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

In the Matter of Illumina, Inc. and GRAIL, Inc. Respondents.	)	**PUBLIC** DOCKET NO. D09401

NON-PARTY PERSONAL GENOME DIAGNOSTICS INC.'S RENEWED MOTION FOR *IN CAMERA* TREATMENT

Pursuant to Rule 3.45 of the Federal Trade Commission's Rules of Practice, 16 C.F.R § 3.45(b), non-party Personal Genome Diagnostics, Inc. ("PGDx") moves this Court for *in camera* treatment. PGDx respectfully requests an order requiring that the highly confidential and competitively sensitive portions of nine documents sought to be introduced as exhibits in this matter be afforded full *in camera* treatment for five years and three documents sought to be introduced as exhibits in this matter be afforded full *in camera* treatment indefinitely. PGDx is a third party to this litigation, and its confidential business documents would not have been made public but for subpoenas it received in this case. *In camera* treatment is necessary to prevent PGDx's competitors from gaining access to PGDx's most competitively sensitive information.

PGDx's motion is fully supported by the Declaration of Scott Gotshall, Vice President, Head of Legal and Business Operations at PGDx, (the "Gotshall Declaration" or "Gotshall Decl."), attached as **Exhibit A**, which provides additional details about the documents for which PGDx is seeking *in camera* treatment, such as the measures that PGDx has taken to protect the confidentiality of the documents and competitive harm PGDx would suffer if these documents were made publicly available. Rule 3.45(b) provides that *in camera* protection is appropriate where "public disclosure will likely result in a clearly defined, serious injury to the person,

partnership or corporation requesting *in camera* treatment." 16 C.F.R. § 3.45(b). *In camera* treatment is warranted where the information is "sufficiently secret and sufficiently material to the applicant's business that disclosure would result in serious competitive injury." *In re General Foods Corp.*, 1980 FTC LEXIS 99, at *10 (Mar. 10, 1980). PGDx's proposed redactions are tailored to ensure that the information sought to be protected is narrow and would result in serious competitive injury if disclosed.

I. Documents for Which *In Camera* Treatment is Requested

PGDx requests *in camera* treatment for reasons of competitive sensitivity for the entirety of only five of the seventeen documents identified as administrative trial exhibits (PX8546, PX8548, PX8549, PGDX_00018797, and PGDX_00023088), and limited portions of PX7049, PX7112, PX8366, PX8550, PX8551, PGDX_00018805, and PGDX_00020563, described in the chart below. These documents contain highly sensitive, confidential information and, if made public, would cause irreparable harm to PGDx. PGDx is requesting indefinite *in camera* treatment for documents PX8548, PX8549, and PGDX_00018797 because they contain extremely sensitive information related to technical trade secrets and intellectual property and five years of *in camera* treatment for documents PX7049, PX7112, PX8366, PX8550, PX8551, PGDX_00018805, PGDX_00018797, and PGDX_00020563. This narrowly tailored request is focused on preventing public disclosure of specific material that would cause competitive harm to PGDx and undermine the robust market competition. An unredacted copy of each of the exhibits for which PGDx seeks to redact is attached as **Exhibits B1-B12**.

***In Camera* Exhibit No.**	**Plaintiff Exhibit No.**	**Defendant Exhibit No.**	**Bates - Begin**	**Document Name**
B-1	PX7049	-	-	Investigative Hearing Transcript of Megan Bailey
B-2	PX7112	-	-	Deposition Transcript of Megan Bailey
B-3	PX8366	-	FTC-PGDx-00000130	PGDx Email Exchange between Megan Bailey and Jay Foust
B-4	PX8546	-	PGDX_00003065	May 2018 Presentation
B-5	PX8548	-		Project Ion Presentation
B-6	PX8549	-	PGDX_00023417	PGDx Board of Directors Meeting
B-7	PX8550	-	PGDX_00023764	Sequencing Cost Breakdown
B-8	PX8551	-	PGDX_00023765	Undated Presentation
B-9	-		PGDX_00018797	Email exchange between Megan Bailey and Jennifer Dickey
B-10	-		PGDX_00018805	PGDx Email exchange between Rami Zahr, Samuel Angiuoli, and Megan Bailey
B-11	-		PGDX_00020563	Email from Megan Bailey
B-12	-		PGDX_00023088	April 2021 Presentation

II. Legal Standard

Under Commission Rule 3.45(b), an Administrative Law Judge may order that material offered into evidence be placed *in camera* "after finding that its public disclosure will likely result in a clearly defined, serious injury to the person, partnership, or corporation requesting *in camera* treatment." 16 C.F.R. § 3.45(b). The requesting party must "make a clear showing that the information concerned is sufficiently secret and sufficiently material to [its] business that disclosure would result in serious competitive injury." *In the Matter of Otto Bock HealthCare N. Am., Inc.*, 2018 WL 2491602, at *1 (July 2, 2018) (quoting *General Foods Corp.*, 1980 FTC

LEXIS 99, at *10 (Mar. 10, 1980)); *In the Matter of 1-800-Contacts, Inc.*, 2016 FTC LEXIS 146, at *2 (Aug. 8, 2016).

In camera treatment is routinely granted for competitively sensitive business records, including documents revealing financial metrics such as costs, margins, and revenues, competitive positioning, strategic plans, and marketing and pricing strategies. *See, e.g., 1-800 Contacts*, 2016 FTC LEXIS 146, *8-35 (granting third parties' requests for five-year *in camera* treatment of documents discussing customer-specific pricing, marketing and bidding strategies, financial metrics, and other competitively sensitive information); *In re North Texas Specialty Physicians*, 2004 FTC LEXIS 109, *5-21 (April 23, 2004) (granting third parties' requests for five-year *in camera* treatment of documents containing competitively sensitive information, such as fee schedules, strategic plans, and negotiating strategies). When *in camera* treatment is granted for these types of business records, it is typically provided for two to five years. *See Otto Bock*, 2018 WL 3491602, at *3; *North Texas Specialty Physicians*, 2004 FTC LEXIS 109, at *2.

Under Commission Rule 3.45(b)(3), indefinite *in camera* treatment is warranted in circumstances where "the need for confidentiality of the material…is not likely to decrease over time…" 16 C.F.R. § 3.45(b)(3). "In determining the length of time for which *in camera* treatment is appropriate, the distinction between trade secrets and ordinary business records is important because ordinary business records are granted less protection than trade secrets. [citation]. Examples of trade secrets meriting indefinite *in camera* treatment include secret formulas, processes, other secret technical information, or information that is privileged." *Otto Bock*, 2018 WL 3491602, at *5-6 (internal citations omitted).

A party's status as a third party is also relevant to the treatment of its Confidential Documents. The Commission has held that "[t]here can be no question that the confidential records of businesses involved in Commission proceedings should be protected insofar as possible." *H.P. Hood & Sons*, 58 F.T.C. 1184, 1186, 1961 FTC LEXIS 368 (Mar. 14, 1961). This is especially so for a third party, which is entitled to "special solicitude" for its request for *in camera* treatment for its confidential business information. *See In re Kaiser Aluminum & Chem. Corp.*, 103 FTC 500, 500 (1984) ("As a policy matter, extensions of confidential or *in camera* treatment in appropriate cases involving third party bystanders encourages cooperation with future adjudicative discovery requests."). PGDx's third-party status therefore weighs in favor of granting *in camera* status for the Confidential Documents.

III. The Confidential Documents Are Secret and Material Such that Disclosure Would Result in Serious Injury to PGDx

PGDx, a third party to this litigation, requests *in camera* treatment for reasons of competitive sensitivity for limited portions of PX7049, PX7112, PX8366, PX8546, PX8548, PX8549, PX8550, PX8551, PGDX_00018797, PGDX_00018805, PGDX_00020563, and PGDX_00023088. This narrowly tailored request is focused on specific material the disclosure of which to the public and to PGDx's competitors would cause competitive harm to PGDx and lessen the robustness of competition. As discussed in the attached Gotshall Declaration (**Exhibit A**), these documents reveal business strategies, financial reports, pricing analyses and strategies, marketing plans, supply chain information, business development strategies, and market assessments that PGDx does not share outside the company, and limits internal dissemination to those with a need to know the information. PGDx would suffer competitively if this information were made available through these proceedings to its competitors. And the competition would

suffer if PGDx's business strategies, pricing, and other sensitive information became known to its competitors.

PX7049 (**Exhibit B-1**) is Megan Bailey's March 2, 2021 investigative hearing transcript in this matter. Ms. Bailey made certain statements in these transcripts that are material and, if disclosed, could harm PGDx's commercial partnerships and provide competitors with an unfair advantage. Gotshall Decl. ¶ 10. PGDx request that the following portions of Megan Bailey's March 2, 2021 deposition transcript be redacted: 31:3-24; 38:21-23; 40:6-16; 41:17-23; 42:3-11; 42:13-19; 43:20-24; 44:8; 44:11-13; 45:10-16; 46:11-20; 46:22; 47:2-16; 47:22-25; 48:1-8; 48:10-11; 48:15; 48:19; 48:21-25; 53:19-25; 54:3-5; 75:11-15; 75:17-20; 75:22-25; 76:1-10; 76:13-15; 78:7-9; 78:11-16; 78:18-19; 79:12-25; 80:2-5; 80:17-22; 99:21-23; 100:22-25; 102:1-15; 103:10-17; 103:23-25; 104:1-11; 104:18-22; 105:7; 105:12-13; 105:23; 106:15-25; 107:1-17; 107:20-25; 108:1-15; 108:17-25; 114:7-25; 115:1-17; 117:7-22; 118:1-10; 118:16; 118:18-19; 119:2; 119:4-13; 119:16-25; 120:1; 120:5-8; 121:24-25; 122:1-7; 123:13; 123:15; 123:23-24; 124:1-3; 124:6-7; 124:11; 124:13-14; 124:22; 125:3; 125:14; 125:24; 126:16-20; 127:8; 128:15-20; 141:5-17; 141:19-21; 146:9-25; 147:1; 147:6; 147:12-14; 148:10-25; 149:1-4; 149:18; 150:5; 150:8; 150:16; 150:19-22; 151:3-5; 151:13-20; 152:15; 152:17; 152:18-21; 153:6-10; 153:23-25; 154:1-4; 154:9-17; 154:21-22; 155:3-8; 155:14-25; 156:1-3; 156:5; 156:9-22; 156:25; 163:8-15; 163:17-25; 164:1-17; 165:21-25; 166:1-11; 166:13-14; 166:16; 166:23-25; 167:1-5; 167:7-8; 167:12-13; 167:20-25; 168:1-8; 169:21-25; 170:1-6. PX7112 (**Exhibit B-2**) is Megan Bailey's June 9, 2021 deposition transcript for this matter. PGDx request that the following portions of Megan Bailey's June 9, 2021 deposition transcript be redacted: 19:5; 19:10-18; 19:25; 20:4; 20:20; 20:22; 21:11-24; 22:6-7; 22:13; 22:16; 22:20-25; 23:1-2; 23:6-12; 23:19-23; 24:6-9; 24:12-13; 24:17-24; 25:1-5; 25:7-15; 25:17; 25:22-25; 70:8-10; 70:13-15; 70:19-20; 70:23; 72:8;

72:19; 73:8; 73:15; 73:17; 74:15-20; 74:23; 74:25; 75:6; 75:12; 75:20; 76:9; 76:11; 76:14; 76:18; 77:1; 77:5; 77:22-25; 78:1; 78:7; 78:11; 78:22-25; 79:1-2; 79:13; 79:15-22; 79:24-25; 80:5; 80:6; 80:15-16; 81:1-2; 81:7-8; 81:9; 81:13; 81:19-21; 86:20; 88:2-9; 89:6; 89:10-13; 89:15; 89:20; 89:25; 90:8; 90:13; 90:16; 91:14; 91:23; 92:5; 93:10; 104:23-25; 105:1-15; 105:20-25; 106:1; 106:3; 106:18; 106:23-25; 107:1; 108:23-25; 109:1-4; 109:7-9; 109:14-17; 111:10; 111:13; 111:17-20; 112:4-7; 112:10; 112:13; 112:18-21; 114:16-25; 115:1-5; 115:10-11; 116:3-12; 117:23-25; 118:1-7; 118:10-11; 124:4-7; 124:14-16; 125:7; 125:18-22; 127:21-23; 128:11; 128:16-22; 129:2-5; 129:7; 129:8-13; 129:15; 129:17-19; 129:25; 130:1-2; 130:9-14; 130:16; 137:10; 137:11; 137:17; 137:24; 146:13-17; 146:23-25; 147:10-18; 147:21; 147:24-25; 148:3-5; 148:8; 148:13; 148:19; 148:20-24; 149:1; 149:21; 149:22; 149:23; 150:3; 150:4; 150:5-12; 150:14-15; 151:9-10-; 151:12-13; 151:24-25; 152:4; 152:12-13; 152:15-19; 152:21-25; 153:1-8; 153:11-13; 153:19-24; 154:1-4; 154:6-10; 154:13-15; 154:17-19; 154:21-23; 154:25; 155:1-2; 155:5-6; 155:10-13; 155:15-17; 155:19-23; 156:1-2; 156:4-6; 156:8-12; 156:14-18; 156:20-25; 157:1-6; 157:9-25; 158:1-20; 158:23-25; 159:1-5; 159:8-10; 159:14-21; 159:23-24; 160:1-6; 160:9: 160:11-13; 160:16-19; 160:23-25; 161:1-7; 161:9-14; 161:16-18; 161:20-22; 162:20-24; 163:2-4; 163:6-8; 164:3; 164:23-25; 165:1-3; 165:4-11; 165:20-22; 166:6-11; 166:15-18; 166:20-21; 166:23-25; 167:1-3; 167:5-6; 167:8-21; 168:4-8; 168:10-11; 170:4-7; 170:12-16; 170:22-25; 171:1; 171:8-15; 171:17-20; 175:2; 175:18-23; 176:2-25; 177:1; 186:25; 187:1-12; 188:5-6; 189:6-7; 189:12-13; 189:17; 189:25; 190:2; 190:3; 190:9; 190;12-17; 191:4; 191:7; 191:9; 191:13-14; 191:23; 192:1; 192:7; 192:9-11; 192:17-18; 192:20; 193:6; 193:11; 193:17; 193:19; 193:22; 193:24; 193:25. These portions of both transcripts reference documents PGDx intends to keep confidential and includes similar sales, pricing, margin, and customer information that would meet the *in camera* standard if contained in a standalone document. *See*

In re Basic Research, 2006 FTC LEXIS 14, at *4 (Jan. 25, 2006) *citing In re Aspen Tech., Inc.,* 2004 FTC LEXIS 56, at *5-6 (May 5, 2004) ("Respondent's request for *in camera* treatment shall be made only for those pages of documents or of deposition transcripts that contain information that meets the *in camera* standard."); *In re Union Oil Co. of Calif*, 2005 FTC LEXIS 9, at *1 (Jan. 19, 2005) (granting *in camera* treatment where parties sought it only "for narrowly tailored portions of deposition testimony").

Documents including business confidential information related to a nonparty's financial condition, pricing strategies, and techniques for marketing and advertising its products are entitled to *in camera* treatment. *See In re 1-800 Contacts, Inc.*, 2017 FTC LEXIS 55, at *20 (FTC April 4, 2017); *See In re Mcwane, Inc., & Star Pipe Prods., Ltd.,* 2012 WL 5879803, at *1 (FTC Nov. 8, 2012) (granting non-party's motion for *in camera* treatment of "strategic planning" documents); *See In re Polypore Int'l, Inc.,* 2009 WL 1499350, at *5 (FTC May 13, 2009) (granting *in camera* treatment for documents containing "business plans and strategies," "customer-specific documents," and "documents containing 'pricing strategy' and 'market analysis'"). Accordingly, the following materials, **Exhibits B-3 – B-12**, meet the legal standard for *in camera* treatment.

PX8366 (**Exhibit B-3**), is an email exchange between Megan Bailey and Jay Foust. The information in this document is material and, if disclosed, would provide competitors with an unfair advantage by disclosing information about commercial negotiations as well as information related to intellectual property. Gotshall Decl. ¶ 11. Portions of PX8336 contain sensitive information such as, *inter alia*, PGDx's confidential business negotiations and intellectual property, that warrant redaction.

PX8546 (**Exhibit B-4**), is a version of a May 2018 slide deck created by L.E.K. Consulting. The information contained in this document is material and, if disclosed, would provide competitors with an unfair advantage by disclosing highly confidential market and strategic information including information related to customers and the competitive landscape. Gotshall Decl. ¶ 12.

PX8548 (**Exhibit B-5**), is a document detailing PGDx's technical review of a platform. This working document contains sensitive information such as, *inter alia*, PGDx's technical specifications, performance details, and intellectual property, that warrant redaction. The information contained in this document is material and, if disclosed, could harm PGDx's commercial partnerships and provide competitors with an unfair advantage by disclosing highly confidential material such as technical information and intellectual property. Gotshall Decl. ¶ 13.

PX8549 (**Exhibit B-6**), is version of a presentation prepared for PGDx's April 30, 2021 Board of Directors Meeting. This working document contains sensitive information such as, *inter alia*, PGDx's intellectual property, legal advice, price increases, net profits, margins, market analysis, and marketing and pricing strategies, that warrant redaction. The information contained in this document is material and, if disclosed, could harm PGDx's commercial partnerships and provide competitors with an unfair advantage by disclosing highly confidential material such as customer information and intellectual property. Gotshall Decl. ¶ 14.

PX8550 (**Exhibit B-7**), is a cost breakdown of essential inputs to PGDx's NGS solutions. The information contained in this document is material and, if disclosed, would provide competitors with an unfair advantage by disclosing highly confidential cost information.

Gotshall Decl. ¶ 15. Portions of PGDX_00023764, contain sensitive information such as, *inter alia*, PGDx price inputs, net costs, margins, and pricing strategies, that warrant redaction.

PX8551 (**Exhibit B-8**), is a competitive landscape presentation. The information contained in this document is material and, if disclosed, would provide competitors with an unfair advantage by disclosing highly confidential information about PGDx's business model and technical specifications. Gotshall Decl. ¶ 16. Portions of PX8551, contain sensitive information such as, *inter alia*, PGDx net costs and pricing strategies, that warrant redaction.

PGDX_00018797 (**Exhibit B-9**), is an email exchange between Megan Bailey and Jennifer Dickey. The information contained in this document is material and, if disclosed, would provide competitors with an unfair advantage by disclosing commercial partnership information as well as proprietary information related to FDA approval. Gotshall Decl. ¶ 17. The document contains sensitive information such as, *inter alia*, PGDx's customer information, intellectual property, legal advice, and marketing strategy, that warrant redaction.

PGDX_00018805 (**Exhibit B-10**), is an email exchange between Rami Zahr, Samuel Angiuoli, and Megan Bailey. The information contained in this document is material and, if disclosed, would provide competitors with an unfair advantage as portions of PGDX_00018805, contain sensitive information such as, *inter alia*, PGDx's marketing strategy and competitively sensitive technical specifications, that warrant redaction. Gotshall Decl. ¶ 18.

PGDX_00020563 (**Exhibit B-11**), is an email exchange involving Megan Bailey. The information contained in this document is material and, if disclosed, would provide competitors with an unfair advantage by disclosing commercial partnership information. Gotshall Decl. ¶ 19. Portions of PGDX_00020563 and PGDX_00020564 contain sensitive information such as, *inter*

alia, PGDx's competitively sensitive customer and partnership information, that warrant redaction.

PGDX_00023088 (**Exhibit B-12**), is an April 2021 presentation created by Evercore. The information contained in this document is material and, if disclosed, would provide competitors with an unfair advantage by disclosing competitively sensitive information such as, *inter alia*, PGDx's financial conditions, net profits, margins, and pricing strategies, that warrant redaction. Gotshall Decl. ¶ 20.

CONCLUSION

As set forth fully above and in the accompanying Gotshall Declaration, the confidential information in these twelve documents is entitled to protection through *in camera* treatment and redactions because the information is both secret and material to PGDx's business and would seriously injure PGDx and competition if disclosed to the public (including PGDx's competitors). The public has relatively little interest in the sensitive, narrowly redacted information, and PGDx's third-party status weighs in favor of granting *in camera* status to these documents as a matter of policy, including encouraging non-parties in Commission proceedings to cooperate fully by ensuring them that their business secrets will not be publicly revealed by doing so. PGDx respectfully requests that the Commission grant *in camera* treatment for the nine documents as outlined above for five years and three as outlined above indefinitely from the date of this Order.

