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

69. In assessing such efficiency claims, courts have applied strict standards in their review. *Heinz*, 246 F.3d at 720-21; *H&R Block*, 833 F. Supp. 2d at 890. Specifically, "the court must undertake a rigorous analysis of the kinds of efficiencies being urged by the parties in order to ensure that those 'efficiencies' represent more than mere speculation and promises about post-merger behavior." *Heinz*, 246 F.3d at 721; *see also FTC v. Wilh. Wilhelmsen Holding ASA*, 341 F. Supp. 3d 27, 72 (D.D.C. 2018); *FTC v. CCC Holdings, Inc.*, 605 F. Supp. 2d 26, 72-73 (D.D.C. 2009).

Response to Proposed Conclusion of Law No. 69:

The proposed conclusion is incomplete for the reasons explained in Respondents' responses to CCCoL ¶ 68, which Respondents incorporate herein. Further, while Respondents must prove "merger-specificity and verifiability" of their claimed efficiencies, *Anthem*, 855 F.3d at 364, with respect to verifiability, efficiencies need not be "capable of precise quantification." *Arch Coal*, 329 F. Supp. 2d at 153. Rather, they must be based on "credible evidence" of "a prediction backed by sound business judgment." *Staples, Inc.*, 970 F. Supp. at 1089-90. With respect to merger-specificity, "[t]he real question is whether the alternatives to merger are practical and more than merely theoretical." *Anthem*, 855 F.3d at 357.

Respondents also note that like its suggestion that efficiencies do not matter under the Clayton Act, Complaint Counsel's claim that the efficiencies resulting from the Transaction are speculative, unverified and not merger-specific is, to be frank, nonsense. It is also the product of a double standard, as Complaint artificially inflates the threshold for proving efficiencies, while artificially deflating its own burden to show anticompetitive effect (for which, according to Complaint Counsel, speculation and mere assertions suffice).

As set out in Respondents' Post-Trial Brief and Proposed Findings of Fact, the overwhelming and unrefuted evidence showed that the Transaction will result in numerous, merger-specific benefits, including that it will save thousands of lives (in the U.S. alone, and many more throughout the world) and billions of dollars. Far from being unsubstantiated, these

efficiencies are supported by every Illumina and GRAIL witness to address them, including: Francis deSouza, Dr. Alex Aravanis, Dr. Phil Febbo, Ammar Qadan, Jay Flatley, Hans Bishop, Dr. Joshua Ofman, Aaron Freidin and Dr. Arash Jamshidi. (PFF ¶ 1108.) They are supported by "analogous past experience" (Mergers Guidelines § 10), including most notably Illumina's vertical acquisition of Verinata resulting in expanded access to NIPT testing and the discovery of GRAIL. And they are supported by the testimony of highly qualified experts and reluctant admissions by Complaint Counsel's own experts.

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

70. Assuming *arguendo* that the efficiency or EDM defense is even potentially available, Respondents would bear the heavy burden to show that their efficiencies and EDM claims are cognizable, meaning that they are "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *Horizontal Merger Guidelines* § 10; *see also Hackensack*, 2022 WL 840463, at *10-11*; Heinz*, 246 F.3d at 720; *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016); *Sysco*, 113 F. Supp. at 82.

Response to Proposed Conclusion of Law No. 70:

The proposed conclusion is incorrect and incomplete for the reasons explained in Respondents' responses to CCCoL ¶ 69, which Respondents incorporate herein.

71. To substantiate each efficiency, Respondents would be required to demonstrate that "it is possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency, how and when each would be achieved (and any costs of doing so), how each would enhance the merged firms' ability and incentive to compete, and why each would be merger specific." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *H&R Block*, 833 F. Supp. 2d at 89); *see also Hackensack*, 2022 WL 840463, at *10-11; *Horizontal Merger Guidelines* § 10.

Response to Proposed Conclusion of Law No. 71:

The proposed conclusion is incomplete for the reasons explained in Respondents' responses to CCCoL ¶ 68, which Respondents incorporate herein.

72. To demonstrate merger specificity, Respondents would need to "present a type of cost saving that could not be achieved without the merger[.]" *Wilhelmsen*, 341 F. Supp. at 72; *see also Hackensack*, 2022 WL 840463, at *11 ("*i.e.*, the efficiencies cannot be achieved by either party alone").

Response to Proposed Conclusion of Law No. 72:

The proposed conclusion is incomplete for the reasons explained in Respondents' responses to CCCoL ¶ 69, which Respondents incorporate herein.

73. Even verifiable, merger-specific efficiencies are no defense absent "clear evidence" that they "will offset the anticompetitive effects and ultimately benefit consumers." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *Penn State Hersey*, 838 F.3d at 350). "The critical question raised by the efficiencies defense is whether the projected savings from the mergers are enough to overcome the evidence that tends to show that possibly greater benefits can be achieved by the public through existing, continued competition." *Cardinal Health*, 12 F. Supp. 2d at 63*; see also Anthem*, 855 F.3d at 355–56 (affirming district court's rejection of the efficiencies defense "because the amount of cost saving that is both merger-specific and verifiable would be insufficient to offset the likely harm to competition"); *FTC v. Peabody Energy Corp.*, 492 F. Supp. 3d 865, 918 (E.D. Mo. 2020) ("[E]ven granting Defendants every dollar of their claimed efficiencies . . . and making the implausible assumption that they would pass every penny of those efficiencies on to their customers, Defendants' claimed efficiencies still would not offset the likely competitive harm to those same customers[.]").

