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

In the Matter of **Illumina, Inc.** **a corporation,** **and** **GRAIL, Inc.** **a corporation,** **Respondents.**	**Docket No. 9401**

RESPONDENT GRAIL, LLC.'S SUPPLEMENTAL MOTION FOR *IN CAMERA* REVIEW OF CERTAIN TRIAL EXHIBITS

Respondent GRAIL, LLC. ("GRAIL") respectfully moves under 16 C.F.R. § 3.45 for supplemental *in camera* treatment of confidential and competitively sensitive information on the Parties' proposed Joint Exhibit No. 3 ("JX3"). On September 3, 2021 and September 13, 2021, the Court granted GRAIL's third and fourth motions for *in camera* treatment of certain trial exhibits (the "Orders", collectively). In the time between the Orders and this Motion, additional GRAIL documents have been included on JX3 for potential admission into the record. GRAIL has reviewed JX3 and has identified 14 exhibits containing sensitive information that "will likely result in a clearly defined, serious injury" to GRAIL if publicized.[1] 16 C.F.R. § 3.45(b). Accordingly, GRAIL respectfully requests the Court grant its supplemental motion for *in camera*

[1] There are pending disputes regarding certain additional exhibits that each of the parties seek to admit into evidence. *See* Feb. 16, 2022 Order on Pending Motions at 2. Because Respondents must file a final proposed *in camera* order by February 24, *see* Feb. 18, 2022 Order, GRAIL has included documents subject to those evidentiary disputes in the present motion in the event the documents in question are admitted.

treatment. Complaint Counsel has indicated that it takes no position regarding the relief sought in this Motion—it cannot join the Motion, but does not plan to file an opposition.

I. LEGAL STANDARD

Parties to a Part 3 proceeding may move the Court to "obtain *in camera* treatment for material, or portions thereof, offered into evidence." *Id*. *In camera* treatment is appropriate if public disclosure of the information is likely to "result in a clearly defined, serious injury to the person, partnership, or corporation requesting *in camera* treatment." *Id.* "[M]aterial made subject to an *in camera* order will be kept confidential and not placed on the public record of the proceeding in which it was submitted." 16 C.F.R. § 3.45(a). "Only respondents, their counsel, authorized Commission personnel, and court personnel concerned with judicial review may have access thereto, provided that the Administrative Law Judge, the Commission and reviewing courts may disclose such *in camera* material to the extent necessary for the proper disposition of the proceeding." *Id*.

In camera treatment may be granted if "public disclosure will likely result in clearly defined, serious injury." § 3.45(b). In considering whether to grant *in camera* treatment, the Court may consider (1) the extent to which the information is known outside of the business; (2) the extent to which it is known by employees and others within the business; (3) the extent of measures taken to protect the information's secrecy; (4) the value of the information to the business and its competitors; (5) the effort or investment made in developing the information; and (6) the ease of difficulty with which the information could be acquired or duplicated by others. *In re Bristol-Meyers Co.*, 90 F.T.C. 455, 456-57 (1977). *In camera* review may be appropriate not just for trade secrets and highly detailed cost data, but also for information in many ordinary-course business records "such as customer names, pricing to customers, business costs and profits, as well as

business plans, marketing plans, or sales documents." *In re 1-800 Contacts, Inc.*, No. 9372, 2017 FTC LEXIS 55, at *5-6 (Apr. 4, 2017).

II. ARGUMENT

The limited amount of documents identified in this Motion contain sensitive materials central and indispensable to GRAIL's operations. GRAIL's business has always focused on researching and developing methods to detect cancer. These research-and-development efforts, their results, and GRAIL's pathway to commercialization are central to the subject-matter of the present litigation. Due to the centrality of these subjects, GRAIL's most sensitive documents are frequently introduced as exhibits in this litigation. JX3 is no exception, containing several sensitive documents that, if publicized, would result in real and material harm to GRAIL.