Dated: August 5, 2021

Respectfully submitted,

By: /s/ Nana Wilberforce

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CERTIFICATE OF SERVICE

I hereby certify that on August 5, 2021, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

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I also certify that I delivered via electronic mail a copy of the foregoing document to:

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CERTIFICATE OF ELECTRONIC FILING

I certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original and that I possess a paper original of the signed document that is available for review by the parties and the adjudicator.

August 5, 2021

By: /s/ Nana Wilberforce
Nana Wilberforce

Attorney for Personal Genome Diagnostics Inc.

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

In the Matter of Illumina, Inc. and GRAIL, Inc. Respondents.	)	**PUBLIC** DOCKET NO. D09401

[PROPOSED] ORDER GRANTING MOTION OF NON-PARTY PGDx FOR *IN CAMERA* TREATMENT OF PROPOSED TRIAL EXHIBITS

On August 5, 2021, non-party Personal Genome Diagnostics, Inc. ("PGDx") moved for *in camera* treatment of certain proposed trial exhibits. Upon consideration, the Motion is GRANTED and it is hereby ORDERED that the following documents are provided with *in camera* treatment under 16 C.F.R. § 3.45(b) for five years from the date of this order.

***In Camera* Exhibit No.**	**Plaintiff Exhibit No.**	**Defendant Exhibit No.**	**Bates - Begin**	**Document Name**
B-1	PX7049	-	-	Investigative Hearing Transcript of Megan Bailey
B-2	PX7112	-	-	Deposition Transcript of Megan Bailey
B-3	PX8366	-	FTC-PGDx-00000130	PGDx Email Exchange between Megan Bailey and Jay Foust
B-4	PX8546	-	PGDX_00003065	May 2018 Presentation
B-5	PX8548	-		Project Ion Presentation
B-6	PX8549	-	PGDX_00023417	PGDx Board of Directors Meeting
B-7	PX8550	-	PGDX_00023764	Sequencing Cost Breakdown
B-8	PX8551	-	PGDX_00023765	Undated Presentation Slides
B-9	-		PGDX_00018797	Email exchange between Megan Bailey and Jennifer Dickey
B-10	-		PGDX_00018805	PGDx Email exchange between Rami Zahr, Samuel Angiuoli, and Megan Bailey
B-11	-		PGDX_00020563	Email from Megan Bailey
B-12	-		PGDX_00023088	April 2021 Presentation

ORDERED:

The Honorable D. Michael Chappell
Chief Administrative Law Judge

Date: August [ ], 2021

EXHIBIT A

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

In the Matter of Illumina, Inc. and GRAIL, Inc. Respondents.	)	**PUBLIC** DOCKET NO. D09401

DECLARATION OF SCOTT GOTSHALL IN SUPPORT OF NON-PARTY PERSONAL GENOME DIAGNOSTICS INC. MOTION FOR *IN CAMERA* TREATMENT

I, Scott Gotshall, hereby declare as follows:

1. I am the Vice President, Head of Legal & Business Operations at Personal Genome Diagnostics Inc. ("PGDx"). I make this declaration in support of Non-Party PGDx's Motion for *In Camera* Treatment (the "Motion"). Because of my current position, I have personal knowledge of the matters stated herein and, if called upon to do so, could competently testify about them.

2. PGDx was founded in 2010 and is based in Baltimore, Maryland. PGDx provides advanced cancer genome analysis to help researchers and partners identity elusive cancer related changes.

3. I joined PGDx in 2021 as VP of Legal and Business Operations. In my current position, I have responsibility for PGDx's legal operations and the operations supporting the commercial business.

4. I have reviewed the documents PGDx produced in response to subpoenas issued by the Federal Trade Commission ("FTC") and Respondents Illumina, Inc. ("Illumina") and GRAIL, Inc. ("GRAIL"). I have also reviewed the documents that PGDx seeks *in camera*

treatment for, the "Confidential Documents"[1] —documents that the FTC and Respondents Illumina and GRAIL (together "Illumina/GRAIL") may seek to introduce as evidence in the administrative hearing in this matter.

5. Given my position at PGDx, I am familiar with the type of information contained in the Confidential Documents and its competitive significance to PGDx's business. Based on my review of the documents, my knowledge of PGDx's business, and my familiarity with the confidentiality protection afforded this type of information by PGDx, the disclosure of the Confidential Documents to the public and to competitors of PGDx would cause serious competitive injury to PGDx. As set forth in its Motion, PGDx seeks partial *in camera* protection of the Confidential Documents because they contain competitively sensitive and confidential business information.

6. PGDx has developed a number of clinical diagnostic NGS solutions for laboratories. These products are crucial to PGDx's business and help enable faster results to guide treatment decisions in oncology. PGDx depends on its ability to compete with other similar developers, to negotiate with laboratories and pharmaceutical partners, and to engage in commercialization and fundraising efforts. To do so, PGDx both uses confidential models and analyses to determine how best to negotiate terms with various partners to bring its products to market. These confidential efforts are critical to its business development and competition strategies.

7. The public disclosure of the Confidential Documents would reveal pricing, sales, customer, marketing, and margin information. PGDx has invested significant resources to market

[1] In camera treatment requested: PX7049, PX7112, PX8366, PX8546, PX8548, PX8549, PX8550, PX8551, PGDX_00018797, PGDX_00018805, PGDX_00020563, and PGDX_00023088.

and place the products, in the manner which is reflected in the Confidential Documents, such that this business information constitutes substantial competitive value to PGDx.

8. This proprietary information is not publicly available and PGDx has devoted its resources to protecting the confidentiality of the information in the Confidential Documents. PGDx generally limits the distribution of this information to a restricted group of PGDx employees. Specifically, only senior level management (e.g., at the VP or SVP level) has access to detailed sales data (especially margin information) and even those individuals do not routinely have access to such detailed data unless necessary to that individual's area of responsibility. The partnership, investment, and commercialization material found within the Confidential Information is restricted to a select group of users, and PGDx takes care to limit the distribution of such data by email to prevent distribution beyond the authorized users. The Confidential Documents for which full *in camera* treatment is sought were never shared outside of PGDx or are based on PGDx data that was not shared outside of PGDx except as required by the subpoenas in this matter. Also, in producing the Confidential Documents to the FTC and Illumina/GRAIL, PGDx designated all of this information "Confidential" under the Protective Order in this proceeding.

9. PGDx is a party to multiple Non-Disclosure Agreements ("NDAs") with pharmaceutical and health system partners. Those NDAs restrict PGDx's ability to publicly disclose certain analyses, compilations, studies, data, inventions, innovations, improvements, know-how or other proprietary information including product information, samples of products, reports, interpretations, projections, forecasts, records, notes, documents, excerpts, or other materials concerning PGDx or the partner's business, finances, plans and pricing, research and development activities, software and hardware specifications, proprietary formulae and

proprietary algorithms operations, marketing or other business strategies, business and employment contracts, customers, suppliers, financing sources, or strategic partners.

10. I have reviewed portions of investigative hearing and deposition transcripts of Megan Bailey, PGDx's Chief Executive Officer. Ms. Bailey testifies about specific non-public cost information, intellectual property, and potential commercial partnerships. This information is highly sensitive, and if that information becomes public, it may significantly impact PGDx's relationships with commercial partners, financial position, and provide competitors an unfair advantage.

11. PX8366 is an email exchange between Megan Bailey and Jay Foust. The discussions contained in this document reveals valuable information about PGDx's business relationships and contractual negotiations related to intellectual property that would be harmful to the business if made public, particularly to a competitor.

12. PX8546 is a confidential presentation by L.E.K. Consulting on strategic initiatives for PGDx. It contains highly confidential market, customer, and competitively sensitive information. If made public, the document would provide an unfair advantage to PGDx's competitors.

13. PX8548 is a draft presentation is a highly technical presentation. The technology, trade secrets, and intellectual property discussed in this presentation are crucial to PGDx's success as a company. If made public, the document would provide an unfair advantage to PGDx's competitors and other partners.

14. PX8549 is a draft presentation of a presentation intended for the Board of Directors. Presentations such as these are delivered periodically to the PGDx Board of Directors to inform management about the performance of PGDx's business. The presentations are highly

confidential in the ordinary course of business and have not been disclosed to the business. This presentation contains detailed information about PGDx's financial performance, market plans, intellectual property, legal, and other highly sensitive information.

15. PX8550 was generated at the request of counsel in this matter. It contains highly confidential financial and cost and expense information that is not otherwise made generally available to PGDx employees.

16. PX8551 is a confidential presentation on the competitive landscape for PGDx's plasma portfolio. It contains highly confidential technical and commercial information. If made public, the document would reveal valuable information to PGDx's competitors.

17. PGDX_00018797 and PGDX_00020563 are emails related to commercial partnerships. The discussions contained in these documents reveal valuable information about PGDx's business opportunities that would be harmful to the business if made public, particularly to a competitor.

18. PGDX_00018805 is a document related to technical aspects of PGDx's NGS solutions. The document contains information about highly sensitive technical partnerships, that are non-public, and which if are disclosed, will provide an unfair advantage to competitors.

19. PGDX_00020563 are emails related to commercial partnerships and strategic planning. The discussions contained in these documents reveal valuable information about PGDx's business opportunities that would be harmful to the business if made public, particularly to a competitor.

20. PGDX_00023088 is a presentation by Evercore intended for the PGDx Board of Directors. The presentation includes highly sensitive strategic information and financial information. The presentation uses detailed financial information from PGDx to help the Board

of Directors assess and make business decisions. This information would provide an unfair competitive advantage if made available to competitors.

21. Given the consistency in pricing and the importance of intellectual property and trade secrets in the laboratory assay market, the Confidential Documents reflecting such information (PX8548, PX8549, PGDX_00018797) are unlikely to decrease in confidentiality over time and thus, indefinite protection from public disclosure is appropriate.

I declare under penalty of perjury that the foregoing is true and correct. Executed on August 5, 2021.

DocuSigned by:
Scott Gotshall
AE7B70962312480...

Scott Gotshall

EXHIBIT B1

In the Matter of:

Illumina, Inc. and Grail, Inc.

March 2, 2021
Megan Bailey

Condensed Transcript with Word Index

For The Record, Inc.
(301) 870-8025 - www.ftrinc.net - (800) 921-5555

FEDERAL TRADE COMMISSION

In the Matter of:)
ILLUMINA, INC.,)
a corporation,) File No. 201-0144
and)
GRAIL, INC.,)
a corporation.)

Tuesday, March 2, 2021
Via Zoom Conference

The virtual deposition of MEGAN BAILEY, pursuant to subpoena, taken before Stephanie A. Battaglia, CSR and Notary Public in and for the County of DuPage and State of Illinois, on March 2, 2021, 9:31 a.m., Eastern Time.

PRESENT: (ALL PARTIES APPEARED VIA ZOOM)
U.S. FEDERAL TRADE COMMISSION
BY: MS. LAUREN GASKIN
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
(202) 326-2118
e-mail: lgaskin@ftc.gov
appeared on behalf of the Federal Trade Commission;

MR. SCOTT GOTSHALL
Vice President, Head of Legal, Business Operations at Personal Genome Diagnostics.

ALSO PRESENT:
Mr. John McAdams, Bureau of Economics
Ms. Stephanie A. Battaglia, CSR, RMR, CRR.

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E X H I B I T S

MS. REPORTER: All parties are to be made aware that the witness will be sworn in remotely. The parties agree not to challenge the validity of any oath administered by the court reporter, even if the court reporter is not physically present with the witness and not a notary public in the state where the witness resides.

Here begins the webconference of MEGAN BAILEY in the matter of Illumina, Inc., and Grail, Inc.

Today's date is March 2, 2021, and the time is 9:31 a.m. Eastern Time.

My name is Stephanie Battaglia on behalf of For the Record.

Beginning with the noticing party, will counsel please introduce themselves, state whom they represent, and stipulate to the swearing in of the witness remotely.

We will start with Ms. Gaskin.

MS. GASKIN: I am Lauren Gaskin. I am an attorney at the Federal Trade Commission.

MS. REPORTER: And you agree to the stipulation I read?

MS. GASKIN: Yes, I do.

MS. REPORTER: Mr. Gotshall?

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then we have some custom configurations for pharma where we take what is largely the backbone of either elio tissue complete or elio plasma resolve, but we will make some minor modifications to meet the pharma specific needs.

Q. And you used the term kit when you were describing those two tests. Can you describe what a kit is?

A. Yes.

When we refer to the kit it is really a system that combines both the kitted chemistry, so everything needed to do the wet lab part of the workflow from DNA extraction. So from the point that DNA is extracted either from a tissue sample or a blood sample our kit provides the chemistries needed to do everything from that step to the samples being prepared to go on the sequencing platform.

At that point the test is -- or the samples are run on the Illumina NextSeq platform and then the remainder of what we refer to as the kit is the back-end data analysis portion of the workflow.

So we provide a server when we implement a customer that contains all of the software needed to fully automate the data analysis. So when the data comes off the server it flows through our analysis

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pipelines, machine learning algorithm, quality control, software, and then the case record for that patient and the report that gives the variant calls associated with that sample all of that is produced on the server, which is also part of what we consider the kit.

Q. And the tissue complete and plasma resolve, are those therapy selection tests?

A. Yes. Largely therapy selection. There are some research efforts for elio plasma resolve around use for monitoring as well, later stage patient monitoring, so meaning when a patient is -- a specific therapy is selected for that patient the test could also be run subsequent to the patient going on that treatment to see if there is any change in the variants to help identify whether the treatment is working effectively or not.

Q. And is that feature of the monitoring portion of the plasma test is that called a minimal residual disease test?

A. No, but good question. They often lump together.

Minimum residual disease is looking for postsurgical intervention looking for essentially whether everything from the tumor was removed

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successfully or whether additional treatment is needed.

[redacted]

Q. [redacted]

A. [redacted]

Q. And is the elio tissue complete test

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considered a liquid biopsy test?

A. No, it's not. That test can only be run out of a tissue sample.

Q. Okay.

A. You can -- did you hear that --

Q. Yes, I did hear that.

MS. GASKIN: Stephanie, did you hear that okay?

MS. REPORTER: What am I missing?

MS. GASKIN: It looked like Megan's signal cut out, I think we are okay.

BY MS. GASKIN:

Q. Is the elio plasma resolve test considered a liquid biopsy test?

A. Yes.

Q. What is a liquid biopsy test?

A. A liquid biopsy test is one that can be run out of a blood sample.

Q. And how is that blood analyzed?

A. In a very similar way as the tissue is analyzed. There is similar workflow steps associated with looking for the same sort of data. But everything has to be optimized to that specific sample type.

Q. And is the blood analyzed using next

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throughput higher capacity alternative.
And then we do still have a Thermo platform in our lab, the Thermo S5 platform that was used previously for a pilot program. We never fully validated or launched any content on that platform, but we do still have it in the lab.
Q. And no other sequencers besides the Illumina and the Thermo?
A. Correct.
Q. And you said that you are going to NovaSeq. Do you currently have a NovaSeq in your lab?
A. No, not yet.
Q. How many NextSeqs do you all have?
A. I can get back to you with the exact number, but our total platform number is in the range of 15 to 20, but I don't know the exact breakdown.
Q. Ballpark is fine, 15 to 20, you guys have a lot.
A. Yes.
Q. And how much does a NextSeq instrument cost?
A. Usually in the range of 250 to 300,000 per instrument.
Q. And how much does a NovaSeq cost?
A. In the range of about 850,000 to a

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million per instrument.
Q. What is the average life span of a NextSeq instrument?
A. I believe they say five to seven years.
Q. And I know you guys are going away from the HiSeq, but what was the life span on the HiSeq?
A. I'd have to confirm that, but I think it was around the same.
Q. And what does PGDx use the Illumina instruments for?
A. We use them for -- in the research and development lab they are used to do all of the feasibility verification validation tests that are required to bring the products to market in the distributed manner. And then in the CAP/CLIA laboratory they are used just like one of our end users would use them they from the time the samples are prepared for sequencing, that is what they are run on to be able to produce the results that were -- for our pharma partnerships.
Q. [redacted]
A.
Q. And what, if anything, do you currently use that machine for?

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A. Nothing currently.
Q. What did you previously use that machine for?
A. So there was in early 2018, I believe is when it was initiated, because it started before I joined the company. It was brought in to do some pilot work around elio tissue complete, the 505 gene panel, to see if that could be successfully validated on that platform as an alternative to the Illumina platform.
But the program only ran about four months, I believe, and was never taken past the feasibility stage.
Q. And can you walk me through that evaluation process of the Thermo platform? I know you said it started in I believe it was early 2018. What did you all consider, what did you evaluate on that?
A. I don't know. That was ahead of my time so I saw some of the readout information around when I joined, but I wasn't involved to see how that was scoped or decided upon. I don't have a lot of context on that.
Q. Were you evaluating the Thermo Fisher platform for use in the tissue complete test or the tissue prototype?

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A. Yes.
Q. And do you know why PGDx did not use Thermo Fisher?
A. Yes.
I think the decision was made based on [redacted]
Q. So other than sensitivity was there any other metrics that PGDx looked at?
A. Usually the key ones are sensitivity and specificity. But for panels like this sensitivity can differ based on the specific variant or the class of variants like amplifications as a category, translocations as a category, and so looking at the limit of detection related to the customer requirements there there was a perceived gap that the

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performance looked better and more uniform on the Illumina platform.

Q. And you just mentioned sensitivity and specificity. Can you define what those terms mean?

A. Yes.

So specificity, a way to think about that is that you do not want to call a false positive, so you typically run studies like limit of blank where you have known normals and make sure that a positive doesn't come up in those, so essentially you are trying to make sure that you never call something that's not there for the patient.

sensitivity is you don't want to miss anything. Sensitivity is how deep can you go in terms of limit of detection before the level of presence would not be found.

Q. [redacted]

A. [redacted]

Q. And why was PGDx looking for an alternative platform?

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A. There were two reasons, as I understood it at the time.

[redacted]

And the other driving factor, again, as I understood it at the time was that [redacted]

Q. So for this co-development partnership between PGDx and Illumina in 2017 can you describe what that co-development partnership was for?

A. So traditionally when you take a product through the FDA you need to be able to demonstrate control around quality across what is considered the

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device, and so in our case because as you ask the question around the kit because our kit covers all of the front-end chemistry and back-end analytics but sitting in between those is the samples going on the sequencer, they want to see a co-development agreement typically demonstrating that there is a direct and formal partnership between the instrument provider and the content provider to control for those.

Q. So the FDA requires this agreement between the sequencer and the manufacturer?

A. Typically, yes.

Q. And does PGDx call these agreements IVD agreements internally?

A. Yes. We usually refer to them as an IVD co-development agreement.

Q. And for what test was this agreement around in 2017?

A. There were discussions around both elio tissue complete and elio plasma resolve.

[redacted]

Q. Would it be accurate to say that the

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discussions that went on in regard to this development plan led PGDx to consider a different platform?

A. Yes.

Q. And that platform was Thermo Fisher?

A. Yes.

Q. What portion of PGDx's 2020 revenue came from oncology tests?

A. [redacted]

Q. And how much did PGDx spend on R&D in 2020? Ballpark numbers are fine.

A. [redacted]

MS. GASKIN: At this point we have been going for about an hour, is it okay if we take a five-minute break, does that work with everyone?

MR. GOTSHALL: Sure.

MS. GASKIN: Ms. Stephanie, can we go off the record for a five-minute break?

MS. REPORTER: Off the record at 10:26 Eastern.

(Recess taken.)

MS. REPORTER: We are back on the record at 10:33.

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BY MS. GASKIN:

Q. We are back from our break.

Ms. Bailey, you were speaking earlier about the Thermo Fisher pilot program that PGDx ran and you were listing some reasons why PGDx did not ultimately choose Thermo Fisher.

Is there any other reasons that you can think of that PGDx did not select Thermo Fisher?

A. I think there were also questions around the size of the install base in the market. [redacted]

Q. It may seem like a basic question, but why is install base important when it comes to instruments?

A. It just reduces a potential barrier to adoption, so there is certainly the opportunity for a laboratory that wants to run your test to go out and purchase a piece of equipment needed to do it, but if you bring something to market where there is a significant number of those instruments already placed

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in laboratories and they have the opportunity to add content that they feel like is important to patient care without needing to go invest in capital infrastructure to do it, it just makes it more seamless for the laboratory to adopt the test, and that obviously has business implications for us as well.

Q. Is there any other reasons why PGDx did not select Thermo Fisher?

A. Not that I can recall.

Q. [redacted]

A. [redacted]

Q. PGDx made the decision early on to not use the Thermo platform because of the [redacted] **that it had?**

A. Yes.

Q. Are you considering switching to the

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Thermo Fisher platform now?

A. [redacted]

Q. And you mentioned that if you were to switch the tissue test now to Thermo you would have to revalidate or redo certain parts of your tissue test. Can you walk me through what that process would be like if you had to switch to Thermo?

