PUBLIC

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

DOCKET NO. 9401

In the Matter of

ILLUMINA, INC.,
a corporation, and

GRAIL, INC.,
a corporation,

Respondents.

INITIAL DECISION

D. Michael Chappell
Chief Administrative Law Judge

Date: September 9, 2022

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I. INTRODUCTION

A. Summary of the Case

The Complaint in this case, issued by the Federal Trade Commission ("FTC" or "Commission") on March 30, 2021, alleges that Illumina, Inc. ("Illumina") and GRAIL, Inc. ("Grail") (collectively "Respondents") have executed a merger agreement in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, which, if consummated would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18. Since the issuance of the Complaint, Illumina consummated the transaction on August 18, 2021, and acquired Grail ("Acquisition").

In summary, the Complaint asserts the following: Illumina is the dominant provider of a DNA sequencing tool referred to as "next-generation sequencing" or "NGS," which is an essential input for the development and commercialization of multicancer early detection tests ("MCED" tests). Complaint ¶¶ 1, 3, 5-6. MCED tests are designed to detect multiple cancers by a blood test. Complaint ¶ 4. Grail's MCED test, known as Galleri, was projected to be the first to launch in the United States. Complaint ¶ 9. According to the Complaint, Grail is "racing against" several other firms to develop and commercialize an MCED test. Complaint ¶ 4. After the Complaint was issued, Grail launched Galleri as the first commercially available MCED test in the United States.

The Complaint further alleges that, as the dominant provider of NGS, Illumina has the ability to foreclose or disadvantage Grail's MCED test rivals, and that after the acquisition, Illumina will gain the incentive to foreclose or disadvantage firms that pose a significant competitive threat to Grail. Complaint ¶¶ 11-14. The Complaint avers that the acquisition will "substantially lessen competition in the market for the research, development, and commercialization of MCED tests," resulting in reduced innovation and potentially increased prices and reduced choice and quality in MCED tests, and ultimately, harm to American consumers. Complaint ¶¶ 31, 48.

Respondents filed an answer to the Complaint on April 13, 2021, and an amended answer, together with asserted affirmative defenses and other defenses, on September 2, 2021 (collectively, "Answer"). In summary, Respondents deny the material allegations of the

Complaint, including the allegations as to the relevant market, and further contend that before the FTC filed its Complaint, Illumina offered binding, irrevocable contractual commitments to all of its United States oncology customers, which, according to Respondents, address the foreclosure concerns presented in the instant case. Answer at 3-5. Respondents further assert that the Acquisition will result in "[e]normous" procompetitive effects, including accelerating Grail's availability to more potential patients, which will thereby save lives. Answer at 11. Finally, Respondents raise a number of affirmative defenses, including defenses targeting the validity of the administrative proceedings herein. Answer at 35.

Upon full consideration of the entire record, and as explained more fully below, Complaint Counsel has failed to prove its asserted *prima facie* case that Illumina's post-Acquisition ability and incentive to foreclose or disadvantage Grail's alleged rivals is likely to result in a substantial lessening of competition in the relevant market for the research, development, and commercialization of MCED tests. Accordingly, the Complaint is DISMISSED.

B. Procedural Background

The evidentiary hearing in this matter, which began on August 24, 2021, was conducted over several weeks. The final witness to testify live at the evidentiary hearing completed testimony on September 24, 2021. The hearing was recessed and the record was left open to allow the parties to take trial depositions of several expert witnesses; to enable Respondents to pursue litigation to obtain disputed discovery from a nonparty; and to resolve the parties' disputes regarding admissibility of additional exhibits. The evidentiary hearing reconvened on March 18, 2022. Thereafter, the parties submitted post-trial briefs, proposed findings of fact, and replies to each other's briefs and proposed findings of fact.[1] The record in this matter consists of

[1] Rule 3.51(a) of the Commission's Rules of Practice states that "[t]he Administrative Law Judge shall file an initial decision within 70 days after the filing of the last filed initial or reply proposed findings of fact, conclusions of law and order . . . ." 16 C.F.R. § 3.51(a). The last replies to proposed findings of fact and conclusions of law and reply briefs were filed on May 25, 2022. Absent an order pursuant to Rule 3.51, the Initial Decision was to be filed on or before August 3, 2022. Based on the voluminous and complex record in this matter, an Order was issued finding good cause for extending the time period for filing the Initial Decision by 30 days. Accordingly, issuance of the *in camera* version of this Initial Decision by September 2, 2022 is in compliance with Commission Rule 3.51(a).

the testimony of 56 fact witnesses and 10 expert witnesses (3 for Complaint Counsel and 7 for Respondents), presented live or by deposition. Over 4,500 exhibits were admitted into evidence.[2]

C. Evidence

This Initial Decision is based on a consideration of the whole record relevant to the issues and addresses the material issues of fact and law. The briefs and proposed findings of fact and conclusions of law, and the replies thereto, submitted by the parties, and all contentions and arguments therein were thoroughly reviewed and considered. Proposed findings of fact submitted by the parties that were not accepted in this Initial Decision were rejected, either because they were not supported by the evidence or because they were not dispositive or material to the determination of the merits of the case. Similarly, legal contentions and arguments of the parties that are not addressed in this Initial Decision were rejected, because they lacked support in fact or law, were not material, or were otherwise lacking in merit.

Ruling upon a decision of the Interstate Commerce Commission, and interpreting language in the Administrative Procedure Act ("APA") that is almost identical to language in Commission Rule 3.51(c)(1), the United States Supreme Court held that "[b]y the express terms of [that Act], the Commission is not required to make subordinate findings on every collateral contention advanced, but only upon those issues of fact, law, or discretion which are 'material.'"

[2] Pursuant to Commission Rule 3.45(b), several orders were issued in this case granting *in camera* treatment to material, after finding, in accordance with the Rule, that its public disclosure would likely result in a clearly defined, serious injury to the entity requesting *in camera* treatment or that the material constituted "sensitive personal information," as that term is defined in Commission Rule 3.45(b). In addition, when the parties sought to elicit testimony at trial that revealed information that had been granted *in camera* treatment, the hearing went into an *in camera* session. Commission Rule 3.45(a) allows the Administrative Law Judge ("ALJ") "to grant *in camera* treatment for information at the time it is offered into evidence subject to a later determination by the [administrative] law judge or the Commission that public disclosure is required in the interests of facilitating public understanding of their subsequent decisions." *In re Bristol-Myers Co*., 1977 FTC LEXIS 25, at *6 (Nov. 11, 1977). As the Commission later reaffirmed in another leading case on *in camera* treatment, since "in some instances the ALJ or Commission cannot know that a certain piece of information may be critical to the public understanding of agency action until the Initial Decision or the Opinion of the Commission is issued, the Commission and the ALJs retain the power to reassess prior *in camera* rulings at the time of publication of decisions." *In re General Foods Corp*., 1980 FTC LEXIS 99, at *12 n.7 (March 10, 1980). Thus, in instances where a document or trial testimony had been given *in camera* treatment, but the portion of the material cited to in this Initial Decision does not in fact merit *in camera* treatment, such material is disclosed in the public version of this Initial Decision, pursuant to Commission Rule 3.45(a) (the ALJ "may disclose such *in camera* material to the extent necessary for the proper disposition of the proceeding"). Where *in camera* information is used in this Initial Decision, it is indicated in bold font and braces ("**{ }**") in the *in camera* version and is redacted from the public version of the Initial Decision, in accordance with Commission Rule 3.45(e). 16 C.F.R. § 3.45(e).

Minneapolis & St. Louis Ry. Co. v. United States, 361 U.S. 173, 193-94 (1959). *Accord Stauffer Labs., Inc. v. FTC*, 343 F.2d 75, 82 (9th Cir. 1965). *See also Borek Motor Sales, Inc. v. NLRB*, 425 F.2d 677, 681 (7th Cir. 1970) (holding that it is adequate for the Board to indicate that it had considered each of the company's exceptions, even if only some of the exceptions were discussed, and stating that "[m]ore than that is not demanded by the [APA] and would place a severe burden upon the agency"). Issues of fact or law that do not affect the result in a case are not fairly deemed "material," for purposes of Section 557(c)(3)(A) of the APA, 5 U.S.C. § 557(c)(3)(A), or Rule 3.51(c)(1) of the Commission's Rules of Practice, 16 C.F.R. § 3.51(c)(1), notwithstanding that there may be allegations or evidence presented on such issues. Rather, "a fact is only material if its resolution will affect the outcome" of the case. *Lenning v. Commer. Union Ins. Co.*, 260 F.3d 574, 581 (6th Cir. 2001) (summary judgment case). *See also Timpa v. Dillard*, 20 F.4th 1020, 1028 (5th Cir. 2021) (stating in a summary judgment case that "[a] fact is 'material' if it 'might affect the outcome of the suit under the governing law'") (*quoting Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). Furthermore, the Commission has held that Administrative Law Judges are not required to discuss the testimony of each witness or all exhibits that are presented during the administrative adjudication. *In re Amrep Corp.*, 1983 FTC LEXIS 17, at *566-67 (Nov. 2, 1983). In addition, all expert opinion evidence submitted in this case has been fully reviewed and considered. Except as expressly relied on or adopted in this Initial Decision, such opinions have been rejected, as either unreliable, unsupported by the facts, or unnecessary to the findings and conclusions herein.

Under Commission Rule 3.51(c)(1), "[a]n initial decision shall be based on a consideration of the whole record relevant to the issues decided, and shall be supported by reliable and probative evidence." 16 C.F.R. § 3.51(c)(1); *see In re Chicago Bridge & Iron Co.*, 2005 FTC LEXIS 215, at **8 n.23 (Jan. 6, 2005), *aff'd, Chicago Bridge & Iron Co. v. FTC*, 534 F.3d 410, 423 n.5 (5th Cir. 2008). The parties' burdens of proof are governed by Commission Rule 3.43(a), Section 556(d) of the Administrative Procedure Act, and case law. Pursuant to Commission Rule 3.43(a), "[c]ounsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto." 16 C.F.R. § 3.43(a). Under the APA, "[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof." 5 U.S.C. § 556(d). The

APA, "which is applicable to administrative adjudicatory proceedings unless otherwise provided by statute, establishes '. . . the traditional preponderance-of-the evidence standard.'" *In re Rambus, Inc.*, 2006 FTC LEXIS 101, at *45 (Aug. 20, 2006) (quoting *Steadman v. SEC*, 450 U.S. 91, 95-102 (1981)), *rev'd on other grounds*, 522 F.3d 456 (D.C. Cir. 2008). Under the APA, an Administrative Law Judge ("ALJ") may not issue an order "except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence." 5 U.S.C. § 556(d). All findings of fact in this Initial Decision are supported by reliable, probative, and substantial evidence. Citations to specific numbered findings of fact in this Initial Decision are designated by "F."[3]

II. FINDINGS OF FACT

A. The Parties and the Acquisition

1. Jurisdiction

1. Respondent Illumina, Inc. ("Illumina") is a publicly traded, for-profit Delaware corporation, founded in 1998, with its headquarters in San Diego, California. (PX0061 at 005 (Illumina 2020 Form 10-K); JX0001 (Joint Stipulations of Law and Fact) ¶ 1).

2. Respondent Grail, Inc. ("Grail"[4]) is a corporation with its principal office and laboratory in Menlo Park, California. (PX4082 (Grail) at 130 (email attaching Grail 2020 S-1/Amended, Sept. 2020)).

[3] References to the record are abbreviated as follows:

PX – Complaint Counsel's Exhibit
RX – Respondents' Exhibit
JX – Joint Exhibit
Tr. – Transcript of testimony before the ALJ
Dep. – Transcript of Deposition
IHT – Transcript of Investigational Hearing
CCB – Complaint Counsel's Post-Trial Brief
CCRB – Complaint Counsel's Post-Trial Reply Brief
CCFF – Complaint Counsel's Proposed Findings of Fact
CCRRFF – Complaint Counsel's Reply to Respondents' Proposed Findings of Fact
RB – Respondents' Post-Trial Brief
RRB – Respondents' Post-Trial Reply Brief
RFF – Respondents' Proposed Findings of Fact
RRCCFF – Respondents' Reply to Complaint Counsel's Proposed Findings of Fact

[4] The term "GRAIL" in all capital letters is used when it is shown as "GRAIL" in the source transcripts or exhibits. The terms "Grail" and "GRAIL" are used interchangeably.

3. Illumina and Grail engage in activities in or affecting commerce as defined in Section 4 of the FTC Act, 15 U.S.C. § 44 (2006), and Section 1 of the Clayton Act, 15 U.S.C. § 12 (2006). (Complaint Counsel's Proposed Conclusion of Law No. 7; Respondents' Response to Complaint Counsel's Proposed Conclusion of Law No. 7).

2. Illumina

4. Illumina's principal product offerings are short-read next-generation sequencing ("NGS") instruments used for deoxyribonucleic acid ("DNA") sequencing and associated consumables and analytical software.[5] (PX0061 at 005 (Illumina 2020 Form 10-K)).

5. Consumables are "the materials that are actually consumed in a sequencing run." For "every sequencing run you need a new set of consumables, but you use the same instrument." (Aravanis (Illumina) Tr. 1845-46).

6. Illumina's products and services serve customers in a wide range of markets, enabling the adoption of genomic solutions in research and clinical settings. (PX0061 (Illumina) at 005; *see also* Berry (Illumina) Tr. 807-08). Illumina's customers include leading genomic research centers, academic institutions, government laboratories, and hospitals, as well as pharmaceutical, biotechnology, commercial molecular diagnostic laboratories, and consumer genomics companies. (PX0061 (Illumina) at 005; *see also* deSouza (Illumina) Tr. 2313-15; Berry (Illumina) Tr. 807-09; RX1254 (Illumina) at 028).

7. Illumina's core business consists of selling NGS instruments and consumables. In 2018, 2019, and 2020, total sequencing revenue comprised 83%, 87%, and 89%, respectively, of total revenue. (PX0061 at 007-08 (Illumina 2020 Form 10-K); *see also* PX0091 (Illumina) at 010).

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

9. Illumina has "an extensive intellectual property portfolio," including ownership or exclusive licenses to over 900 U.S. patents and 650 pending U.S. patent applications. (PX0061 at 009 (Illumina 2020 Form 10-K)).

10. Illumina sells a variety of NGS sequencing instruments, including the "high-throughput"[6] NovaSeq model; "mid-throughput" NextSeq models; and "low-throughput" MiSeq, MiniSeq, and iSeq models. (PX0091 (Illumina) at 011-13 (Illumina Source Book, August 2020); *see* PX0114, Illumina Sequencing Platforms, https://www.illumina.com/systems/sequencing-platforms.html (listing Illumina sequencing platforms)).

[5] These product offerings are described in more detail, *infra.*

[6] "Throughput" means the number of patient samples that can be processed over a given period. (Conroy (Exact/Thrive) Tr. 1580-81; deSouza (Illumina) Tr. 2265).

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

12. Illumina's sequencing instruments require, from a technical perspective, the use of Illumina consumables. (PX6056 (Illumina) at 018 (Illumina, Narrative Response to Second Request, Mar. 1, 2021)).

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

14. Illumina sells consumables, which include reagents, flow cells, and microarrays. In 2020, Illumina's consumable sales accounted for 71% of Illumina's total revenue. (PX0061 at 007 (Illumina 2020 Form 10-K)).

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

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

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

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

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

3. Formation of Grail

20. In mid-2015, a team within Illumina assembled a presentation proposing the creation of a new company to develop a blood-based cancer detection test. (PX2007 (Illumina) at 013 (Illumina, ScreenCo Opportunity Overview, July 20, 2015)).

21. Illumina formed Grail with the goal of achieving the "holy grail" in the war on cancer: a test enabled by Illumina's sequencing technology to detect multiple types of cancer in asymptomatic individuals through a blood draw. (Aravanis (Illumina) Tr. 1872-73; PX0036 (Grail) at 005; PX7079 (Flatley (Illumina) Dep.) at 35-37; PX7104 (Aravanis (Illumina) Dep.) at 159-60).

22. Illumina seeded Grail with the talent, research and development ("R&D") capabilities, and development plans and data that Grail would need to investigate how to use NGS technology for multicancer early detection through foundational, population-scale trials. (PX7107 (deSouza (Illumina) Dep.) at 182-83).

23. Illumina's leadership considered several reasons to form Grail as a separate company, rather than as a unit within Illumina. According to a 2015 Illumina presentation, forming a new startup would enable Grail to "retain[] and attract[] best-in-class people through equity, culture, and quality of the science." (PX2005 (Illumina) at 012 (Illumina, ScreenCo: Early Cancer Detection on a Global Scale, 2015)). Forming a separate company would allow Illumina to attract additional investment for Grail. (PX2006 (Illumina) at 001 (email from R. Klausner, Illumina, to M. Stapley et al., Illumina, July 14, 2015)).

24. Illumina's leadership assessed that creating a separate company would allow Grail to be "more nimble," "make decisions more quickly [and] . . . change directions more quickly." (PX7089 (Naclerio (Illumina) Dep.) at 252-53).

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

26. Illumina incorporated Grail in Delaware in September 2015 as a wholly-owned subsidiary of Illumina. (PX4082 (Grail) at 175, 211 (email attaching Grail 2020 S-1/Amended, Sept. 2020)).