Response to Proposed Conclusion of Law No. 73:

The proposed conclusion is incomplete for the reasons explained in Respondents' responses to CCCoL ¶ 68, which Respondents incorporate herein. Further, once Respondents prove verifiable, merger-specific efficiencies, the burden returns to Complaint Counsel to prove that the efficiencies do not outweigh the alleged anticompetitive effects such that the Transaction is still likely to substantially lessen competition. *FTC v. Wilh. Wilhelmsen Holding ASA*, 341 F. Supp. 3d 27, 45 (D.D.C. 2018) ("Where defendants successfully rebut the presumption of illegality, 'the burden of producing additional evidence of anticompetitive effect shifts to the government, and merges with the ultimate burden of persuasion, which remains with the government at all times.'") (citated omitted). Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

74. Where, as here, Respondents have failed to produce evidence that merger-specific, verifiable efficiencies will "neutralize if not outweigh the harm caused by the loss of competition and innovation," *Anthem*, 855 F.3d at 369 (Millett, J., concurring), the purported efficiencies defense fails. *See* (CCFF ¶¶ 5014-966).

Response to Proposed Conclusion of Law No. 74:

The proposed conclusion is incorrect and incomplete.

First, as explained in their responses to CCCoL ¶ 61, because Complaint Counsel has failed to establish a *prima facie* case of competitive harm, Respondents have no burden to rebut Complaint Counsel's Section 7 case.

Second, as explained in RRCOL § V, Respondents' Opening Br. § IV, and Respondents' Reply Br. § IV, the Transaction will result in numerous merger-specific benefits that more than offset the alleged harm. The reunion of Illumina and GRAIL will accelerate market access to a life-saving test; lead to new innovations from synergistic R&D; reduce costs through the elimination of a royalty that GRAIL was otherwise contractually required to pay to Illumina and elimination of double marginalization, the savings from which will be passed on to consumers; and lead to supply chain, operational and international efficiencies, resulting in lower prices and faster testing for patients.

Third, Complaint Counsel suggests that Respondents have the burden to prove that efficiencies will outweigh alleged anticompetitive harms. However, even under the horizontal merger framework, once Respondents prove verifiable, merger-specific efficiencies, the burden returns to Complaint Counsel to prove that the efficiencies do not outweigh the alleged anticompetitive effects such that the Transaction is still likely to substantially lessen competition. *FTC v. Wilh. Wilhelmsen Holding ASA*, 341 F. Supp. 3d 27, 45 (D.D.C. 2018) ("Where defendants successfully rebut the presumption of illegality, 'the burden of producing additional

evidence of anticompetitive effect shifts to the government, and merges with the ultimate burden of persuasion, which remains with the government at all times.'") (citated omitted).

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

75. Respondents cannot, however, reliably quantify the claimed value of EDM or any efficiency resulting from the Acquisition. *See* (CCFF ¶¶ 5364-78, 5706-15, 5721-51, 5778-79, 5786-99, 5837-47).

Response to Proposed Conclusion of Law No. 75:

The proposed conclusion should be disregarded because it violates the Court's Order on Post-Trial Filings (at 2) requiring that "[a]ll legal contentions, including, but not limited to, contentions regarding liability and the proposed remedy, shall be supported by applicable legal authority."

The proposed conclusion is improper and should be disregarded because it is a proposed finding of fact couched as a proposed conclusion of law. In any event, the proposed conclusion is incorrect and unsupported by the record. As Respondents have explained, the record shows that "[u]sing a low estimate of $5 million for the value of lives saved, Dr. Carlton estimated a low-end value of the efficiencies of $37 million." (PFF ¶ 1123.4; *see also* Resps.' Opening Br. at 185-86; Resps.' Reply Br. § IV.) The Proposed Conclusion also assumes an incorrect legal standard—that Respondents' efficiencies must be quantifiable to be verifiable. By contrast, Respondents have no burden to quantify these efficiencies. *Arch Coal*, 329 F. Supp. 2d at 153 (efficiencies need not be "capable of precise quantification."). Instead, [redacted] (*See* PFF ¶¶ 764–66.) Further, the Proposed Conclusion relies on a double standard in which *Complaint Counsel* need not provide

robust proof of the harm from foreclosed competition in the future, as the future is unknown, but *Respondents* must quantify any future efficiencies from the Transaction with precision.

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

76. Respondents have also failed to demonstrate that their claimed efficiencies and EDM are merger specific. *See* (CCFF ¶¶ 5379-408, 5631-74, 5678-705, 5752-77, 5800-47).