A. [redacted]

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[redacted]

Q. And how long would that process take?

A. I mean, it could take a [redacted]

Q. And how much would you expect that to cost?

A. I would estimate that -- I mean, that could be to a [redacted] kind of investment.

Q. And what would you have to see from the Thermo Fisher platform now in order to make that switch?

A. [redacted] I think they have a good workflow, I think it would come down to making sure that we [redacted]

Q. When you say [redacted] **do you mean** [redacted] **do you mean** [redacted]**, what does that mean?**

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then the flow cell with its reagents?
A. Yes.
Q. Can you describe what is the difference between a flow cell and the reagents?
A. There is no difference, sorry, I used two different terms. You will hear it referred to as the flow cell, but it is essentially the reagents or consumable needed to operate the sequencing platform.
Q. And what are reagents?
A. Chemicals needed for the process to occur on the instrument.
Q. And those have to be Illumina reagents?
A. Yes.
Q. You can't use a third party's reagents?
A. No, not to my knowledge.
Q. Was the elio tissue complete test first launched as a laboratory developed test?
A. Good question.
[redacted]

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So our first use of it was as an IUO in our CAP/CLIA lab, and that was associated with a clinical trial where the [redacted]
Q. Can you describe what a laboratory developed test is?
A. I mean, it's a term that is used frequently and not always consistently, but the way I would describe it is a single laboratory running a test. They can take materials that are research use only materials from other vendors and validate a configuration together under CAP requirements of what that level of validation needs to entail to be able to report results clinically.
So the example I just gave you, although it was investigational use only, you could think about it in the same way because since that test was not yet fully clinically validated through something like the FDA there is a different bar then in what the lab has to do to demonstrate the level of quality needed to be able to report results for clinical purposes.
And so any time a lab does that they will often refer to it as their LDT.
Q. And is LDT the abbreviation for laboratory developed test?
A. Yes.
Q. So is a laboratory developed test used in a centralized manner in the sense that samples are sent to the lab to be run?
A. Usually. It's more frequently the case that it's a centralized laboratory. But you will find, for example, academic medical centers that may refer to a test they've validated on their own also as an LDT. So another way to think about it is you are transferring the burden on to the end user of validating its performance, its analytical validity and performance, in contrast to something like elio tissue complete whereby taking it through the FDA then the laboratory does not have to do a full validation because it's already been validated by us as the manufacture and supplier, that's kind of the key difference.
Q. So when the tissue complete test was in the clinical trial assay where it was only for investigational use, were samples being sent to PGDx's lab in this centralized model we just talked about?
A. Yes.
Q. Can you describe the regulatory process an LDT goes through?

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A. There isn't one. So the -- in terms of if you are speaking of regulatory as the FDA the FDA is not involved when it's a laboratory developed test, its more the -- it's more CAP requirements at that point, the College of American Pathologists.
There are some guidelines around the level of validation required to be able to report a diagnostic test for clinical use, and so the laboratory will typically follow those guidelines to scope the validation they need to do for a test like this. But there is no involvement from the FDA at that point.
Q. And what are the benefits of having a test run as an LDT?
A. You are asking somebody who leads a company that is trying to like help people move away from LDTs.
I guess the argument would probably be flexibility, if they develop it on their own and they want to make changes they can do that with more control and flexibility over them, versus when you have an FDA-regulated product, the parameters around what you can do and can't do to stay on label with the clearance is stricter. So flexibility would probably be one.

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Q. And how does the elio tissue complete test help in a patient's treatment?

A. It identifies targetable mutations. There are a number of them across tumor types that the -- a specific mutation in that patient's tumor indicates that they are more likely to respond to a specific therapy.

Q. And you mentioned a few times how the elio tissue complete test can measure 500 genes. Can you walk me through what the tissue complete test can measure?

A. I probably can't walk you through 500, I can use them in categories.

It measures SNVs, which is single nucleotide variants; INDELs, so insertions and deletions; translocations or sometimes referred to as fusions, and amplifications. So those are all different types of genomic changes that can be seen at the DNA -- from the DNA at the molecular level. And so our test covers a number of variants within each of those categories and then also reports tumor mutation burden and microsatellite instability.

Q. You just mentioned that the elio tissue test looks at the DNA. Is that the only analyte that the test examines?

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A. Yes.

Q. Does it make a difference what analyte is being examined in a particular test?

A. It depends -- so there are tests in the therapy selection realm where we are that also look at RNA for specific variants. There are tradeoffs either way typically between workflow, ease of use, sensitivity levels, but you will see -- so there can be a DNA/RNA combination and others are DNA only and ours just happens to be DNA only.

Q. And you mentioned a list of variants that your test can call. Do all those variants indicate for cancer?

A. Well, so first we are only running tests or I should say our customers are only running tests on patients that are already known to have cancer. So nothing about our test is intended as sort of screening to see if the patient has cancer. They already know they have cancer and they are looking at this data to determine how best to treat the cancer.

I lost my train of thought, what was the beginning of the question?

Q. I think you answered my question fully. That was great.

A. Oh.

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And to your point are all of them, do all of them pertain to cancer, not all 505 are actionable, meaning there are some that you could find a variant and it's actually referred to as a VUS, variant of unknown significance, so it can produce data that doesn't necessarily point directly to a therapeutic indication across all 505 genes.

So part of building it that way was to make it more future proofed based on other things that pharma and other key opinion leaders in the market are looking for, and [redacted]

Q. And you've mentioned a few times [redacted] I'd like to talk more about that. Can the elio tissue complete test call or measure [redacted]

A. [redacted]

Q. If I abbreviate [redacted] will you understand what I mean?

A. Yes.

Q. [redacted]

A. [redacted]

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[redacted]

There are -- [redacted] but there is a number of other trials ongoing to look at what the right cutoff would be in different indications to designate between high and low, but the hypothesis is that [redacted]

Q. What is an immuno-oncology therapy drug?

A. It's one really that's trying to use the body's immune system to fight the cancer.

Q. And how does that differ from other drug therapies?

A. Others are more usually targeted directly at the mutation. So, for example, in lung, if you have an ALK mutation there is a drug that is linked to basically slow that mutation down or directly target that mutation.

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Q. And is it important for a test to indicate for immuno-oncology therapies?

A. Yes. Yes.

I mean, again, using Keytruda as an example they have a wide number of approvals now in different tumor types. Often it's a less toxic type of treatment option for a patient. And in many cases it is kind of pan-cancer utility, so it can be applicable often more broadly than some of the targeted therapies which do tend to be specific to a tumor type.

Q. You mentioned that it's important for pharma to have an immuno-oncology therapy indication. Why is that?

A. Sorry, I meant to the patient it's important because this may be a really good treatment option for them.

To pharma it depends on their portfolio. So those that have a lot of drugs either in that space, IO space or that they are working on in clinical trials, these sorts of biomarkers like TMB and MSI are important for them to look at. That depends on the pharma, what their drug portfolio and strategy looks like.

Q. Are immunotherapies starting to be the most up and coming area of drugs, what's your impression?

A. Yes. Yes. I mean, I think they certainly -- there is a lot of promise in them, there is a lot of recently improved indications for them. Yes, I would say so.

Q. [redacted]

A. [redacted]

Q. And why would it be disadvantaged?

A. [redacted]

Q. And has the elio tissue complete test always measured [redacted]**?**

A. [redacted]

Q. Can the elio tissue complete test measure microsatellite instability?

A. Yes.

Q. If I abbreviate microsatellite instability as MSI, will you understand what I mean?

A. Yes.

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Q. Can you explain what MSI is?

A. I am not sure I can give a great technical explanation of that other than to say it is another thing looking at the ability of the immune system to respond appropriately to the cancer it's fighting, and so if it's microsatellite instability high then it's typically more targetable by an IO therapy versus a cancer that is microsatellite stable.

Q. And IO means immuno-oncology therapy?

A. Yes, sorry.

Q. No problem.

A. [redacted]

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that you understand the other aspects.

Q. [redacted]

A. [redacted]

Q. And why is that?

A. Based on what I just said, that it's not always, you know -- it's not always that one answer sort of answers it all, there may be drugs that are associated with patients who are MSI high and can have very strong responses to them, and if you saw -- if you could report TMB but not MSI it doesn't necessarily mean that an MSI high is a TMB high. So based on the drug indications there would be different -- both data sets are important to be able to select the best drug.

Q. [redacted]

A. [redacted]

So our goal in developing tissue complete was to make sure it covered as much information as possible that could be actionable from a treatment

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approval did you seek an IVD agreement with Illumina?
A. My understanding is that we did.
I was not directly involved in those discussions, but I would say 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.
Q. Do you have any impressions on why Illumina did not provide the approval when you first asked for it?
A. The feedback I heard at the time was because of the development of the TSO500 test that would be a competitive test on that platform.
Q. So because Illumina had a competitive test they did not want to provide PGDx FDA approval, is that correct?
A. I wouldn't say didn't want to provide us FDA approval, but 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 the FDA submission process.
Q. Why would the development of the TSO500 impact your ability to enter into an IVD agreement

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with Illumina?
A. Again, it was the feedback I heard at the time was because that product would be developed and launched on the same platform and was quite comparable in content to what we were developing, that it was more a desire not to enable the standard path forward for elio tissue complete through the FDA submission process.
Q. What do you mean by enable?
A. That those agreements had been a standard request by the agency to see that there was in fact that direct relationship between manufacture of platform and manufacture of content, and so not having that required us 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.
Q. So this collaboration with the FDA did not require Illumina approval?
A. Correct.
Q. And how did this non-Illumina approved test work?
A. Essentially the product is cleared for use on the NextSeq Dx platform, so it was important to the FDA that it was on the Dx registered box that had

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the supporting data around it, but it is run in the research use only software mode on the Dx platform.
Because -- by not having the co-development agreement in place we didn't have access to develop the product on the Dx partition of the software of the instrument.
So it is cleared for the Dx instrument in research use only software mode and what we aligned with the FDA on was a piece of software that would reside on the server that was part of our product and it would serve as essentially a screen to make sure that the data coming off the NextSeq platform was operating within spec, and if there was anything off about it the system would flag it and would hold the report. And if everything seemed to be working as intended then the rest of our -- the analysis pipeline/the machine learning algorithms would be applied to produce the end report.
So ultimately what we aligned on with the FDA was the ability to use an RUO component, that component being the software. [redacted]
Q. Why is it important to the FDA to use the NextSeq Dx registered box?

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A. I believe that in a distributed model they always prefer an IVD cleared platform or IVD cleared component to be utilized.
In a single site submission, because there is more control just at that site, there have been RUO platforms or components as part of a workflow filed as part of a submission, but in a distributed clearance the preference is for components that have already been deemed to be the IVD level quality.
Q. Were the results coming off the non-Illumina approved test different from the original test you all sought?
A. So because we never got the IVD co-development agreement we never had results out of the IVD software mode so I don't know how that would have compared.
We did have a fairly substantial dataset comparing results from the NextSeq RUO instrument and the NextSeq Dx instrument just because we had a number of them internally and the concordance there was extraordinarily high. [redacted]

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instruments.
But I can't say what the difference would have been in the IVD software mode because we were unable to test that.
Q. So is the NextSeq RUO a separate machine from the NextSeq Dx?
A. Yes. There is a NextSeq 550 that's RUO and then one that's labeled Dx.
Q. Could the non-Illumina approved test make clinical diagnosis?
A. What do you mean by non-Illumina, the product that we have FDA cleared and launched today just without their --
Q. The product that you were running as RUO mode that Illumina did not give you the IVD agreement for, the product that was this alternative test, could it make clinical diagnosis?
A. Yes.
So that is the product that's FDA cleared on market today indicated for tumor profiling. So, again, it doesn't -- it's not intended for diagnosis of cancer, but it is indicated for tumor profiling such that the healthcare provider in accordance with guidelines can utilize the data from that to inform clinical treatment decisions.

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Q. [redacted]
A. [redacted]
Q. So traditionally to get FDA clearance for a distributed test you need an IVD agreement with Illumina, is that correct?
A. Yes. Or with whatever platform your content is validated for, yes.
Q. But your content uses Illumina so you'd have to get an IVD agreement with Illumina, is that correct?
A. Traditionally, yes.
Q. So can Illumina traditionally decide

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which test gets FDA clearance as a distributed test on its platform?
A. I think they have the ability to develop a partnering strategy that can influence that, certainly either in terms of who they are working with or not and what the financials of the agreement are.
But, as I said, in our case it didn't block or prohibit us, we did find another path that didn't require the agreement with them.
[redacted]
Q. Did the non-Illumina approved tests add time to the commercialization process of the tissue complete product?
A. Based on the feedback I got from our head of regulatory I believe so, in the sense that the [redacted]

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[redacted]
Q. By not having an IVD agreement with Illumina was there added time to commercialization of the tissue complete test?
A. Yes.
I would say added time on the front end presubmission on trying to align with the FDA on an alternative path. [redacted]
Q. And how much added time?
A. I don't know that I can answer that because I -- when I came into the organization it was

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already understood that we didn't have and couldn't obtain a partnering agreement, so the plans I saw at that time already accounted for that, but I have heard estimates of the time, but I never saw two plans side-by-side.

Q. And what were those estimate times?

A. [redacted]

Q. By not having an IVD agreement with Illumina was there an added cost to commercialization of the tissue test?

A. Probably only in the additional data required around the quality control module for the [redacted]. And I would say in the grand scheme of the total cost that was probably relatively minor.

Q. Do you have an estimate of how much the alternative route cost?

A. I don't.

Q. And when you say it was minor, it was a minor cost compared to the grand scheme, what do you mean by that?

A. I mean the total investment end to end to get a product like this fully validated through the agency I think was in the [redacted] range in terms of cost for all of the studies.

So there were portions of those that were

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influenced and I think increased as a result of not having the IVD agreement in place, but relative to the total much of that work still would have had to be done.

Q. But pursuing this alternative route did it cost PGDx a certain amount of additional funds?

A. Yes.

Q. Was this non-Illumina approved test eventually approved by the FDA?

A. Yes.

Q. Can you walk me through how PGDx was able to get this non-Illumina test approved by the FDA without Illumina's involvement?

A. Yes.

[redacted]

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[redacted]

Q. What were customers' reactions to the non-Illumina approved test?

A. [redacted]

108

[redacted]

Q. What were those concerns?

A. [redacted]

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And usually they know that typically by 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.

Again, it never proved out to stop a sale and largely because there was no clear substance behind the concerns created, but there were members of their commercial team who would say they are not approved or they are not licensed, different terms used, but approved or licensed to run this content on this instrument. And in all cases we were able to overcome that through our own documentation.

But I would say it caused some questions and slowdown in some instances.

Q. When a customer orders reagents from Illumina how does Illumina know what tests the reagents will be used for?

A. I mean, they don't from a centralized corporate standpoint, right, it is an orderable part number, in 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

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negotiate pricing with Illumina and establish that to be able to order it.

Or, as I said, 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.

Q.

A.

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Q. Who was the

that you talked to at Illumina?

A.

Q.

A.

But I will say he and I quickly established a positive relationship, he asked would we describe why we did it and how, of course we didn't give detail on the how, but just the general approach and what components it used from them and what was required by us but not provided. So we did have a couple transparent discussions that way.

But largely my objective at that time and

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his shared one was we wanted to move down the path of a formal partnership agreement.

So I think he was surprised, but I wouldn't say there was any negative repercussions. In fact, I think he became a supporter for the next steps in us formalizing an agreement with them, which we did in November of last year.

Q. So the negotiations that took place after this April, 2020 call to put in place a formal partnership, can you just describe how those went?

A. Yes.

And I should clarify, that didn't initiate the negotiation, so there was a changeover in many of the leadership team at Illumina at the time, again, my understanding, I didn't actually interact with the previous ones, but I think there had already been a sort of changing of the guard at the leadership level thinking about the partnership strategy differently, and so my predecessor in the CEO role as well as at the time the head of business development and a director level of business development, they had re-engaged with Illumina already in the fall of 2019 so try to re-initiate discussions and progress a partnership path forward.

So my first call and direct involvement

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with him was in April of 2020, but there was already a redlined contract that was going back and forth that was already in progress.

Q. And why would PGDx need this formal partnership agreement if the RUO model of the test was producing the same results?

A. [redacted]

Q. You mentioned investors. Why were investors reluctant to invest in an RUO model of the test?

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A. [redacted]

Q. And did any of the pharmaceutical partners you mentioned that had concerns with the tissue test did any of them decline using the tissue test because you did not have an IVD agreement with Illumina?

A. [redacted]

Q. And what customers were those?

A. [redacted]

Q. Were any willing to partner with PGDx even though the test was in the RUO mode?

A. None that I'm aware of. We did not sign a companion diagnostic agreement preceding that formal agreement with Illumina for the tissue test.

Q. And was not having these pharma partners

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a big impact on PGDx's business?

A. [redacted]

Q. What was that impact?

A. [redacted]

Q. Does a drug company normally have one companion diagnostic test or do they have several?

A. [redacted]

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[redacted]

Q. But not having an IVD agreement in place with Illumina prevented PGDx from pursuing these companion diagnostics with pharma companies?

A. [redacted]

Q. When the renegotiations started to happen in fall of 2019 were there different terms proposed in the second round of negotiations with Illumina for an IVD agreement?

A. I don't know if there were any terms previous to what I saw directly.

But what I can say is from the time I saw it to the time we closed it there was not a lot of change.

There was some adjustments, for example, in timing of certain payments, how those would be divided, how much was upfront, how much was upon validation in the IVD mode, things like that, but the total sum of the financial impact was not changed from the time I saw it.

Q. Did Illumina request anything from PGDx in exchange for an IVD agreement?

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A. No. I mean, just the financial payments contained within the agreement and then there are requirements within that around certain validation plans that have to be provided associated to what they call their LRF module, which is the lab module that validates you in the IVD mode.

I guess all of the parameters of work around the co-development agreement were contained within it, but no requests outside of that.

Q. What were these financial payments that Illumina requested?

THE WITNESS: Scott, am I able to share?

That has a confidentiality clause in it as well, I am not sure I can share the numbers, but I can share the framework if that's helpful.

BY MS. GASKIN:

Q. That's helpful.

A. So the framework of the agreement is there is a tech access fee, so that is a lump sum that is essentially granting you access to develop content on their platform.

There are then additional fees that are laid out associated with specific claims.

[redacted]

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[redacted]

And then when the product is on market under this IVD cleared plan there is a revenue share component, so a percentage of all net sales then goes to Illumina.

MS. GASKIN: Ms. Stephanie, can we go off the record one second?

MS. REPORTER: We are off at 12:48.

(Recess taken.)

MS. REPORTER: Back on at 12:58.

BY MS. GASKIN:

Q. Welcome back from our short break there.

Ms. Bailey, you were previously discussing the financial payments involved in the Illumina IVD agreement.

You had mentioned a tech access fee, a companion diagnostic fee, a reporting fee, and then a revenue sharing fee, is that correct?

A. Correct, with the exception of the reporting fee.

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Once the IVD cleared mode is validated that's actually a milestone within the tech access fee, so it's the tech access fee -- I am sorry, I do know what you are talking about.

So there is a tech access fee. There is a fee for any companion diagnostic claim. And then there is one specific report out, clinical report out, that they designate an additional fee for, and then the revenue share, yes.

Q. For that clinical report out fee what is that for?

A. That's for [redacted]

Q. So any time your tissue test indicates for [redacted] that is an extra fee that Illumina charges?

A. Yes. Once it's launched through the IVD mode, so even though our current on-market product reports that we are not paying them that fee currently. But once the version through the IVD mode and IVD plan is on market then, yes, that's correct.

Q. And do you have an idea of why they require this reporting fee for [redacted]?

A. Yes.

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[redacted]

Q. And who conveyed this to you?

A. This was through the discussions in the negotiation which ultimately was under [redacted] who [redacted]

Q. And what is the dollar amount range for this clinical reporting fee for tumor mutational burden?

A. [redacted].

Q. And PGDx has to pay that fee once their test goes through FDA approval and can call [redacted]?

A. Yes.

Q. Is there a clinical reporting fee for any other measurements of the tissue test?

A. No.

The rest is broadly just if it's a companion diagnostic claim, so irrespective of what variant that claim is based on. Any CDx claim is a [redacted] fee.