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

28. In connection with its formation in June 2016, Grail raised $100 million in Series A financing from investors including Illumina, Arch Ventures, Bill Gates, and Jeff Bezos. (RX0667 (Illumina) at 002 (email from J. Flatley, Illumina, to W. Rastetter, Illumina, attaching "Illumina Forms New Company to Enable Early Cancer Detection via Blood-Based Screening," Jan. 10, 2016); PX2069 (Illumina) at 005 (Python Board Approval, Dec. 20, 2015); RX3984 (Illumina) (April 2017 Illumina Form 10-Q) at 014)).

29. In connection with the transaction summarized in F. 27-28, Illumina retained 55 percent ownership of Grail on a fully diluted basis and over 90 percent of share voting rights. (PX2069 (Illumina) at 005-06 (Python Board Approval, Dec. 20, 2015)). Additionally, Illumina and Grail "executed a long-term supply agreement in which [Illumina] contributed certain perpetual licenses, employees, and discounted supply terms in exchange for" shares of common stock. (RX3984 (Illumina) (April 2017 Illumina Form 10-Q) at 014)).

30. At the time of Grail's formation, no other oncology testing companies were developing liquid biopsy cancer screening tests. (PX7107 (deSouza (Illumina) Dep.) at 182; PX2554 (Illumina) at 014 (email from J. Owens, Illumina, to P. Scagnetti, Illumina, et al., attaching Illumina, Python Board Slides, Oct. 26, 2015) (most oncology testing companies were then "currently focused in therapy selection [and were] not yet pursuing screening."); *see also* PX2543 (Illumina) at 001 (Illumina, Grail FAQs, Jan. 11, 2016) ("We do not believe GRAIL is competing with the customers we're enabling in the liquid biopsy space. We don't believe any of our customers have the ability to economically deploy this test in the next five years, due to the scale of clinical trial work required."); PX7060 (Naclerio (Illumina) IHT) at 172-73 (At the time Illumina first started exploring the option of starting Grail, there were not "any companies who had quite the audacious goal of saying let's – let's go right to screening asymptomatic people for cancer.")).

31. At the time of Grail's formation, Illumina perceived some skepticism that Grail could successfully develop a multicancer screening test. As Dr. Nick Naclerio, Illumina's Senior Vice President of Corporate and Venture Development at the time of Grail's formation testified, "I think at the time most of the other companies in the field thought – and what they told their investors was Illumina is kind of crazy to go after this [asymptomatic] pan cancer screening, that we're going after more reasonable commercial applications, like screening high-risk people or minimal residual disease or other things like that, and, you know, Illumina is kind of going after this crazy thing. Well, it's kind of good for the field, but I think most people thought it was a science project." (PX7089 (Naclerio (Illumina) Dep.) at 274-76).

32. At the time of Grail's formation, Illumina believed that "no customer ha[d] the ability to implement a pan-cancer screening test responsibly and economically anytime in the next 5 years, and therefore [Illumina] felt an imperative to organize an entity" focused on achieving that goal. (RX1088 (Illumina) at 007; PX7079 (Flatley (Illumina) Dep.) at 111-12).

33. In forming Grail, Illumina undertook "to create something that we thought no one else was going to do. . . . [I]f you look at the original agreements around what GRAIL can and can't do . . . [GRAIL] was really meant to be bringing in something that might some day be possible in the future by years. And I think if you look at the original GRAIL business plan, they talk about how this would save tens of thousands of lives by having this available sooner." (PX7089 (Naclerio (Illumina) Dep.) at 274-76).

34. Illumina's "strategic rationale" for forming Grail was to "[a]ccelerat[e] development of the ctDNA [F. 102] cancer screening market by 10 years." At the time of the formation of Grail, Illumina identified cancer screening as "the largest liquid biopsy market opportunity," but that "analysts estimate 7-15 years" for that market to develop. Illumina also identified the "[c]ost of sequencing" as among the most "significant barriers" to innovation and adoption of liquid biopsy cancer screening. Illumina assessed that forming Grail would "accelerate[] development of the market" by enabling Illumina to provide "[g]roundbreaking deep sequencing R&D that is not economical for others today" and

allowing "[i]nvestment in large scale clinical validation that is cost-prohibitive to most venture-backed start-ups." Illumina also expected that forming Grail would "enable[] Illumina to capitalize on [the] screening market years earlier AND own a substantial portion of the value created." (PX2069 (Illumina) at 018 (Python Board Approval, Dec. 20, 2015)).

35. While Illumina controlled Grail, Illumina helped to accelerate development of Grail's multicancer early detection ("MCED") test by providing Grail with "forward pricing." (PX7089 (Naclerio (Illumina) Dep.) at 250). "Forward pricing" meant that Illumina charged Grail what Illumina expected its prices to be a number of years in the future. (PX7089 (Naclerio (Illumina) Dep.) at 250-51). The impact of providing forward pricing to Grail was that Illumina gave Grail discounts on reagents. (PX7089 (Naclerio (Illumina) Dep.) at 251). It would have been difficult for Grail to develop its MCED test without discounts such as forward pricing. (PX7060 (Naclerio (Illumina) IHT) at 201-02).

36. Illumina's assumptions at the formation of Grail about the volume of sequencing that would be required to develop a cancer screening test were significantly higher than what is actually required. Grail was able to the reduce the required volume of sequencing. (PX7079 (Flatley (Illumina) Dep.) at 118-20).

4. Spin-off of Grail

37. Grail required a substantial amount of capital to conduct the foundational clinical trials necessary to build the data sets for its machine learning algorithm that differentiates abnormal tumor patterns. (PX7079 (Flatley (Illumina) Dep.) at 92-94; PX7065 (Aravanis (Illumina) Dep.) at 61-64; RX3083 (Bryce et al., 2021) at 1).

38. Illumina decided to bring in outside investors to spread the risk while ensuring Grail had the capital it needed to move from concept through clinical trials, and the freedom of a biotech startup to experiment and fail in pursuit of its objective. (Aravanis (Illumina) Tr. 1772-74; PX7079 (Flatley (Illumina) Dep.) at 92-94).

39. In 2016, Grail engaged investors in an effort to raise capital. (PX6049 (Grail) at 103 (Narrative Response to Second Request, Mar. 1, 2021)).

40. In February 2017, Illumina completed a capital raise in connection with which Illumina reduced its stake in Grail to less than 20%. Illumina thereafter reduced its equity stake in Grail to approximately 12% of Grail's outstanding shares on a fully diluted basis. (RX3972 (Illumina) at 002; RX3984 (Illumina) at 014-15; Aravanis (Illumina) Tr. 1876-77; *see* deSouza (Illumina) Tr. 2202).

41. When Illumina spun off Grail in February 2017 by reducing Illumina's stake in Grail to less than 20%, Illumina signed an amended long-term supply agreement with Grail to supply Grail with NGS instruments and reagents. The agreement included a royalty payment to Illumina of approximately 7% of future net sales of any Grail oncology

products or services until it has paid cumulative royalties of $1 billion, at which point the royalty rate would decline to 5%. (RX1371 (Illumina) at 010-12 (Amended and Restated Supply and Commercialization Agreement between Illumina, Inc. and Grail, Inc.)).

42. The Grail royalty payment (F. 41) was a unique feature of Grail's supply agreement with Illumina, in that the payment was not tied to licensing any intellectual property or particular technology, but was designed to provide revenue sharing to Illumina. No other customer of Illumina pays a royalty on their sales of tests. (deSouza (Illumina) Tr. 2463-64; PX7107 (deSouza (Illumina) Dep.) at 190-91; Strom (Morgan Stanley) Tr. 3543-44).

43. Once Illumina's ownership decreased to 20%, the relationship between Illumina and Grail "became one of a vendor and an important customer." (Aravanis (Illumina) Tr. 1876).

5. Grail

44. As of September 2020, Grail had raised $1.9 billion "through a combination of leading venture capital and strategic partners." (PX4082 (Grail) at 086 (email attaching Grail 2020 S-1/Amended, Sept. 2020); Freidin (Grail) Tr. 3015-16; PX5023 (Illumina) at 003 (Illumina, Project Grail, Phil Febbo & Corporate Development, Mar. 2020)).

45. By late 2020, Grail had built a multi-disciplinary organization of scientists, engineers, and physicians to use the power of next-generation sequencing, population-scale clinical studies, and state-of-the-art computer science and data science to develop a multicancer early detection test. (PX0043 (Grail) at 004; *see also* Aravanis (Illumina) Tr. 1907; deSouza (Illumina) Tr. 2334-35).

46. Grail has grown to over 400 employees. (PX5045 (Grail) at 014 (Grail, Grail Board Session Meeting Materials, Sept. 10, 2020)).

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

6. Galleri

48. Grail's flagship test is its multicancer early detection ("MCED") test, called Galleri. (RX3256 (Grail, Our Products, https://grail.com/our-products); RX3255 (Grail, The Galleri Test, https://www.galleri.com/the-galleri-test)).

49. The Galleri test is "[i]ntended to be used as a cancer screening test in asymptomatic individuals." (PX6049 (Grail) at 012 (Grail, Narrative Response to Second Request, Mar. 1, 2021); *see also* PX4572 (Grail) at 006, 032 (Grail, Early Cancer Detection: Investor Presentation, Dec. 2020)).

50. Grail's Galleri test analyzes DNA methylation[7] patterns, or methylation abnormalities, to detect the presence of cancer in the blood and predict where the cancer came from in the body (*i.e.*, the molecular cancer signal of origin). (Ofman (Grail) Tr. 3285-88; RX3255 (Grail, The Galleri Test, https://www.galleri.com/the-galleri-test); Jamshidi (Grail) Tr. 4042-43).

51. Grail states that Galleri has the ability to detect over 50 cancers from a single blood draw. (RX3255 (Grail, The Galleri Test, https://www.galleri.com/the-galleri-test); RX3256 (Grail, Our Products, https://grail.com/our-products)).

52. Galleri was offered for sale on a limited basis as a laboratory developed test ("LDT")[8] in April 2021. (PX6061 (Grail) at 013 (Responses and Objections to the Federal Trade Commission's First Set of Interrogatories, May 3, 2021); RX3279 (Grail) at 002-03).

53. To sell the Galleri test as an LDT, Grail is targeting large, self-insured employers; concierge medicine practices; executive health programs; and progressive healthcare institutions that focus on preventative health. (PX4082 (Grail) at 009, 011 (email attaching Grail 2020 S-1/Amended, Sept. 2020)).

54. As of August 2021, Grail had executed deals with three health systems, two self-insured employers, and roughly fifteen concierge practices. (Ofman (Grail) Tr. 3372, 3374-75, Della Porta (Grail) Tr. 464; Bishop (Grail) Tr. 1332-33)).

55. As of August 2021, Grail had sold around 3,000 Galleri tests. (Freidin (Grail) Tr. 2969).

56. Grail's Galleri test costs $949. (Bishop (Grail) Tr. 1322, 1404; deSouza (Illumina) Tr. 2342).

7. The Acquisition

57. As of September 20, 2020, Illumina held 14.5% of Grail's shares outstanding, and approximately 12% on a fully diluted basis. (PX0122 (Illumina) at 002; RX3349 (Grail) at 003).

58. On September 20, 2020, Illumina entered into an Agreement and Plan of Merger to acquire Grail for total consideration of $8 billion, consisting of $3.5 billion in cash and $4.5 billion in shares of Illumina common stock, subject to a collar (the "Acquisition"). (PX0061 at 005 (Illumina 2020 Form 10-K); *see also* Bishop (Grail) Tr. 1353; deSouza

[7] Methylation is a biological process that affects how cells behave; in the context of cancer, methylation tends to "turn off" tumor-suppressing genes and "turn on" tumor-promoting genes. (Aravanis (Illumina) Tr. 1881-82; Ofman (Grail) Tr. 3286).

[8] A laboratory developed test is a test developed on-site at a single clinical laboratory, which uses components from multiple suppliers to put together a specific test that is then validated in that laboratory. (Febbo (Illumina) Tr. 4320; *see also* PX0043 at 041 (Grail 2020 Form S-1)).

(Illumina) Tr. 2215; PX5048 at 002-03 (Grail, Notification and Report Form, Oct. 9, 2020)).

59. On September 21, 2020, Illumina and Grail announced they had entered into the merger agreement referenced in F. 58. (PX0122 (Illumina) at 001; RX3349 (Grail) at 001).

60. On August 18, 2021, Illumina consummated the transaction, but committed to holding Grail as a separate company during the regulatory review being undertaken by the European Commission. (PX0377 (Illumina) at 001; *see also* deSouza (Illumina) Tr. 2234-38 (discussing PX0378, Illumina 2021 Form 8-K); PX2851 (Illumina) (Hold-Separate Commitments, Aug. 18, 2021) (listing voluntary hold-separate commitments to the European Commission, in a document signed by Illumina CEO Francis deSouza)).

61. As part of its voluntary hold-separate commitment, Illumina represented that "from Closing until the [European Commission] Decision Date," "the management and staff of Illumina will have no involvement in GRAIL" and that "the day-to-day operation of GRAIL will remain the sole responsibility of GRAIL's management and the day-to-day operation of Illumina will remain the sole responsibility of Illumina's management. (PX2851 (Illumina) at 002 (Hold-Separate Commitments); *see also* PX0378 (Illumina) at 004 (Illumina Form 8-K, Aug. 18, 2021)).

62. As of the time of trial, due to the hold separate agreement, Illumina's clinical affairs team, market access team, regulatory team, and sales teams have not been collaborating with Grail's respective teams. (deSouza (Illumina) Tr. 2286-88).

63. Following the close of the transaction, the royalty payment to Illumina, referenced in F. 41 was eliminated. Grail no longer pays Illumina a royalty. (Aravanis (Illumina) Tr. 1959; deSouza (Illumina) Tr. 2358, 2463 (Grail has moved "to a standard purchasing agreement like everyone else, . . . where they just buy products from us, and we don't get a royalty from their sales."); Freidin (Grail) Tr. 2977).

64. Illumina has now paid Grail the $8 billion consideration owed under the merger agreement and Grail's Board of Directors has been dissolved. (deSouza (Illumina) Tr. 2239, 2282).

B. Industry Background

1. Cancer Screening

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

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

67. "Standard of care" screening methods refer to existing cancer screening methods approved and accepted in the medical field. (Lengauer (Exact/Thrive) Tr. 169).

68. There are no standard screening options for the majority of cancers today. (Conroy (Exact/Thrive) Tr. 1736-37; Nolan (Freenome) Tr. 2725; PX2009 (Illumina) at 017 (April BoD M&A Strategy Presentation, Apr. 28, 2020); PX7040 (Getty (Guardant) IHT) at 32).

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

70. Radiologic tests are used to screen for breast cancer and lung cancer. (Cance (ACS) Tr. 606).

71. Pap smears and examinations of the human papilloma virus DNA in the blood screen for cervical cancer. (Cance (ACS) Tr. 606).

72. Examinations of prostate-specific antigen levels screen for prostate cancer. (Cance (ACS) Tr. 606).

73. Colonoscopy is the gold standard for colon cancer screening. (Conroy (Exact/Thrive) Tr. 1547-48).

74. Although traditional imaging screenings are typically focused on screening for cancer in a single organ of the body, positron emission tomography ("PET"), computed tomography ("CT"), and PET/CT may in some circumstances be used for whole-body scanning, with PET/CT being more accurate in detecting cancer and providing fewer equivocal findings than PET alone, CT alone, or separately acquired PET and CT studies in a head-to-head comparison. (Bishop (Grail) at 1432; RX3624 (Schöder & Gönen 2007) at 009; Cote Tr. 3812).

75. A PET/CT scan is not recommended for routine early cancer screening, because of cost and radiation concerns, as well as the inability of PET/CT scanning to detect very small tumors. (RX3624 (Schöder & Gönen 2007) at 009-10; Cote Tr. 3812-13; RX3869 (Cote Expert Report) ¶ 72).

76. The stage identified for a cancer describes the extent or spread of cancer at the time of diagnosis. (RX3030 at 011 (American Cancer Society, Cancer Facts & Figures 2019)).

77. Stages of cancer range from Stage 0 to Stage IV. Stage 0 correlates with "in situ" cancer, which means that "cancer cells are present only in the layer of cells where they developed and have not spread." Stage I cancer is "early" stage cancer and Stage IV indicates "the

most advanced disease." From Stage 0 to Stage IV, "[t]he higher the number, the larger the cancer tumor and the more it has spread into nearby tissues[,]" until Stage IV, which means the "cancer has spread to distant parts of the body." (RX3500 at 003 (Cancer Staging – National Cancer Institute, https://www.cancer.gov/about-cancer/diagnosis-staging/staging); RX3030 at 011 (American Cancer Society, Cancer Facts & Figures 2019); RX3500 at 003 (Cancer Staging – National Cancer Institute, https://www.cancer.gov/about-cancer/diagnosis-staging/staging).

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

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

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

81. Detection of cancer after it has progressed leads to high mortality rates. (PX2005 (Illumina) at 003 (ScreenCo - Early Cancer Detection on a Global Scale); Conroy (Exact/Thrive) Tr. 1736).

82. By some estimates, patients with cancers diagnosed early, or when it is considered "localized," have an 89 percent survival rate, compared to a 21 percent survival rate if diagnosed late or after distant metastases. (PX5024 (Illumina) at 022 (Board of Directors M&A Landscape Presentation, Apr. 28, 2020); PX8317 (Exact) at 020 (Spectre Diligence Kickoff, Oct. 4, 2020)).