Indeed, the limited amount of JX3 documents identified in this Motion almost exclusively discuss GRAIL's trade secrets, regulatory and commercialization strategies, and near-term strategic planning and positioning—all subjects striking at the core of GRAIL's business and carrying enormous implications for GRAIL. Accordingly, GRAIL has a vested interest in preventing disclosure of these highly confidential documents. Their publication would be catastrophic for GRAIL, allowing other entities to free-ride on GRAIL's billion-dollar investments and years of hard work, which would undermine GRAIL's mission and its future endeavors as a company.[2]

[2] GRAIL notes that the documents identified in this motion are largely similar to other GRAIL documents that have received *In Camera* treatment from this Court. *See, e.g.*, GRAIL's August 27, 2021 Motion for *In Camera* Review of Certain Trial Exhibits; GRAIL's September 8, 2021 Motion for *In Camera* Review of Certain Trial Exhibits; the Court's September 3, 2021 Order on GRAIL's Third Motion for *In Camera* Treatment; the Court's September 13, 2021 Order on GRAIL's Fourth Motion for *In Camera* Treatment.

Even so, GRAIL is mindful of the Court's requirement that *in camera* motions be detailed and narrowly-tailored to only GRAIL's most sensitive materials. In line with this expectation, GRAIL has only identified 14 documents for *in camera* treatment in this Motion, representing the core of materials central to GRAIL's efforts.[3] The below chart lists each category of documents for which GRAIL seeks *in camera* treatment, the paragraph discussing each category in the Barth Declaration,[4] and the time period for which GRAIL requests *in camera* treatment. Exhibit 2 contains copies of the proposed exhibits, with yellow highlighting to indicate where documents should be redacted. GRAIL respectfully requests that documents without highlighting be granted *in camera* treatment in full.

Category	Barth Declaration	Time period for *In Camera* Treatment
Trade Secrets and Product Development	¶8	See Exhibit 1
Sales and Marketing Strategy	¶9	
Regulatory Strategy	¶10	
Strategic Initiatives	¶11	

A. Trade Secrets and Product Development

Documents that contain trade secrets, such as the technical specifications of GRAIL's multi-cancer early detection test, Galleri, and GRAIL's development of future tests and versions of those tests, warrant in camera treatment. *See 1-800 Contacts*, 2017 FTC LEXIS 55, at *5

[3] GRAIL has expended its best efforts to conform this Motion's requests to only unpublicized materials. However, given the continuing and evolving nature of this litigation, GRAIL's activities and publications, and other developments that may destroy confidentiality, GRAIL respectfully requests that the Court grant it an opportunity to further correct any erroneous *in camera* request made in this Motion that may be identified by the Court or any other party.

[4] The Barth Declaration provides a similar level of detail as the declarations that this Court has previously found sufficient to support GRAIL's previous requests for *in camera* treatment. *See, e.g.*, GRAIL's August 27, 2021 Motion for *In Camera* Review of Certain Trial Exhibits; GRAIL's September 8, 2021 Motion for *In Camera* Review of Certain Trial Exhibits; the Court's September 3, 2021 Order on GRAIL's Third Motion for *In Camera* Treatment; the Court's September 13, 2021 Order on GRAIL's Fourth Motion for *In Camera* Treatment.

("Examples of trade secrets meriting indefinite *in camera* treatment include secret formulas, processes, other secret technical information, and information that is privileged."); *Altria Grp.*, 2021 WL 2258803 at *4 (granting *in camera* treatment for a period of ten years to trade secrets, specifications and product development plans).

Documents containing GRAIL's product development plans are also highly sensitive and should be protected from public disclosure. Multi-cancer screening is a nascent technology and while there are other companies developing other types of early cancer detection tests, those tests are many years behind GRAIL in development. Information about GRAIL's current and future products is competitively sensitive and the disclosure of this otherwise confidential material would allow potential competitors to copy GRAIL's technology, and develop commercial strategies designed to undermine GRAIL's current products.

Ultimately, because GRAIL would experience a clearly defined, serious injury if its trade secrets and product development plans were publicly disclosed, GRAIL respectfully requests 5 years of protection for product development documents, and requests 10 years of protection for trade secret documents, as denoted in Exhibit 1. This level of protection is consistent with protections granted by this Court in previous proceedings and is consistent with the protections that other third party test developers will receive for similar information. *See, e.g.*, *Altria,* 2021 WL 2258803 at *4.

B. Sales and Marketing Strategy

Recent detailed information regarding GRAIL's strategy and considerations related to sales and marketing also warrant *in camera* treatment. *See 1-800 Contacts*, 2017 FTC LEXIS 55, at *11 (protecting documents containing "marketing and bidding strategies").