Respondents also have not met their burden to show that efficiencies or EDM would be passed through to consumers. *See* (CCFF ¶¶ 5716-20, 5780-85).

Response to Proposed Conclusion of Law No. 76:

The proposed conclusion should be disregarded because it violates the Court's Order on Post-Trial Filings (at 2) requiring that "[a]ll legal contentions, including, but not limited to, contentions regarding liability and the proposed remedy, shall be supported by applicable legal authority."

The proposed conclusion is improper and should be disregarded because it is a proposed finding of fact couched as a proposed conclusion of law. In any event, the Proposed Conclusion is incorrect and unsupported by the record. For example, Complaint Counsel's claim that Illumina's ability to accelerate market access is not merger-specific, is baseless. Complaint Counsel points to a number of GRAIL's achievements in developing Galleri, such as receiving a "breakthrough device" designation. (CC Post-Trial Br. at 148–50.) While important, those achievements do not give GRAIL all that it needs to accelerate FDA and payor approval (in fact, breakthrough designation is granted by FDA early in a product development process, before a company conducts pivotal studies necessary for FDA approval). Numerous witnesses testified that GRAIL needs what Illumina has to accelerate the approval of Galleri. (PFF ¶¶ 1133-33.26.) For example, Francis DeSouza, CEO of Illumina, testified that Illumina "has been working with payers in the U.S. and around the world, again, for almost a decade. We have a very talented

team that . . . has the right innovation focus to come up with new models to accelerate the evidence generation needed to get payers on board." (PFF ¶ 1132.2.) [redacted] Respondents also incorporate their responses to CCFF ¶¶ 5379–408, 5631–74, 5678–705, 5752–77, 5800–47 herein.

Also meritless is Complaint Counsel's contention that the resulting efficiencies or EDM will not be passed to consumers. The cost savings and consumer surplus arising from EDM is a well-accepted benefit of vertical integrations, as numerous courts have recognized. *See*, *e.g.*, *Viamedia, Inc. v. Comcast Corp.*, 951 F.3d 429, 465 (7th Cir. 2020); *Alberta Gas Chems Ltd. v. E.I. Du Pont de Nemours & Co.*, 826 F.2d 1235, 1247 (3d Cir. 1987); *AT&T I*, 310 F. Supp. 3d at 197. Both Drs. Carlton and Scott Morton acknowledge that EDM is a benefit that can often arise from vertical mergers. (PFF ¶¶ 1152.1–52.2.) [redacted] (PFF ¶ 1154.)

Respondents also incorporate their responses to CCFF ¶¶ 5716–20, 5780–85 and the relevant discussion in their opening and reply post-trial briefs.

77. Respondents have failed to demonstrate that EDM and efficiencies would offset the harm from this anticompetitive acquisition. *See* (CCFF ¶¶ 5364-78, 5706-15, 5721-51, 5778-79, 5786-99, 5837-47).

Response to Proposed Conclusion of Law No. 77:

The proposed conclusion is incorrect. As explained in Respondents' Opening Br. § IV and Respondents' Reply Br. § IV, the Transaction will result in numerous merger-specific benefits that more than offset the alleged harm. The overwhelming and unrefuted evidence showed that the Transaction will result in numerous, merger-specific benefits, including that it will save tens of thousands of lives (in the U.S. alone, and many more throughout the world) and tens of billions of dollars. To that end, the reunion of Illumina and GRAIL will accelerate market access to a life-saving test; lead to new innovations from synergistic R&D; reduce costs through the elimination of a royalty that GRAIL was otherwise contractually required to pay to Illumina and elimination of double marginalization, the savings from which will be passed on to consumers; and lead to supply chain, operational and international efficiencies, resulting in lower prices and faster testing for patients.

Far from being unsubstantiated, these efficiencies are supported by every Illumina and GRAIL witness to address them, including: Francis deSouza, Dr. Alex Aravanis, Dr. Phil Febbo, Ammar Qadan, Jay Flatley, Hans Bishop, Dr. Joshua Ofman, Aaron Freidin and Dr. Arash Jamshidi. (PFF ¶ 1108.) They are supported by "analogous past experience" (Mergers Guidelines § 10), including most notably Illumina's vertical acquisition of Verinata resulting in expanded access to NIPT testing and the discovery of GRAIL. And they are supported by the testimony of highly qualified experts and reluctant admissions by Complaint Counsel's own experts.

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

IX. RESPONDENTS FAIL TO MEET THEIR BURDEN TO SHOW THEIR PROPOSED REMEDY REPLACES THE COMPETITIVE INTENSITY LOST FROM THE PROPOSED ACQUISITION

78. Respondents "bear the burden of showing that any proposed remedy would negate any anticompetitive effects of the merger[.]" *Otto Bock,* 2019 WL 5957363, at *44 (quoting *Staples*, 190 F. Supp. 3d at 137 n.15 (D.D.C. 2016)).