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

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

85. Screening for cancer increases the chances of detecting certain cancers early, when they might be easier to treat. (PX8398 (Cance (ACS) Decl.) ¶ 5).

86. Advancements in blood-based cancer diagnostics present the possibility that some cancers previously undetectable until the late stages of disease could be detected at earlier stages, when treatment has a higher likelihood of success. (PX8398 (Cance (ACS) Decl.) ¶ 6).

2. Liquid Biopsy

87. Traditionally, cancers are detected and diagnosed through a tissue biopsy or involve an invasive procedure like a colonoscopy. (PX8398 (Cance (ACS) Decl.) ¶ 5).

88. Tests that sample blood or other bodily fluids – rather than tissue – are referred to as "liquid biopsy" tests. (PX7051 (Lengauer (Exact/Thrive) IHT) at 28-29).

89. Liquid biopsy tests are a new type of cancer screening test being developed. (Cance (ACS) Tr. 608).

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

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

92. Once at the laboratory, the test developer performs a "series of chemistry steps to isolate the DNA from" the patient's blood and prepares it for sequencing in a process known as library preparation. (Bishop (Grail) Tr. 1379-81; Chudova (Guardant) Tr. 1157-59).

93. Following library preparation, the test sample is sequenced on a sequencing instrument to identify the order of base pairs in each molecule in the library. (Chudova (Guardant) Tr. 1159; PX0043 at 105-06 (Grail 2020 Form S-1)).

94. The sequencing data is analyzed using bioinformatic and analytical techniques to determine whether the results indicate the potential presence of a particular type of cancer. (Chudova (Guardant) Tr. 1159; PX7051 (Lengauer (Exact/Thrive) IHT) at 33-37; PX7048 (Klausner (Grail) IHT) at 117-19).

3. Analyte Molecules in Blood and Other Body Fluids

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

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

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

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

98. DNA resides in the nucleus of most cells in the form of long (up to hundreds of millions of base pairs) molecules called chromosomes. (PX4035 (Grail) at 010-11 (PiperJaffray, The 2015 Liquid Biopsy Report, Sept. 2015); PX0043 at 105 (Grail 2020 Form S-1)).

99. As cells within the body die, their chromosomes are broken down into small pieces and released into the blood stream as cell-free DNA ("cfDNA"). These cfDNA fragments are typically less than 200 base pairs long. (PX2010 (Illumina) at 008 (TruSight Oncology 500 ctDNA Sales Training); *see also* Chudova (Guardant) Tr. 1157-62).

100. cfDNA is a harmless byproduct of cell death that is present in all human bloodstreams. (PX4035 (Grail) at 010-11 (PiperJaffray, The 2015 Liquid Biopsy Report, Sept. 2015) (noting 50 to 70 million cells die every 24 hours)).

101. When cancer cells die, their chromosomes are broken down into short fragments that are shed into the bloodstream as cfDNA. (PX2010 (Illumina) at 008 (TruSight Oncology 500 ctDNA Sales Training)).

102. The subset of cfDNA in the blood that originated from cancerous tumor cells is specifically called circulating tumor DNA ("ctDNA"). ctDNA reflects the genetic makeup of the tumor cells that released it and can differ from normal non-cancerous cfDNA in a variety of ways. (PX2010 (Illumina) at 009 (TruSight Oncology 500 ctDNA Sales Training); PX4035 (Grail) at 011-12 (PiperJaffray, The 2015 Liquid Biopsy Report, Sept. 2015)).

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

104. Because most of the DNA in blood is derived from normal cells, there is a very small amount of ctDNA in blood relative to normal cfDNA. (Lengauer (Exact/Thrive) Tr. 161-62).

105. Detecting cancer signals in the blood plasma of otherwise healthy individuals is difficult because finding ctDNA in the blood is like finding a "needle in a haystack of normal cfDNA." (PX2013 (Illumina) at 009 (Science & Technology Committee: Cancer Screening, Apr. 28, 2020); PX7040 (Getty (Guardant) IHT) at 38-39; PX7045 (Chudova (Guardant) IHT) at 30-31).

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

107. Some cancer types are more difficult to detect than others because they involve tumors which do not readily shed ctDNA into the bloodstream. (PX7111 (Fesko (Natera) Dep.) at 28-29).

108. The challenges of detecting ctDNA become more significant as you go from late-stage disease to early-stage and then into screening. (Chudova (Guardant) Tr. 1162-63).

b. Cell-Free RNA (cfRNA) and Proteins

109. In the first step of the "central dogma" of molecular biology, DNA is transcribed into RNA. (*See* Jamshidi (Grail) Tr. 4055-56).

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

111. RNA may be found in blood plasma in the form of cell-free or circulating-free RNA ("cfRNA"). (*See* Jamshidi (Grail) Tr. 4055-56).

112. Cell-free RNA is an analyte that may be useful in the identification of cancer. (Bishop (Grail) Tr. 1481-82).

113. In the next step of molecular biology, RNA is translated into proteins. (*See* Jamshidi (Grail) Tr. 4056-57).

4. Classes of Biomarkers Utilized for Cancer Detection

114. MCED test developers may utilize different classes of biomarkers to detect cancer. (*See, e.g.*, Lengauer (Exact/Thrive) Tr. 160, 175); Aravanis (Illumina) Tr. 1880-81)).

115. A biomarker is some form of signature or fingerprint that may indicate the existence of cancer. (Lengauer (Exact/Thrive) Tr. 160).

116. A biomarker is either a protein or DNA or RNA or other molecule in the body that is present when cancer is present and not present when cancer is not present. (PX7058 (Conroy (Exact/Thrive) IHT) at 31-32).

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

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

119. "[C]ancer has certain specific mutations or changes that only occur in cancer settings." (PX7091 (Lengauer (Exact/Thrive) Dep.) at 25).

120. Interrogating mutations in cfDNA falls within the field of study called "genomics." (PX2369 (Illumina) at 014 (email from J. Godsey, Illumina, to D. Baker et al., Illumina, Apr. 12, 2020, attaching "Recent Advances in Genomics-based Cancer Screening" draft, Apr. 28, 2020) (listing various types of mutations – including single nucleotide variants, insertions/deletions, fusions, and copy number variants – as "genomic alterations" that provide a signal in ctDNA)).

121. Methylation is a process that plays a role in regulating gene expression, protein function, and RNA processing. (PX0043 at 106 (Grail 2020 Form S-1); *see also* Ofman (Grail) Tr. 3286 (stating that methylation refers to "little methyl groups that actually attach to the DNA" but do not change the DNA code); Rabinowitz (Natera) Tr. 357-58 (explaining that methylation "is a methyl group or . . . one carbon and three hydrogen atoms that can attach to cytosine, which is one of the nucleotides of DNA")).

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

123. Abnormal methylation patterns are a hallmark of cancer, such as where unmethylated C in a nucleotide becomes a methylated C, or vice versa. (Chudova (Guardant) Tr. 1166-67; Ofman (Grail) Tr. 3286).

124. "Fragmentomics" refers to the analysis of aberrant patterns of cfDNA fragment lengths. (Lengauer (Exact/Thrive) Tr. 175).

125. A gain or loss of a significant portion of genetic material can cause genetic instability and, in some cases, cancer. (PX7051 (Lengauer (Exact/Thrive) IHT) at 36-37; *see also* Lengauer (Exact/Thrive) Tr. 175-76).

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

127. Elevated protein expression level is a potentially informative class of biomarker for cancer detection. (Lengauer (Exact/Thrive) Tr. 175).

128. Proteomics platforms are used to analyze proteins in patient samples. (deSouza (Illumina) Tr. 2325).

129. Multiomics refers to utilizing more than one class of biomarker – and potentially more than one type of analyte molecule – to analyze a sample. (*See* Della Porta (Grail) Tr. 492; Nolan (Freenome) Tr. 2710-11).

C. Background on MCED Tests

1. Overview

130. MCED tests examine blood samples to detect multiple cancers at an early stage. (Cance (ACS) Tr. 609).

131. MCED tests are intended to be used for the general population, with the goal of screening asymptomatic adults for cancer. (*See, e.g.*, PX4082 (Grail) at 008-09 (email attaching Grail 2020 S-1/Amended, Sept. 2020); PX7051 (Lengauer (Exact/Thrive) IHT) at 28-29;

PX7100 (Chudova (Guardant) Dep.) at 15-16; PX7094 (Nolan (Freenome) Dep.) at 252-53; PX4116 (Grail) at 013 (email from M. Podoll, Morgan Stanley, to A. Freidin, Grail, et al., attaching IPO Roadshow Video Outline: Project Galileo, Aug. 2020)).

132. MCED tests are intended to detect multiple types of early-stage cancer in asymptomatic individuals by examining the presence of ctDNA in the bloodstream. (PX2005 (Illumina) at 004-05, 009 (ScreenCo - Early Cancer Detection on a Global Scale Presentation, 2015); *see also* PX5027 (Illumina) at 016-17 (Board of Directors Meeting, Aug. 4, 2020)).

133. Particular areas of the genome that an MCED test focuses on are referred to collectively as a panel. (Chudova (Guardant) Tr. 1197).

134. MCED tests examine fragments of DNA in the bloodstream and determine whether any DNA has been shed from cancer cells. (PX8398 (Cance (ACS) Decl.) ¶ 7).

135. Research into MCED tests has revealed that a number of DNA mutations and methylation biomarkers are actually common across many different cancers. (Bishop (Grail) Tr. 1375) ("the cancer signal, the abnormalities we're looking at are actually shared between many different types of cancer"); [redacted] ("[W]e know that the DNA mutations that [redacted] in his lab curated are the very driver mutations that are common to most cancers"); Chudova (Guardant) Tr. 1201 ("We have identified regions that are typically quiet in blood, like you don't see methylation signals in those regions in blood, and so any upsignal in those regions . . . will be indicative of cancer in the appropriate indication. . . . [B]y such this design is encompassing all cancer types. It's not specific to particular cancer types where we expect to see separation.").

136. In terms of the technical approaches used by MCED test developers, some companies focus on methylation sites in DNA found in blood samples, and others combine a multiomic approach, which focuses on genomics, proteomics, and metabolomics. (Cance, Tr. 612-13; PX5024 (Illumina) at 025 (Illumina Board of Directors Meeting Minutes)).

137. The presence of a cancer signal in an individual's blood at an early stage is "very subtle." (PX7042 (Gao (Singlera) IHT) at 39-40).

138. Finding cancer cell DNA in a blood sample has been analogized to looking for the "proverbial needle in the haystack . . . ." (Lengauer (Exact/Thrive) Tr. 163). "[I]n ten [milliliters] of blood, . . . which you get from a regular blood draw, there might be only one such copy of the DNA with a [cancer-related] change in there. One copy." (PX7051 (Lengauer (Exact/Thrive) IHT) at 41-42).

139. In discussing early detection of cancer signals in the blood, Guardant's Dr. Darya Chudova explained:

> What you're looking for is a mutation that originate[s] in the tumor, so you have to test all thousand molecules to find that single one that potentially has the mutation. And so, in addition to covering [a] large number of mutations, you have to sequence each locus deeply to find that needle in the haystack that potentially contains the mutation that you're looking for, so it's a combination of testing multiple sites and testing them deeply for any one individual patient to give them a comprehensive answer.

(PX7045 (Chudova (Guardant) IHT) at 30-31).

2. Metrics used in MCED Tests

140. Metrics that are used to assess the performance of cancer detection tests, including blood-based early-stage multicancer screening tests, include sensitivity, specificity and cancer signal of origin (also known as tissue of origin, or "TOO") analyses. (PX8398 (Cance (ACS) Decl.) ¶ 9; Cote Tr. 3778-82; RX3869 (Cote Expert Report) ¶ 90).

141. Sensitivity, also called the true positive rate, measures the proportion of actual positive samples that are correctly identified as such, or how often a test correctly generates a positive result for people who have the condition for which they are being tested. (RX3869 (Cote Expert Report) ¶ 91). Low sensitivity leads to high *false negative* rates. (Cote Tr. 3778-81; RX3869 (Cote Expert Report) ¶ 91 (emphasis in original)).

142. Relatively high sensitivity is an important requirement for an early cancer screening test designed for use in asymptomatic individuals. (Cote Tr. 3778-81; RX3869 (Cote Expert Report) ¶ 92).

143. Specificity, or the true negative rate, measures the proportion of actual negative samples that are correctly identified as such, or how often a test correctly generates a negative result for people not having the condition for which they are being tested. Low specificity leads to high *false positive* rates. (Cote Tr. 3778-81; RX3869 (Cote Expert Report) ¶ 93 (emphasis in original)).

144. According to the U.S. Food and Drug Administration, "high specificity is needed to minimize the potential harms from false positive results. A false positive result will lead to potentially harmful follow-up procedures and result in unnecessary anxiety to the individual." [redacted]

145. The FDA has stated that a specificity of 95% "will result in an unacceptably high number of false positive results." In order to minimize the potential harms from a false positive result, the FDA recommends that for reasonable assurance of clinical success, the specificity for a screening test should exceed 99%. [redacted]

146. Positive Predictive Value ("PPV") is related to false positive rate. It is the percentage of patients with a positive test who actually have cancer. (Cote Tr. 3778-81; RX3869 (Cote Expert Report) ¶ 93).

147. PPV represents the probability a patient has cancer when the test result is positive. (Cote Tr. 3778-79; RX3869 (Cote Expert Report) ¶ 93). The PPV is an important metric for cancer screening tests. (Cote Tr. 3778-81; RX3869 (Cote Expert Report) ¶ 93).

148. Because a cancer screening test is a test used in the general population, the baseline rate of cancer in that population is very low. (Cote Tr. 3778-81; RX3869 (Cote Expert Report) ¶ 93). As a result, the rate of true positives – individuals with cancer in the population – will be extremely low, around 4 in 1000 individuals. (RX3869 (Cote Expert Report) ¶ 93; RX3501 (National Cancer Institute, Cancer Statistics)).

149. Both false positive results and false negative results of a cancer screening test will have significant negative impact on the patient's well-being. (Cote Tr. 3868-69; 3778-81, 3814; RX3869 (Cote Expert Report) ¶ 94; *see also* PX7086 (Cance (ACS) Dep.) at 90-91).

150. False negative findings may cause physicians to not diagnose a cancer that either is already causing or will soon cause harm to patients and miss precious early treatment opportunities. False positive findings may lead to unnecessary follow-ups, invasive procedures to rule out cancer, and emotional distress to patients and their families. (Cote Tr. 3868-69, 3778-81, 3814; RX3869 (Cote Expert Report) ¶ 94; *see also* PX7086 (Cance (ACS) Dep.) at 90-91).

151. High specificity, *i.e.*, low false positive rates, is important for a cancer screening test. **(**Cote Tr. 3868-69, 3778-81, 3814; RX3869 (Cote Expert Report) ¶ 94; *see also* PX7086 (Cance (ACS) Dep.) at 90-91).

152. A test developer focusing on a cancer screening test for a large number of cancer types must focus on attaining a very high specificity rate, and a high PPV, which will often result in correspondingly lower sensitivity rates. (Cote Tr. 3778-81; RX3869 (Cote Expert Report) ¶ 95). This is because when screening the general population of individuals over age 50, or those with a family history of cancer, it is critical that the morbidity and expense of following up on a false positive test is minimized. (RX3869 (Cote Expert Report) ¶ 95).

153. A test developer focusing on a single cancer screening test or a test directed to only a handful of targeted cancer types may elect to focus on sensitivity more than specificity. (PX6097 (Abrams Expert Report) ¶ 29; RX3869 (Cote Expert Report) ¶ 95).

154. A blood test, unlike a biopsy of a specific organ, does not automatically indicate the possible cancer signal of origin for the cancer to be detected. (Cote Tr. 3782; RX3869 (Cote Expert Report) ¶ 96).

155. Cancer signal of origin or tissue of origin refers to the tissue or location in the body from which the cancer signal originates. Tissue of origin is "a necessary component" of an MCED test in order for the test "to be clinically useful." Without tissue of origin, doctors

would "be on an endless diagnostic odyssey to figure out where the positive [cancerous] signal is coming from . . . ." (Chudova (Guardant) Tr. 1204-05).

156. Identification of a cancer signal of origin allows for the follow-up from a positive test result to be efficiently directed to a targeted imaging step or a biopsy. (RX3869 (Cote Expert Report) ¶ 96).

157. A cancer screening test that is capable of detecting multiple cancer types that returns a positive result, but does not indicate the possible cancer signal of origin, could result in a possibly extensive, invasive, and expensive workup to rule in or out the presence of cancer. (Cote Tr. 3782, 3814, 3868-69; RX3869 (Cote Expert Report) ¶ 97).

158. The FDA has stated that an MCED test will have "limited clinical utility in the absence of reporting" the cancer signal of origin "in a population of patients at average risk for developing cancer." [redacted]

159. A survey conducted by one cancer screening test developer of twelve primary care physicians and twelve radiologists found that tissue of origin reporting is a "[h]ighly desirable feature that is a must-have to defend [a] competitive market position," and a "very helpful and, in most cases, a critical part" of an MCED test. [redacted]

160. Providing accurate cancer signal of origin to facilitate cancer diagnosis would improve clinical utility and patient compliance and would thus impact decision-making by physicians using cancer screening tests. (PX6097 (Abrams Expert Report) ¶¶ 10 g., 22, 27; RX3869 (Cote Expert Report) ¶¶ 97-98; Cote Tr. 3782).