Q. And CDx is the abbreviation for companion diagnostic?

A. Yes.

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Q. You talked about a tech access fee. What is the dollar amount range for that fee?
A. [redacted].
Q. And the revenue sharing that is under the IVD agreement, is that just for the tissue complete test or is that for all IVDs created under this agreement?
A. All IVDs created under the agreement.
Q. And how many IVD tests are allowed or covered under this agreement?
A. Three.
Q. And what is the percentage range of this revenue share?
A. [redacted].
Q. Did PGDx negotiate these financial terms with Illumina?
A. Yes.
Q. Can you explain what those negotiations entailed?
A. Yes.
Again, I wasn't involved in the earlier stages, but my understanding is it was much broader in scope and, therefore, the fees were even more significant like in the [redacted] even for the initial fee, but based on covering multiple

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platforms more test kits.
So I think a lot of the negotiation was to draw the scope down in a way more proportional to our current plans around content and make it more financially feasible for where we were as an organization.
I don't know the -- all the specifics back -- all the specific back and forths on the exact numbers, but I would say most of the negotiation to my knowledge was, again, more about kind of rescoping than it was around getting a lot of flexibility on the numbers themselves.
Q. Was the decrease in dollar amount of financial payments because there was a decrease in scope of the IVD agreement?
A. Exactly. [redacted]
Q. You mentioned that NovaSeq was not included in the IVD agreement. Why was it not included?
A. To narrow the scope to have less of an up-front payment required, and because at this point

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there isn't a NovaSeq Dx registered instrument so at this point there wouldn't be a viable path through the FDA for a distributed kit. It would have to either be a single site at this point or wait until there is a Dx, so that could be something that we need at some point in time.
We are developing a new liquid biopsy product on the [redacted], but currently we are doing that as a research use only kit CAP/CLIA service.
So there could be a point in time if we wanted to take a product like that through the FDA, we would have to renegotiate adding that scope, but for the time being we removed it because it doesn't apply currently to the portfolio of kits or the options we had for a distributed clearance.
Q. Would PGDx have to engage in a new IVD agreement if you wanted to add NovaSeq as an instrument?
A. Yes. I believe it would be considered an addendum or extension, likely not a completely new agreement with new master terms and conditions, but it would be something we would have to add on and renegotiate at a later time.
Q. And would that addendum include an

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additional financial payment?
A. Yes.
Q. Does the IVD agreement with Illumina include any territory limitations?
A. No.
Q. So PGDx can sell its IVD test kit in the US and outside the US?
A. Yes.
Q. How does this IVD agreement impact the profitability of PGDx's tissue test?
A. It impacts it -- it will impact it more when the IVD kit cleared under this plan is on market and we pay them the revenue share, so that will directly come out of the profit margin to PGDx.
[redacted]
Q. Will PGDx's profitability be lower on its tissue complete test because of the IVD agreement?
A. Yes.
Q. Does this lower profitability take funds away from the research and development efforts PGDx

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sequencing between the Thermo Fisher instrument and the Illumina instrument?

A. I don't know the answer to that.

Q. Is the plasma resolve test less robust because [redacted]?

A. [redacted]

Q. And when the plasma resolve test in the future [redacted]

A. [redacted]

Q. Has PGDx worked with Illumina in any way to develop the plasma resolve test?

A. No, not to date.

Q. We are going to switch over to Agile Law

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and I am going to reveal a document. Do you have the ability to look at that screen?

A. Yes, I think so.

Q. You should be able to go to the Agile Law screen.

A. Okay, I am looking at it now.

Q. And I will -- I just revealed the document to you, it should show up on the left side of your screen. I can show you a particular page if that's helpful.

Did it show up on your screen?

A. It did.

Q. Okay, great.

(Document referred to as Exhibit PX8366 for identification.)

BY MS. GASKIN:

Q. I'd like to show you a document that is marked for identification as PX8366. Do you see it on your Agile Law screen?

A. I do, yes.

Q. It appears on its face to be an e-mail exchange between yourself and Jay Foust. It is dated Wednesday, June 13, 2018 through Thursday, June 14, 2018. It begins with Bates No. FTCPGDX-00000130 and ends with Bates No. FTCPGDX-00000132.

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Will you please take a moment to review this document and let me know when you've had a chance to familiarize yourself with it?

A. I am just scrolling.

Q. The e-mail thread starts at the bottom, if that's helpful. And there are multiple pages to this e-mail thread. Do you see the multiple pages?

A. No, I don't think so.

The one I see -- so where it starts for me is "any concern on publicly supporting Thermo," is that the whole thing, or is there something below that?

Q. Yes, there is something below that. Let me see if I can reveal to you.

Can you see this page?

A. Okay.

Yes. This one starts with "our marketing team would like to get pre-approval," is that right?

Q. Yes.

So can you scroll up from there?

A. No.

Q. You are locked in on that screen. Let me see how I can --

MS. GASKIN: Stephanie, can we go off the record for one second?

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MS. REPORTER: Yes.

(A discussion was held off the record.)

MS. REPORTER: We are back on at 2:06.

BY MS. GASKIN:

Q. Ms. Bailey, have you had a chance to review PX8366?

A. I have.

Q. Can you tell me what this e-mail thread is about?

A. Yes.

So I don't remember the specifics around what our technical team was testing from Thermo, but it was not one of our kits on their platform, they had asked for us to run some of their components or one of their assays on our -- sorry -- on their platform here and give them feedback on it, on its performance, and then that subsequently led to the request seen in the e-mail around whether we would provide a positive quote around the performance of that plasma assay.

So that was the start of it and I will pause there and then give you the rest of it if you'd like.

Q. Who is Jay Foust?

A. Jay Foust is no longer with PGDx, but at the time he was head of business development and

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pharma partnering for PGDx.

Q. So on the last e-mail on page PX8366-001, in this e-mail you ask Jay Foust, quote, "any concerns on publicly supporting Thermo on plasma assay before having Illumina Phoenix agreement signed?" Did I read that correctly?

A. Yes.

Q. What is Phoenix?

A. Phoenix was our project code name for elio plasma resolve.

Q. And is Thermo short for Thermo Fisher?

A. Yes.

Q. What is the meaning of your e-mail to Jay Foust?

A. So my understanding at this time was that Jay was leading negotiations of an IVD co-development agreement for elio plasma resolve with Illumina post the time in which, again, based on my understanding they had said they would not work with us on an agreement for tissue, but at the time Illumina did not have a similar liquid biopsy product in development, and so there were ongoing discussions being led by Jay with Illumina about an IVD co-development agreement specifically around elio plasma resolve.

And this was the point at which I had

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understood that to be relatively close to being signed where we would formally partner with Illumina to take that product through the FDA under the co-development agreement.

And so my question was really around a public statement about working with Thermo on plasma assays relative to the discussions he was having at the time with Illumina.

Q. [redacted]

A. [redacted]

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[redacted]

Q. Can you look at the e-mail midway down the page of PX8366 01 here Jay Foust responds to you, quote, "yes, some, however, they are behaving badly recently so unlikely to get much worse anyway. Trying to bully us into giving them our [redacted] **in exchange for plasma. Keep that quiet, please. At this point I think it would be helpful for them to really know we are not dependent on them."**

Did I read that correctly?

A. Yes.

Q. What is [redacted]

A. [redacted]

Q. And does plasma refer to the elio plasma resolve test?

A. Hang on, let me read it.

Yes.

Q. What did you interpret Jay Foust's e-mail to mean?

A. I interpreted it to mean that we were not in a great negotiation position, the discussions were ongoing but some combination of the financials or requests for what was negotiated as part of that weren't favorable.

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Q. When Mr. Foust says, "however, they are behaving badly recently so unlikely to get much worse anyway," who was he referring to when he said they are behaving badly?

A. Illumina.

Q. To your knowledge in what ways was Illumina acting badly?

A. I don't know the specifics around those negotiations.

[redacted]

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[redacted]

Q. And when you say financials, do you mean the financial payments that PGDx would have to pay Illumina?

A. Yes. And similar structure, so tech access fee, fees for companion claims and revenue share components.

Q. And these financials were bad because they were higher than PGDx expected?

A. Yes, and higher than what would make sense given the revenue contribution that product was expected to make for the business.

Q. And what were those rough numbers?

A. I don't remember the exact, but it was in the [redacted].

Q. And that was just for the tech access fee or that was for all the fees put together?

A. No, I think it was for all.

But also, I should state, I don't know what was in scope of that agreement, so similar to my earlier discussion to complete where we really negotiated scope down to negotiate numbers down, I

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don't know when he was sharing those numbers, I don't know what was scoped into that agreement.

It's possible we could have taken a similar path, but the numbers I heard were in the [redacted].

Q. What did you understand Mr. Foust to mean by Illumina is, quote, "trying to bully us into giving them our [redacted] in exchange for plasma"?

A. I only had one conversation with him about that, but essentially it was they wanted a sublicense as part of the negotiation for the IVD co-development agreement on plasma.

I don't know how that was presented in context of how it would change the scope in financials, but just that they wanted some exchange around [redacted] as part of the deal.

Q. And how would that sublicense to Illumina affect PGDx?

A. That's a good question. [redacted]

Q. And did PGDx ever provide such a sublicense to Illumina?

A. No.

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Q. Would the sublicense make Illumina's test more competitive against PGDx's test?

A. [redacted]

Q. So Illumina agreed that PGDx would not have to provide a sublicense?

A. Well, we never executed this agreement, so I think it was one thing discussed as part of the negotiations, but the agreement was never successfully negotiated.

Q. Are you still negotiating this agreement?

A. [redacted]

Q. So at the time of this e-mail, which is June, 2018, did Illumina know PGDx was developing a plasma test?

A. Yes.

Q. And how did they know this?

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A. Because of this negotiation.

Q. So as part of this negotiation PGDx had to provide Illumina development plans for the plasma resolve test?

A. I don't believe we ever provided them development plans because that would have been a requirement subsequent to signing the agreement.

But I think there was information requested on -- not the specific details of the panel, but kind of general scoping information around what this product was and what its intended utility would be.

So they did have a general understanding of the product from that standpoint.

Q. So even though PGDx has [redacted] it still has to pay Illumina clinical reporting fees whenever it calls [redacted]?

A. [redacted]

Q. The last sentence -- the last sentence in the e-mail Mr. Foust writes, "At this point I think it would be helpful for them to really know we are not dependent on them."

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Who is this "them" that Mr. Foust is referring to?

A. Illumina.

Q. What do you interpret this last sentence to mean?

A. [redacted]

Q. And could PGDx leverage the ability to switch to another sequencing provider to help negotiations with Illumina, is that actually possible?

A. I presume so. I mean, again, there is nothing exclusive either way, but potentially they could negotiate their financials differently if there was the belief that you would go in another direction entirely.

Q. But your tests currently are predicated on Illumina's NGS instruments?

A. Yes, that's right. And it is significant investment of development funding to validate it.

[redacted]

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[redacted]

Q. Does PGDx know if there are any alternatives as good as Illumina's NGS platforms out there?

A. I don't know.

[redacted]

Q. You just mentioned that PGDx is talking with or communicating with other NGS providers. Which ones are those and what has been discussed?

A. I mean, very early stage, so [redacted] is an example of a company that is designing and developing a new sequencing platform and their strategy is well aligned to ours in terms of thinking about a decentralized model and what is

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important to end users, but very early stage. So not even yet where we could do some sort of pilot work.

[redacted]

Q. So is it fair to say that right now there are no other viable alternatives to Illumina's NGA instruments?

A. I would say Thermo is, Thermo does have an IVD cleared instrument.

[redacted]

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[redacted]

Q. You mentioned earlier that there is [redacted] with the Thermo Fisher platform in terms of sensitivity and specificity.

Even with those issues you still consider it an alternative to Illumina's platform right now?

A. [redacted]

Q. Does PGDx have plans to create a companion diagnostic out of its plasma resolve test?

A. [redacted]

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the NovaSeq has a Dx registered instrument by that time, which Illumina has publicly said 2022, or whether we would consider a single site approval strategy over a fully distributed, but preceding that Dx clearance on the NovaSeq distributed would be hard to obtain.

And then economics, as sequencing costs continue to come down I think it becomes more viable for a product like that to be run in a routine setting. But today it would be pretty cost prohibitive in the lab market.

Q. And why will the elio plasma complete test be using the NovaSeq Dx?

A. For that size panel to get to the sensitivity levels that are required the NovaSeq is much more well suited for that than the NextSeq platform.

Q. And will the elio plasma complete test be able to call TMB?

A. Yes.

Q. And why is that?

A. Why will it be able to or why do we want it to?

Q. Let's start with why will it be able to compared to the elio plasma resolve test that cannot

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call TMB?

A. The breadth and size of the panel is sufficient to accurately call TMB.

Q. And then why would PGDx want the plasma complete test to be able to call TMB?

A. Yes, similar to what we caused about tissue, its implication around immuno-oncology treatment decisions.

And, as I said, today there is not a drug label that is tied to that report out of blood, but if and when that happens that would be an important product capability to ensure you could give the most comprehensive information in the report for the oncologist.

Q. And will the elio plasma complete test fall under the current IVD agreement with Illumina?

A. It would not because right now that agreement is restricted to the NextSeq platform, so we would have to negotiate an extension or addendum to encompass the NovaSeq -- rights to the NovaSeq platform.

Q. Does the requirement to get a new IVD agreement or an addendum to the current IVD agreement go into the consideration of bringing the plasma complete test through FDA clearance?

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A. Yes.

I mean, any investment we make we need a business case analysis to do it, and I would say that would be considered part of the cost equation we would look at for bringing the product to market and how those costs looked in relation to the product's potential from a revenue perspective.

Q. Does PGDx have any plans to offer [redacted] test in the future?

A. [redacted]

Q. And what is this clinical trial that PGDx is currently in that has some relations to [redacted]?

A. [redacted]

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[redacted]

Q. [redacted]

A. [redacted]

Q. [redacted]

A. [redacted]

Q. Has PGDx looked at any other platforms?

A. No.

Q. Is there a reason why you guys haven't looked at any other platforms?

A. For that, again, the leading strategy is to see if the existing portfolio is capable of additional clinical applications. It's a much more efficient way to address larger patient needs than

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market needs versus building different products on different instruments for every clinical application. And it ends up being more challenging for the end user as well.

I mean, ultimately if you bring multiple products that address different clinical needs if a lab can put those on the same platform, that's very helpful for adoption of the assays, versus if we tested everything on a different platform and then came and said we have this product, we need to buy that platform, this product you need to buy that platform. Some of it is just to drive a more cohesive approach now that we already developed the earlier Phase I on the NextSeq.

Q. Because you guys have Illumina instruments and everybody else who used your tests have Illumina instruments, you just decided to do it on the Illumina sequencer?

A. Yes.

Q. Do you have a sense of what test will complete with [redacted]?

A. [redacted]

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[redacted]

Q. Does PGDx expect to compete with [redacted]?

A. [redacted]s

Q. And does PGDx have plans to seek FDA approval for its future [redacted]?

A. [redacted]

Q. You said that multi-cancer early detection is a natural extension [redacted] is that correct?

A. Just that the technology application, it makes sense. I mean, early detection you need very good specificity so you don't have false positives, but you need very good sensitivity as well because earlier stage disease is just going to be harder to pick up, and [redacted]

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[redacted]

Q. So given that extension quality of the [redacted]

A. [redacted]

Q. Does PGDx believe that a multi-cancer early detection test could be a future iteration of [redacted]?

A. [redacted]

Q. And why not?

A. I mean, frankly some of it is focus and investment of where we have in the number of things we believe we can still address from a cancer care standpoint, it's more easily done with the core capabilities that we already have.

[redacted]

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[redacted]

MS. GASKIN: I think we are at a good stopping point to take a break.

Stephanie, can we go off the record?

MS. REPORTER: We are off at 2:46.

(Recess taken.)

MS. REPORTER: Back on at 2:58.

BY MS. GASKIN:

Q. Welcome back from our short break there. Can PGDx use any technology other than next generation sequencing for its therapy selection test?

A. No, not to my knowledge.

Q. Could PGDx use PCR as a technology for its therapy selection test?

A. No. Our panels are too broad for that.

Q. And could PGDx use microarray technology for its therapy selection test?

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A. Not to my knowledge.
Q. And what do you mean by your panels are too broad for PCR?
A. The PCR panels I'm aware of tend to be much more like single biomarker or couple, so for a 500-plus gene panel I don't believe PCR is capable of doing that, of looking at that much genomic data at once.
Q. If you had to use PCR for your therapy selection test would that limit the capabilities of that test?
A. Yes.
Q. Do you have an idea of how many genes the PCR technology would allow that test to indicate for?
A. I don't.
Q. Has PGDx ever considered using any technology other than NGS for its therapy selection test?
A. No.
Q. Can PGDx use any other technology for its [redacted]?
A. [redacted]

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[redacted]

Q. When we were discussing PCR just a minute ago you mentioned biomarkers. Can you explain for me what biomarkers are?
A. Yes, sorry, I'm using terms interchangeably in a way I probably shouldn't.
I just mean the gene content and the genomic results that come out of our products are much broader than what you would use a PCR application for.
Q. Is a biomarker different than a gene mutation?
A. Not in the way I just used it, no. Probably somebody would correct me on that, but I use them interchangeably.
Q. So for your therapy selection tissue complete test it looks for 505 gene mutations or how you use biomarker interchangeably it would be 505 biomarkers, is that correct?
A. Right, yes.
Q. And how many biomarkers would PCR look for?
A. I don't know the answer to that, just that every application I've known on using PCR is much, much more limited and smaller in scope.
Q. But how you use biomarkers is the same as a gene mutation meaning?
A. Yes.
Q. In addition to PGDx's IVD agreement does PGDx have a separate supply agreement with Illumina?
A. Yes, we do. We have a supply agreement that more pertains to all of the materials that we purchased for our own use here in the research and development lab and the CAP/CLIA lab.
Q. So are the reagents that you purchased for your kitted test included in that supply agreement or is that governed by the IVD agreement?
A. The reagents we purchase for running everything here is governed by the supply agreement, not the IVD agreement.
Q. Can you describe the contracting process with Illumina for that supply agreement?
A. I wasn't involved in that at all. We have a -- somebody in our procurement team who led the negotiations around that contract. I don't know what that process looked like.

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Q. From your understanding of that negotiation process was it a back and forth negotiation on price?
A. I'm sure it was. I don't know how successful we were, but, yes, I'm sure there were price-related negotiations.
Q. And what type of leverage does PGDx have with Illumina in regards to pricing under the supply agreement?
A. I mean, typically a leverage point is volume because we are a significant size customer of theirs just based on the number of purchases we make to develop our products and to run our assays in-house, so I would presume volume of purchases and what that would mean in terms of total sales to Illumina was part of the discussion.
Q. And besides volume is there any other negotiation leverage that PGDx has with Illumina?
A. Not that I can think of.
Q. Can Illumina dictate terms of the supply agreement with PGDx?
A. It depends what you mean by dictate. I mean, I presume they will comply with the terms as they were agreed upon.
Again, I didn't -- I wasn't involved in

EXHIBIT B2

VERITEXT
LEGAL SOLUTIONS

Deposition of:

Megan Bailey

June 9, 2021

In the Matter of:

Illumina, Inc. and GRAIL, Inc. (In the Matter of)

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FEDERAL TRADE COMMISSION

In The Matter Of:	
FEDERAL TRADE COMMISSION	
	File No. 201-1044
and	Docket No. 9401
ILLUMINA/GRAIL INC.	

CONFIDENTIAL BUSINESS INFORMATION

Wednesday, June 9, 2021

Video Deposition of MEGAN BAILEY, taken virtually via Zoom, with the witness participating from 3600 Boston Street, Suite 10 Baltimore, Maryland, beginning at 9:33 a.m., before Ryan K. Black, a Registered Professional Reporter, Certified Livenote Reporter and Notary Public and for the Commonwealth of Pennsylvania.

consumables from Illumina. In the case of our products that are on market, the end lab customer purchases those straight from Illumina.

Q. So when PGDx was developing the Tissue Complete Test, you all bought Illumina sequencing consumables?

A. Yes.

Q. But now if a customer wants to run the test, they purchase the Illumina consumables themselves?

A. That's right.

Q. Is the Elio Tissue Complete Test FDA-cleared?

A. Yes.

Q. When was the FDA clearance process completed for the Tissue Complete Test?

A. April 24th, 2020.

Q. How much does the Elio Tissue Complete Test cost per patient?

A. Are you asking what it costs the laboratory to run it when we sell them the kit, the full cost to run it or the cost of the kit itself?

Q. The laboratory to run it. Let's -- let's start there.

A. So it does differ from lab to lab because of things like the sequencing costs from Illumina, which differ based on specific contracts that they might have. But I would estimate it to be in the range of [redacted] to [redacted] a test.

Q. And you made a distinction there of the cost. Why -- why did you make that distinction?

A. [redacted]

Q. And that second cost we were just speaking of, the -- the one that includes labor costs and sequencing costs, do you have a range of what that, typically, runs for -- for the Tissue Complete Test?