Response to Proposed Conclusion of Law No. 78:

The proposed conclusion is incorrect and incomplete. Since Complaint Counsel has failed to establish a prima facie case of competitive harm for the reasons given in Resps.' Reply Br. §§ II and III, Respondents have no burden to propose a remedy. It is well-established that there is no basis for a remedy under the law where there is no violation. *See Bacon v. City of Richmond*, 475 F.3d 633, 638 (4th Cir. 2007) ("Remedies . . . are the consequence of some wrong. At its most basic, this principle limits the reach of judicial decrees to parties found liable for a legal violation"); *Breaux Bros. Farms v. Teche Sugar Co.*, 21 F.3d 83, 89 (5th Cir. 1994) ("[C]ompetition has not been injured and [thus] the antitrust laws offer them no relief."). Complaint Counsel effectively concedes this. (CC Post-Trial Br. at 180–81, 191) (noting that remedy is only appropriate where there has been a violation of Section 7). For all the reasons discussed in Respondents' Reply Brief, Respondents' Post-Trial Brief and Proposed Findings of Fact and Conclusions of Law, Complaint Counsel cannot show that the Transaction violates Section 7 of the Clayton Act. Thus, the proposed divestiture bears no "reasonable relation to [any] unlawful practices". *Jacob Siegel v. FTC*, 327 U.S. 608, 611–13 (1946). Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

79. The purpose of a remedy in Section 7 cases is "to restore competition lost through the unlawful acquisition." *Otto Bock*, 2019 WL 5957363, at *43.

Response to Proposed Conclusion of Law No. 79:

The proposed conclusion is incomplete for the reasons explained in Respondents' responses to CCCoL ¶ 78, which Respondents incorporate herein.

80. Here, Respondents' Open Offer is a remedy proposal. *See, e.g.*, Mot. For Conference to Facilitate Settlement, *In re Illumina, Inc. and GRAIL, Inc.*, Docket No. 9401, at 6-7 (F.T.C. July 13, 2021) (characterizing the Open Offer as "a consent agreement with protections in place to address the FTC's purported concerns . . . ."). *See* (CCFF ¶¶ 4484-5012).

Response to Proposed Conclusion of Law No. 80:

Respondents have no specific response except to note that even if a remedy were required here, there are less extreme remedies than the proposed divestiture, including an order embodying the terms of the Open Offer, which would be more than sufficient to address the alleged harm.

Here, a divestiture order would be disproportionate to any legitimate need as it would eliminate the life-saving benefits of the Transaction in order to address concerns that are unproven and in any case eliminated by the Open Offer. As explained in detail in Section V, Illumina's Open Offer eliminates all of the alleged concerns raised by Complaint Counsel. Illumina has committed to formalize these binding contractual commitments in a consent order. An order requiring Illumina to abide by the terms of the Open Offer would be a more appropriate and effective remedy than divestiture. *See AT&T II*, 916 F.3d at 1041 (noting that the government has recognized that "especially in vertical mergers, . . . conduct remedies . . . can be a very useful tool to address the competitive problems while preserving competition and allowing efficiencies that may result from the transaction"); *Butterworth*, 946 F. Supp. at 1298 (holding that respondents successfully rebutted FTC's prima facie case with their proposed "Community Commitment" that served as an "additional assurance" that the merged entity could

not engage in any anticompetitive behavior); *see also Jacob Siegel*, 327 U.S. at 611–13 (remedy must bear "reasonable relation to the unlawful practices found to exist.")

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

81. To meet their burden, Respondents must show that the Open Offer would "replac[e] the competitive intensity lost as a result of the merger." *Aetna*, 240 F. Supp. 3d at 60 (quoting *Sysco*, 113 F. Supp. 3d at 72) (emphasis in original).

Response to Proposed Conclusion of Law No. 81:

The proposed conclusion is incomplete for the reasons explained in Respondents' responses to CCCoL ¶¶ 78 and 80, which Respondents incorporate herein. Respondents also note that the Open Offer prevents any possible anticompetitive harms. Illumina made an Open Offer to its oncology customers, which a number of them have now accepted, addressing point-by-point the concerns Complaint Counsel has raised about the Transaction. The Open Offer extends protections far beyond what is necessary to address Complaint Counsel's most speculative concerns, even though there is no credible evidence of a need for a "fix" of any kind. (*See* Resps.' Opening Br. at 148–70; Resps.' Reply Br. § V; PFF ¶¶ 987–1056.)

82. To meet its burden, it is insufficient that the remedy replaces some or most of the lost competition. Rather Respondents must show that the remedy completely "replac[es] the competitive intensity lost as a result of the merger." *Aetna*, 240 F. Supp. 3d at 60 (quoting *Sysco*, 113 F. Supp. 3d at 72).

Response to Proposed Conclusion of Law No. 82:

The proposed conclusion is incorrect and incomplete. As explained in their responses to CCCoL ¶ 78, Respondents have no burden to propose a remedy when Complaint Counsel have failed to prove its prima facie case.