D. Regulatory Approval Process and Reimbursement for MCED Tests

1. Laboratory-Developed Tests

161. A laboratory-developed test ("LDT") is a test developed on-site at a single clinical laboratory, which uses components from multiple suppliers to put together a specific test that is then validated in that laboratory. (Febbo (Illumina) Tr. 4320; *see also* PX0043 (Grail) at 041 (Grail 2020 Form S-1)).

162. An LDT must meet Clinical Laboratory Improvement Amendments ("CLIA") and College of American Pathologists ("CAP") guidelines, which are clinical lab guidelines. (Febbo (Illumina) Tr. 4320; Goswami (Illumina) Tr. 3185-86; *see also* Rabinowitz (Natera) Tr. 382).

163. To be offered to patients, LDTs must be performed in labs that have CLIA certification. (Febbo (Illumina) Tr. 4320).

164. CLIA is a regulatory framework by which independent labs self-certify the quality of their own product. (PX7111 (Fesko (Natera) Dep.) at 181; *see also* Goswami (Illumina) Tr. 3185-86; PX7097 (Felton (Thermo Fisher) Dep.) at 51).

165. The FDA does not review or validate safety or efficacy data associated with a test sold as an LDT. (Goswami (Illumina) Tr. 3262; *see also* PX0043 (Grail) at 041 (Grail 2020 Form S-1) (stating that "[a]lthough LDTs are classified as medical devices and FDA has statutory authority to ensure that medical devices are safe and effective for their intended uses, FDA has historically exercised enforcement discretion and has not enforced certain applicable FDA requirements, including premarket review, with respect to LDTs")).

166. LDTs have lower rates of adoption than FDA-approved tests. [redacted]

2. FDA Approval Process

167. The FDA and CMS (via the CLIA) regulate MCED tests. (PX0043 (Grail) at 115, 127-28, 132 (Grail 2020 Form S-1)).

168. Medical devices marketed in the United States must adhere to regulatory requirements as set forth in the Federal Food, Drug, and Cosmetic Act and 21 CFR §§ 1-58, 800-1299. (RX3326 (FDA) at 001). Devices are classified as Class I, II, or III, where each class corresponds to a differing degree of risk. (RX3326 (FDA) at 002).

169. To gain widespread commercialization and reimbursement of an MCED test, developers need FDA approval for their tests. (PX7092 (Ofman (Grail) Dep.) at 175-76; PX0043 (Grail) at 115, 132 (Grail 2020 Form S-1); PX7058 (Conroy (Exact/Thrive) IHT) at 87-88).

170. FDA approval is a necessary input to achieve Medicare coverage of MCED testing from CMS. (deSouza (Illumina) Tr. 2414; Ofman (Grail) Tr. 3319-20; Conroy (Exact/Thrive) Tr. 1734; Chahine (Helio) Tr. 1029-30; PX4172 (Grail) at 059 (Grail Board of Directors Meeting, Nov. 21, 2019) (stating that premarket approval is "[n]ecessary for broad CMS coverage"); PX9090 (Roche) at 019 (Cowen, The Liquid Biopsy Report: Early Detection of a Huge Opportunity, Sep. 18, 2020) (stating that it "is clear that CMS reimbursement [for asymptomatic cancer screening tests] will require FDA approval")).

171. A Premarket Approval ("PMA") is a regulatory approval from the FDA that applies to Class III diagnostic tests. (Febbo (Illumina) Tr. 4324-25; Ofman (Grail) Tr. 3319).

172. Unless an MCED test can be shown to be "substantially equivalent to a legally marketed predicate device," the test will be "automatically classified under the [Food, Drug, and Cosmetic Act] into class III, which generally requires PMA." (PX0043 (Grail) at 043 (Grail 2020 Form S-1)).

173. Medical devices categorized as Class III devices are considered to be the highest-risk category of medical devices. (PX7056 (Silvis (Tempus) IHT) at 37).

174. The FDA classifies an MCED test as a Class III high risk device and will require MCED tests to obtain PMA for FDA approval. (Gao (Singlera) Tr. 2872-73; Rabinowitz (Natera) Tr. 302-03; *see also* F. 175).

175. Galleri will be considered a Class III medical device and will require PMA. (Febbo (Illumina) Tr. 4445; PX7099 (Febbo (Illumina) Dep.) at 83-84; PX0043 (Grail) at 043-44 (Grail 2020 Form S-1)).

176. The FDA's requirements for PMA exceed those to meet LDT standards: "[T]he FDA has many additional requirements in terms of quality, manufacturing, inspections. The evidence requirements are quite different." (Ofman (Grail) Tr. 3319). "[T]here's just a lot more to getting an FDA approval above and beyond what it takes to get CAP/CLIA certification." (Ofman (Grail) Tr. 3319; *see also* Bishop (Grail) Tr. 1345 (stating that a PMA has "an entirely different set of requirements" than an LDT)).

177. The PMA pathway is a costly, lengthy, and uncertain process. (Rabinowitz (Natera) Tr. 395).

178. The PMA process requires submitting a lengthy application involving clinical and analytical validation data collected during clinical trials using the device. (PX4082 (Grail) at 135 (email attaching Grail 2020 S-1/Amended, Sept. 2020)).

179. Analytical validation means ensuring that a test measures what it purports to measure at certain levels of precision. (Ofman (Grail) Tr. 3284).

180. Analytical validation is typically followed by clinical validation, which means demonstrating that a test performs as indicated to detect the given disease in the intended use population. (Ofman (Grail) Tr. 3284-85).

181. Clinical validation is critical for the commercialization of a test, as it is necessary to receive FDA approval, Medicare coverage, and reimbursement by private insurance. (*See* Gao (Singlera) Tr. 2886-87; PX7099 (Febbo (Illumina) Dep.) at 35-36 (testifying that clinical validation is necessary for FDA approval); *see also* PX4160 (Grail) at 094 (Grail, Board of Directors Meeting, Nov. 10, 2020) (listing clinical validation as an element of regulatory and reimbursement strategy)).

182. Like clinical validation, demonstrating clinical utility requires evidence that a test can detect disease in the intended use population. (Qadan (Illumina) Tr. 4110).

183. Establishing clinical utility also involves assessing how a test's results may impact patient management and outcomes. (Qadan (Illumina) Tr. 4110-11).

184. Evidence of clinical utility relates to how a test changes patient management and outcomes. (PX7084 (Qadan (Illumina) Dep.) at 14 ("'[C]linical utility' . . . mean[s] how does the test change the management of a patient, resulting in better outcomes.")).

185. MCED test developers must conduct clinical trials for their tests to obtain regulatory approval. (Della Porta (Grail) Tr. 584; *see also* Lengauer (Exact/Thrive) Tr. 170 (explaining that for FDA approval, test developers must undergo a "registrational trial," which allows the FDA to evaluate the benefit-to-risk ratio of a test or device)).

186. MCED tests will require multi-year, large-scale clinical studies to receive FDA approval and payor reimbursement. [redacted] PX7091 (Lengauer (Exact/Thrive) Dep.) at 134-35; PX7077 (Chahine (Helio) Dep.) at 32-33 (Clinical trials for a multicancer test would be more costly than a single cancer trial because of the number of patient samples required to clinically prove the robustness of a multicancer test)).

a. Single-Site IVDs

187. An in-vitro diagnostic ("IVD") test is a test of human tissue or blood samples that is performed outside the body. (PX7040 (Getty (Guardant) IHT) at 79).

188. An IVD test for cancer screening requires PMA from the FDA. (PX7044 (Stahl (Invitae) IHT) at 52; PX7045 (Chudova (Guardant) IHT) at 76; *see also* RX3867 (Deverka Expert Report) ¶ 35). As part of its review, the FDA will typically inspect the manufacturer's facilities. (PX4082 (Grail) at 135 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

189. A single-site, or centralized, IVD test is approved by the FDA to run in a single approved lab, typically the developer's own laboratory. (Goswami (Illumina) Tr. 3185-86; PX7112 (Bailey (PGDx) Dep.) at 14; PX7093 (Young (Illumina) Dep.) at 43-44; PX7065 (Aravanis (Illumina) IHT) at 139-40; PX7055 (Otte (Freenome) IHT) at 41-42; PX7063 (Berry (Illumina) IHT) at 202; PX7064 (Goswami (Illumina) IHT) at 28-31; PX7040 (Getty (Guardant) IHT) at 78-79; PX7049 (Bailey (PGDx) IHT) at 25).

b. Distributed or Kitted IVDs

190. A distributed or kitted IVD is an IVD test that has received PMA from the FDA permitting analysis by independent testing providers, such as hospitals or large reference labs like LabCorp or Quest Diagnostics. (Leite (Illumina) Tr. 2150; Goswami (Illumina) Tr. 3186-87; PX7049 (Bailey (PGDx) IHT) at 68-69; PX7063 (Berry (Illumina) IHT) at 201-02; PX7112 (Bailey (PGDx) Dep.) at 14-18; PX7093 (Young (Illumina) Dep.) at 44).

191. A kitted IVD test must "lock-in" its specific NGS instrument, reagents, and other system components as part of the final FDA approval. (Leite (Illumina) Tr. 2151-52; PX7045 (Chudova (Guardant) IHT) at 73-74; PX7044 (Stahl (Invitae) IHT) at 60-61).

192. Modifying any component of the approved kitted IVD could require conducting an additional clinical trial with the modified component. (PX7045 (Chudova (Guardant) IHT) at 73-74).

193. Because the test is locked-in with a particular NGS platform, switching to new technology platforms is difficult. (PX7045 (Chudova (Guardant) IHT) at 73-74; PX7044 (Stahl (Invitae) IHT) at 60-61).

194. The distributed kitted IVD test developer has "responsibility for quality control and quality analysis" of the distributed kitted IVD test. (Goswami (Illumina) Tr. 3187).

195. A distributed kitted IVD test developer must follow FDA guidelines and submit to regular FDA audits following PMA of a distributed kitted IVD. (Goswami (Illumina) Tr. 3187).

196. An MCED test developer that relies on Illumina sequencing would need an IVD agreement with Illumina to distribute a kitted IVD test to third-party labs. (Leite (Illumina) Tr. 2151-52; Goswami (Illumina) Tr. 3262-63).

197. An MCED test developer would not need an IVD agreement with Illumina to distribute an LDT or a single-site IVD test. (Goswami (Illumina) Tr. 3273; Leite (Illumina) Tr. 2154-55).

3. Payer Reimbursement

198. FDA approval will likely be a requirement for an MCED test to receive broad-based reimbursement from payers. (Ofman (Grail) Tr. 3354-55; Conroy (Exact/Thrive) Tr. 1734; Bishop (Grail) Tr. 1343-44; PX7055 (Otte (Freenome) IHT) at 32-33; PX7068 (Perettie (FMI/Roche) IHT) at 33).

199. Obtaining reimbursement coverage from payers expands an MCED test developer's customer base by providing access to patients who otherwise could not afford to pay the out-of-pocket price of a test. (PX7083 (Bishop (Grail) Dep.) at 145-46).

200. Payers may be more apt to cover a test that is perceived to have undergone a more rigorous review process, and therefore may cover an FDA approved test more readily than an LDT, with an FDA-cleared test treated as an intermediate preference between the two. (PX7085 (Harada (Exact/Thrive) Dep.) at 258; PX7090 (Sood (Guardant) Dep.) at 123-24; PX7077 (Chahine (Helio) Dep.) at 41-42; PX7116 (Dolan (Quest) Dep.) at 66).

E. Grail and Purported Rivals in MCED Test Development

201. Grail's Galleri is the only NGS-based multicancer early screening test currently on the market in the United States and is currently marketed at $949 per test. (Bishop (Grail) Tr. 1401; RX3292 (Grail)).

202. Most of the companies researching and developing MCED tests are still in the early stages of development. *E.g.*, F. 338, 340, 361, 368, 398, 436, 460.

203. Most of the companies developing MCED tests do not expect to launch a screening test for more than one cancer type for many years. *E.g.*, F. 355, 370, 372, 409-411, 442, 460, 502.

204. The sensitivity and specificity have not been shown in most of the in-development MCED tests. *E.g.*, F. 362, 367, 468, 471.

205. The prices of yet-to-be marketed MCED tests have not yet been determined. F. 311, 406.

206. A cancer screening test that screens for numerous cancer types is not a close substitute for tests that screen for two or three cancer types. (F. 268, 269, 520; Cote Tr. 3874-75; PX6097 (Abrams Expert Report) ¶ 42).

207. In addition to the number of cancers that a screening test is capable of detecting, the metrics, described in F. 140, 141, 143, 155, provide grounds for differentiating between different tests and defining whether physicians are likely to substitute one test for another. (Cote Tr. 3778-82; RX3869 (Cote Expert Report) ¶ 90). Physicians may also evaluate and select tests based on other factors, such as the ease of using the test. (RX3869 (Cote Expert Report) ¶ 90).

1. Grail

a. Overview of Galleri

208. The Galleri test consists of one blood draw that may be conducted as part of an annual physical exam. (PX0043 (Grail) at 112, 114).

209. Grail's Galleri test aims to detect cancer signals by identifying abnormal methylation patterns in a patient's DNA. (Bishop (Grail) Tr. 1319-20, 1373).

210. Galleri identifies regions of a patient's DNA that are hypermethylated or hypomethylated and seeks to differentiate hypermethylation or hypomethylation patterns from those in healthy patients. (Bishop (Grail) Tr. 1320). "GRAIL's test looks at over a million of these methylation sites in over a hundred thousand regions of the genome." (Ofman (Grail) Tr. 3286-87).

211. The Galleri test detects cfDNA shed by cancer cells using a targeted methylation assay. (Bishop (Grail) Tr. 1319-21; Ofman (Grail) Tr. 3286-88; RX0760 (Grail) at 030-39, 054-56; RX3869 (Cote Expert Report) ¶ 134).

212. Grail developed a machine learning algorithm that differentiates abnormal tumor cfDNA methylation patterns from normal cfDNA methylation patterns. (RX3083 (Bryce et al.,

2021) at 001; Jamshidi (Grail) Tr. 4032-33, 4036-40; RX3869 (Cote Expert Report) ¶ 134).

213. As Dr. Joshua Ofman explained: "[Galleri] looks at over a million of these methylation sites in over a hundred thousand regions of the genome. And so then you take these patterns, and [subjected them] across cancer types and across cancer stages to train a machine learning algorithm to discriminate what is a cancer signal from what is a noncancer signal. And we made sure that the control group had lots of confounding indications and diseases to create a lot of biological noise so that our classifier was effectively trained and we didn't have models that were overfit. So once you subject these patterns to the machine learning algorithm, it will classify the pattern as either a cancer-like signal or a noncancer signal. And then if a cancer signal gets detected, the patterns then get subjected to a second step, which is another classifier, which looks and weights different features from these patterns to predict the tissue of origin or where this cancer signal came from in the body, so we call it a cancer signal origin or a tissue of origin." (Ofman (Grail) Tr. 3287-88).

214. Grail has developed two versions of Galleri and is currently developing a third version of Galleri, [redacted] (PX7083 (Bishop (Grail) Dep.) at 204-05; Ofman (Grail) Tr. 3301-02, 3291-94).

b. Clinical Studies and Results

215. As of September 2021, Grail had enrolled over 130,000 participants in clinical studies. (PX0390 (ClinicalTrials.gov Search Results for "Grail," Sept. 23, 2021)). Since 2016, Grail has undertaken four clinical studies to validate its test, while another clinical study was enrolling participants at the time of trial. (Ofman (Grail) Tr. 3291-94; RX0744 (Grail Core Slide Deck) at 46-47; Cote Tr. 3789-94; RX3869 (Cote Expert Report) ¶ 138).

i. Circulating Cell-Free Genome Atlas Study

216. Grail's first clinical study program, the Circulating Cell-Free Genome Atlas Study ("CCGA"), started in August 2016. (Ofman (Grail) Tr. 3291-92; RX0867 (Grail) at 003; RX3287 (Grail) at 002; RX0744 (Grail) at 047-48).

217. Grail completed enrollment in the CCGA study in February 2019. (PX6049 (Grail) at 015 (Grail, Narrative Response to Second Request, Mar. 1, 2021)).

218. The CCGA study was designed to determine whether genome-wide cfDNA sequencing in combination with machine learning could detect and localize a large number of cancer types at sufficiently high specificity to be considered for a general population-based cancer screening program. (RX3430 (Liu et al., 2020) at 003; Ofman (Grail) Tr. 3291-92).

219. "The goals of CCGA [study] include[d] development and evaluation of models to distinguish cancer from non-cancer circulating free DNA ('cfDNA') and identification of classifiers for the cfDNA localization of cancer signals." (PX6049 (Grail) at 015 (Grail, Narrative Response to Second Request, Mar. 1, 2021)).

220. The CCGA study involved the collection of de-identified biospecimens (blood and tissue samples) from pre-specified analysis groups that included all cancer types (more than 50 cancer types) and clinical data from 142 clinical networks in the United States and Canada, involving the enrollment of 15,254 participants and a cost of about $30 million. (RX3430 (Liu et al., 2020) at 003; PX5044 (Grail) at 007). Of those participants, 44% did not have a known cancer diagnosis, while 56% had a newly diagnosed cancer ranging early to late-stage (Stage I-IV). (RX3430 (Liu et al., 2020) at 003).