By way of example, this category includes documents that provide insight on GRAIL's commercial planning related to which distribution channels GRAIL plans to target and why, they

identify specific potential customers that GRAIL has approached or intends to approach in the future; and they disclose GRAIL's sales strategy for approaching those customers. These materials serve as the basis for the formulation of GRAIL's business plans, and disclosure of these confidential materials would provide GRAIL's potential future competitors with previously unavailable details about GRAIL's sales and marketing strategies, which they could use in their own negotiations with retailers or as they consider marketing plans to compete with GRAIL. Moreover, disclosure could undermine GRAIL's relationships and negotiating positions with its customers, resulting in competitive and commercial harm to GRAIL. Because GRAIL would experience a clearly defined, serious injury if the information on sales and market strategies in these documents were publicly disclosed, GRAIL respectfully requests 5 years of protection for these documents. Five years of protection, as noted in Exhibit 1, is warranted for information in this category due to the nascent nature of GRAIL's products. *See, e.g.*, *E.I. DuPont de Nemours*, 151 F.T.C. at 680 (granting ten year in camera protection for unique information whose competitive utility was not likely to diminish due to the characteristics of the industry at issue).

C. Regulatory Strategy

Documents that reflect GRAIL's regulatory strategy and efforts – including confidential details regarding the design and execution of its clinical trials – are also highly competitively sensitive and should not be disclosed publicly. This information is sensitive because it provides direct insight into GRAIL's regulatory strategy and deliberative process related to obtaining FDA approval for multi-cancer early detection tests, and its interactions with the FDA. Disclosure of this information could impact GRAIL's ongoing discussions with the FDA, which are essential to GRAIL's ability to obtain FDA approval. In addition, providing potential competitors with insight into this information may give them an unfair advantage over GRAIL in the FDA approval process, resulting in competitive and commercial harm to GRAIL. Because GRAIL would experience a

clearly defined, serious injury if the information on regulatory strategy in these documents were publicly disclosed, GRAIL respectfully requests 5 years of protection for these documents as noted in Exhibit 1. *See, e.g.*, *Altria*, 2021 WL 2258803 at *6. This level of protection is warranted for information regarding GRAIL's regulatory strategy due to the unique issues raised by GRAIL's attempts to obtain FDA approval for a multi-cancer early detection test, which has never been granted by the FDA. Today, no one knows whether the competitive value of this data will diminish or when it will diminish. *See, e.g.*, *E.I. DuPont de Nemours*, 151 F.T.C. at 680 (granting ten year in camera protection for unique information whose competitive utility was not likely to diminish due to the characteristics of the industry at issue). Indeed, other test developers sought *permanent* in-camera treatment for the same types of materials and Complaint Counsel had no objections. Natera Mot. at 9-10; Exact Mot. at 16-17.

D. Strategic Initiatives

Strategic initiatives – such as GRAIL Board's analyses of potential transactions, financing options and timing, and other strategic initiatives – contain confidential information about the company's strategic direction and also require in camera treatment. *See 1-800 Contacts*, 2017 FTC LEXIS 55 at *9 (protecting documents including "evaluations of market factors, market risks, company advantages, company disadvantages, and company risks, and which also review future strategic plans"); *see also McWane*, 2012 FTC LEXIS 143 at *7-8 (protecting documents "which contain. . . . business strategies, and negotiating strategies").

Disclosure of this information could result in serious injury to GRAIL because it would reveal GRAIL's internal analyses of its business and provide direct insight into the company's deliberative process with respect to strategic initiatives. *Altria*, 2021 WL 2258745 at *5 (granting in camera status to documents that reflect "discussions among or presentations to Altria's board of directors or top executives about what opportunities to pursue and how such decisions are made.").

Moreover, disclosure of this information could undermine GRAIL's position in future corporate transactions or financing efforts by revealing GRAIL's internal targets for such financing or rationales for future transactions.

Particularly, because GRAIL was already exploring financing pathways prior to the merger with Illumina, GRAIL is likely to be seriously harmed if its confidential materials, including those related to the 2020 GRAIL Initial Public Offering ("IPO"), are disclosed here. Complaint Counsel is seeking to unwind the merger here. *See e.g.*, Aug. 24, 2021 Tr. at 53:4-6 ("[W]hich is why at the close of this case complaint counsel will be asking you [the Court] to unwind this transaction."). If Complaint Counsel prevails and the merger is unwound, disclosure of GRAIL's strategic initiative documents, including those related to the 2020 GRAIL IPO, will immediately harm GRAIL's ability to resume its search for alternative financing pathways by giving a wide range of third parties insight into GRAIL's goals, priorities, internal business analyses, and other confidential strategies, disadvantaging GRAIL in negotiations and other commercial activities.