The proposed conclusion should also be disregarded because it violates the Court's Order on Post-Trial Filings (at 2) requiring that "[a]ll legal contentions, including, but not limited to,

contentions regarding liability and the proposed remedy, shall be supported by applicable legal authority." The proposed conclusion is not supported by the cited legal authority as the cited case does not state that a remedy must "completely" replace the competitive intensity as a result of the merger. *See Aetna*, 240 F. Supp. 3d at 60 (quoting *Sysco*, 113 F. Supp. 3d at 72). In any case, the Open Offer does prevent any possible anticompetitive harms. (*See* Resps.' Post-Trial Br. at 148-70; Resps.' Reply Br. § V; PFF ¶¶ 987–1056.)

83. Here, Complaint Counsel has shown that the Acquisition clearly runs afoul of antitrust laws. Accordingly, "all doubts as to remedy are to be resolved in [Complaint Counsel's] favor." *Otto Bock*, 2019 WL 2118886, at *54 (Chappell, A.L.J.) (quoting *United States v. E.I. du Pont de Nemours & Co.*, 366 U.S. 316, 334 (1961)); *Ford Motor*, 405 U.S. at 575.

Response to Proposed Conclusion of Law No. 83:

The proposed conclusion is incomplete and misleading. The full sentence in *Otto Bock*, only a part of which Complaint Counsel quotes, is: "[I]t is well settled that *once the government has successfully borne the considerable burden of establishing a violation of law*, all doubts as to the remedy are to be resolved in its favor." 2019 WL 2118886, at *54 (emphasis added).

Complaint Counsel has failed to meet its burden of establishing that the Transaction violates any antitrust laws, because Complaint Counsel failed to prove its alleged relevant market; Complaint Counsel failed to prove its alleged related product market; Complaint Counsel failed to prove the Transaction is likely to substantially lessen competition; Complaint Counsel erred in dismissing the Open Offer; the benefits of the Transaction more than offset the alleged harm; Complaint Counsel's challenge to the Transaction violates the U.S. Constitution; and Complaint Counsel's case runs counter to the overwhelming proof and rests on "evidence" that is inadmissible and/or deserving of no weight. (*See* Resps.' Opening Br. §§ I–VI; Resps.' Reply Br. §§ I–V.)

It is well-established that there is no basis for a remedy under the law where there is no violation. *See Bacon*, 475 F.3d at 638 ("Remedies . . . are the consequence of some wrong. At its most basic, this principle limits the reach of judicial decrees to parties found liable for a legal violation"); *Breaux Bros. Farms*, 21 F.3d at 89 ("[C]ompetition has not been injured and [thus] the antitrust laws offer them no relief."). Complaint Counsel effectively concedes this. (CC Post-Trial Br. at 180–81, 191) (noting that remedy is only appropriate where there has been a violation of Section 7). For all the reasons discussed above, and in Respondents' Post-Trial Brief and Proposed Findings of Fact and Conclusions of Law, Complaint Counsel cannot show that the Transaction violates Section 7 of the Clayton Act. Thus, the proposed divestiture bears no "reasonable relation to [any] unlawful practices". *Siegel*, 327 U.S. at 611–13.

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

84. As a federal court explained when enjoining a merger in which the parties made a behavioral commitment not to raise prices, "the mere fact that such representations had to be made strongly supports the fears of impermissible monopolization." *Cardinal Health*, 12 F. Supp. 2d at 67.

Response to Proposed Conclusion of Law No. 84:

The proposed conclusion is incomplete and thus misleading. This case is distinguishable from *FTC v. Cardinal Health, Inc.* 12 F. Supp. 2d 34, 67 (D.D.C. 1998), as in *Cardinal Health*, defendants merely represented to the court that they would not raise the charge of their services, Illumina has agreed to be contractually bound to the Open Offer, and [redacted] Thus, unlike mere "representations" in *Cardinal Health*, the Open Offer and the resulting agreements set out a series of all-encompassing

protections that prevent any foreclosure by Illumina. Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

85. Respondents' post-merger incentives can compromise the efficacy of their proposed remedy. For example, in *United States v. H&R Block*, defendants pledged to maintain the same price of TaxACT, one of the merged firm's tax preparation software. The court found such a commitment to be unavailing, noting:

> Even if TaxACT's list price remains the same, the merged firm could accomplish what amounts to a price increase through other means. For example, instead of raising TaxACT's prices, it could limit the functionality of TaxACT's products, reserving special features or innovations for higher priced, HRB-branded products. The merged firm could also limit the availability of TaxACT to consumers by marketing it more selectively and less vigorously.

H&R Block, 833 F. 2d at 82.

The *H&R Block* court recognized that when a merger decreases competition, the merged firm will find ways to capitalize on the lower competitive intensity by circumventing any specific commitments designed to prevent anticompetitive consequences.

Response to Proposed Conclusion of Law No. 85:

The proposed conclusion is incomplete and thus misleading. In a horizontal merger case such as *United States v. H&R Block*, 833 F.2d 36 (D.D.C. 2011), the merging parties' incentives differ greatly from the incentives of parties in a vertical merger.