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

222. Grail used CCGA-1 and CCGA-2 to develop Galleri and gather information about Galleri's performance. (PX7069 (Bishop (Grail) IHT) at 80).

223. In the CCGA-1 study, Grail investigated a variety of approaches to determine which approach performed the best for purposes of an early cancer detection test. (Ofman (Grail) Tr. 3291-92).

224. The data from the CCGA-1 study showed that the methylation-based assay outperformed the other prototype assays and was better at localization of the cancer signal. (PX6049 (Grail) at 016 (Grail, Narrative Response to Second Request, Mar. 1, 2021)).

225. From the results of the CCGA-1 study, Grail concluded that interrogating methylation was the best approach for detecting cancer signals and that some regions of the genome and their methylation status were more informative than others with regard to cancer signals. (Ofman (Grail) Tr. 3291-92; PX7103 (Jamshidi (Grail) Dep.) at 60-67).

226. Grail used the CCGA-2 study to assess "Version 1 of Galleri." (PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021)).

227. The CCGA-2 study was designed to develop, train, and validate a methylation-based assay for simultaneous multicancer detection across stages as well as tissue of origin localization in preparation for clinical validation and utility studies. (RX3430 (Liu et al., 2020) at 003).

228. As published in Annals of Oncology in March 2020, the results of the CCGA-2 study on Version 1 of Galleri showed: "cfDNA sequencing leveraging informative methylation patterns detected more than 50 cancer types across stages." (RX3430 (Liu et al., 2020) at 001).

229. Grail used the CCGA-3 study to assess Version 2 of Galleri ("Galleri v2"), the current version that Grail subsequently launched as an LDT in 2021. (PX7092 (Ofman (Grail) Dep.) at 250-52; PX6049 (Grail) at 016 (Grail, Narrative Response to Second Request, Mar. 1, 2021)).

230. The CCGA-3 study was designed to evaluate Galleri's performance by testing samples from 4,077 participants with and without cancer and to validate Galleri v2 as a multicancer early detection test. (RX0744 (Grail) at 047-48; PX7069 (Bishop (Grail) IHT) at 80; RX3408 (Klein, et al., 2021) at 010; RX3869 (Cote Expert Report) ¶ 144).

231. The CCGA-3 study reported that the Galleri v2 test achieved a specificity of 99.5% across more than 50 cancer types, a false-positive rate of 0.5%, sensitivity of 51.5% for all cancers, and a signal of origin prediction accuracy of 88.7%. (RX3408 (Klein, et al., 2021) at 010; RX3409 (Klein, et al., 2021) at 001; RX3869 (Cote Expert Report) ¶ 144).

ii. STRIVE and SUMMIT

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

233. "STRIVE is a prospective, observational, longitudinal cohort study that enrolled 99,252 women" undergoing mammography for screening indications and associated medical care, whose samples were taken around the time of a screening mammogram appointment. (PX6049 (Grail) at 017 (Grail, Narrative Response to Second Request, Mar. 1, 2021); Ofman (Grail) Tr. 3293-95; RX0744 (Grail) at 073).

234. [redacted]

235. SUMMIT is a prospective, observational, cohort study conducted in partnership with London's University College. (RX3291 (Grail) at 001; RX0744 (Grail) at 047-48, 074; PX6049 (Grail) at 017-18 (Grail, Narrative Response to Second Request, Mar. 1, 2021); RX3869 (Cote Expert Report) ¶ 149).

236. SUMMIT enrolled approximately 13,000 participants between the ages of 50-77 from the United Kingdom with a substantial smoking history. (RX3291 (Grail) at 001; RX3135 (Clinicaltrials.gov) at 001-02; RX3869 (Cote Expert Report) ¶ 149).

237. Among the goals of the SUMMIT study is the generation of evidence for "[c]linical validation and utility" of Galleri. (PX4430 (Grail) at 021 (Grail, Grail's RWE Strategy & Galleri PMA, Dec. 22, 2020); PX6049 (Grail) at 017-18 (Grail, Narrative Response to Second Request, Mar. 1, 2021)).

238. [redacted]

iii. PATHFINDER

239. In December 2019, Grail initiated a study referred to as "PATHFINDER." PATHFINDER is a "prospective, interventional multi-center study" that "returns results to providers and participants . . . . In January 2021, Grail announced that it completed enrollment of PATHFINDER, with a final enrollment of 6,662 participants." (PX6049 at 017 (Grail, Narrative Response to Second Request, Mar. 1, 2021)).

240. Grail received FDA approval to conduct the PATHFINDER study. (PX6049 (Grail) at 017 (Grail, Narrative Response to Second Request, Mar. 1, 2021)).

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

242. The primary goal of PATHFINDER is to assess the extent and types of diagnostic testing required to achieve a diagnostic resolution after a patient has received a cancer screening test result that indicates "Signal Detected," meaning the potential presence of cancer, along with a predicted or indeterminate tissue of origin. (Ofman (Grail) Tr. 3295-98; RX0611 (Grail) at 9; RX3869 (Cote Expert Report) ¶ 145).

243. Results from the Galleri test in the PATHFINDER study were returned to participants and their clinicians to allow them to undertake any diagnostic steps necessary for a proper cancer diagnosis. (Ofman (Grail) Tr. 3296-97; RX0873 (Grail) at 002; RX3869 (Cote Expert Report) ¶ 145).

244. The PATHFINDER study has allowed Grail to evaluate the implementation of Galleri in clinical practice. (Ofman (Grail) Tr. 3296-97; RX3869 (Cote Expert Report) ¶ 145).

245. The interim results of the PATHFINDER study showed that the Galleri test detected seven types of Stage One through Stage Three cancer in an asymptomatic screening population. (Cote Tr. 4000-01; RX3041 at 005 (Interim Results of Pathfinder, June 4, 2021) (showing seven cancers as being detected in Stages One through Three: head and neck, liver/bile duct, lung, lymphoma, ovary, pancreas, and small intestine); *see also* Cote Tr. 4000-01 ("Q. So as of today, Galleri has been clinically shown to detect seven types of stage one through three cancer in an asymptomatic screening population, correct? A. That's correct.").

246. [redacted]

247. [redacted]

248. [redacted]

iv. Other Studies

249. In September 2021, Grail launched a 140,000-person clinical trial for Galleri in partnership with the United Kingdom (UK) National Health Service ("NHS"). (Ofman (Grail) Tr. 3293-94; PX7092 (Ofman (Grail) Dep.) at 123; PX6049 (Grail) at 019 (Grail, Narrative Response to Second Request, Mar. 1, 2021)).

250. [redacted]

251. [redacted]

252. [redacted]

253. [redacted]

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

255. Grail's Memorial Sloan Kettering ("MSK") Discovery is an observational study, wherein blood and tissue samples are collected from 725 breast cancer patients across seven test sites in collaboration with Memorial Sloan Kettering Cancer Center, Hartford Healthcare

Cancer Institute, Baptist Alliance MCI. (RX3134 (National Institutes of Health, U.S. National Library of Medicine, Development Of A Blood Test To Improve The Performance Of Breast Cancer Screening, https://clinicaltrials.gov/ct2/show/NCT03372902); PX6093 (Navathe Expert Report) at 026; PX6049 (Grail) at 020 (Grail, Narrative Response to Second Request, Mar. 1, 2021)).

256. [redacted]

257. [redacted]

c. FDA Approval Status

258. As of the end of the evidentiary hearing in this matter, Galleri has not been approved by the FDA. (Bishop (Grail) Tr. 1323).

259. Grail made its first submission to the FDA in connection with Galleri in July 2018, and the FDA issued a breakthrough device designation in August 2018, which enables easier access to FDA staff and feedback throughout the PMA process. (PX4171 (Grail) at 030 (Grail Board of Directors Meeting Presentation, Aug. 20, 2019)).

260. [redacted]

d. Grail's View of Competition

261. Grail's Executive Leadership Team, including its former Chief Executive Officer ("CEO"), Hans Bishop, has tracked potential competitors, often in coordination with Grail's internal competitive intelligence analysis team ("CIA Team"). (*E.g.*, PX4066 (Grail) at 003; PX4005 (Grail) at 001; PX4021 (Grail) at 001; PX4519 (Grail) at 001-02; PX4046 (Grail) at 094; PX4111 (Grail) at 001).

262. Grail's CIA Team surveyed the scientific and commercial landscape in the context of cancer screening and related technologies. (Della Porta (Grail) Tr. 467-68).

263. Grail's CIA Team was involved in "evaluating all of the advances going on in our spaces" and was "intended to understand how [the multiple cancer early detection] field

is advancing," including "events, progression, and new data." (PX7069 (Bishop (Grail) IHT) at 35-36). To achieve this, the competitive intelligence team "track[s] to various degrees many potentially competitive technologies, academic projects, small companies that span the gamut in terms of development stage, indication, biomarker type, technology platform, cancer type, and other factors." (PX4259 (Grail) at 001; PX7069 (Bishop (Grail) IHT) at 35-36).

264. Grail evaluated competitors according to three categories: viable technology approach, clinical studies, and commercial capabilities. (Della Porta (Grail) Tr. 478-79; PX4145 (Grail) at 006 (describing the above three categories as the "[l]ens through which we evaluate competition" and "[o]bjective criteria in [the] specific context of multi-cancer early detection")).

265. Grail's competitive intelligence team assessed potential competitors' clinical studies. The clinical development representative would review the competitors' studies, validation, utility, and design which were published on Clinicaltrials.gov. (Della Porta (Grail) Tr. 476).

266. The objective of Grail's CIA function is to "track, analyze and report on competitor activities, to: (a) Gain insights into competitor strategies, (b) Inform Commercial and Product, (c) Develop competitive strategies, [and] (d) Help position GRAIL in the marketplace." (PX4018 (Grail) at 002 (CIA function @ Grail); PX4444 (Grail) at 002).

267. In Grail's internal presentation entitled "Competitive Threats to Galleri After Launch," Grail identified several "competitive threats that could affect Galleri after launch," including Exact, Thrive, Guardant, Singlera, and Freenome, who were labeled as "Top Tier" threats; however, Grail noted that others "[m]ay launch seemingly similar products based on bad science (with poorer clinical performance that could be harder to discern" or could "shortcut validation using less data, biobanked samples." Grail assessed the relative features of other developers' tests and commercialization strategies and noted that the other tests (1) are not multiple-cancer early detection tests (*e.g.*, Natera and FMI are identified as developing a minimal residual disease test[9]), or (2) do not come close to Galleri in number of cancers detected (*e.g.*, Exact, Singlera, Freenome, and Guardant are identified as developing a solely colorectal cancer ("CRC") test). (PX4250 (Grail) at 003, 004, 009, 011).

[9] Minimal residual disease ("MRD") tests are used to determine whether remnants of cancer remain in a patient who has been treated for cancer. (PX7092 (Ofman (Grail) Dep.) at 94). MRD tests are used to determine whether a patient's cancer has recurred after successful treatment for cancer, *i.e.*, when a patient is in remission without symptoms or signs of disease and only a minimal amount of cancer cells and other cancer biomarkers are circulating in the body available to be tested at this stage. (Cote Tr. 3735-36; RX3869 (Cote Expert Report) ¶ 65).

Cancer screening tests are used in a different patient population than MRD tests, as MRD tests are typically used in patients who have already been diagnosed with cancer. (PX7111 (Fesko (Natera) Dep.) at 134).

268. Dr. Josh Ofman, Grail's Chief Medical Officer, believes that Galleri will not compete with MCED tests that are first pursuing colon cancer tests: "We screen for colon cancer with stool-based colon cancer screening tests or colonoscopy, which is the gold standard, and so . . . for people who want to use blood to look for colon cancer, they'll just do that. But adding a multicancer early detection test to the single cancer screening test is a very different activity. They're not really competing." (Ofman (Grail) Tr. 3310-11).

269. Dr. Ofman believes Galleri would not compete with a test that detects two or three cancers, because "conceptually what you're trying to do with Galleri is very different than something you'd be trying to do with a test that says we can find stomach and esophageal cancer . . . ." (Ofman (Grail) Tr. 3312-13).

2. Exact/Thrive

a. Exact/Thrive and CancerSEEK

270. Exact Sciences Corporation ("Exact") is a molecular diagnostics company based in Madison, Wisconsin with locations across the United States and in Europe. (RX3197 (Exact/Thrive) at 001, 004; PX7058 (Conroy (Exact/Thrive) IHT) at 33-34).

271. Exact currently sells a stool-based colorectal screening test called Cologuard that looks for specific changes in DNA to detect cancer. (PX7058 (Conroy (Exact/Thrive) IHT) at 19-20, 54-56).

272. Exact acquired Thrive Earlier Detection Corporation ("Thrive") in early January 2021. (RX3197 (Exact/Thrive) at 004; PX4331 (Grail)).

273. Exact, through Thrive ("Exact/Thrive"), is developing an MCED test called CancerSEEK. (Lengauer (Exact/Thrive) Tr. 157-58; PX7091 (Lengauer (Exact/Thrive) Dep.) at 13-14).

274. Exact/Thrive has spent roughly [redacted] to develop the CancerSEEK test and projects to spend another [redacted] on the development of CancerSEEK prior to launch. (PX7091 (Lengauer (Exact/Thrive) Dep.) at 87; PX7051 (Lengauer (Exact/Thrive) IHT) at 50-51; PX7058 (Conroy (Exact/Thrive) IHT) at 80-82).

275. CancerSEEK is a cancer screening test that looks for certain biomarkers in the blood that indicate the existence of cancer in the body. (Lengauer (Exact/Thrive) Tr. 158-59; PX7051 (Lengauer (Exact/Thrive) IHT) at 28-29).

276. CancerSEEK "uses a combination of several different markers in order to find cancer early, prior to the detection of cancer by symptoms." (PX7051 (Lengauer (Exact/Thrive) IHT) at 28-29).

277. [redacted]

[redacted]

278. The technology underlying CancerSEEK is capable of "detect[ing] all cancers that shed cancer-related DNA into blood or secretes proteins at high levels." (PX7051 (Lengauer (Exact/Thrive) IHT) at 53-55, 57-59).

279. CancerSEEK has gone through several iterations. CancerSEEK started with "v0 prototype" before moving on to "v0," "v1" and "v1+." (RX0074 (Exact) at 008 (Exact, Thrive Series B Investment Presentation, July 9, 2020)).

280. The current version of CancerSEEK is [redacted] CancerSEEK [redacted] contains "several improvements within the test" compared to its previous version zero. (PX7051 (Lengauer (Exact/Thrive) IHT) at 141).

281. [redacted]

b. Clinical Studies and Results

282. There are two published studies on CancerSEEK, the Cohen study (F. 283-288) and the DETECT A study (F. 289-299). (Conroy (Exact/Thrive) Tr. 1697-99, 1703).

i. The Cohen Study

283. The first CancerSEEK study, referred to as the "Cohen study," was published in the Journal of Science in 2018. (RX3142 (Cohen et. al, Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test, Feb. 23, 2018)).

284. The Cohen study examined the ability of the original version of CancerSEEK to "detect eight common cancer types through [the] assessment of the levels of circulating proteins and mutations in cell-free DNA." (Conroy (Exact/Thrive) Tr. 1545-46; Lengauer (Exact/Thrive) Tr. 202; RX3142 at 001 (Cohen et. al, Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test, Feb. 23, 2018)).

285. The Cohen study focused on eight cancer types: ovary, liver, stomach, pancreas, esophagus, colorectal, lung, and breast. (RX3142 (Cohen et al., Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test)).

286. The Cohen study applied CancerSEEK to 1,005 patients with "nonmetastatic, clinically detected cancers of the ovary, liver, stomach, pancreas, esophagus, colorectum, lung, or breast." (RX3142 at 001 (Cohen et al., Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test)).

287. The researchers in the Cohen study estimated that the sensitivity of CancerSEEK was 55 percent among all eight cancer types selected. (Conroy (Exact/Thrive) Tr. 1702-03; RX3142 at 004 (Cohen et. al, Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test, Feb. 23, 2018)).

288. The Cohen study found that the PET-CT scan approach to cancer screening is not well suited to be a primary screening modality for the general population because of the potential harm associated with the radiation exposure from a diagnostic PET-CT scan. (Conroy (Exact/Thrive) Tr. 1707-08).

ii. The DETECT-A Study

289. The second CancerSEEK study, "DETECT-A," used version zero of CancerSEEK. (Conroy (Exact/Thrive) Tr. 1703-04; RX0074 (Exact) at 008 (Exact, Thrive Series B Investment Presentation, July 9, 2020)).

290. The results of DETECT-A were published in July 2020 in Science Magazine, a peer-reviewed scientific journal, under the title, "Feasibility of blood testing combined with PET-CT to screen for cancer and guide intervention." (Conroy (Exact/Thrive) Tr. 1703; Lengauer (Exact/Thrive) Tr. 164-65; RX3419 (Lennon et al., Feasibility of Blood Testing Combined with PET-CT to Screen for Cancer and Guide Intervention, *Science* 369, 49 (2020))).