A. That's the one I gave. I would give in the range of [redacted] to [redacted].

Q. Okay. And how much is just the cost of the kit that you -- that you provide the lab?

A. Yeah. The kit costs per sample can range anywhere from [redacted] to [redacted] a sample.

Q. Okay. What is PGDx's costs of goods sold for the Tissue Complete Test?

A. May I ask if that's a question I should answer?

Q. You -- you can give -- you know, broad numbers if that -- round numbers if that's -- if that's more comfortable for you.

MS. WILBERFORCE: Objection. Can you just, kind of, in a --

MS. GASKIN: Yeah. What I'm getting at here is --

MS. WILBERFORCE: This is confidential.

MS. GASKIN: Right. What I'm getting at here, and maybe this will help if I provide a little context is, you -- you just mentioned that the test kit can run [redacted] to [redacted]. I'm just curious of how much Illumina products are -- make up that [redacted] to [redacted] price. I'm just -- I'm trying to get a range of how -- how much costs of goods sold Illumina products make up. So I was going to start with, you know, what is the costs

of goods sold and then work my way to the percentage that Illumina makes up, if that's helpful.

MS. WILBERFORCE: Objection. Can you now just ask a, kind of, clear question for her?

MS. GASKIN: No problem.

BY MS. GASKIN:

Q. Ms. Bailey, what percentage of Illumina -- or PGDx's costs of goods sold for the Tissue Complete Test derive from Illumina products?

A. [redacted]

Q. You mentioned that you have three kits.

Page 22

Just talking about the Tissue Complete Test that is run in your CLIA lab, what are the approximate percentages of costs of goods sold that relate to the Illumina products?

A. Yeah. That would be the lowest of the three, because that would get [redacted] samples per flow cell, and I believe it's around [redacted] to [redacted] percent, then, of the total cost would be sequencing.

Q. And for PGDx's Plasma Resolve Test, what are the costs of goods sold percentages for the Illumina products?

A. Yeah. That would be the higher-range one. That one has -- we can get [redacted] samples per flow cell through, so that one -- I'll have to come back to you on the -- on the cost, but that one's more at the [redacted] percent.

Q. And why -- why is there a difference in -- in the percentage for the plasma compared to the tissue?

A. [redacted]

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[redacted]

Q. And do you have to run deeper sequencing because of the DNA sample or -- or why do you have to sequence deeper?

A. [redacted]

Q. For the Plasma Resolve Test, which NGS sequencer are you running that on?

A. The same, the Illumina NextSeq platform.

Q. How does deeper sequencing help ensure that you find the mutation you're looking for?

A. [redacted] t

Q. Going back to discussing the Tissue Complete Test, does PGDx have plans to lower the

Page 24

cost of the Tissue Complete Test in the future?

MS. WILBERFORCE: Objection.

BY MS. GASKIN:

Q. Go ahead. You can -- you can answer if you know the -- if you know the answer.

A. [redacted]

Q. Who, primarily, orders the Tissue Complete Test?

A. [redacted]

Q. In terms of is it oncologists that are ordering the tests, or is it family practitioners? I just wanted to get a sense.

A. [redacted]

Q. Can the Elio Tissue Complete Test

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indicate for [redacted]?

A. [redacted]

Q. If I abbreviate [redacted], will you understand what I mean?

A. [redacted]

Q. What is the importance of testing for [redacted]?

A. [redacted]

Q. And what are [redacted] therapies?

A. [redacted]

Q. What are [redacted]?

A. It's another term [redacted]

Q. Would a therapy selection test be at a [redacted]?

MR. JOHNSON: Object to form.

BY MS. GASKIN:

Q. Go ahead. You can answer, if -- if you know.

A. [redacted]

roadmap to Illumina impact PGDx?
MR. JOHNSON: Object to form.
THE WITNESS: Unclear. I think it would depend on competitive content or aspirations they had that may overlap with what we were doing.
BY MS. GASKIN:
Q. Does PGDx hold any [redacted]?
A. [redacted].
Q. Can you briefly describe, at a high level, what that IP is?
A. Yeah. [redacted]
Q. What do you mean by "exclusive IP"?
A. I'll probably leave it at that.
Q. Okay. Are you aware of any other companies that have IP dealing with [redacted]?
A. I do believe there are some patents within the Illumina patent portfolio that relate to [redacted], but I don't know the specifics.
Q. What financial contributions does

PGDx have to pay Illumina under the current IVD agreement?
A. The structure of it is there's a tech access fee. Then there are -- or is a fee specific to each IVD kit, and then there's a revenue-share component when the product is on market.
Q. You mentioned a "tech access fee." What is the value of that fee?
A. I think we declined to disclose the specifics last time, so I'd prefer to do that, as well.
Q. Is the value of the tech access fee in the low seven figures?
A. Yes.
Q. And was this a one-time payment?
A. The tech access fee is a one-time payment for up to three IVD kits specific to the NextSeq platform. So additional kits or additional platforms would require an addendum likely with additional fees. But up to three kits on the NextSeq, and so it's a one-time tech access fee.
Q. Is there a milestone payment for access to Illumina technology?

A. The tech access fee itself was split into three milestone payments, at least under our structure, based on how the development process with the LRM module, or specific dates, whichever came sooner, happened, but they were all part of the tech access fee I described.
Q. And those milestone payments added up to this [redacted] amount?
A. Yes.
Q. You also mentioned fees specific to each test kit. Are those different from the milestone payments?
A. Yes.
Q. How are those different?
A. So this is new with the addendum that we just recently signed that I mentioned at the beginning. Previously, there were specific fees for any companion diagnostic claim added, and a specific fee for [redacted]. Those are no longer in the updated agreement, but there is a specific fee for each IVD kit of the three as they're added.
Q. Why was this change made?
A. This was related to the open letter that was put out by Illumina, and Scott led discussions and negotiations on our side to

convert under that framework versus some of the parameters of the initial agreement we signed last November.
Q. Did PGDx initiate these discussions with Illumina?
A. To my knowledge, yes.
Q. To the best of your knowledge, why was the [redacted] you just re -- referred to taken out of the agreement?
A. I don't know.
Q. Prior to your investigational hearing on March 2nd, had you tried to get an addendum such as the one you just described with Illumina?
A. We had not tried to get an addendum. We had tried to negotiate the [redacted], specifically, because the current product that we are converting under the [redacted].
Q. And no -- no agreement was entered into between Illumina and PGDx for this fee?
A. No, none prior to converting under the new amendment.
Q. So it was only after your investigational hearing when we discussed this fee that an agreement was made between PGDx and Illumina?

A. Yes.
Q. In your investigational hearing you mentioned that there were fees associated with specific claims that the PGDx Tissue Complete Test could make. What specific claims were those?
A. There was the fee specific to TMB, and then there was a fee for any companion diagnostic claim. So it didn't designate on what specific variant, just anything that achieved a companion diagnostic-level claim there had previously been a separate fee for.
Q. So previous to this addendum, PGDx had to pay a fee anytime its Tissue Complete Test indicated for [redacted]?
A. [redacted]
Q. And how much was that up-front payment, and you -- you can do generalities, as well.
A. Yeah. Close to [redacted].
Q. How much did PGDx pay for this new addendum which took out this up-front [redacted]

payment?
A. Can you repeat the question?
Q. Yes. Of course.
How much did PGDx pay Illumina for this new addendum to the agreement which took out the up-front [redacted] fee?
A. Yeah. We haven't paid anything additional yet under the new amendment. There will be fees per kit to pay, but we had already paid the tech access fee, so nothing additional was paid upon signature, to my knowledge.
Q. You mentioned that the up-front [redacted] fee was mid-seven figures. How much is the fee specific for each kit?
A. Lower than that. So this -- the terms were more favorable under the new amendment.
Q. Did it have a -- a range of what the decrease was?
A. Yeah. A little less than a third per kit versus the previous [redacted] fee.
MS. GASKIN: Looks like we've been going for another hour, let -- let's take a 10-minute break.
Can we go off the record?
THE VIDEOGRAPHER: Yes, ma'am.

Off the record at 11:31 a m.
(Recess taken.)
THE VIDEOGRAPHER: This is the beginning of Media Unit Number 2. We are back on the video record at 11:42 a m.
BY MS. GASKIN:
Q. Ms. Bailey, welcome back from our short break there.
Even though there's no [redacted] fee anymore, under the IVD agreement is the Tissue Complete Test still allowed to indicate for [redacted]?
A. Yes.
Q. What is your understanding of why Illumina changed its position relating to the [redacted] fee?
A. I don't know the answer to that.
Q. What leverage did PGDx use to eliminate the [redacted] fee with Illumina?
A. Just review of the open letter partnership document and, in cases like that, more favorable terms we saw.
Q. This open offer letter is -- is the one on Illumina's website; is that correct?
A. Yes.
Q. Prior to this new addendum, had PGDx

paid any of the [redacted] fee to Illumina?
A. No.
Q. Going back to the open offer letter for a minute, PGDx used the open offer letter to eliminate the [redacted] fee; is that correct?
A. Yes.
Q. Were you involved in -- in those discussions?
A. Not directly with Illumina. Only internally.
Q. Who at PGDx was involved in those discussions?
A. Scott Gotshall.
Q. Were you made aware of what Mr. Gotshall told Illumina?
MS. WILBERFORCE: Objection. That's privileged.
BY MS. GASKIN:
Q. I'm only asking what Mr. Gotshall told Illumina, not any counsel he might -- might have provided to you personally or to PGDx.
A. [redacted]

[redacted], and that initiated discussions around the fee as it was originally stated in the IVD agreement. And when we saw that that same fee wasn't in the open letter, that prompted the discussion so that we could take the path forward with this production reporting [redacted] without the fee.

Q. When PGDx and Illumina signed the IVD agreement in November of 2020, did PGDx tell Illumina that the tissue test could call for [redacted]?

A. Yes. And the test was already cleared at that time, so that information was public.

Q. I'm going to direct your attention back to PX7049, Page 123, which is located at PX7049-032.

A. Okay.

Q. Do you see Page 123?

A. I do.

Q. Starting at Line 22, I asked Question: "And do you have an idea of why they require this reporting fee for [redacted]?"

Answer: "[redacted]

[redacted]

Was this answer accurate when you made it?

A. Yes.

Q. Is this answer accurate today?

A. Yes.

Q. This "them" that you're referring to, is that Illumina?

A. Yes.

Q. How would this fee position Illumina favorably with pharma for clinical trials associated with [redacted]?

MR. JOHNSON: I'll object to form.

THE WITNESS: [redacted]

BY MS. GASKIN:

Q. [redacted]

agreement"?

I'm just -- I'm a little confused.

A. So if we had signed -- under the old agreement, if we had signed a companion diagnostic partnership agreement for a [redacted] and reporting [redacted], that sizable fee associated with it would have either been factored into how we priced the deal or funding it directly through other sources by PGDx.

Q. Continuing on IH transcript Page 124, Line 4, I asked, Question: "And who con -- conveyed this to you?"

Answer: "This was through the decisions in the negotiation which, ultimately, was under [redacted]

Was this answer accurate when you made it?

A. Yes.

MR. JOHNSON: I object to the -- I think there was a misreading there.

BY MS. GASKIN:

Q. I can re-read your answer. On Line 5, Page 124 you answered: "This was through the discussions in the negotiation which ultimately

was under [redacted]

Did I read that accurately?

A. Yes.

Q. Continuing on, Line 8, Page 124, I asked, Question: "And what is the dollar amount range for this clinical reporting fee for [redacted]

Answer: "[redacted]."

Is this the -- the testimony you also provided today?

A. Yes. I think I -- today I said just under [redacted], but, yes.

Q. Turning to Page 152 in the IH -- IH transcript, which is on PX7049-039 --

Are you -- are you at Page 152?

A. Yes, I am.

Q. -- starting on Line 15 I asked, Question: [redacted]

Answer: "Yeah. As the agreement is written today. I mean, this is something we have been discussing. It does seem incongruent, but we have not yet enforced anything around that

Q. How did the financial terms of PGDx's IVD agreement with Illumina impact the profitability of PGDx's tissue test?

A. There's a revenue share component of the agreement, so there is a percentage of all net sales that will go to Illumina.

Q. How does that revenue share percentage impact the profitability of PGDx's tissue test?

A. Well, it, essentially, takes that percentage out of the margin that would otherwise come to the company.

Q. So is it accurate to say the IVD agreement with Illumina makes the tissue test less profitable?

A. Yes, versus if we didn't have a revenue share component.

Q. Approximately what percentage of a revenue share is agreed to under the IVD codevelopment agreement?

A. Just above [redacted].

Q. Does this lower profitability take funds away from the research and development efforts PGDx will explore?

A. Broadly speaking, all of the revenue generated by the business and external sources of

financing are what fund research and development, so the higher the profitability of any given test the more money there is to reinvest in areas of the business including research and development.

Q. So because the tissue test is less profitable, less funds are going towards research and development; --

MR. JOHNSON: Object to form.

BY MS. GASKIN:

Q. -- is that correct?

MR. JOHNSON: Sorry. Object to form.

THE WITNESS: Yeah. I'd rather not answer it in any more detail.

BY MS. GASKIN:

Q. I'd like to turn your attention back to PX7049 IH transcript Page 128, which is located on PX7049-033.

Let me know when you've -- when you've made it there.

A. You said 128, right?

Q. Yes. That's correct.

A. Okay.

Q. On Page 128, Line 24, I asked, Question: "Does this lower profitability take funds away from the research and development

efforts PGDx will explore?"

Answer: [redacted]

Was your statement accurate when you made it?

A. Yes.

MR. JOHNSON: Object to form.

BY MS. GASKIN:

Q. Is your statement accurate today?

A. Yes. I think that's consistent with how I just answered it.

MS. GASKIN: If we can go off the record?

THE VIDEOGRAPHER: All right. One second.

Off the record at 12:05 p.m.

(Lunch Recess taken.)

THE VIDEOGRAPHER: Back on the record at 12:37 p m.

BY MS. GASKIN:

Q. Ms. Bailey, welcome back from our lunch break.

In regards to our discussion of PGDx's pharma partnerships, has PGDx ever discussed a pharma partnership with [redacted]?

A. Yes.

Q. And when was that?

A. We've had ongoing discussions with [redacted]

Q. To the best of your knowledge, when did PG -- PGDx start discussions with [redacted] in regards to a pharma partnership?

A. Certainly as early as 2017. I don't know before that.

Q. Does PGDx currently have a pharma partnership with [redacted]?

A. We have ongoing discussions with them. To my knowledge, we don't have any active contracts with them.

Q. What is your understanding of why there's no active contract with [redacted]?

A. I don't think I could answer that.
Q. And why is that?
A. Just I don't have full context on different opportunities in discussion and where they are in timeline to decision or what the factors are. I'm not directly involved in those.
Q. Who at PGDx is involved in discussions with [redacted]?
A. Our business development director, Roger Bowman, and he reports to our head of commercial, Chris Hauck.
Q. To the best of your knowledge, does Illumina have a pharma partnership with [redacted]?
A. Yes.
Q. And how are you aware of Illumina's partnership with [redacted]?
A. At least part of it was publicly announced.
Q. To the best of your knowledge, is that partnership for Illumina's TSO500 test?
A. Yes.
MS. GASKIN: Okay. Great. I will reserve the -- the remainder of my time for rebuttal, and the defendants can -- can now start their questioning, or if you need to go off the

record, David?
MR. JOHNSON: Great. Thank you very much, Lauren. And good afternoon, Ms. Bailey. My name is David Johnson, and I represent GRAIL. And I'll just be asking you some questions this afternoon, as well.
I just wanted to make sure the court reporter just switches over the time for the questioning since we both have time limits, but I'll go ahead and jump in.
EXAMINATION
BY MR. JOHNSON:
Q. I wanted to return back to some of the questioning about the [redacted] reporting fee that you were speaking with Ms. Gaskin about. I just want to make sure I have everything clear on that so I'm just going to run through it here.
So in November of 2020, PGDx entered into an IVD codevelopment agreement with Illumina; is that right?
A. Yes.
Q. And that agreement contained a fee for [redacted] reporting; is that right?
A. Yes.
Q. And then in June of 2021, PGDx entered

into an amendment to that agreement with Illumina; is that right?
A. Yes.
Q. And the amendment does not contain that [redacted] reporting; is that right?
A. That's correct.
Q. And your understanding is that the amendment is more favorable to PGDx than the original IVD agreement was?
MS. GASKIN: Objection; form.
THE WITNESS: Yes.
BY MR. JOHNSON:
Q. Sorry. I missed that answer.
A. Yes.
Q. You talked about the Illumina open offer. Do you recall that?
A. Yes.
Q. And is your -- when you were referring to the open offer, what were -- were you referring to?
A. The fees and the parameters around what there would be fees for when we saw and we reviewed that, some of which were different and more favorable than the agreement that we had signed at that time.

Q. So you're talking about the open offer on Illumina's website that Illumina made available in connection with its proposed acquisition of GRAIL?
A. Yes.
Q. So PGDx looked at the terms of that open offer and used those terms to improve its own agreement with Illumina; is that right?
A. Yes.
Q. Other than the removal of the [redacted] reporting fee, were there other elements of the open offer that you incorporated into the June 4th, 2021, amendment?
A. The other one that I'm aware of was the removal of the companion diagnostic fees. Then there was an incremental fee that was not in our agreement that was in the open letter for a fee per each kit. But the net-net was still an improvement, and so we moved in that direction.
Q. So the net financial effect of the amendment was more -- was beneficial to PGDx?
A. Yes.
Q. Was there also a firewall provision that was added in the amended agreement?
A. I don't know.

A. Potentially in the future. We don't have any active programs around it, but we're always looking at opportunities to expand impact on how cancer is managed.
Q. So you're monitoring the market, generally, but you haven't taken any steps towards developing a multi-cancer early detection test?
A. Correct.
Q. So safe to say by 2026 you won't have a multi-cancer early detection test commercially available?
MS. GASKIN: Objection; form.
MS. WILBERFORCE: Asked and answered.
MS. GASKIN: Objection; form and speculation.
BY MR. JOHNSON:
Q. You can answer.
A. Yeah. I can't speculate on timing.
Q. If you were going to have a early multi-cancer early detection test available by 2026, would you need have to have plans in place today to do that?
MS. GASKIN: Objection; form.
BY MR. JOHNSON:

Q. You can answer.
A. Not necessarily. I would say some of the core capabilities of the company could be leveraged to move into adjacent areas of the market.
Q. PGDx does not currently have any multi-cancer early detection test on any type of clinical path?
MS. WILBERFORCE: Objection; form.
MS. GASKIN: Objection. Asked and answered.
BY MR. JOHNSON:
Q. I'm sorry. Did you say no to that?
A. I'm sorry. Can you repeat how you framed the question so I make sure I remember if it was a yes or no?
Q. Certainly.
Does PGDx currently have any multi-cancer early detection tests on a clinical path?
A. No.
Q. Does PGDx currently have any singer -- single-cancer early detection tests on a clinical path?
A. No.

MS. GASKIN: Objection; form.
BY MR. JOHNSON:
Q. Does PGDx currently have plans to develop a single-cancer early detection test?
MS. GASKIN: Objection; form.
THE WITNESS: Yeah. Same answer as I gave previously on multi-cancer detection.
BY MR. JOHNSON:
Q. So that answer was that PGDx does not have any such plans?
A. That we are always evaluating the market landscape and opportunities to broaden impact to cancer care, but we don't have any active programs around it.
Q. Are you familiar with the phrase MRD test?
A. Yes.
Q. And do you understand that to mean Minimal Residual Disease test?
A. Yes.
Q. Okay. And does PGDx currently offer an MRD product?
A. [redacted]
Q. [redacted]

[redacted]
A. [redacted]
[redacted]
Q. [redacted]
A. [redacted]
[redacted]
Q. [redacted]
[redacted]
A. [redacted]
[redacted]
Q. [redacted]
A. [redacted]
[redacted]
Q. [redacted]
MS. WILBERFORCE: Objection. Asked and answered.
BY MR. JOHNSON:
Q. You can answer.
A. [redacted]
[redacted]
Q. [redacted]
[redacted]
A. [redacted]
[redacted]

[redacted]

Q. Now, previously you testified during your IH that PGDx does not have an [redacted] assay on a clinical path or path through the FDA at this time. Is that still true?

MS. GASKIN: Objection. Misstates evidence.

THE WITNESS: Yeah. I was referring to that as not having a routine clinical test or an established companion program to take that product through the FDA at this time.

BY MR. JOHNSON:

Q. You do not have those things at this time?

A. Correct.

Q. And at the time of your investigational hearing you said it was not yet clear that PGD -- PGDx will [redacted].

MS. GASKIN: Objection.

BY MR. JOHNSON:

Q. Is that still true?

MS. GASKIN: Objection; form.