First, as two Commissioners noted in dissenting from the withdrawal of the Vertical Merger Guidelines, "the fact remains that vertical mergers are different animals from mergers of competitors, changing incentives in ways that are, on the whole, more likely to improve efficiency, bolster competition, and benefit consumers", and "[a]s such, they require an approach that fully accounts for their good as well as their bad effects" because "[a]nything less will hurt consumers, not help them". Fed. Trade Comm'n, Dissenting Statement of Commissioners Phillips and Wilson, at 3–4.

Second, in a horizontal merger, the merging parties' incentive to raise prices is largely unchecked by market forces so long as the merging parties hold a large enough market share. In

contrast, any claim that Illumina has a post-merger ability and incentive to harm putative GRAIL rivals is refuted by (1) intensifying upstream competition, which is far more concrete and certain than Complaint Counsel's claims of entry in the alleged MCED market; (2) the shrinking costs and margins on Illumina's NGS inputs, which represent powerful constraints on Illumina that Complaint Counsel ignores; and (3) the fact that Illumina would lose far more than it would gain if it attempted Complaint Counsel's hypothesized foreclosure tactics. (*See* Resps.' Br. § III.B–C.3.)

Third, unlike in *United States v. H&R Block*, 833 F.2d 36, 82 (D.D.C. 2011), where the defendants pledged to maintain current prices for three years but did not pledge to prevent any other possible anticompetitive harms, Respondents' Open Offer provides comprehensive, long-term protections for customers regarding every "lever" that Complaint Counsel argues Illumina could pull to disadvantage potential GRAIL rivals and eliminates any incentive Illumina could have had to favor GRAIL. (*See* Resps.' Opening Br. at 148–49, 153–70; Resps.' Reply Br. § V.B.)

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

86. Competitors in the relevant market are not immune from harm if they accept a supply agreement with the merged entity. To the contrary, "it can be a problem to allow continuing relationships between the seller and buyer . . . such as a supply arrangement or technical assistance requirement, which may increase the buyer's vulnerability to the seller's behavior." *Sysco*, 113 F. 3d at 77 (internal quotation marks and citations omitted).

Response to Proposed Conclusion of Law No. 86:

The proposed conclusion is incomplete and misleading. Unlike in *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 77 (D.D.C. 2015), where defendants offered no conduct remedy that would eliminate any risk to the buyers, Respondents' Open Offer provides comprehensive, long-term

protections for customers regarding every "lever" that Complaint Counsel argues Illumina could pull to disadvantage potential GRAIL rivals and eliminates any incentive Illumina could have had to favor GRAIL. (*See* Resps.' Opening Br. at 148–49, 153–70; Resps.' Reply Br. § V.B.) Thus, rather than increasing customers' "vulnerability", the Open Offer provides customer protections that extend beyond those requested by individual customers because its primary goal was to guarantee that ***all*** of its oncology customers, including any potential GRAIL competitors, were secure in their supply relationships with Illumina after the Transaction. (PFF ¶ 1000.2.) Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

87. Rather than "replac[ing] the competitive intensity" lost from the Acquisition, Respondents' attempted behavioral remedy only applies to a small fraction of the relevant market who signed the Open Offer and does not scratch the surface of reversing the Acquisition's anticompetitive harms.

Response to Proposed Conclusion of Law No. 87:

The proposed conclusion should be disregarded because it violates the Court's Order on Post-Trial Filings (at 2) requiring that "[a]ll legal contentions, including, but not limited to, contentions regarding liability and the proposed remedy, shall be supported by applicable legal authority." The proposed conclusion is also incorrect, as Respondents' Open Offer provides comprehensive, long-term protections for customers regarding every "lever" that Complaint Counsel argues Illumina could pull to disadvantage potential GRAIL rivals and eliminates any incentive Illumina could have had to favor GRAIL. (*See* Resps.' Opening Br. at 148–49, 153–70; Resps.' Reply Br. § V.B.) That not every possible customer has signed the agreement shows that no one was pressured into signing the agreement. In fact, quite the opposite is true. Customers can continue to sign the Open Offer at any time until six years after the close of the Transaction. (PFF ¶ 995.) And if any customer who signs the Offer decides it no longer likes its

terms that customer can unilaterally terminate its supply agreement at any time and for any reason. (PFF ¶ 1001.) Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

88. The Open Offer does not change Illumina's incentives to foreclose Grail's rivals. *See* (CCFF ¶¶ 4175-93).

Response to Proposed Conclusion of Law No. 88:

The proposed conclusion should be disregarded because it violates the Court's Order on Post-Trial Filings (at 2) requiring that "[a]ll legal contentions, including, but not limited to, contentions regarding liability and the proposed remedy, shall be supported by applicable legal authority."