291. DETECT-A was an interventional study involving the multicancer screening of 10,000 women. (Lengauer (Exact/Thrive) Tr. 164-65; Conroy (Exact/Thrive) Tr. 1704).

292. DETECT-A used a three-step testing process: (1) a baseline blood test, (2) a confirmation blood test, given to participants that scored positive on the baseline blood test, and (3) imaging using a PET-CT scan to confirm the results of CancerSEEK and localize the potential cancer. (Conroy (Exact/Thrive) Tr. 1704; RX3419 (Lennon et al., Feasibility of Blood Testing Combined with PET-CT to Screen for Cancer and Guide Intervention, *Science* 369, 49 (2020))).

293. The version of CancerSEEK used in the DETECT-A study requires three separate tests conducted at three separate times. (Lengauer (Exact/Thrive) Tr. 246-49).

294. CancerSEEK does not identify tissue of origin through liquid biopsy alone. (Conroy (Exact/Thrive) Tr. 1645). If a patient receives a positive cancer result, CancerSEEK uses a PET-CT scan to identify the tissue of origin. (Lengauer (Exact/Thrive) Tr. 226-27, 270-72).

295. The radiation exposure from diagnostic PET-CT scan and follow-up imaging tests in the participants without cancer is a recognized source of potential harm associated with the DETECT-A CancerSEEK protocol; investigators of the DETECT-A trial recognized that the diagnostic PET-CT scans are not well suited to be the primary screening modality for the general population, in part because of a low disease prevalence and a relatively high

rate of incidental findings; and even after the full-body PET-CT scan, there may be a need to do additional biopsies to further characterize the cancer. (F. 288; Lengauer (Exact/Thrive) Tr. 248-50; Conroy (Exact/Thrive) Tr. 1707-08).

296. Doing a PET-CT scan as a primary screening modality is financially and operationally impractical. (Conroy (Exact/Thrive) Tr. 1707-08).

297. CancerSEEK identified ten types of cancer in the DETECT-A study: appendix, breast, carcinoma, unknown primary origin, colorectal, kidney, lung, lymphoma, ovary, thyroid, and uterine. (Conroy (Exact/Thrive) Tr. 1706).

298. In the DETECT-A study, CancerSEEK obtained specificities of 95.3% in its baseline blood test (with a single blood test), 98.9% with both baseline and confirmational blood tests (two blood tests) without PET-CT imaging, and 99.6% with both blood tests and PET-CT imaging, and sensitivity of 30.2% in its baseline blood test, 27.1% with both baseline and confirmational blood tests without PET-CT imaging, and 15.6% with both blood tests and PET-CT imaging. (RX3419 (Lennon et al., 2020) at 008 & Table 2; RX3869 (Cote Expert Report) ¶ 178).

299. In the DETECT-A study, CancerSEEK obtained PPV (positive predictive value) of 5.9% with its single baseline blood test, 19.4% with baseline and confirmational blood tests without PET-CT imaging, and 28.3% with both blood tests and PET-CT imaging. (RX3419 (Lennon et al., 2020) at 008 & Table 2; Lengauer (Exact/Thrive) Tr. 257-59; RX3869 (Cote Expert Report) ¶ 178).

iii. Other Studies

300. For FDA approval, test developers undergo a "registrational trial," which allows the FDA to evaluate the benefits-to-risk ratio of a test or device. (Lengauer (Exact/Thrive) Tr. 170).

301. [redacted]

302. [redacted]

303. [redacted]

304. [redacted]

[redacted]

c. FDA Approval Status

305. Exact/Thrive's CancerSEEK test has received breakthrough device designation from the FDA. Breakthrough device designation is a designation that the FDA can give if there is very strong medical need and where it would be beneficial to accelerate the potential approval of such a test for the benefit of patients. (Lengauer (Exact/Thrive) Tr. 171).

306. [redacted]

d. Commercial Status

307. [redacted]

308. [redacted]

309. [redacted]

310. [redacted]

311. [redacted]

e. Views on Competition

i. Exact/Thrive's View of Grail

312. Exact/Thrive considers Grail to be its [redacted] relevant competitor in the area of blood-based multicancer screening. (Lengauer (Exact/Thrive) Tr. 205; *see also* PX8530

(Exact/Thrive) at 003 (describing Grail as Exact's "most direct competitor"); Conroy (Exact/Thrive) Tr. 1614).

313. While other companies are working towards developing MCED tests, Exact/Thrive does not see [redacted] as competitors in the area of blood-based multicancer screening. (Lengauer (Exact/Thrive) Tr. 205-06).

314. Exact/Thrive sees Galleri as likely to be CancerSEEK's [redacted] competitor in the foreseeable future. (Lengauer (Exact/Thrive) Tr. 209).

315. Exact/Thrive views itself as competing with Grail because Exact/Thrive wants to "bring the very best test that we can bring, the most accurate test, the one that discovers the most cancers as early as possible." (Conroy (Exact/Thrive) Tr. 1616-18).

316. Exact/Thrive is currently competing with Grail with respect to prelaunch activities associated with bringing a new medical test to market such as "competing for mindshare with physicians, with health systems, with payers." (Conroy (Exact/Thrive) Tr. 1614).

317. Exact/Thrive is currently competing with Grail for scientists and talent for its research and development efforts because individuals working in early cancer detection have a specialized skill set and there are a limited number of companies requiring those specialized skills. (Conroy (Exact/Thrive) Tr. 1614-15).

318. As part of its development efforts, Exact/Thrive assessed the data generated and published or made available by Grail to try to improve its CancerSEEK product. (Conroy (Exact/Thrive) Tr. 1615).

319. [redacted]

320. [redacted]

ii. Grail's View of Exact/Thrive

321. Grail's competitive intelligence team monitored a long list of companies exploring the multicancer and cancer diagnostic space that were potential competitors to Grail, including Exact and Thrive. (Della Porta (Grail) Tr. 473, 503-04).

322. Although Grail believes that Exact/Thrive is "reformulating" their test and has not validated this reformulated version, Exact/Thrive is one of the companies that Grail's

competitive intelligence team monitored. (Della Porta (Grail) Tr. 482-83, 547-48; PX4145 (Grail) at 009 (Competitive Intelligence, Aug. 14, 2019)).

323. In its SEC S-1 filing, Grail described Exact and Thrive as "competitors." (PX4082 (Grail) at 036 (email attaching Grail 2020 S-1/Amended, Sept. 2020) (defining "competitors" as companies "that have stated that they are developing tests designed to detect cancer. . . .")).

324. In a competitive intelligence analysis, Grail identified Exact and Thrive as two of six "market leaders/front runners" in "early detection" and in the "top tier" of competition based on "threat characteristics." Grail also noted that the "current state of the [early detection] market" is "[n]ascent outside" of colorectal cancer and that Exact and Thrive had entered with a "narrower claim[] (single indication)" of CRC (Exact) or "fewer cancers" (Thrive). (PX4018 (Grail) at 005-06 (Grail, presentation labeled "CIA function @ GRAIL")).

325. In July 2020, Grail's CEO "Hans [Bishop] requested an expert regulatory view of Thrive's best LDT launch and PMA approval scenarios and risk assessment for Thrive getting a PMA before [Grail]." (PX4007 (Grail) at 002 (email from A. Chen, Grail, to Grail's Executive Leadership Team, et al., July 15, 2020)).

326. Grail convened a "Thrive Red Team" in 2020 – a small team of employees to address certain questions related to Thrive. (Bishop (Grail) Tr. 1487; PX4442 (Grail) at 001-02 (email from A. Chen, Grail, to H. Bishop et al., Grail, July 7, 2020)).

327. The Thrive Red Team reported to the members of Grail's Executive Leadership Team ("ELT"), including Hans Bishop and Dr. Josh Ofman, as well as to other Grail employees, including FDA and Regulatory Affairs Lead and Senior Vice President of Market Access. (Bishop (Grail) Tr. 1485-88, 1497; PX4442 (Grail) at 001-02 (email from A. Chen, Grail, to H. Bishop et al., Grail, July 8, 2020)).

328. Grail's "'Thrive Red Team' was tasked with evaluating key questions about Thrive's product, regulatory, reimbursement, clinical and commercial strategy, as well as risks that GRAIL should mitigate in our own strategies." (PX4456 (Grail) at 002 (Thrive Red Team Update: ELT Discussion, July 9, 2020); *see also* (Bishop (Grail) Tr. 1491).

329. Grail's Thrive Red Team "was convened to evaluate several questions regarding Thrive's product, regulatory, reimbursement, clinical and commercial strategy, and recommended GRAIL mitigations." (PX4006 (Grail) at 001 (email from A. Chen, Grail, to Executive Leadership Team et al., Grail, July 7, 2020)).

330. In an internal presentation labeled "Thrive Red Team Questions" dated July 29, 2020, Grail's Thrive Red Team stated: "We have new competitive intelligence that suggests that Thrive's primary strategy may NOT be an early 2021 LDT commercial launch. Rather their primary strategy may be focused on generating clinical evidence to support a PMA submission of their technology to be used with standard of care (*e.g.*, PET-CT or

other imaging). We want to carefully consider likelihood and implications of this for GRAIL." (PX4554 (Grail) at 003-04 (Grail, "Thrive Red Team Questions")).

331. In an internal presentation labeled "Thrive Red Team Questions" dated July 29, 2020, Grail highlighted "Thrive is already making public statements that their 'unique' offering combines a blood test + integrated service model (differentiating themselves from GRAIL's blood test used for TOO [tissue of origin] localization)." (PX4554 (Grail) at 008 (Grail, "Thrive Red Team Questions")). The presentation later mentioned "Thrive is likely developing a market on early detection with positive tests follow-up by whole body imaging, and may influence public opinion on what is best practice approach that raises visibility with FDA without needing a formal FDA process." (PX4554 (Grail) at 008 (Thrive Red Team Questions)).

3. [redacted]

a. [redacted]

332. [redacted]

333. [redacted]

334. [redacted]

335. [redacted]

336. [redacted]

337. [redacted]

338. [redacted]

339. [redacted]

340. [redacted]

341. [redacted]

342. [redacted]

343. [redacted]

344. [redacted]

b. Views of Competition

345. Grail's competitive intelligence team monitored a long list of companies exploring the multicancer and cancer diagnostic space that were potential competitors to Grail including [redacted] (Della Porta (Grail) Tr. 473, 511-12).

346. In a competitive intelligence analysis, referenced in F. 267, Grail did not include [redacted] as a market leader or in the top tier of competition. In its evaluation of [redacted] based on "threat characteristics," Grail noted: [redacted] makes no early detection performance claims; and [redacted] entry is with MRD. (PX4018 (Grail) at 007 (CIA function @ Grail).

347. Grail does not consider [redacted] as a threat to Galleri in a commercial sense as it is not aware of any studies [redacted] has conducted to support an MCED test. (Della Porta (Grail) Tr. 557).

4. Freenome

a. Freenome and its Planned MCED Test

348. Freenome Holdings, Inc. ("Freenome") is a biotech company with headquarters in South San Francisco, California. (PX7055 (Otte (Freenome) IHT) at 14).

349. Freenome was founded in 2014 and has been working on a colorectal early cancer detection test since its founding. (Nolan (Freenome) Tr. 2724, 2792; PX7121 (Otte (Freenome) Dep.) at 13).

350. Freenome is developing cancer screening tests based on multiomics. (Nolan (Freenome) Tr. 2706).

351. In general, multiomics describes a biological analysis approach that involves identifying and measuring "a range of analytes" such as DNA methylation, genomics, proteomics, and transcriptomics, among others. (Nolan (Freenome) Tr. 2710-11).

352. Freenome's multiomics platform is designed to detect tumor-derived biological signatures and non-tumor derived biological signatures. (Nolan (Freenome) Tr. 2712).

353. Freenome's cancer screening test development efforts started with developing a test to detect colorectal cancer and advanced adenomas from a blood sample. (Nolan (Freenome) Tr. 2706).

354. [redacted]

355. [redacted]

356. [redacted]

357. [redacted]

358. [redacted]

359. [redacted]

360. [redacted]

361. [redacted]

362. [redacted]

363. [redacted]

364. [redacted]

365. [redacted]

366. [redacted]

367. [redacted]

368. [redacted]

369. [redacted]

370. [redacted]

371. [redacted]

372. [redacted]

373. [redacted]

b. FDA Approval Status

374. [redacted]

375. [redacted]

c. Views on Competition

i. Freenome's View of Grail

376. If he were a patient, Freenome's former CEO Gabe Otte would "take both" Grail's multicancer screening test and Freenome's test, and views Freenome's multiomics test as "complementary" to Galleri. (PX7121 (Otte (Freenome) Dep.) at 152-53).

377. Otte wrote in a September 2020 email to Grail's then-CEO Hans Bishop, "I don't see GRAIL and Freenome as competitors nor do I ever speak of the two in that way . . . ." (PX4107 (Grail) at 004-05).

ii. Grail's View of Freenome

378. Grail's competitive intelligence team monitored a long list of companies exploring the multicancer and cancer diagnostic space that were potential competitors to Grail, including Freenome. (Della Porta (Grail) Tr. 473, 503-04).

379. Although Grail believes that Freenome's colorectal cancer early detection blood test will not compete with Galleri, Freenome is one of the companies that Grail's competitive intelligence team monitored. (Della Porta (Grail) Tr. 483, 554-55; PX4145 (Grail) at 009 (Competitive Intelligence: An Overview, Aug. 14, 2019)).

380. In a competitive intelligence analysis, Grail identified Freenome as one of six "market leaders/front runners" in "early detection" and in the "top tier" of competition based on "threat characteristics." Grail also noted that the "current state of the [early detection] market" is "[n]ascent outside of CRC," and that Freenome had entered with a "narrower claim[] (single indication)" of CRC. (PX4018 (Grail) at 005-06 (Grail, presentation labeled "CIA function @ GRAIL")).

5. Guardant

a. Guardant and its Planned MCED Test

381. Guardant Health, Inc. ("Guardant"), a publicly traded company, is headquartered in Redwood City, California. (PX0059 (Guardant) at 001 (Guardant Health FY 2019 Form 10-K)).

382. Guardant is a clinical diagnostics company that is currently developing blood-based tests for oncology applications. (Chudova (Guardant) Tr. 1135).

383. Guardant commercially offers only therapy selection tests and MRD tests. (RX3295 (Guardant); RX3869 (Cote Expert Report) ¶ 214).

384. Guardant is developing a single cancer screening test focused on colorectal cancer. This test, now named Guardant Reveal, was formerly known as LUNAR-1. (PX7040 (Getty (Guardant) IHT) at 114; Getty (Guardant) Tr. 2492-93).

385. LUNAR-1, which is designed "to detect minimal residual disease in colorectal cancer patients," is not an MCED test. (PX7040 (Getty (Guardant) IHT) at 114; Chudova (Guardant) Tr. 1146-47).

386. Guardant is currently developing an NGS-based blood biopsy early cancer screening test using genomic and methylation signatures called LUNAR-2. (RX3296 (Guardant) at 007).

387. The initial version of Guardant's LUNAR-2 test will screen for colorectal cancer. (Chudova (Guardant) Tr. 1153-54).

388. Guardant's business strategy involves first creating a CRC test that it hopes will be adopted, then moving to a test that detects more than one cancer. (Getty (Guardant) Tr. 2495-96).

389. [redacted]

390. [redacted]

391. [redacted]

392. [redacted]

393. Guardant is currently conducting a clinical trial – called Eclipse – on the use of its screening test for colorectal cancer. (Chudova (Guardant) Tr. 1154-55).

394. [redacted]

395. [redacted]

396. [redacted]

397. [redacted]

398. [redacted]

399. [redacted]

400. [redacted]

401. [redacted]

402. [redacted]

403. [redacted]

404. [redacted]

405. [redacted]

406. [redacted]

407. [redacted]

408. [redacted]

409. [redacted]

410. [redacted]

411. [redacted]

b. FDA Approval Status

412. [redacted]

413. [redacted]

414. [redacted]

415. [redacted]

c. Views on Competition

i. Guardant's View of Grail

416. Guardant is "really focused" on Grail as a competitor. (Getty (Guardant) Tr. 2505-07).

417. Guardant considers Grail "the most formidable" competitor to its MCED test under development. (PX7105 (Getty (Guardant) Dep.) at 37; *see also* PX7040 (Getty (Guardant) IHT) at 157).

ii. Grail's View of Guardant

418. Guardant is focused on developing a blood-based, single cancer test to detect colon cancer and Grail does not expect this test to compete against Galleri. (Bishop (Grail) Tr. 1389-93, 1401).

419. Grail's competitive intelligence team monitored a long list of companies exploring the multicancer and cancer diagnostic space that were potential competitors to Grail, including Guardant. (Della Porta (Grail) Tr. 473, 503-04).

420. Although Grail believes that Guardant's colorectal cancer early detection blood test will not compete with Galleri, Guardant is one of the companies that Grail's competitive intelligence team monitored. (Della Porta (Grail) Tr. 482, 553-54; PX4145 (Grail) at 009 (Competitive Intelligence: An Overview, Aug. 14, 2019)).

421. In an internal memo dated September 28, 2020 discussing "Potential Competitors to Galleri," Grail noted that "Guardant is a strong player in the late stage disease, with active programs to move to MRD and early detection" and further stated that "[f]or early cancer detection [Guardant] discuss[es] unlocking multiple dimensions of ctDNA: genomic alterations leveraged by their extensive biobank, methylation, and fragmentomics; these three dimensions enable high sensitivity and specificity." (PX4444 (Grail) at 009 (Grail, "Potential Competitors to Galleri, DAC and MRD," Sept. 28, 2020)).