Because GRAIL would experience a clearly defined, serious injury if the information on strategic initiatives in these documents were publicly disclosed, GRAIL respectfully requests 5 years of protection for these documents, as listed in Exhibit 1, due to the nascency of the multi-cancer early detection test industry and the potentially long time horizon before other potential test developers bring any cancer screening tests to market. *See, e.g.*, *E.I. DuPont de Nemours*, 151 F.T.C. at 680 (granting ten year in camera protection for unique information whose competitive utility was not likely to diminish due to the characteristics of the industry at issue).

III. CONCLUSION

Given the serious risk that public disclosure of these materials would cause serious injury to GRAIL's business, GRAIL respectfully requests an *in camera* order to protect the exhibits and deposition testimony listed in Exhibit 1 to the Barth Declaration from public disclosure. Complaint

Counsel has indicated that it takes no position regarding the relief sought in this Motion—it cannot join the Motion, but does not plan to file an opposition.

Dated: February 22, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 22, 2022, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

April Tabor
Acting Secretary Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-113
Washington, DC 20580
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The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-110
Washington, DC 20580

I also certify that I caused the foregoing document to be served via email to:

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February 22, 2022

/s/ Anna M. Rathbun
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In the Matter of **Illumina, Inc.** **a corporation,** **and** **GRAIL, Inc.** **a corporation,** **Respondents.**	**Docket No. 9401**

[PROPOSED] ORDER

Upon consideration of Respondent GRAIL LLC.'s ("GRAIL") Supplemental Motion for *In Camera* Review of Certain Trial Exhibits, it is hereby

ORDERED, that GRAIL's motion is GRANTED, and it is further

ORDERED, that pursuant to Rule 3.45(b) of the Federal Trade Commission Rules of Practice, 16 C.F.R. § 3.45(b), the exhibits and testimony identified in Exhibit 1 to the Motion, and any related trial testimony, shall be subject to *in camera* treatment and will be kept confidential and not placed on the public record of this proceeding.

Date: _____

_____
D. Michael Chappell
Chief Administrative Law Judge

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In the Matter of **Illumina, Inc.** **a corporation,** **and** **GRAIL, Inc.** **a corporation,** **Respondents.**	**Docket No. 9401**

DECLARATION OF ABRAM BARTH IN SUPPORT OF RESPONDENT GRAIL, LLC'S SUPPLEMENTAL MOTION FOR *IN CAMERA* REVIEW OF CERTAIN TRIAL EXHIBITS

I, Abram Barth, declare as follows:

1. I am the Head of Legal at GRAIL, LLC ("GRAIL"), a defendant in the above-listed action. I have been employed by GRAIL since September 2018.

2. I make this declaration in support of GRAIL, LLC's Supplemental Motion for *In Camera* Review of Certain Trial Exhibits. GRAIL seeks *in camera* treatment for the trial exhibits and portions of exhibits identified in Exhibit 1, which are also attached in Exhibit 2. The portions of exhibits for which GRAIL seeks in camera treatment are highlighted in yellow. I have personal knowledge of the competitive significance and confidential nature of these documents. Based on my review of Exhibit 1, my conversations with the individuals who reviewed the documents at my direction, my knowledge of GRAIL's business, and my knowledge of the confidential nature of these documents, I respectfully submit that disclosure of the exhibits listed in Exhibit 1 to the public would

either result in clearly defined, serious injury to GRAIL or would reveal sensitive personal information.

3. In the ordinary course of business, GRAIL treats this information as strictly confidential and limits its disclosure to employees that need to know it to perform their business functions. GRAIL also takes reasonable steps to protect its network and electronically stored information to prevent access by outside parties.

4. Each investigatory hearing and deposition transcript identified in Exhibit 1 was designated as "Confidential Material" pursuant to the Protective Order entered on March 30, 2021.

5. The Motion is narrowly tailored to protect GRAIL's confidential information. GRAIL's counsel carefully reviewed the investigatory hearing and deposition transcripts identified in Exhibit 1 and provided me with their designations of confidential materials contained therein. I then reviewed Exhibit 1 and GRAIL's outside counsel described to me the approach used to review and designate portions of the transcripts containing confidential information.