THE WITNESS: [redacted]

[redacted]

BY MR. JOHNSON:

Q. So the path -- path forward clinically to that product depends on the results of the trial that's currently underway?

A. Yes. At this time.

MS. GASKIN: Objection; form.

THE REPORTER: I'm sorry. Can you repeat your answer? I didn't hear that.

THE WITNESS: Yes. At this time it is dependent on that.

BY MR. JOHNSON:

Q. Ms. Bailey, earlier you were asked some questions about the sequencers that PGDx's tests run on. Do you remember that?

A. Yes.

Q. I believe you said that PGDx, its tests run on the Illumina NextSeq sequencer; is that right?

A. That's right. For Elio Tissue Complete and Elio Plasma Resolve, which are the ones I was asked about. Elio Plasma Complete is run on the NovaSeq platform.

Q. Thank you for that clarification.

In 2018 did PGDx consider running its

Elio Tissue Complete assay on a different sequencer?

A. Yes. We did have a pilot program on the Thermo platform.

Q. The purpose of that pilot program, was it to assess the feasibility of the performing the Elio Tissue Complete assay on Thermo's S5 sequencer?

A. Yes.

MS. GASKIN: Objection to form.

BY MR. JOHNSON:

Q. Was the result of that feasibility assessment that Elio Tissue Complete could be performed on Thermo's S5 platform?

MS. GASKIN: Objection; form.

THE WITNESS: The assessment for us was the combination of performance, throughput, cost and install base that we could access for the distributed solution.

During the pilot, there were portions of the test that performed well on the Thermo platform, there were other portions that did not,

[redacted]

[redacted]

BY MR. JOHNSON:

Q. So is it fair to say that the

[redacted]

MS. GASKIN: Objection; form and foundation.

BY MR. JOHNSON:

Q. You can answer.

A. [redacted]

MR. JOHNSON: Okay. I'd like to take a look at a document, if we can.

Marcus, could we mark Tab 6 as Exhibit 1?

(Exhibit No. 1, a document Bates Numbered PGDX_00018805 thorough PGDX_00018813 was introduced electronically.)

BY MR. JOHNSON:

Q. And please just let me know when the document is available on your screen. I don't have it up yet.
A. Should it be in the same folder as the previous one we were looking at?
Q. It should be uploading now.
Okay. I -- I have it on my screen. Are you able to access it?
A. Looks like it just came up. Is it titled Exhibit 1, 2020.06.29?
Q. Yes. That's it.
A. Okay. Yes, I have it.
Q. Okay. For the record, this is a document with Bates stamp PGDX_00018805. Ms. Bailey, could you turn to the second page in this e-mail chain, and there's an e-mail from you there to two people, Samuel Angiuoli and Rami Zahr.
Do you see that?
A. I do.
Q. Who are the individuals that you sent this e-mail to, and what are their --
A. Sam Ang --
Q. Sorry. What are their positions at PGDx?

A. Sam Angiuoli is the Chief Informatics Officer, and Rami Zahr is the Director of Product Strategy.
Q. And what are you asking them to do in this e-mail?
A. I have to scroll down.
Yes, this was specific to discussions with Oncocyte, whose strategy is all around a testing portfolio for immuno-oncology therapy. So they had interest specifically around [redacted] and preferred for a test to be optimized on the Thermo platform and had asked to see data from that. And our [redacted] data during that pilot was, actually, quite good, and that's what we were putting together here to share with them.
Q. And in the -- in your e-mail, there is a Number 1 where you write, "[redacted]
Is that right?
A. Yep. That's right.
Q. So is that your understanding, that it's clear the product could be adapted to another platform?

A. Yeah. I think it depends where the focus is, because the product is broad in nature, in both the number of genes and the types of variants that it reports. [redacted]
Q. It could be adopted across platforms; is that right?
A. [redacted]
Q. At the top e-mail, there's a response from Rami, and in the third sentence he says, [redacted] so we wanted to sell it as much as possible."
Is that consistent with your understanding, as well?
MS. GASKIN: Objection; form.
THE WITNESS: [redacted]
BY MR. JOHNSON:
Q. The initial feasibility assessment that you did of the Thermo S5 platform, how long did that last?

MS. GASKIN: Objection; form and foundation.
THE WITNESS: Yeah. I actually can't answer that accurately because it was initiated before I arrived at the company.
BY MR. JOHNSON:
Q. Do you know if it was completed?
A. The pilot was completed, but I don't know what the scope of that was in terms of the time or studies.
Q. Is it your understanding that some of the performance limitations identified in the feasibility study could have been corrected through additional study?
MS. GASKIN: Objection; form, speculation.
THE WITNESS: Yeah. I'm --
BY MR. JOHNSON:
Q. You can answer if you can.
A. Yeah. I -- I can't answer that sufficiently. I would have to defer to the technical leaders on that.
Q. Okay. Could we turn to your investigative hearing transcript, and if we could go to Page 46, please?

MS. WILBERFORCE: Do you mean 46 of the hearing pages or of the PDF?

MR. JOHNSON: Forty-six of the minuscript pages, the hearing transcript, so the small number in the up -- upper right of the four pages.

MS. WILBERFORCE: Okay.

MR. JOHNSON: The Bates Number ends in 013.

BY MR. JOHNSON:

Q. Do you have Page 46 up, Ms. Bailey?

A. I do.

Q. So I'm looking at the question and answer that begins on Line 11 where the questioning -- question is: "And how would using [redacted]

[redacted]

Did I read that right?

A. Yes.

Q. So is it your testimony that, if taken through a more complete validation process, there's [redacted]

MS. GASKIN: Objection; form and foundation.

THE WITNESS: It's possible.

BY MR. JOHNSON:

Q. You can answer.

A. I don't know, because we didn't progress beyond the pilot plan.

Q. Your assessment of the Thermo S5 platform stopped at that initial pilot?

A. Yes.

Q. Would you agree that, technically, it is feasible to switch the platforms that the Elio Tissue Complete Test runs on?

MS. GASKIN: Objection; form and

foundation.

THE WITNESS: I would answer that in [redacted]

BY MR. JOHNSON:

Q. So it was technically feasible to switch platforms?

MS. GASKIN: Objection; form.

THE WITNESS: There were some limitations in areas that were important to us.

BY MR. JOHNSON:

Q. Has PGDx been in communications with any other sequencing developers -- sequencing platform developers about performing a pilot on their sequencer?

A. We haven't initiated pilots with anybody else, but we're always looking at the

market landscape of other options, and we have had conversations with other platform manufacturers, none of which have given us any options today.

Q. Which platform manufacturers did -- have you had conversations with?

A. Just recently?

MR. GOTSHALL: Objection. Confidentiality concerns.

MR. JOHNSON: Thank you, Counsel. I do appreciate the need for confidentiality, and I'm happy to designate the entirety of the transcript, or at least portions that you'd prefer, with the highest level of confidentiality. And we do have a protective order in this -- in this case, and that is sufficient to cover the confidentiality concerns. But we do have to go into alternative sequencers that PGDx has considered or been in communications with. It's critical to this case.

BY MR. JOHNSON:

Q. So, Ms. Bailey, you can answer.

A. [redacted].

[redacted],
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]

Q. But which sequencing platform companies have you spoken with?

A. [redacted] Those are the most recent couple, at least that I've been made aware of.

Q. Okay. I'd like to talk about the process by which PGDx obtained FDA clearance For the Elio Tissue Complete product, and that product that you already mentioned is run on the Illumina NextSeq platform; is that right?

A. That's right. Specifically -- I -- I should clarify, specifically for the NextSeq DX platform is the on-label instrument for that clearance.

Q. And PGDx currently has FDA clearance to sell the Elio Tissue Complete product as a distributed the IVD test; is that right?

A. Yes.

Q. And Illumina did not participate in your application to the FDA to obtain that clearance; is that right?

MS. GASKIN: Objection; form.

BY MR. JOHNSON:

Q. PGDx did not have a IVD codevelopment agreement with Illumina at the time PGDx submitted its application?

A. Correct.

Q. And PGDx, ultimately, obtained FDA clearance without an IVD agreement being complete in place with Illumina; is that right?

MS. GASKIN: Objection; form.

THE WITNESS: That's right.

BY MR. JOHNSON:

Q. Did Illumina provide any data to the FDA in connection with PGDx's application specifically?

MS. GASKIN: Objection; form.

THE WITNESS: Not to my knowledge.

BY MR. JOHNSON:

Q. Was Illumina involved in any way in PGDx's application to the FDA for 510(k) clearance for ability to issue a complete product?

MS. GASKIN: Objection; form.

THE WITNESS: No.

BY MR. JOHNSON:

Q. So Illumina did not have to grant PGDx approval to seek FDA clearance to use an Illumina sequencer as part of the PGDx's distributed IVD kit and test; is that right?

MS. GASKIN: Objection; form.

THE WITNESS: That's correct for the path we took through, which did require setting a new policy and precedent with the FDA.

BY MR. JOHNSON:

Q. Yeah. And I'd like to talk about that a bit. During your investigative hearing, you mentioned some internal capabilities at PGDx that facilitated that path through the FDA. Do you recall that?

A. Can you be a bit more specific?

Q. Sure.

Let me -- let me go this way:

Who is -- who oversaw the application -- PGDx's application for 510(k) clearance before the FDA?

A. Jennifer Dickey, our Vice President of Quality and Regulatory.

Q. Ms. Dickey, she previously worked for

the FDA; is that correct?

A. That's correct.

Q. And she had some experience working on IVD applications while at the FDA?

A. That's correct.

Q. Do you consider her experience to have helped facilitate PGDx finding a path through the FDA that did not require a codevelopment agreement?

MS. GASKIN: Objection; form.

THE WITNESS: Yes.

BY MR. JOHNSON:

Q. Would you consider PGDx's internal expertise at obtaining FDA clearance to be an advantage when seeking FDA clearance?

MS. GASKIN: Objection; form.

THE WITNESS: Yes, I do.

BY MR. JOHNSON:

Q. Do you think that Ms. Dickey's experience helped accelerate PGDx's application before the FDA?

MS. WILBERFORCE: Objection; form.

BY MR. JOHNSON:

Q. You can answer.

A. By accelerate, do you mean in terms of

the actual time of submission and review?
Q. Yes. That's what I mean.
A. No, I do not.
Q. What about to the completion of the review?
MS. GASKIN: Objection; form.
THE WITNESS: No. The -- the time taken for review was the standard amount of time. We received a deficiency letter, but that was done in the standard amount of time. And I actually delivered the clearance at 11:57 p.m. the day the deadline was due, so it followed the timeline.
BY MR. JOHNSON:
Q. Were there some communications between PGDx employees and the FDA prior to the formal submission?
MS. GASKIN: Objection; form. Foundation.
THE WITNESS: I'm not sure I understand your question.
Communication between our regulatory team and the FDA prior to submission?
BY MR. JOHNSON:
Q. Yes.

A. Yes. Through formal pre-submission letters and meetings that are opportunities for any company to take advantage of in getting early feedback from the FDA, we did have those things.
Q. Would you say that Ms. Dickey's experience contributed to PGDx developing this alternative route to obtain FDA approval?
MS. GASKIN: Objection; form --
THE WITNESS: That's --
MS. GASKIN: -- and speculation.
BY MR. JOHNSON:
Q. You can answer.
A. Yes.
Q. How many employees does PGDx have on its regulatory team?
A. Today just one. At the time, there was an additional team member.
Q. And that one is just Ms. Dickey?
A. That's right.
Q. But when the application was submitted there was -- there were two employees?
A. Yes.
Q. Do you believe that PGDx's experience working through that alternative route to obtaining FDA clearance will make it easier for

PGDx to pursue the same route in the future?
MS. GASKIN: Objection; form. Speculation.
THE WITNESS: [redacted]
BY MR. JOHNSON:
Q. So setting aside the IVD agreement, now that you have been through that process once, you have the internal knowledge on how to complete it. Is that fair to say?
MS. GASKIN: Objection; form.
THE WITNESS: [redacted]
BY MR. JOHNSON:
Q. Of course not. And that's -- and I understand that. What I'm asking here is, now that PGDx has developed that route, it would be easier to follow that route in the future, setting aside the existence of the IVD agreement?
MS. WILBERFORCE: Objection; form.
THE WITNESS: In terms of know-how, yes.

BY MR. JOHNSON:
Q. PGDx has set a type of precedent on how a company could progress through the FDA without an IVD codevelopment agreement?
MS. GASKIN: Objection; form. Speculation.
THE WITNESS: [redacted]
BY MR. JOHNSON:
Q. Sorry. Just checking to see if I got that answer.
Okay. Got it.
Is the route that PGDx used to obtain FDA clearance without a codevelopment agreement something that other companies could pursue as well?
MS. GASKIN: Objection; form. Speculation.
THE WITNESS: [redacted]
BY MR. JOHNSON:
Q. You don't think the FDA made an exception or created a path specifically for PGDx

only to follow, right?
MS. GASKIN: Objection; form. Speculation.
MR. JOHNSON: I'm just seeing if the court reporter got that answer. I think there was some cross-talk.
THE REPORTER: I didn't hear an answer.
MR. JOHNSON: Okay. It doesn't look -- okay. So the answer didn't get recorded, so let me just ask it again.
BY MR. JOHNSON:
Q. But you don't think that the FDA created a path that would only allow PGDx to obtain clearance without a codevelopment agreement, right?
A. Right.
MS. GASKIN: Same objection.
MR. JOHNSON: I think we got it that time. Maybe it would help if you paused a minute before your -- a second before your answer so that we can get the objections in. It's just really hard with the online court reporting because he can't record us both at once.
I'd like to look at an exhibit now,

Marcus, if we could mark Tab 7 as Exhibit 2.
(Exhibit No. 2, a document Bates Numbered PGDX_00018797 through PGDX_00018800, was introduced electronically.)
BY MR. JOHNSON:
Q. Ms. Bailey, are you able to see the Exhibit 2?
A. Yes, I am.
Q. Okay. For the record, this is Bates stamped PGDX_00018797.
Ms. Bailey, have you seen this e-mail before?
A. Just a moment. I'm looking at it now.
MS. GASKIN: Yeah. One second. It's still load -- there it goes.
Sorry for the interruption.
THE WITNESS: Yes, I am.
BY MR. JOHNSON:
Q. In the bottommost e-mail in this chain, what are you requesting in this e-mail?
A. [redacted]
Q. And then Ms. Dickey responds to you on June 29th, 2020, with the, kind of, numbered and

bulleted list; is that right?
A. Yes.
Q. And so that's the path of how PGDx obtained FDA approval that you requested that she lay out?
A. Yes.
Q. If you'll go to the last page in her bulleted list with the Bates Number ending in 799, and looking at the page with the bullet point, the first one begins with the text, [redacted]
Do you see that page?
A. Not yet. Sorry. One moment.
Yes.
Q. Okay. So in the top bullet point in Ms. Dickey's list on this page it says, [redacted]
Do you see that?
A. Yes.
Q. What did you understand Ms. Dickey's

comment to be here -- to mean?
A. [redacted]
Q. For other test-developers to follow?
A. [redacted]
Q. And the next bullet point says, [redacted]
Do you see that?
A. [redacted]
Q. What do you understand that to mean?
A. [redacted]
I do want to note that this exchange was prior to entering the agreement within Illumina within which we committed not to take this path forward with other Elio assays.
Q. Understood. Thank you.
And third bullet point says, [redacted]

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[redacted]
[redacted]
Do you see that?
A. I do.
Q. What do you understand that to mean?
A. I don't actually know what that one means.
Q. Okay. And then looking down at the second-to-last bullet point, it says, [redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
MS. GASKIN: Objection; form.
THE WITNESS: [redacted]
BY MR. JOHNSON:
Q. Okay. We can virtually set that exhibit aside.
You were asked some questions earlier today about PGDx's negotiation with Illumina to obtain an IVD agreement back in 2017; is that right?
A. Yes.
Q. And at that point you were not an

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employee of PGDx, right?
A. That's correct.
Q. At that time you were working for Roche?
A. That's right.
Q. And you joined PGDx in March of 2018; is that right?
A. Yes.
Q. So during PGDx's initial negotiation with Illumina about an IVD agreement, you didn't participate in that negotiation at all, did you?
A. No.
Q. You never had any direct communications with any Illumina employee about an IVD agreement at that time, right?
A. Right.
Q. So anything that you would know about what was said or what happened during those discussions would have reached you secondhand, right?
MS. GASKIN: Objection; form.
THE WITNESS: That's right.
BY MR. JOHNSON:
Q. Make sure we got that in the record.
A. That's right.

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Q. Thank you.
Earlier today I believe you testified that Illumina was unwilling to enter an IVD agreement. Is that what you said?
MS. GASKIN: Objection; form.
MS. WILBERFORCE: Can you clarify the time period?
MR. JOHNSON: Yeah. Let me -- let me clarify the question.
BY MR. JOHNSON:
Q. So I'm still asking you about the initial IVD negotiations between Illumina and PGDx in 2017 and I believe, potentially, into 2018. Do you understand that?
A. Yes.
Q. Did you testify earlier that Illumina was unwilling to enter into an IVD agreement at that time?
A. Yes. That was my understanding.
Q. But your testimony isn't that Illumina refused to enter into any IVD agreement with PGDx, is it?
MS. GASKIN: Objection; form.
Misstates witness's testimony.
BY MR. JOHNSON:

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Q. You can answer.
A. I was answering that specific to the Elio Tissue Complete product on the NextSeq platform.
Q. And that's what I'm asking about now. So are you -- is -- is it your understanding that Illumina refused to enter into any form of IVD agreement with PGDx for the Elio Tissue Complete on the Illumina NextSeq platform?
MS. GASKIN: Objection; form.
THE WITNESS: Yes. That was my understanding.
BY MR. JOHNSON:
Q. But you don't think that there was -- let me strike that. Let me rephrase.
Is it your understanding that there were IVD agreements exchanged between Illumina and PGDx at that time?
MS. GASKIN: Objection; form.
THE WITNESS: Yeah. I don't know the level of information or contract exchange that happened at that time.
BY MR. JOHNSON:
Q. Well, who approached whom for a IVD agreement back in 2017?

A. And I --
MS. GASKIN: Objection; form.
MS. WILBERFORCE: Objection. Asked and answered.
BY MR. JOHNSON:
Q. You could answer.
A. Yeah. I don't know the answer. I don't know the specifics on the discussions or negotiations. As you stated, that was before I joined the company.
Q. So you don't know if it was PGDx that asked for an IVD agreement from Illumina, or if it was Illumina that asked PGDx if they wanted an IVD agreement?
MS. GASKIN: Objection; form.
MS. WILBERFORCE: Objection -- objection. Asked and answered.
BY MR. JOHNSON:
Q. You can answer.
A. Yeah. I don't know the specifics about who initiated the dialogue and the status of the actual negotiations. It was just my understanding that we were not able to enter into an agreement with Illumina.
Q. You were unable to ultimately enter

into an agreement. Is that what happened?
MS. GASKIN: Objection; form. Misstates testimony.
BY MR. JOHNSON:
Q. I'm asking you if that's what happened.
A. My understanding is that Illumina was unwilling to enter into an IVD codevelopment agreement specifically for Elio Tissue on the NextSeq platform, but I don't have any other specifics around the discussions that happened prior to me joining the company.
Q. Do you know if Illumina ever sent a draft IVD agreement to PGDx in order to allow the Elio Tissue Complete product to -- let me -- strike that and let me rephrase it.
Are you aware if Illumina ever sent a draft IVD agreement for the Elio Tissue Complete product to PGDx in 2017?
MS. WILBERFORCE: Objection. Asked and answered. Ms. Bailey has responded many times that she's unaware about the details in 2017.
BY MR. JOHNSON:
Q. You can answer, Ms. Bailey.
MS. GASKIN: I have the same -- same objection and foundation.

Sorry for the interruption, David.
BY MR. JOHNSON:
Q. You can answer, Ms. Bailey.
A. I'm not aware.
Q. In your former test -- in your testimony during the investigational hearing, you referred to redlines that arose from the original negotiation of an IVD agreement between PGDx and Illumina. Do you recall that?
MS. GASKIN: Objection. Misstates testimony.
THE WITNESS: I do. If it's the portion of the hearing I recall, that was specific to redlines of the agreement, the negotiations of which were negotiated in the fall of 2019 that I picked up oversight of when I became CEO in April 2020; in other words, I didn't initiate it at that time. There were already negotiations in process that had begun in fall of 2019.
BY MR. JOHNSON:
Q. And those were before or after PGDx submitted its application to the FDA for the approval with the workaround?
MS. GASKIN: Objection; form.