422. In a competitive intelligence analysis, Grail identified Guardant as one of six "market leaders/front runners" in "early detection" and in the "top tier" of competition based on "threat characteristics." Grail also noted that the "current state of the [early detection] market" is "[n]ascent outside of CRC," and that Guardant had entered with a "narrower claim[] (single indication)" of CRC. (PX4018 (Grail) at 005-06 (Grail, presentation labeled "CIA function @ GRAIL")).

423. In its SEC S-1 filing, Grail described Guardant as a "competitor." (PX4082 (Grail) at 036 (email attaching Grail 2020 S-1/Amended, Sept. 2020) (defining "competitors" as companies "that have stated that they are developing tests designed to detect cancer. . . .")).

6. Helio Health

a. Helio Health and its Planned MCED Test

424. Helio Health, Inc. ("Helio") is a healthcare company focused on the early detection of cancer using blood specimens. (Chahine (Helio) Tr. 1000; PX7077 (Chahine (Helio) Dep.) at 12).

425. Helio previously operated under the name Laboratory for Advanced Medicine ("LAM"). (Chahine (Helio) Tr. 1001-02).

426. Helio's predecessor in name, LAM, was formed in 2014 as a cancer detection company. (PX8655 (Helio) at 006 (email from D. Taggart, Helio, to M. Gallant, Helio, attaching LAM Company and Technology Overview, Mar. 7, 2019)).

427. Helio is headquartered in Irvine, California and has operations in the United States and China. (Chahine (Helio) Tr. 1025; PX8655 (Helio) at 020, 046).

428. Helio is developing a test for the early detection of liver cancer named the "HelioLiver" test. (Chahine (Helio) Tr. 1009-10; PX7077 (Chahine (Helio) Dep.) 15-17).

429. [redacted]

430. HelioLiver uses NGS to interrogate [redacted] and Helio developed its underlying algorithm to focus on a subset of [redacted] (Chahine (Helio) Tr. 1069).

431. Helio received FDA breakthrough device designation on September 3, 2019 for its liver cancer detection test. (PX6049 (Grail) at 038 (Narrative Response to Second Request, Mar. 1, 2021)).

432. [redacted]

433. [redacted]

434. [redacted]

435. [redacted]

436. [redacted]

437. Helio has not conducted any clinical trials on tests to screen for cancers other than liver cancer. (Chahine (Helio) Tr. 1085-86, 1091).

438. [redacted]

439. [redacted]

440. [redacted]

441. [redacted]

442. [redacted]

443. [redacted]

444. [redacted]

b. Views on Competition

i. Helio's View of Grail

445. Helio monitors Grail and other companies who are working on developing screening MCED tests to understand what other companies are doing and how the whole field is evolving. (Chahine (Helio) Tr. 1066-67).

ii. Grail's View of Helio

446. Grail's competitive intelligence team monitored a long list of companies exploring the multicancer and cancer diagnostic space that were potential competitors to Grail, including LAM/Helio. (Della Porta (Grail) Tr. 473, 503-04).

447. In a competitive intelligence analysis, Grail did not include LAM/Helio as a market leader or in the top tier of competition. In its evaluation of LAM/Helio based on "threat characteristics," Grail noted: LAM/Helio's entry with fewer cancers, high risk. (PX4018 (Grail) at 007 (CIA function @ Grail)).

448. Grail does not consider LAM/Helio to be a threat to Galleri in a commercial sense as it is not aware of whether Helio has an available launched test. (Della Porta (Grail) Tr. 557).

449. In its SEC S-1 filing, Grail described LAM as a "competitor." (PX4082 (Grail) at 036 (email attaching Grail 2020 S-1/Amended, Sept. 2020) (defining "competitors" as companies "that have stated that they are developing tests designed to detect cancer. . . .")).

7. [redacted]

a. [redacted]

450. [redacted]

451. [redacted]

452. [redacted]

453. [redacted]

454. [redacted]

455. [redacted]

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463. [redacted]

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465. [redacted]

466. [redacted]

467. [redacted]

468. [redacted]

469. [redacted]

470. [redacted]

471. [redacted]

472. [redacted]

473. [redacted]

b. FDA Approval Status

474. [redacted]

475. [redacted]

c. Views on Competition

i. [redacted] View of Grail

476. [redacted]

ii. Grail's View of [redacted]

477. Grail's competitive intelligence team monitored a long list of companies exploring the multicancer and cancer diagnostic space that were potential competitors to Grail, including [redacted] (Della Porta (Grail) Tr. 473, 503-04).

478. In a competitive intelligence analysis, Grail did not include [redacted] as a market leader or in the top tier of competition. In its evaluation of [redacted] based on "threat characteristics," Grail noted: [redacted] does not make early detection performance claims and entry is with MRD, genetic testing. (PX4018 (Grail) at 007 (CIA function @ Grail); noting also, "current state of [the early detection] market" is "[n]ascent outside of CRC." (PX4018 (Grail) at 005).

479. Grail competitive intelligence identified [redacted] as a company moving from other types of tests into cancer screening. (PX4267 (Grail) at 009 (Deep Dive: Competitive Strategy, May 2, 2019)).

480. Grail does not view [redacted] an MRD test, as a test that could be marketed as an MCED test. Grail is not aware of any clinical trials related to multicancer early detection tests being conducted by [redacted] (Della Porta (Grail) Tr. 552-53).

8. Singlera

a. Overview of Singlera and its PanSeer Test

481. Singlera Genomics, Inc. ("Singlera") is headquartered in Shanghai, China and has United States offices in La Jolla, California. (Gao (Singlera) Tr. 2870; PX7042 (Gao (Singlera) IHT) at 21).

482. Singlera currently operates four laboratories, including one in the United States. (Gao (Singlera) Tr. 2870).

483. Singlera is a test developer focused on early cancer detection using targeted DNA methylation technology for cell-free DNA. (Gao (Singlera) Tr. 2869-70).

484. Singlera is working on developing four single cancer screening tests and one MCED test, called PanSeer. (Gao (Singlera) Tr. 2873, 2914).

485. Singlera's ColonES test is a blood-based early detection test for colorectal cancer that uses DNA methylation to detect colorectal cancer. (Gao (Singlera) Tr. 2873-74; PX7102 (Gao (Singlera) Dep.) at 25).

486. Singlera has not begun a clinical trial for its colorectal cancer test in the United States. (Gao (Singlera) Tr. 2911-12).

487. Singlera is far from starting FDA clinical trials for ColonES in the United States and believes it will take at least three to four years for a 10,000-person ColonES study. (PX7102 (Gao (Singlera) Dep.) at 120-21).

488. Singlera expects it will be several years before ColonES obtains FDA approval. (Gao (Singlera) Tr. 2920).

489. There is no clear timeline for when Singlera will be able to launch its single cancer ColonES test in the United States. (Gao (Singlera) Tr. 2920).

490. Singlera does not expect to launch PanSeer until after it has launched ColonES. (Gao (Singlera) Tr. 2918).

491. Singlera's PanSeer test is a blood-based early detection test designed to detect multiple cancers which uses the same methylation analysis, assay, and software and algorithm as ColonES. (Gao (Singlera) Tr. 2876, 2881-82; PX7042 (Gao (Singlera) IHT) at 117, 119-20).

492. The PanSeer test uses targeted DNA methylation technology to analyze over 500 regions on a DNA sample. (Gao (Singlera) Tr. 2874-75; *see* PX7042 (Gao (Singlera) IHT) at 21).

493. Singlera completed a proof-of-concept study of its PanSeer test in China, called the Taizhou Longitudinal Study. (Gao (Singlera) Tr. 2877-79; PX7042 (Gao (Singlera) IHT) at 28-30, 33).

494. Singlera published a paper in the peer-reviewed Nature Communications Journal in 2020 based on data from the Taizhou Longitudinal Study, which reported on PanSeer's sensitivity and specificity at detecting five different cancers (lung, esophageal, liver, colorectal, and gastric cancers) four years before participants showed symptoms. (Gao (Singlera) Tr. 2878-80, 2884; RX1699 (Illumina) (email from M. Nguyen, Illumina, to J. Godsey et al., Illumina attaching Chen X. et al., Non-invasive Early Detection of Cancer

Four Years before Conventional Diagnosis Using a Blood Test," *Nature Communications* 11:3475 (2020), July 21, 2020)).

495. In the Taizhou Longitudinal Study, while 123,115 healthy subjects provided plasma samples for long-term storage and were then monitored for cancer occurrence, the study looked at approximately 1200 samples (approximately: 200 during the biomarker development phase of the study; 500 in the training set for PanSeer; and 500 for the test set for PanSeer). (Gao (Singlera) Tr. 2925; PX7102 (Gao (Singlera) Dep.) at 147; RX3115 (Chen et al., 2020) at 001; RX3637 (Singlera) at 006; RX3869 (Cote Expert Report) ¶ 239).

496. In the retrospective, observational study from part of the Taizhou Longitudinal Study, PanSeer detected five common types of cancer with a 96.1% specificity, 87.6% sensitivity in post-diagnostic cancer patients, and 94.9% sensitivity in 98 pre-diagnostic cancer patients. (Gao (Singlera) Tr. 2876-77; RX3115 (Chen et al., 2020) at 001, 004 (Table 1)).

497. Singlera envisions that any patient testing positive on PanSeer would undergo an additional blood test and/or follow-up imaging to allow tissue of origin mapping. (RX3115 (Chen et al., 2020) at 006 ("We . . . envision a clinical context where PanSeer could be used as a first-line screen; any patient testing positive on PanSeer would then undergo a more expensive reflex blood test and/or follow-up imaging to allow tissue of origin mapping. Pathological examination could then confirm the presence of cancer.")).

498. Singlera has spent between $60 million to $100 million on research and development efforts related to the PanSeer test. (Gao (Singlera) Tr. 2888-89).

499. Singlera is working to "reduce cost, improve accuracy, and improve convenience" of its test. (PX7042 (Gao (Singlera) IHT) at 100).

500. For a multicancer trial, Singlera estimates that a clinical trial would need to be for 100,000 or 200,000 people, and would take somewhere between 8 or 10 years. (Gao (Singlera) Tr. 2925-26; PX7102 (Gao (Singlera) Dep.) at 122-23).

501. Singlera has not begun any clinical trials for PanSeer in the United States, and has not begun designing a clinical trial plan for PanSeer. (Gao (Singlera) Tr. 2942-43).

502. Singlera is a long way away from starting clinical trials for PanSeer in the United States. Even if it started now, Singlera would need approximately ten years to do the clinical trial work to get the necessary results to get a ten-cancer screening test to be approved by the FDA. (Gao (Singlera) Tr. 2925-26).

b. FDA Approval Status

503. Singlera plans to further develop the PanSeer test design before seeking FDA approval. (Gao (Singlera) Tr. 2881).

504. Singlera plans to seek FDA approval for its PanSeer test. (Gao (Singlera) Tr. 2881).

505. Singlera does not intend to launch its PanSeer test until it receives FDA approval. (Gao (Singlera) Tr. 2881-82).

506. Singlera believes it will take at least seven to ten years for Singlera's PanSeer test to be submitted to the FDA for approval. (Gao (Singlera) Tr. 2881-82).

c. Views on Competition

i. Singlera's View of Grail

507. Singlera believes that cost and accuracy of multicancer screening tests are the main drivers for competition; considers Grail, Freenome, and Thrive as its top competitors; and expects to compete with Grail on additional innovation. (PX7042 (Gao (Singlera) IHT) at 98-100).

ii. Grail's View of Singlera

508. Grail's competitive intelligence team monitored a long list of companies exploring the multicancer and cancer diagnostic space that were potential competitors to Grail, including Singlera. (Della Porta (Grail) Tr. 473, 503-04).

509. In a competitive intelligence analysis, Grail identified Singlera as one of six "market leaders/front runners" in "early detection" and in the "top tier" of competition based on "threat characteristics." Grail also noted that the "current state of the [early detection] market" is "[n]ascent outside of CRC," and that Singlera had entered with a "narrower claim[] (single indication)" of CRC. (PX4018 (Grail) at 005-06 (Grail, presentation labeled "CIA function @ GRAIL")).

510. Although Singlera is one of the companies that Grail's competitive intelligence team monitors, Grail does not view Singlera as a competitive threat because Singlera has not performed any studies in the United States and Grail's clinical team questioned some of Singlera's evidence. (Della Porta (Grail) Tr. 483, 555; PX4145 (Grail) at 009 (Competitive Intelligence: An Overview, Aug. 14, 2019)).

511. In an internal document, Grail notes "[o]n a high level approach Singlera [is] similar to GRAIL [because it] uses targeted methylation and specifically analyses looking at signals from highly coordinated regions at the fragment level. However upon a careful look, the quality of their data is subpar." (PX4048 (Grail) at 015 (email from M. Chin, Grail, to C. Della Porta, Grail, attaching Potential Competitors to Galleri, DAC and MRD, Sep. 28, 2020)).

512. In its SEC S-1 filing, Grail described Singlera as a "competitor." (PX4082 (Grail) at 036 (email attaching Grail 2020 S-1/Amended, Sept. 2020) (defining "competitors" as

companies "that have stated that they are developing tests designed to detect cancer. . . .")).

9. Illumina's View

513. Prior to the announcement of Illumina's proposed acquisition of Grail, Illumina grouped certain customers to contact proactively, including some of Illumina's largest oncology testing customers as well as customers specifically participating in early cancer detection. (Berry (Illumina) Tr. 752-53).

514. Illumina's CEO Francis deSouza and Illumina's then-Chief Commercial Officer, Mark Van Oene participated in making customer outreach calls prior to the proposed acquisition of Grail. The purpose of the outreach was to try to assure customers that the Grail acquisition would have no impact on Illumina's relationship with them. (Berry (Illumina) Tr. 753-55).

515. As part of determining which customers to reach out to proactively about the proposed acquisition, Illumina considered, among other factors, whether a given customer would be a future competitor to Grail, by assessing "the degree to which any [customer] may be developing a multicancer screening test." (Berry (Illumina) Tr. 937-38).

516. The customers Illumina contacted proactively included, among others, Foundation Medicine, Freenome, Natera, Thrive, and Guardant. (Berry (Illumina) Tr. 753, 948).

517. In a text message from Nicole Berry, Illumina's Senior Vice President and General Manager of the Americas Commercial Region, to Jeremy Preston, Illumina's Vice President of Global Regional Marketing, dated September 16, 2020, Berry expressed her belief that Illumina's acquisition of Grail would result in Illumina being perceived as competing with their customers in the same segment, including Guardant, Thrive, Freenome, Natera, Tempus, and FMI. (PX2158 (Illumina) at 001; Berry (Illumina) Tr. 743-44).

518. In the April 28, 2020 presentation materials prepared by Joydeep Goswami, Illumina's Senior Vice President of Corporate Development and Strategic Planning, four potential targets are identified for oncology screening, Grail, Guardant, Freenome, and Thrive. (deSouza (Illumina) Tr. 2249-51; PX2549 (Illumina) at 021 (Board of Directors Meeting, Apr. 28, 2020)).

519. Illumina's Scientific and Technology Committee noted in an April 2020 presentation to Illumina's Board of Directors that "the early movers" in the "early cancer detection space" included Grail, Guardant, Freenome, and Thrive, and noted also that other potential entrants include Natera. (PX2013 (Illumina) at 010 (Science & Technology Committee Cancer Screening, Apr. 28, 2020)).

520. Illumina's Chief Technology Officer, Dr. Alex Aravanis, believes that it is "unlikely" Galleri will compete with a test that screens for fewer than ten cancers and that Galleri

would not compete with a test that does not identify cancer signal of origin, since it would be used in a very different clinical context than Galleri. (Aravanis (Illumina) Tr. 1921-22).

F. Next-Generation Sequencing

1. Next-Generation Sequencing Function and Process

521. Next-generation sequencing ("NGS") is a method of DNA sequencing, which is the process of determining the order of nucleotides (A, C, G, or T) in a DNA molecule. (RX3333 (Illumina) at 007 (Illumina 2020 Form 10-K); Rabinowitz (Natera) Tr. 304).

522. NGS is used across many applications, including genetic disease testing, non-invasive prenatal testing ("NIPT"), and various oncology applications, including therapy selection, minimal residual disease ("MRD") monitoring, and early cancer screening. (Aravanis (Illumina) Tr. 1842-43, 1951-52; Berry (Illumina) Tr. 808).

523. Illumina's website summarizes the NGS process: "The basic next-generation sequencing process involves fragmenting DNA/RNA into multiple pieces, adding adapters, sequencing the libraries, and reassembling them to form a genomic sequence. . . . NGS sequences millions of fragments in a massively parallel fashion, improving speed and accuracy while reducing the cost of sequencing." (PX0113 at 002 (A Beginner's Guide to NGS)).

524. "The way [DNA sequencing] works at a high level is you prepare the DNA," and perform library preparations "where you take the DNA that you've extracted from the sample" and prepare it. (Rabinowitz (Natera) Tr. 304, 307-08).