Further, the proposed conclusion is improper and should be disregarded because it is a proposed finding of fact couched as a proposed conclusion of law. In any event, the proposed conclusion is incorrect and unsupported by the record. The crux of Complaint Counsel's case is that the Transaction will enable and incentivize Illumina to harm GRAIL's rivals. Complaint Counsel imagines that Illumina will discriminate against GRAIL's rivals by giving GRAIL better NGS products, better service and better prices. While the Transaction will not make Illumina any more likely to do any of that (as discussed above), the Open Offer legally obligates Illumina to refrain from disadvantaging GRAIL rivals in these ways. Were Illumina to try, it would not only lose NGS sales (to the disadvantaged GRAIL rivals) and inflict injury to its own reputation, but it would be in breach of its legal obligations and subject to whatever remedies a third-party arbitrator believed necessary to ensure GRAIL's rivals were treated fairly. Under these circumstances, no rational actor would harm its own customers, even if they were GRAIL's rivals. Respondents also incorporate their responses to CCFF ¶¶ 4175–93 and the relevant discussion in their opening and reply post-trial briefs.

89. The Open Offer does not preclude Illumina from disadvantaging Grail's rivals. *See* (CCFF ¶¶ 4484-5012).

Response to Proposed Conclusion of Law No. 89:

The proposed conclusion is incorrect and misleading for the reasons explained in Respondents' response to CCCoL ¶ 89, which Respondents incorporate herein. Respondents also incorporate their responses to CCFF ¶¶ 4484–5012 herein.

90. Neither Grail's monitors nor an independent auditor can effectively monitor Illumina's compliance with the Open Offer. *See* (CCFF ¶¶ 4843-927).

Response to Proposed Conclusion of Law No. 90:

The proposed conclusion should be disregarded because it violates the Court's Order on Post-Trial Filings (at 2) requiring that "[a]ll legal contentions, including, but not limited to, contentions regarding liability and the proposed remedy, shall be supported by applicable legal authority."

The proposed conclusion is also improper and should be disregarded because it is a proposed finding of fact couched as a proposed conclusion of law. In any event, the proposed conclusion is incorrect and unsupported by the record. As Respondents have explained, Complaint Counsel's attack on the monitoring and enforcement provisions of the Open Offer is without merit. GRAIL's rivals have every incentive to discover any favoritism of GRAIL, as it would result in more favorable treatment for them. Illumina has agreed to a rigorous audit provision to ensure third-party review will unearth any non-compliance, and to give comfort to customers. The Open Offer commits Illumina to biannual audits by a third-party auditor selected from among the "Big 4" to monitor Illumina's compliance (PFF ¶ 1047.1); requires Illumina to engage an auditor to assess any good-faith allegation of a breach (separate from the biannual audits) (PFF ¶ 1047.2); and mandates that Illumina provide customers with a written report of the audits and to ensure that customers are notified of any potential noncompliance within ten

days (PFF ¶ 1048). (*See* PFF ¶¶1047.1–48, 1055–56; Resps.' Post-Trial Br. at 169-70; Resps.' Reply Br. § V.E.) Respondents also incorporate their responses to CCFF ¶¶ 4843–927 herein.

91. The Open Offer cannot be effectively enforced. *See* (CCFF ¶¶ 4928-50).

Response to Proposed Conclusion of Law No. 91:

The proposed conclusion is incorrect and misleading for the reasons explained in Respondents' response to CCCoL ¶ 91 and CCFF ¶¶ 4928–50, which Respondents incorporate herein.

92. Due to the clear inadequacies of the Open Offer, along with the outstanding concerns of those actually subject to the terms of the Open Offer, Respondents' proposed remedy falls well short of meeting their burden.

Response to Proposed Conclusion of Law No. 92:

The proposed conclusion should be disregarded because it violates the Court's Order on Post-Trial Filings (at 2) requiring that "[a]ll legal contentions, including, but not limited to, contentions regarding liability and the proposed remedy, shall be supported by applicable legal authority." In addition, this proposed conclusion is inaccurate. Since Complaint Counsel has failed to establish a prima facie case of competitive harm for the reasons given in Resps.' Reply Br. §§ II and III, Respondents have no burden to propose a remedy. Further, the record demonstrates that Respondents' Open Offer prevents any possible anticompetitive harm and provides comprehensive, long-term protections for customers regarding every "lever" that Complaint Counsel argues Illumina could pull to disadvantage potential GRAIL rivals. Respondents also incorporate their responses to CCCoL ¶¶ 83, 88 and 90 and the relevant discussion from their opening and reply post-trial briefs.

X. THE PROPOSED ORDER IS WARRANTED

93. Illumina's acquisition of Grail violated Section 7 of the Clayton Act, 15 U.S.C. § 18. The Proposed Order is warranted to address competitive harms caused by the acquisition.

Response to Proposed Conclusion of Law No. 93:

The proposed conclusion should be disregarded because it violates the Court's Order on Post-Trial Filings (at 2) requiring that "[a]ll legal contentions, including, but not limited to, contentions regarding liability and the proposed remedy, shall be supported by applicable legal authority."