THE WITNESS: After.
BY MR. JOHNSON:
Q. So the first communication you had -- when was the first communications you had with Illumina about negotiating an IVD agreement?
A. April of 2020.
Q. And who were those negotiations with?
A. Marla, I don't recall her last name, was directly leading them under the leadership of [redacted].
Q. And [redacted], that's an Illumina employee?
A. Was. He's no longer with Illumina.
Q. He's a former Illumina employee?
A. Yes.
Q. And when you first had discussions with [redacted], is it fair to say that he was generally positive about the prospect of entering into a IVD agreement with PGDx?
MS. GASKIN: Objection; form.
THE WITNESS: Yes.
BY MR. JOHNSON:
Q. Would you say that you entered into a positive working relationship with [redacted]
MS. GASKIN: Objection; form.

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with the question?
BY MR. JOHNSON:
Q. Yeah. Let me try to rephrase it.
Are you aware of other oncology products where a physician might view the products as serving different purposes if one has a broad assessment and the other has a more narrow focused assessment?
MS. GASKIN: Objection; form. Speculation.
BY MR. JOHNSON:
Q. You can answer.
A. [redacted]
Q. And one of the criteria that oncologists might consider in the test is its breadth?
MS. GASKIN: Objection; form and speculation.
THE WITNESS: [redacted]

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BY MR. JOHNSON:
Q. Yeah. I guess, kind of, the crux of my question is if, in your experience, oncologists view a pan-cancer therapy selection test to be a direct competitor with a much more narrow therapy selection test like the Archer test?
MS. GASKIN: Objection to form. Foundation.
THE WITNESS: [redacted]
BY MR. JOHNSON:
Q. Okay. I'd like to shift gears and talk about the company [redacted]. Are you familiar with that company?
A. I am.
Q. What do you understand [redacted] products or services to be?

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A. Quite broad. I don't know their entire portfolio, but I know they have multiple applications DNA-based, [redacted] I mean, their capabilities are quite broad.
Q. And in the oncology space, would you consider [redacted] to be a [redacted]?
MS. GASKIN: Objection; form.
THE WITNESS: Yes.
BY MR. JOHNSON:
Q. Would you also consider Illumina to be a [redacted] in that space?
MS. GASKIN: Objection; form.
THE WITNESS: I think we see Illumina as both a tools and a diagnostic content company.
BY MR. JOHNSON:
Q. And so what is it -- what do you mean by a [redacted], then?
A. [redacted]
Q. Around September 2020 was PGDx in

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discussions with [redacted] about some type of business collaboration?
A. Yes.
Q. What was the nature of the collaboration that you were exploring?
THE WITNESS: I'd like to ask my counsel if that's something I should disclose. That was under confidentiality.
MS. WILBERFORCE: Can we take a quick break?
MR. JOHNSON: Can we go off the record, please?
THE VIDEOGRAPHER: Yes. No problem One second.
Off the record at 2:02 p.m.
(Recess taken.)
THE VIDEOGRAPHER: Back on the record at 2:09 p.m.
BY MR. JOHNSON:
Q. Okay. So we were just speaking about [redacted]. The question is, has PGDx explored a business collaboration with [redacted]?
A. Yes.
Q. And what was the nature of that

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business collaboration, generally?
A. So there are a couple aspects of our relationship with [redacted] starting with them as a supplier, so we do use certain [redacted] components in our own development efforts here. [redacted]
[redacted]
Q. [redacted]
[redacted]
MS. GASKIN: Objection; form.
THE WITNESS: [redacted]
[redacted]
MR. JOHNSON: Okay. I'd like to introduce an exhibit.
Marcus, if you could introduce Exhibit 4, please.
(Exhibit No. 3, a document Bates Numbered PGDX_00020563 through PGDX_00020565, was introduced electronically.)
MS. WILBERFORCE: To clarify, is this marked as Exhibit 4 or Exhibit 3?
MR. JOHNSON: Thank you for that

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clarification. Yes, it looks like it's already been marked as Exhibit 3, so we're on Exhibit 3 here.
BY MR. JOHNSON:
Q. Ms. Bailey, were you able to access that exhibit?
A. Yes.
Q. Is this an e-mail communication between you and [redacted]
[redacted]
A. Yes.
Q. What is [redacted]
[redacted]
A. At least at the time, I haven't tracked if it's still the case, he was Chief Commercial Officer.
Q. And that was in September 2020 when this e-mail was written?
A. Yes.
Q. I'd like to take a look at your e-mail at the top of this page. Just for the record, the document has Bates stamp PGDX_00020563. And the third -- actually, let's start at the second bullet point. It says, [redacted]
[redacted]

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there for now, but what comments are you referring to -- strike that.
Are you -- are you referring to comments by [redacted]
A. Can you give me just one moment and I'll read through the entire document?
Q. Of course.
A. Yes. I do recall what the discussion was about.
Q. Are these -- excuse me.
The second and third bullet point, are these [redacted]
[redacted]
A. Yes.
Q. This third pullet point says, [redacted]
[redacted]
MS. GASKIN: Objection; form.
THE WITNESS: [redacted]
[redacted]

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[redacted]
BY MR. JOHNSON:
Q. And in your e-mail in Bullet Points 2 and 3, [redacted]
[redacted]
MS. GASKIN: Objection; form.
THE WITNESS: Can you repeat the question?
BY MR. JOHNSON:
Q. So your second bullet point with the [redacted]
So is -- in these Bullet Points 2

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and 3, [redacted]

MS. GASKIN: Objection; form.

THE WITNESS: [redacted]

BY MR. JOHNSON:

Q. Okay. And then jumping down to Bullet Point 3 [redacted]

MS. GASKIN: Objection; form.

THE WITNESS: [redacted]

BY MR. JOHNSON:

Q. [redacted]

MS. GASKIN: Objection; form.

THE WITNESS: [redacted]

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[redacted]

BY MR. JOHNSON:

Q. Okay. If you look down at Bullet Point [redacted]

Do you see that?

A. Yes.

Q. What is that a reference to?

A. [redacted]

Q. [redacted]

MS. GASKIN: Objection; form.

THE WITNESS: [redacted]

BY MR. JOHNSON:

Q. [redacted]

A. [redacted]

MS. GASKIN: Objection; form.

BY MR. JOHNSON:

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Q. [redacted]

MS. GASKIN: Objection; form.

THE WITNESS: [redacted]

BY MR. JOHNSON:

Q. [redacted]

A. [redacted]

Q. [redacted]

MS. GASKIN: Objection; form.

THE WITNESS: [redacted]

BY MR. JOHNSON:

Q. [redacted]

A. [redacted].

Q. [redacted]

Page 157

A. [redacted]

Q. [redacted]

A. [redacted]

MS. WILBERFORCE: Objection; form.

BY MR. JOHNSON:

Q. [redacted]

A. [redacted]

Q. [redacted]

A. [redacted]

Q. [redacted]

Page 158

[redacted]
A. [redacted]
Q. [redacted]
[redacted]
A. [redacted]
Q. [redacted]
A. [redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
Q. [redacted]
[redacted]
[redacted]
[redacted]
[redacted]
MS. GASKIN: Objection; form.
Speculation.
THE WITNESS: [redacted]
[redacted]
[redacted]

Page 159

[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
BY MR. JOHNSON:
Q. Okay. Let me try to break that down so I understand it. [redacted]
[redacted]
[redacted]
MS. GASKIN: Objection; form.
BY MR. JOHNSON:
Q. Sorry. I missed the answer there.
A. [redacted]
[redacted]
[redacted].
Q. [redacted]
[redacted]
[redacted]
[redacted]
[redacted]
MS. GASKIN: Objection; form.
THE WITNESS: [redacted]
[redacted]
BY MR. JOHNSON:

Page 160

Q. [redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
MS. GASKIN: Ob --
BY MR. JOHNSON:
Q. [redacted]
MS. GASKIN: Objection; form.
THE WITNESS: [redacted]
[redacted]
[redacted]
BY MR. JOHNSON:
Q. Okay. And if we go back up to Bullet
[redacted]
[redacted]
[redacted]
[redacted]
Is that a fair read of what this says?
A. Yes.
Q. And what did you mean by that?
A. [redacted]
[redacted]
[redacted]

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[redacted]
[redacted]
[redacted]
Q. [redacted]
[redacted]
[redacted]
[redacted]
MS. GASKIN: Objection; form.
THE WITNESS: [redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted].
BY MR. JOHNSON:
Q. [redacted]
[redacted]
[redacted]
MS. GASKIN: Objection; form.
THE WITNESS: [redacted]
[redacted]
[redacted]
BY MR. JOHNSON:
Q. Okay. Ms. Bailey, when does PGDx typically have its annual board meetings?

I'm sorry. I can -- I'll rephrase that to try to make it more clear what I'm interested in.

Does PGDx typically have a board meeting around May of every year?

A. I -- I don't know about "typically." They're, typically, quarterly. But from the time I took over at CEO, the company had several very challenging things happening, so we actually met every couple weeks. So I -- I'm sure there was one last May, but I don't know that that would be a typical cadence.

Q. All right. But you do believe that there was a board meeting last May?

A. I think it's likely. I don't recall.

Q. Do you recall a presentation by Evercore at that board meeting?

A. I don't.

Q. Do you recall receiving a presentation from [redacted]?

A. [redacted] We ended up not changing from the banker we used, so

we didn't formalize a relationship with them.

Q. And which [redacted]

A. [redacted]

Q. In the course of your discussions with [redacted]

MS. GASKIN: Objection; form. Calls for speculation.

MR. GOTSHALL: Mr. Johnson, are we talking about 2020 or 2021?

MR. JOHNSON: 2021. April of 2021.

THE WITNESS: Oh, thank you for clarifying that, Scott.

Sorry. I was in May of 2020.

MR. JOHNSON: Maybe I'll just pull up a document -- sorry. I didn't mean to cut you off.

Marcus, can we just -- can we go ahead and introduce a Document Tab 10.

(Exhibit No. 4, a document Bates Numbered PGDX_00023088 through PGDX_00023127, was introduced electronically.)

BY MR. JOHNSON:

Q. So, Ms. Bailey, while that document's

loading, does -- the clarification about the time period, does that change your response about PGDx hiring Piper [redacted]?

A. Yes, it does.

Can you repeat the document name I should be looking at now?

Q. Yes. It's not visible yet. It will be Exhibit 4.

Okay. It should be visible now.

Ms. Bailey, take some time to review the document, if you'd like, and just let me know when you're ready. I'm going to have some questions about -- about Slide 8, but feel free to review as much as you need.

A. Okay.

Q. All right. Ms. Bailey, what is this presentation?

A. This was a presentation that Evercore banking team gave to our board a couple months ago.

Q. And what was the context of the presentation?

A. [redacted]

[redacted]

Q. Did you get a sense from [redacted]

A. [redacted]

Q. And this presentation was in 2021; is that right?

A. That's correct.

Q. So this was well after the announcement of the Illumina/GRAIL-proposed transaction; is that right?

A. That's right.

Q. And at this time in April 2021, [redacted]

MS. GASKIN: Objection; form.

THE WITNESS: That's correct.

BY MR. JOHNSON:

Q. On Slide 8, if you could turn there, it has the Bates Number ending in 096. Do you see that?
A. I do.
Q. The heading of the slide says, [redacted]
A. [redacted]
Q. [redacted]
A. I don't know. Good question. I -- yeah. I don't know.
Q. Well, what would be an example of an [redacted]
A. [redacted]
Q. [redacted]
MS. GASKIN: Objection; form.
THE WITNESS: [redacted]
BY MR. JOHNSON:
Q. [redacted]
A. [redacted]

Q. [redacted]
A. [redacted]
Q. [redacted]
MS. GASKIN: Objection; form.
THE WITNESS: [redacted]
BY MR. JOHNSON:
Q. [redacted]
A. [redacted].
Q. [redacted]
A. [redacted]
Q. [redacted]
A. [redacted]
Q. And the Illumina/GRAIL transaction, that was announced in September 2020, right?
MS. GASKIN: Objection; form.
THE WITNESS: I don't actually recall

when it was announced.
BY MR. JOHNSON:
Q. Okay. Is it safe to say that this presentation in April 2021 [redacted]
MS. GASKIN: Objection; form.
THE WITNESS: [redacted].
MR. JOHNSON: Okay. I think we can take a short break and I can look at my outline and hopefully come back and finish up.
THE VIDEOGRAPHER: Okay. Off the record at 2:34 p m.
(Recess taken.)
THE VIDEOGRAPHER: Back on the record at 2:45 p.m.
MR. JOHNSON: Thank you.
BY MR. JOHNSON:
Q. Ms. Bailey, you were asked some questions earlier about how PGDx might use funds that it's instead having to pay in connection with the Illumina IVD agreement. Do you recall

that?
MS. GASKIN: Objection; form.
THE WITNESS: Are you referring to the discussion around profitability and investment into the business?
BY MR. JOHNSON:
Q. Exactly.
A. Yes, I do.
Q. Is it your belief that entering into the IVD agreement with Illumina will be a net financial positive for PGDx?
MS. GASKIN: Objection; form.
MS. WILBERFORCE: Can you also please clarify which agreement you mean? The main agreement? The addendum?
MR. JOHNSON: Sure. Happy to clarify the question.
BY MR. JOHNSON:
Q. So I'm going to ask the question about the IVD agreement, and that will encompass the June 4th, 2021, amendment, so the most current active form of the agreement.
Does that make sense?
A. Yes.
Q. Okay. Is it your understanding that

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the IVD agreement with Illumina will be a net financial positive for PGDx?
MS. GASKIN: Same objection.
THE WITNESS: [redacted]
BY MR. JOHNSON:
Q. I'd like to return to some of the questioning that happened earlier about PGDx's costs of goods sold.
[redacted]
A. That's right.
Q. And which test is that?
A. That's the Elio Plasma Resolve Test.
Q. And then how many samples per flow cell are associated with the Elio Tissue Complete?
A. [redacted]
Q. [redacted]

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A. [redacted]
Q. Is PGDx working to reduce the cost of the kits sold in any way?
A. Yes.
Q. Can you provide some examples of how it's attempting to reduce the costs of its goods sold?
A. [redacted]
Q. [redacted]
MS. GASKIN: Objection; form.
THE WITNESS: [redacted]
BY MR. JOHNSON:
Q. So the percentage of costs associated with PGDx running the test internally; is that right?
A. Yes.

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Q. Okay. So not the -- not the price charged for PGDx's kits?
MS. GASKIN: Objection; form.
THE WITNESS: I think she asked both questions.
BY MR. JOHNSON:
Q. I'm sorry. There was some cross-talk there, so I didn't get your answer. Would you mind restating it?
A. Yeah. I just wanted to make sure I'm clear on the question because I -- I believe Lauren asked me both questions, both price ranges, as well as if we look at it from a cost perspective, the relative cost between the kit and the sequencing consumables. I believe I answered both ways.
Q. Okay. When you were referring to the cost associated with running the -- excuse me, let me restate.
When you were testifying about the costs associated with running the tests yourself, you were discussing Illumina's inputs of the costs of goods sold; is that right?
A. Yes. That's right.
MS. GASKIN: Objection; form.

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MR. JOHNSON: Okay. With that I will reserve the remainder of my time.
FURTHER EXAMINATION
BY MS. GASKIN:
Q. Ms. Bailey, you testified to Mr. Johnson that your knowledge of PGDx's decision -- discussions with Illumina is based on secondhand information; is that right?
A. From the 2017 discussions, yes.
Q. Who did you receive this secondhand knowledge from?
A. From the CEO at the time, the head of business development at the time and discussions with our head of regulatory.
Q. So that was Mr. Doug Ward and Mr. Foust; is that correct?
A. Yes. And Jennifer Dickey.
Q. Do you trust the information you received from Mr. Ward, Mr. Foust and Ms. Dickey?
A. Yes.
Q. Did you rely on the information you received from Mr. Ward, Mr. Foust and Ms. Dickey?
A. Yes.
Q. Did you rely on this information you received about PGDx's prior discussions with

Illumina when you engaged in your own discussions with Illumina about an IVD agreement in 2020?

A. By that time, I would say I relied more on the recent discussions which at the time still involved Jay Foust and somebody that worked on his team.

Q. Do you have any reason to doubt the information provided to you by Mr. Ward, Mr. Foust and Ms. Dickey?

A. No.

Q. You test -- testified to Mr. Johnson that your amended IVD agreement with Illumina removed companion diagnostic fees. Can you explain what companion diagnostic fees were in your initial IVD agreement with Illumina?

A. Yes. The original agreement had a specific dollar amount associated to any companion diagnostic claim that would have been granted on one of the kits developed under the agreement.

Q. So if PGDx wanted to develop a companion diagnostic test, you would have had to pay Illumina a fee to do so?

A. Under the original agreement, yes.

Q. What was the ballpark value of that

companion diagnostic fee?

A. [redacted].

Q. And you testified that entering into companion diagnostic agreements is a core part of PGDx's business; is that correct?

A. Yes.

Q. And why is it a core part of PGDx's business?

A. It provides the opportunity to expand the clinical utility of the product and associate the variant calls that our device produces with specific drugs.

Q. To the best of your knowledge, how would paying companion diagnostic fees to Illumina have impacted the profitability of PGDx's companion diagnostic partnerships?

MR. JOHNSON: Object to form.

THE WITNESS: [redacted]

BY MS. GASKIN:

Q. How would it impact -- how would it

impact your pricing?

A. [redacted]

Q. [redacted]

A. [redacted]

Q. [redacted]

A. [redacted]

Q. [redacted]

A. [redacted]

Q. Is it common for investors to ask questions prior to investing in your company?

A. Yes.

Q. Is it common for investors to ask a lot of questions prior to investing in your company?

A. Yes. They typically do extensive diligence on us, yes.

Q. And do investors sometimes ask questions about many issues facing the company?

A. Yes.

Q. Did any investors who raised concerns about the lack of an IVD agreement with Illumina later invest in PGDx after an IVD agreement was entered into?

A. Yes.

Q. You also testified to Mr. Johnson that you signed your first companion diagnostic agreement after entering into an IVD codevelopment agreement with Illumina; is that correct?

A. Yes.

Q. Are any of your companion diagnostic partners that raised concerns -- I'm sorry. May I start again?

data to your test's performance?
A. I think it makes it less competitive, but, most importantly, we maintain higher requirements around performance because of the impact to the patient's treatment decision.
Q. Why do you maintain high requirements for -- for performance to your patients?
A. We want the highest levels of sensitivity on specificity across variants so that we don't miss a call for a patient or call a false positive.
Q. Turning back to PX7049, which was the IH transcript, I'm going to be looking at Page 40. It's going to take a minute for me to scroll through.
A. I'm sorry. You said that one was PX7049?
Q. Yes. That is correct.
A. And what page?
Q. Page 40.
A. Okay.
Q. On IH transcript Page 40, Line 2, I asked you, Question: "And do you know why PGDx did not use Thermo Fisher?"
Answer: [redacted]

[redacted]
Was your answer accurate when you made it on March 2nd, 2021?
A. Yes.
Q. Is your statement still accurate today?
A. Yes.
Q. What is sensitivity?
A. A way to think about sensitivity is to not miss an important mutation call in a sample, so it's how deeply you can find that mutation.
Q. Why is it important to PGDx to have a high sensitivity level?
A. So you don't miss an actionable mutation in a patient sample.

Q. Was it your understanding that Thermo Fisher's Ion Torrent did not have as good of sensitivity levels as Illumina's NextSeq platform?
A. [redacted]
Q. And PGDx chose not to switch its test to Thermo Fisher's Ion Torrent platform; is that correct?
A. That's correct.
Q. To the best of your knowledge, how much did that Ion Torrent pilot study cost PGDx?
A. I don't know the answer to that.
Q. Do you have a -- an approximation in mind?
A. I don't. I wasn't in a role at the time where I saw that detail.
Q. To the -- to the best of your knowledge, do you know how long the Ion Torrent pilot study took PGDx?
A. I don't know that either. That started before I arrived.
Q. Do you have an approximation of how long that took?
A. It was certainly --

MS. WILBERFORCE: Objection. Asked and answered.
BY MS. GASKIN:
Q. I'm sorry. I heard Nana's objection. Did you start to speak before that?
A. [redacted]
Q. Do you know when the Ion Torrent pilot study ended?
A. I don't recall that.
Q. You also testified to Mr. Johnson that you have had conversations with [redacted]; is that correct?
A. Yes.
Q. Have you performed any studies on how your therapy selection tests will work on [redacted] platform?
A. No.
MS. WILBERFORCE: Objection. I just want to flag here that this is a very confidential area of the business.
MS. GASKIN: Okay.
BY MS. GASKIN:
Q. Do you know how PGDx's test would perform on [redacted] platform?