6. GRAIL has grouped the designated portions of the investigatory hearing and deposition transcripts listed in Exhibit 1 into the following categories:

a. Trade Secrets and Product Development

b. Sales and Marketing Strategy

c. Regulatory Strategy

d. Strategic Initiatives

7. Each category describes materials that either (a) disclose confidential and competitively sensitive information or (b) reveal sensitive personal information. Third parties with access to this information would either gain a significant business advantage at the expense of GRAIL or obtain sensitive personal information to the detriment of the individual whose information

is revealed. For each investigatory hearing and deposition transcript, Exhibit 1 identifies the corresponding exhibit number and describes the portions of the transcript containing confidential material.

8. **Trade Secrets and Product Development**: The documents in this category include information on trade secrets, such as GRAIL's research and development efforts and technical specifications regarding GRAIL's current and future products including the Galleri test. This information is competitively sensitive and the disclosure of this otherwise confidential material would allow other companies to develop commercial strategies designed to undermine GRAIL's current and future products, or develop strategies to try to undermine GRAIL's products. Because GRAIL would experience a clearly defined, serious injury if its trade secrets and product development plans were publicly disclosed, this information should remain confidential for 10 years.

9. **Sales and Marketing Strategy**: The documents in this category contain detailed information regarding GRAIL's strategy and considerations related to sales and marketing to customers, employers, health systems, concierge clinics, patients, healthcare providers, payors, research partners, and investors. GRAIL's documents provide insight as to how GRAIL intends to sell the first-of-its-kind multi-cancer screening test, Galleri, and other products in development in various channels and its plans to scale its tests to achieve wide range adoption. These materials serve as the basis for GRAIL's business plans, and disclosure of these confidential materials would provide third parties with previously unavailable details about GRAIL's current and future sales and marketing strategies, which they could use in their own negotiations with the various stakeholders described above. Because GRAIL would experience a clearly defined, serious injury if the information on sales and marketing strategy in these documents were publicly disclosed, this information should remain confidential for 5 years.

10. **Regulatory Strategy**: The documents in this category reflect GRAIL's analysis and efforts to obtain approval from the U.S. Food and Drug Administration ("FDA") for the Galleri test and other products in development, including interactions with that agency. The documents also contain details regarding clinical and other studies conducted by GRAIL and its partners. This information is sensitive because it provides direct insight into GRAIL's regulatory strategy and deliberative process with respect to FDA approval, and GRAIL's interactions with the FDA. Disclosure of this information could impact GRAIL's discussions with the FDA and could provide third parties with insight into GRAIL's regulatory strategy. This insight could be used to negatively impact GRAIL's relationship with the FDA, resulting in competitive and commercial harm to GRAIL and harm to consumers. Because GRAIL would experience a clearly defined, serious injury if the information on regulatory strategy in these documents were publicly disclosed, this information should remain confidential for 5 years.

11. **Strategic Initiatives**: The documents in this category contain information on strategic initiatives currently or recently under consideration by GRAIL. These documents reflect consideration by GRAIL and/or GRAIL's former Board of Directors of potential transactions, consideration of financing options and timing, and other strategic initiatives, and contain confidential information regarding GRAIL's strategic direction. Disclosure of this information could result in serious injury to GRAIL because it would reveal GRAIL's internal analyses of its business and provide direct insight into the company's deliberative process with respect to strategic initiatives. Although GRAIL has been acquired by Illumina, the Federal Trade Commission is seeking to unwind the deal. In the event that the transaction is unwound, the information contained in these documents would retain their significance to GRAIL. Moreover, disclosure of this information could negatively impact GRAIL's position in future corporate transactions or financing efforts in the event

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of a divestiture. Because GRAIL would experience a clearly defined, serious injury if the information on strategic initiatives contained in these documents were publicly disclosed, this information should remain confidential for 5 years.

12. Because disclosure of the designated portions of the investigatory hearing and deposition transcripts described herein is likely to either reveal sensitive personal information or cause clearly defined, serious injury to GRAIL's financial and competitive position, GRAIL respectfully requests that the designated portions of the investigatory hearing and deposition transcripts listed in Exhibit 1 be given *in camera* treatment.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct and that I executed this declaration on February 20, 2022, in Tiburon, California.

Abram Barth _____

Abram Barth

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EXHIBIT 1

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FILED *IN CAMERA*

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EXHIBIT 2

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FILED *IN CAMERA*

VIA FILE TRANSFER