The proposed conclusion is also incorrect and unsupported by the record. It is well-established that there is no basis for a remedy under the law where there is no violation. *See Bacon*, 475 F.3d at 638 ("Remedies . . . are the consequence of some wrong. At its most basic, this principle limits the reach of judicial decrees to parties found liable for a legal violation"); *Breaux Bros. Farms*, 21 F.3d at 89 ("[C]ompetition has not been injured and [thus] the antitrust laws offer them no relief."). Complaint Counsel effectively concedes this. (CC Post-Trial Br. at 180–81, 191) (noting that remedy is only appropriate where there has been a violation of Section 7). For all the reasons discussed in Respondents' Reply Brief, Respondents' Post-Trial Brief and Proposed Findings of Fact and Conclusions of Law, Complaint Counsel cannot show that the Transaction violates Section 7 of the Clayton Act. Thus, the proposed divestiture bears no "reasonable relation to [any] unlawful practices". *Siegel*, 327 U.S. at 611–13. But even were the Court to find a violation, the Proposed Order would be an extreme and unnecessary remedy, needlessly punitive, and violate the U.S. Constitution.

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

94. Complaint Counsel met its burden of proof in support of Count I of the Complaint.

Response to Proposed Conclusion of Law No. 94:

The proposed conclusion should be disregarded because it violates the Court's Order on Post-Trial Filings (at 2) requiring that "[a]ll legal contentions, including, but not limited to,

contentions regarding liability and the proposed remedy, shall be supported by applicable legal authority."

The proposed conclusion is also incorrect and unsupported by the record. As shown in Respondents' Findings of Fact ¶¶ 797–981 and Respondents' Reply Brief § III, Complaint Counsel failed to prove the Transaction is likely to substantially lessen competition. Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

95. Entry of the Proposed Order is necessary and appropriate to remedy and prevent the violations of law found to exist. *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 611-13 (1946).

Response to Proposed Conclusion of Law No. 95:

The proposed conclusion is incorrect and misleading for the reasons explained in Respondents' responses to CCCoL ¶ 93, which Respondents incorporate herein.

96. The Commission has broad discretion to select a remedy so long as it bears a "reasonable relation to the unlawful practices found to exist." *Jacob Siegel*, 327 U.S. at 611-13.

Response to Proposed Conclusion of Law No. 96:

The proposed conclusion is incomplete. The Court's discretion is far from unlimited.

First, courts have recognized that "[e]quitable relief in an antitrust case should not embody harsh measures when less severe ones will do." *Microsoft II*, 224 F. Supp. 2d at 100 (internal quotations omitted). In particular, as relevant here, "divestiture is a remedy that is imposed only with great caution, in part because its long-term efficacy is rarely certain." *Id.* at 80. Moreover, a court may properly consider "economic hardship" when choosing "among two or more effective remedies." *du Pont*, 366 U.S. at 327. *Second*, "[a]bsent some measure of confidence that there has been an actual loss to competition that needs to be restored, wisdom counsels against adopting radical structural relief." *Deutsche Telekom*, 439 F. Supp. 3d at 230 n.23 (quoting *Microsoft Corp.*, 253 F.3d at 80); *see also* Sherman Act Hr'g, *supra* ("[R]emedies

should be proportional to the strength of the proof that [defendant's] illegal actions actually reduced competition . . . . [W]here you have that relatively weak evidence of likely anticompetitive effect, then you need more evidence to support more [d]raconian remedies."). *Third*, the remedy should not harm "the interest of the general public", *United States v. Am. Tobacco Co*., 221 U.S. 106, 185 (1911). *Fourth*, the remedy should not be needlessly punitive. *du Pont*, 366 U.S. at 326. *Fifth*, courts will not order relief "outside the scope of the violations alleged in the Complaint and outside the scope of the notice of contemplated relief attached to the Complaint." *NCBDE*, 152 F.T.C. at 97. *Sixth*, the remedy cannot violate the U.S. Constitution, which the proposed remedy would for numerous reasons. *See Belk v. Charlotte-Mecklenburg Bd. of Educ*, 233 F.3d 232, 274 (4th Cir. 2000) ("[C]ourt-ordered remedial action cannot be found violative of the Constitution.").

Respondents further incorporate the relevant discussion in their opening and reply post-trial briefs.

97. Both this Court and the Supreme Court have declared complete divestiture as "the usual and proper remedy where a violation of Section 7 has been found." *Polypore,* 2010 WL 9434806, at *256 (Chappell, A.L.J.) (citing *du Pont*, 366 U.S. at 329; *Ford Motor*, 405 U.S. at 573); *see also Otto Bock,* 2019 WL 5957363, at *45 (holding that "a complete divestiture of Freedom . . . is necessary to restore competition in the MPK market").

Response to Proposed Conclusion of Law No. 97:

The proposed conclusion is incorrect and misleading for the reasons explained in Respondents' responses to CCCoL ¶¶ 93 and 96, which Respondents incorporate herein.

Dated: May 25, 2022

Respectfully submitted,

/s David R. Marriott

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CERTIFICATE OF SERVICE

I hereby certify that on June 3, 2022, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

April Tabor
Secretary
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The Honorable D. Michael Chappell
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I also certify that I caused the foregoing document to be served via email to:

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June 3, 2022

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