A. No.
Q. Are you aware that [redacted] is a [redacted] platform?
A. Yes.
Q. You testified earlier that PGDx's Elio Plasma Resolve and Plasma Complete Tests are liquid biopsy tests; is that correct?
A. That's correct.
Q. Would using a [redacted] platform be suitable for liquid biopsy?
MR. JOHNSON: Object to form.
THE WITNESS: [redacted]
BY MS. GASKIN:
Q. So it's important to PGDx that a sequencing provider have a DX option?
A. Yes.
Q. And is that because PGDx pursues a decentralized kitted product?
A. Yes. Decentralized with taking products through the FDA, who requires DX

instruments.
Q. Have you performed any studies on how your therapy selection test will work on [redacted] platform?
A. No.
Q. Do you know how the PGDx test would perform on an [redacted] platform?
A. I don't.
Q. Are you aware of whether [redacted] has any NGS platform currently on the market?
A. They do not, to my knowledge.
Q. Switching gears slightly, Mr. Johnson asked you about your relationship with [redacted]; is that correct?
A. Yes.
Q. You testified --
MS. WILBERFORCE: I just want to flag here -- apologies for interrupting. I just want to flag here for the record that this is also a confidential area of the business.
MS. GASKIN: Yes, ma'am. Thank you.
BY MS. GASKIN:
Q. You testified that [redacted] provides some components of PGDx's newest kit; is that correct?
A. Yes.

Q. What components does [redacted] provide for PGDx's newest kit?
A. I won't disclose that.
Q. Is this newest kit the Plasma -- Plasma Complete Test?
A. Yes.
Q. Does [redacted] provide PGDx [redacted] products for the Plasma Complete Test?
A. [redacted]
Q. Ms. Bailey, I want to assure you that this is a confidential transcript. If you know the answer to the question, I would just ask that you answer it.
I can restate it, if necessary.
A. No. It is not the [redacted]
Q. Thank you.
What is the [redacted] components that are associated with the Plasma Complete Test?
MS. WILBERFORCE: Objection. Asked and answered.
BY MS. GASKIN:
Q. Ms. Bailey, if you know the answer,

this is a confidential transcript, you can answer.
A. I shared what it isn't. I don't think we -- there's close to a hundred components of the assay. I don't know all of the specifics on all of the [redacted] components, just that they are a supplier related to that kit.
Q. Are they an -- an important supplier?
A. Yes.
Q. When did you begin purchasing these components from [redacted]?
A. I don't know the exact time frame, but that product development cycle was at least a year, so it's been some time.
Q. Was this 2020?
A. Yes.
Q. You testified that these [redacted] components are for your newest kit. Did you use [redacted] components for any other kit?
A. None that I'm aware of.
Q. Who do you purchase these components from? Is it [redacted] themselves or somebody else?
A. Yeah. The ones you're asking about directly from [redacted]
Q. Prior to using [redacted], did you purchase

EXHIBIT B3

From: Jay Foust </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6CEEA27ADDA541D685C7A6448C4B3CDC-JAY FOUST>
Sent: Thursday, June 14, 2018 11:15 AM
To: Megan Bailey <mbailey@pgdx.com>
Subject: RE: quote pre-approval request

Right-

I think the quote they suggested in actually pretty good. Its vague and we can spin it multiple ways depending on reactions we may get from [redacted] etc...

PS- so glad you spoke to him. I like him a lot but can't read him very well yet!

From: Megan Bailey
Sent: Thursday, June 14, 2018 10:12 AM
To: Jay Foust <jfoust@pgdx.com>
Subject: RE: quote pre-approval request

Okay, just wanted to make sure we were taking that into consideration. In that case I'm fine with it. We'll have a somewhat competing panel so we should be smart about what we say, but I agree with helping them out. Let's see what [redacted] says about where we are and then I'll jump in (he and I talked yesterday about this too).

Megan Bailey

VP, Marketing
a. 2809 Boston St, Suite 503, Baltimore, MD
e. mbailey@pgdx.com
p. 520.820.8710

From: Jay Foust
Sent: Thursday, June 14, 2018 11:09 AM
To: Megan Bailey <mbailey@pgdx.com>
Subject: RE: quote pre-approval request

Yes.. some.... however they're behaving badly recently so unlikely to get much worse anyway- trying to bully us in to giving them our [redacted] in exchange for plasma (keep that quiet please). At this point I think it would be helpful for them to really know we're not dependent on them.

Sent from Mail for Windows 10

From: Megan Bailey
Sent: Thursday, June 14, 2018 10:06:39 AM
To: Jay Foust
Subject: RE: quote pre-approval request

Any concern on publicly supporting Thermo on plasma assay before having Illumina Phoenix agreement signed?

Megan Bailey

VP, Marketing
a. 2809 Boston St, Suite 503, Baltimore, MD
e. mbailey@pgdx.com
p. 520.820.8710

From: Jay Foust
Sent: Thursday, June 14, 2018 10:36 AM
To: John Thompson <jthompson@pgdx.com>
Cc: Megan Bailey <mbailey@pgdx.com>
Subject: FW: quote pre-approval request

John-

How have the repeated runs fared? I met with thermo yesterday- good people- easy to work with.

I definitely want to provide a quote to them, and I recommended to Doug that we do so. Things are good with them and I feel it's the right thing to do to help them out. This weekend is a big launch for them and I can tell they are stressed out and would be relieved and really appreciative if we give a quote.

So, with that in mind, can you please see their suggested text below, and if we can stand behind it or something like it. Of course we can say what we want, based on our experience, but idea is to cast them in a positive light. I also think its very good for us to have a public record of our collaborating with them (good for us)-

Please consider and advise- and copy megan on your thoughts-

Many thanks
Jay

From: Jay Foust
Sent: Wednesday, June 13, 2018 9:47 PM
To: Doug Ward <dward@pgdx.com>
Subject: Fwd: quote pre-approval request

Get Outlook for iOS

From: Hernandez-Guzman, Francisco G. <Francisco.Hernandez-Guzman@thermofisher.com>
Sent: Thursday, June 7, 2018 7:50:39 AM
To: Jay Foust
Cc: Felton, Andrew C.; Shah, Anjali B.; John Thompson; Kim, MJ
Subject: quote pre-approval request

Hi Jay,

Our Marketing team would like to get pre-approval on a quote from your team. We have drafted the following quote as a starting point, but please review it and modify it to what you feel comfortable saying based on your experience with the technology:

"Ion AmpliSeq HD panels provide exceptional sensitivity that allows me push the limits with difficult samples and interrogate highly heterogeneous tumor samples for my targets of interest. Data quality is excellent, and the workflow allows me to scale up based on my needs"

We don't need the final quote until next week, which hopefully by then you will have data coming from your lab.

We also need the consent form signed in order to use your quote.

Thank you,

Francisco

Francisco G. Hernandez-Guzman, PhD, MBA
Sr. Product Manager
Ion Torrent – Bioinformatics, Custom AmpliSeq and Custom Design Services
Clinical Sequencing Division (CSD), Life Science Solutions Group

Thermo Fisher Scientific
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Tel: +1 (760) 268-5450 | Mobile: +1 (858) 361-3020
francisco.hernandez-guzman@thermofisher.com | www.thermofisher.com

EXHIBIT B4

DOCUMENTS MARKED CONFIDENTIAL
REDACTION IN THEIR ENTIRETY REQUESTED

EXHIBIT B5

DOCUMENTS MARKED CONFIDENTIAL
REDACTION IN THEIR ENTIRETY REQUESTED

EXHIBIT B6

DOCUMENTS MARKED CONFIDENTIAL
REDACTION IN THEIR ENTIRETY REQUESTED

EXHIBIT B7

PUBLIC

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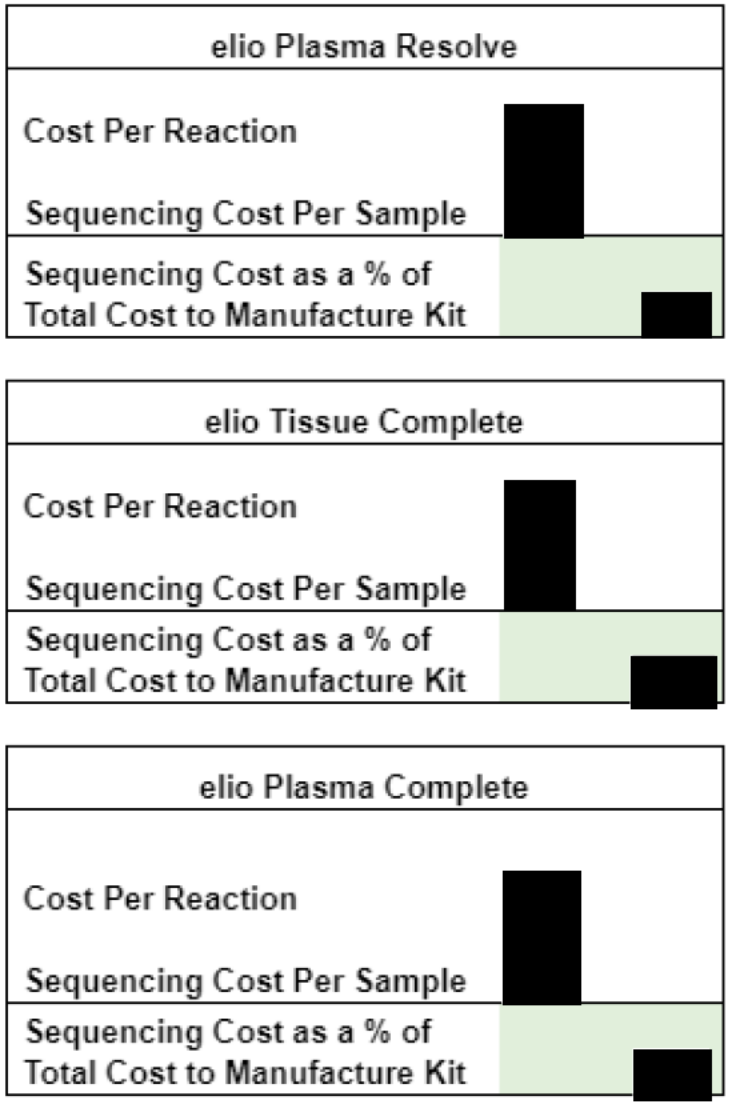
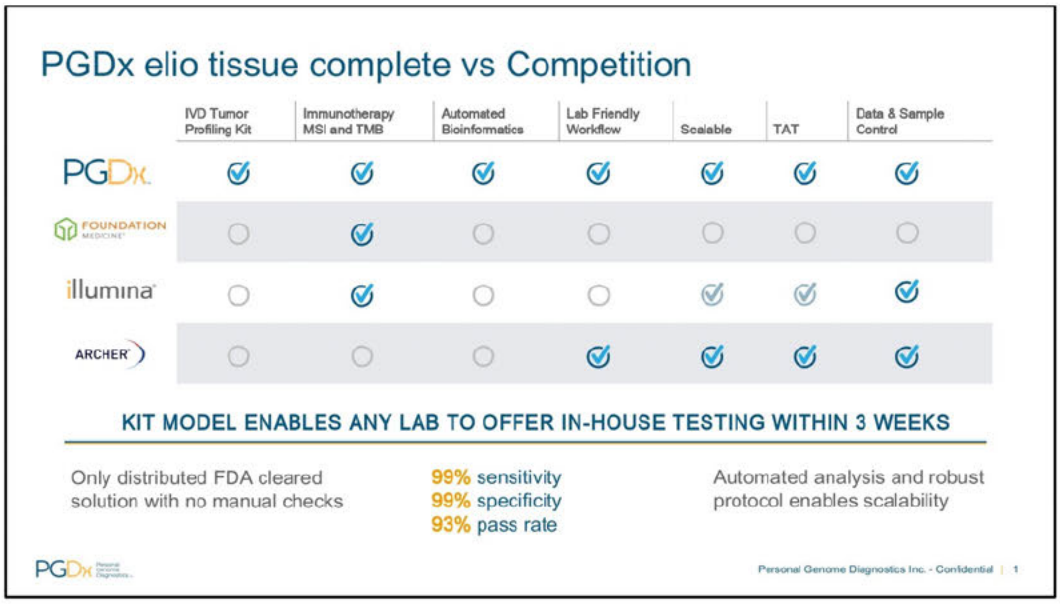
Sequencing Cost Breakdown



PGDX_00023764

PX8550-002

EXHIBIT B8



We are only solution that has tissue+plasma with same lab workflow, similar kits, similar training, same server, same reports, same bioinformatics data flow, same user interface

[redacted]

[redacted]

We provide all the data at the local site. Never leaves the lab. Labs own and control all of it. [redacted]

We have elio-connect that integrates our solution into the lab. Empowering the lab to use make best use, full use of NGS. Why spend all this effort and money running NGS, without squeezing more juice out of the data.

We are the only FDA cleared medical device. [redacted]

[redacted]

We are not an instrument maker or tied to any particular chemistry or sub-components. Our kits are best-in-class component parts.[redacted]

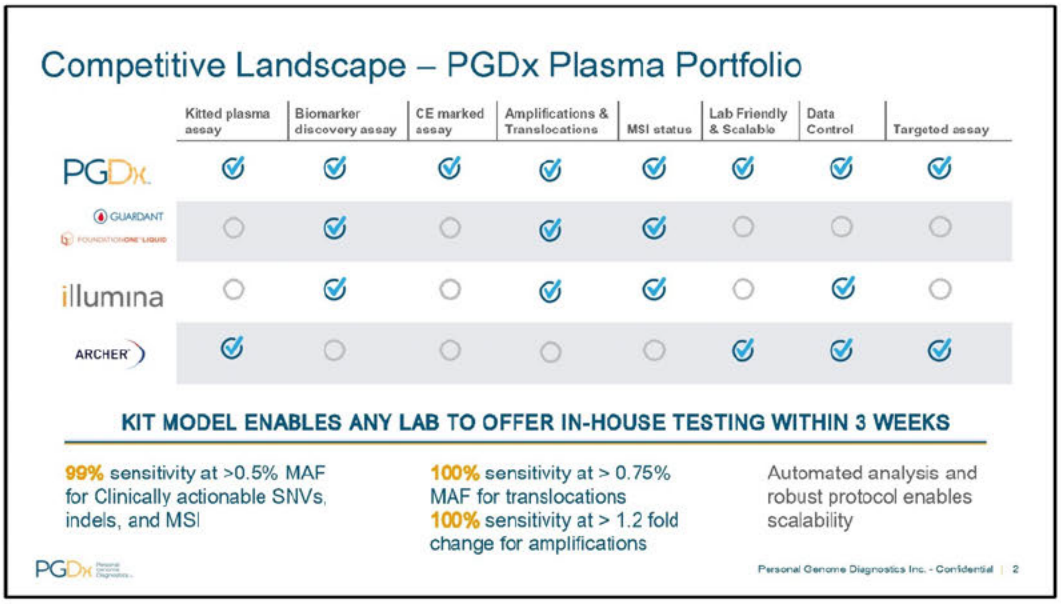
Lab economics.[redacted]

TAT: 4 days for us. As few as three. Send outs are weeks.[redacted]

Lab workflow: [redacted]

End-to-end custom reporting: We have a solution that enables labs to report out as they like.[redacted]

Pan-cancer and tumor profiling: [redacted] I think there are a group of investors that are aware of [redacted] and think we look like them. Our comprehensive use differentiates vs their more narrow use



We are only solution that has tissue+plasma with same lab workflow, similar kits, similar training, same server, same reports, same bioinformatics data flow, same user interface

[redacted]

We provide all the data at the local site. Never leaves the lab. Labs own and control all of it. [redacted]

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[redacted]

We are not an instrument maker or tied to any particular chemistry or sub-components. Our kits are best-in-class component parts. [redacted]

Lab economics. [redacted]

TAT: 4 days for us. As few as three. Send outs are weeks. [redacted]

Lab workflow: [redacted]

End-to-end custom reporting: We have a solution that enables labs to report out as they like. [redacted]

Pan-cancer and tumor profiling: [redacted] I think there are a group of investors that are aware of [redacted] and think we look like them. Our comprehensive use differentiates vs their more narrow use

EXHIBIT B9

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EXHIBIT B10

From: Rami Zahr
Sent: Monday, June 29, 2020 9:29 PM EDT
To: Samuel Angiuoli; Megan Bailey
Subject: Re: Project Ion: Analyte performance data
Attachments: PDGx - Ion Torrent Summary - 29JUN2020.pptx

Hi Megan,

Sam and I worked on Ion slides attached. With [redacted] technical expertise we decided to give them a good amount of detail. [redacted] so we wanted to sell it as much as possible. We kept slide 2 that covers workflow hidden for the sake of time. Let me know if you would like to see anything else.

Have a good night!

Rami Zahr

Director of Product Strategy
a. 3600 Boston St, Suite 10, Baltimore, MD
e. rzahr@pgdx.com
p. 607.351.9049

From: Samuel Angiuoli <angiuoli@pgdx.com>
Date: Monday, June 29, 2020 at 8:21 AM
To: Rami Zahr <rzahr@pgdx.com>, Megan Bailey <mbailey@pgdx.com>
Subject: Re: Project Ion: Analyte performance data

Thanks Rami. I'll do a turn on these this morning and we can discuss

---

From: Rami Zahr <rzahr@pgdx.com>
Sent: Sunday, June 28, 2020 23:09
To: Megan Bailey; Samuel Angiuoli
Subject: Re: Project Ion: Analyte performance data

Hi Sam,

May need your help filling this in because I wasn't involved in the project. I got the ball rolling converting it to the new powerpoint format and taking some of the material from Abby's slide deck. I can also schedule some time tomorrow for a working session.

Thanks,

Rami Zahr

Director of Product Strategy
a. 3600 Boston St, Suite 10, Baltimore, MD
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p. 607.351.9049

From: Megan Bailey <mbailey@pgdx.com>
Date: Sunday, June 28, 2020 at 4:03 PM
To: Samuel Angiuoli <angiuoli@pgdx.com>, Rami Zahr <rzahr@pgdx.com>
Subject: FW: Project Ion: Analyte performance data

Hi – hope you're both having a great weekend, and no need to respond to this until tomorrow, but can you help me put together a 3-5 slide Exec Summary with the goal of communicating the following:

[redacted]

Hard for me to make sense of these, and we don't want it to be a deep dive technical review, but rather something that [redacted]

Thanks!
Megan

From: Abigail McElhinny <amcelhinny@pgdx.com>
Sent: Wednesday, June 24, 2020 5:00 PM
To: Samuel Angiuoli <angiuoli@pgdx.com>; Rami Zahr <rzahr@pgdx.com>

Cc: Megan Bailey <mbailey@pgdx.com>
Subject: Project Ion: Analyte performance data

Hi everyone
These are in depth technical review slides on [redacted] This was the review to prepare for the LCC where we recommended pausing the project due to lack of business case or pharma to move forward with, but the data on our performance is here.

@Samuel Angiuoli @Rami Zahr feel free to take these for investor deck and create whatever needed. We do have a lot of additional slides on findings on [redacted] etc but I removed them due to size of the deck. I can re-send anything else needed.

Abby

EXHIBIT B11

From: Megan Bailey
Sent: Monday, September 21, 2020 5:42 PM EDT
To: [redacted]
Subject: RE: [redacted] Commercial Structure

A bit ☺.

Are the first 3 lines US specific? Are they selling into molecular pathology labs in the sense that they [redacted]

A few other thoughts following our last talk:

1. Commercial scale up numbers I sent you were US only. [redacted] Wanted to make sure that was clear.
2. [redacted]
3. [redacted]

Hope that context is helpful.

Megan

From: [redacted]
Sent: Friday, September 18, 2020 6:09 PM
To: Megan Bailey <mbailey@pgdx.com>
Subject: Re: [redacted] Commercial Structure

[EXTERNAL EMAIL]
Quick response. Multi-tasking:

Three regional sales directors
Each region has two product specific sales managers - syn bio and ngs
Total 65ish(!) heads spread across the groups.
About 12 fas worldwide
6m spend on customer service and tech support worldwide.

Any use?

[redacted]

On Sep 18, 2020, at 2:44 PM, Megan Bailey <mbailey@pgdx.com> wrote:

Hey [redacted]

Appreciate the discussions today. As a follow up, would you be willing to share your commercial org structure – headcount by segment, whether you have a generalist approach supported by technical specialists or what the profiles are, where the NGS portfolio sits from a structure standpoint, what segments they're calling on, and who the key stakeholders are in the sales process?

That would be really helpful as I think through what the most effective commercial strategy might look like upon [redacted]

Thanks,
Megan

Megan Bailey

Chief Executive Officer
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e. mbailey@pgdx.com
p. 520.820.8710
www.personalgenome.com

<image001.png>

EXHIBIT B12

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