525. In most DNA sequencing, "once the DNA is hybridized onto the flow cell,[10] a process is then undertaken called sequencing by synthesis, where you will add a particular nucleotide to the reaction, and the DNA that's attached onto the flow cell will be built up next to a matching fragment of DNA where the nucleotide that is added matches the nucleotide that is on that fragment that is attached to the substrate." (Rabinowitz (Natera) Tr. 307).

526. The DNA is prepared for sequencing by attaching sequencing adapters onto the ends of the DNA fragments to allow the DNA to work with a particular sequencer. (Rabinowitz (Natera) Tr. 307-08).

2. Short-Read Sequencing versus Long-Read Sequencing

527. The two categories of NGS platforms are (1) short read and (2) long read. (PX8399 (Henry (PacBio) Decl.) ¶ 3).

[10] A flow cell is a chamber that can absorb the DNA fragments to be analyzed. It is the size of a cell phone with little lines in it (channels) where the test sample sits during processing through which chemicals flow during the sequencing process. (Berry (Illumina) Tr. 676-78).

528. The main differences between short-read and long-read NGS platforms are (1) the number of DNA fragments that the instrument can sequence simultaneously, and (2) the length of those sequenced DNA fragments. (PX7045 (Chudova (Guardant) IHT) at 44-47; PX8399 (Henry (PacBio) Decl.) ¶¶ 3-4).

529. For short-read NGS platforms, sequencers prepare each DNA sample into a library of short fragments that are typically 350 base pairs or less in length, and replicate and sequence the fragments in parallel on a glass chip known as a flow cell. (PX8399 (Henry (PacBio) Decl.) ¶¶ 3-5; PX7045 (Chudova (Guardant) IHT) at 83-84).

530. Long-read sequencers are "designed specifically to sequence long, contiguous fragments of DNA." (PX7055 (Otte (Freenome) IHT) at 64-65).

531. Long-read sequencers have much lower read counts than short-read sequencers. (PX8399 (Henry (PacBio) Decl.) ¶ 4; PX7045 (Chudova (Guardant) IHT) at 44-47).

532. Short-read sequencing provides high read count and low cost per read relative to long-read sequencing. (PX8399 (Henry (PacBio) Decl.) ¶¶ 3-4).

533. Because circulating tumor DNA (ctDNA) fragments are "typically fewer than 350 base pairs long, Illumina's short-read NGS platforms are capable of analyzing many ctDNA fragments in their entirety." (PX8399 (Henry (PacBio) Decl.) ¶ 5).

534. Long-read sequencers can read tens of millions of DNA fragments per run. (PX7045 (Chudova (Guardant) IHT) at 45-48).

535. Long-read NGS instruments are optimized to provide readout of 10,000 or 100,000 base pairs in a single molecule format. Because native cell free DNA (cfDNA) is formatted into smaller chunks, long-read sequencers are "not directly applicable to being able to profile cell-free DNA efficiently[.]" (Chudova (Guardant) Tr. 1221-22).

536. Given the relatively short length of many ctDNA fragments, long-read sequencing does not present the same technical benefits over short-read sequencing as it does for other sequencing applications. (PX8399 (Henry (PacBio) Decl.) ¶ 5).

537. Illumina's CEO, Francis deSouza, views short-read NGS platforms as much more suitable for detecting ctDNA fragments than long-read platforms. (PX2544 (Illumina) at 026-28 (email from T. Peterson, JP Morgan, to F. deSouza, Illumina, attaching "J.P. Morgan Life Sciences CEO Conference Call Series" transcript, Sept. 5, 2019)).

538. "Long-read sequencers are . . . unsuited for early detection cfDNA liquid biopsy testing" because "the throughput of long-read sequencers are much lower than the throughput of short-read sequencers." (PX7101 (Vogelstein (Johns Hopkins University) Dep.) at 65-66).

539. Long-read NGS platforms "are particularly beneficial for applications such as human whole-genome sequencing because it is easier to determine the entire genomic sequence by assembling fewer long sequence fragments than by assembling many short ones. Using the puzzle analogy, it is easier to piece together a puzzle with fewer larger pieces than many smaller ones." (PX8399 (Henry (PacBio) Decl.) ¶ 3).

540. [redacted] believes "[i]t wouldn't make any sense to use a long-read sequencer for cell-free DNA. It would be enormously cost-prohibitive to do something like that. It probably wouldn't work very well either. The whole chemistry is optimized for longer fragments. Nobody would apply that to short-fragment circulating tumor DNA." [redacted]

3. Parameters of NGS Platforms for MCED Tests

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

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

543. "NGS enables a single-specimen, blood-based test that can screen for multiple cancers simultaneously, improve compliance [with cancer screening protocols], and reduce cancer-related mortality." (PX5027 (Illumina) at 005).

544. Cancer screening companies depend on NGS to detect several biomarkers. (Nolan (Freenome) Tr. 2713-14; Lengauer (Exact/Thrive) Tr. 161-63).

545. MCED tests require highly accurate, high-throughput NGS instruments and consumables. (PX7121 (Otte (Freenome) Dep.) at 48-50).

546. Key performance parameters of an NGS platform for MCED tests are throughput, accuracy, and cost. (Chudova (Guardant) Tr. 1208-09; PX7121 (Otte (Freenome) Dep.) at 48-50).

a. Throughput

547. The term "throughput" means how many samples can be processed over a given period. (deSouza (Illumina) Tr. 2265).

548. Throughput is the "number of people you can get tested in a day," which "relates to cost and the number of people that you can serve." (Conroy (Exact/Thrive) Tr. 1580-81).

549. "Reads" are the strings of nucleotide bases in each library molecule being sequenced. (PX0035 (Illumina) at 002 (An Introduction to Next Generation Sequencing Technology)).

550. "Reads per run" is a measurement of throughput and means the number of DNA library molecules an instrument can sequence on each run of the instrument. (PX0114 at 002, Illumina Sequencing Platforms, https://www.illumina.com/systems/sequencing-platforms.html; PX7044 (Stahl (Invitae) IHT) at 87 ("Q. When you say 'throughput,' is that another way of talking about the depth of read that we were just talking about or is that a different attribute of the machine? A. It is that attribute, so how many millions of reads are you getting.")).

551. Multiplying the number of reads per run by the length of each read calculates the instrument's output in terms of gigabases per run. (PX7044 (Stahl (Invitae) IHT) at 79-80; PX7070 (Felton (Thermo Fisher) IHT) at 31 (Gigabases is "how much overall sequence information is provided. The overall sequencing information and gigabases is a combination of the number of reads times the length of the read.")).

552. Throughput is a factor that companies look at to determine which sequencer to use. (deSouza (Illumina) Tr. 2265-66).

553. Generally, a low-throughput instrument will be used for an application with low reads or if the lab processes roughly 10 to 20 samples at a time. (Goswami (Illumina) Tr. 3193).

554. MCED tests require a "high throughput platform such that you could screen through many thousands of patient samples per day or per week or tens of thousands per week because population screening for early cancer is likely to be a very sample-intensive solution." (PX7070 (Felton (Thermo Fisher) IHT) at 52).

555. Guardant's MCED test in development must sequence approximately [redacted] DNA fragments per patient sample because "the fraction of all the cell-free DNA that is found in circulation that originates [from] the tumor is very small. . . . And so in order for you to capture any trace of the tumor, you have to sample multiple [redacted] of fragments to find any of them that actually come from the tumor." (Chudova (Guardant) Tr. 1211).

b. Accuracy

556. The accuracy of an NGS sequencer refers to the error rate and the type of errors produced by the sequencer. (Chudova (Guardant) Tr. 1208).

557. Accuracy denotes "the fidelity of being able to know that the mutation that you think you're looking for and you find is actually there or the converse of that, that a negative result for a mutation is reliable." (Conroy (Exact/Thrive) Tr. 1581).

558. Accuracy is a factor that companies evaluate to determine which sequencer to use. (deSouza (Illumina) Tr. 2266).

559. The accuracy of an NGS platform is the most important feature to MCED test developers. (PX7051 (Lengauer (Exact/Thrive) IHT) at 66-67, 70 ("[i]f you have wrong reads, you have a wrong result with . . . fatal consequences" for patients); [redacted] Nolan (Freenome) Tr. 2720).

560. "If the sequencer is accurate sometimes, not accurate [other times], and has a variable noise model or run-to-run instability, that creates major issues." (Rabinowitz (Natera) Tr. 310).

561. Low NGS platform accuracy increases costs to run a cancer screening test because low accuracy requires more "sequencing . . . to tell mutation from error." (PX7042 (Gao (Singlera) IHT) at 46-47).

562. An NGS platform's accuracy influences sequencing costs because to accommodate a higher error rate, additional sequencing and higher throughput are required. (PX7045 (Chudova (Guardant) IHT) at 31-34).

c. Cost

563. The cost of an NGS platform is an important feature to MCED test developers. (PX7051 (Lengauer (Exact/Thrive) IHT) at 67-69; PX7102 (Gao (Singlera) Dep.) at 27; PX7045 (Chudova (Guardant) IHT) at 43-44; Nolan (Freenome) Tr. 2723; Ofman (Grail) Tr. 3302-03).

564. NGS instruments with a "low cost per sample [are] likely to be the major requirement" for MCED test developers. (PX7070 (Felton (Thermo Fisher) IHT) at 52).

565. Customers requiring the sequencing of a large number of samples require sequencers with a low price per sample. (Felton (Thermo Fisher) Tr. 2000-01).

4. Illumina's NGS Technology

566. Illumina identifies three categories of "production-scale sequencers": the NextSeq 550 Series, the NextSeq 1000 & 2000, and the NovaSeq 6000. (PX0114, Illumina, Sequencing Platforms, https://www.illumina.com/systems/sequencing-platforms.html).

567. Illumina currently sells eleven models of NGS instruments. (PX2032 (Illumina) at 014 (Illumina, AMR 2021 Revenue Forecast, Oct. 9, 2020)).

568. The NovaSeq is Illumina's "high-throughput platform." (Goswami (Illumina) Tr. 3191-92).

569. Illumina's NovaSeq 6000 instrument can generate more than [redacted] times the number of reads per flow cell as any non-Illumina instrument that is presently widely available for purchase in the United States. (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 015-16 (RFA No. 17)).

570. Illumina's NovaSeq 6000 instrument can generate more than [redacted] times the number of reads per hour as any non-Illumina instrument that is presently widely available for purchase in the United States. (PX6069 (Illumina) at 016 (RFA No. 18)).

571. The NovaSeq is the only sequencer for which Illumina identifies "cell-free sequencing & liquid biopsy analysis" and "methylation sequencing" as "key application[s]." (PX0114, Sequencing Platforms, https://www.illumina.com/systems/sequencing-platforms.html).

572. Illumina describes the NovaSeq as the "bread and butter" instrument for liquid biopsy. [redacted]

573. [redacted]

574. [redacted]

575. The NextSeq is Illumina's "medium or mid-throughput platform." (Goswami (Illumina) Tr. 3191).

576. Illumina identifies the NextSeq as a "production-scale sequencer." (PX0114, Sequencing Platforms, https://www.illumina.com/systems/sequencing-platforms.html).

577. Illumina sequencing instruments include an opt-in performance monitoring system called Proactive. (PX7076 (Berry (Illumina) Dep.) at 27-30, 35-36; PX6056 (Illumina) at 047 (Illumina, Narrative Response to Second Request, Mar. 1, 2021)).

578. Proactive provides customers with improved service by "allow[ing] Illumina to have visibility into specific instrument . . . physical states to try to understand when an instrument is likely to require service." (Berry (Illumina) Tr. 850-52; PX7076 (Berry (Illumina) Dep.) at 36-37).

579. [redacted]

580. [redacted]

581. [redacted]

582. [redacted]

583. [redacted]

584. [redacted]

585. Illumina sells multiple versions of flow cells (SP, S1, S2, and S4): "[t]he main difference between these flow cells is that they have different outputs," with the S4 providing the highest output of data in a single run of the sequencer. (PX7104 (Aravanis (Illumina) Dep.) at 117-22).

586. The S4 flow cell for the NovaSeq can load 10 billion DNA library fragments, yielding 10 billion single-end reads (or 20 billion paired-end reads if each fragment is read both forward and backward). (PX0085 at 001, Illumina, NovaSeq 6000 System Specifications, https://www.illumina.com/systems/sequencing-platforms/novaseq/specifications.html).

587. The NovaSeq is capable of processing two flow cells simultaneously, and thus is capable of reading 20 billion library fragments, yielding 20 billion single-end reads (or 40 billion paired end reads), in a single 44-hour run of the instrument. (PX0085 at 001-02, Illumina, NovaSeq 6000 System Specifications, https://www.illumina.com/systems/sequencing-platforms/novaseq/specifications.html).

588. Illumina sells NGS equipment to Grail, Exact, [redacted] Guardant, Freenome, Singlera, and [redacted] (*See* Berry (Illumina) Tr. 650-51).

589. Grail's Galleri test relies on Illumina's NGS instruments and reagents. (PX0043 at 011 (Grail 2020 Form S-1); PX7069 (Bishop (Grail) IHT) at 208-10).

590. Grail uses Illumina's NovaSeq sequencers for its MCED test. (Jamshidi (Grail) Tr. 4029; Bishop (Grail) Tr. 1336-37, 1381).

591. Grail believes that using Illumina sequencers is "one of the standard approaches to use in the field . . . . " (Jamshidi (Grail) Tr. 4029).

592. Grail considers Illumina to be the "gold standard" and most accurate NGS platform. (PX4140 (Grail) at 007, 010 (R&D Portfolio Planning – Part B: Sequencing Technology)).

593. After evaluating various NGS platforms, Grail concluded that Illumina currently outperforms all other sequencing options across numerous metrics. (PX4140 (Grail) at 004, 010-11 (R&D Portfolio Planning – Part B: Sequencing Technology)).

594. Galleri has been validated for use only on an Illumina NGS sequencer. (Bishop (Grail) Tr. 1337).

595. The accuracy of Illumina's NGS sequencers "approaches about one error in several thousand bases" which is necessary "to get the specificity that you need for an earlier detection test" and avoid "too many false positives." (PX7101 (Vogelstein (Johns Hopkins University) Dep.) at 57-59).

596. The NovaSeq sequencer can test the DNA of significantly more individuals in a single run compared to Illumina's MiSeq sequencer. (Chahine (Helio) Tr. 1022).

597. Illumina's NovaSeq sequencer "provides economies of scale that are advantageous" because of its capacity to sequence more samples at once. (Chahine (Helio) Tr. 1022-23).

598. Dr. Bert Vogelstein, a co-founder and former consultant of Thrive and current Professor of Oncology at the Johns Hopkins University School of Medicine, believes that "[t]he only technology available for short-read sequencing that is at a throughput and cost that would enable liquid biopsy to be analyzed is sold by Illumina." (PX7101 (Vogelstein (Johns Hopkins University) Dep.) at 67-68).

599. "Illumina owns a spectrum of IP [(intellectual property)] covering various improvements that enable Illumina's superior sequencing accuracy, speed, and efficiency. These patents and pending applications have expiration dates ranging from 2023 to beyond 2030. [Illumina's] patented innovations touch every aspect of the sequencing workflow, including nucleotides, enzymes, reagent mixes, instruments, optics, analysis software, and bioinformatics, which result from Illumina's significant investments in research and development." (deSouza (Illumina) Tr. 2229-32; PX2822 (Illumina) at 006-07 (Illumina, Baird Non-Deal Roadshow with Alex Aravanis, Feb. 22, 2021)).

600. Dr. Vogelstein believes that although "[t]here may be other companies that are developing sequencing platforms, . . . the only effective platform today is Illumina's platform." (PX7101 (Vogelstein (Johns Hopkins University) Dep.) at 67-68).

5. Importance of Illumina for MCED Test Developers

a. [redacted]

601. [redacted]

602. [redacted]

603. [redacted]

604. [redacted]

b. Guardant

605. The throughput of Illumina's NovaSeq platform is the reason that Guardant uses it for its MCED test in development. The NovaSeq is capable of tens of billions of reads per run and can analyze hundreds of patient samples in a single run. (PX7100 (Chudova (Guardant) Dep.) at 60-61).

606. Running Guardant's screening test on an NGS sequencer with throughput lower than Illumina's NovaSeq would increase Guardant's cost per test. (PX7100 (Chudova (Guardant) Dep.) at 61-62).

607. If Guardant attempted to run its LUNAR-2 screening test on a PacBio long-read platform, Guardant believes "[i]t would cost about [redacted] more per million reads than NovaSeq costs today . . . ." (PX7045 (Chudova (Guardant) IHT) at 48-49; PX8399 (Henry (PacBio) Decl.) ¶ 5).

608. Guardant uses Illumina's NovaSeq NGS platform for its MCED test in development because it believes the "NovaSeq is the only one that comes with the throughput[,] accuracy, cost, and turnaround time that meets the criteria." (Chudova (Guardant) Tr. 1196, 1212).

609. Guardant believes Illumina's NGS platforms are the only option for Guardant's MCED test in development and that "[t]here's no alternative for [it] to switch to." (Chudova (Guardant) Tr. 1300).

610. Guardant believes that in comparison to Illumina's NovaSeq, other NGS platforms are "two or three or five factor[s] away" from what Guardant needs for its MCED test. (Chudova (Guardant) Tr. 1224).

611. Other than the Illumina NovaSeq, Guardant believes "[t]he sequencing instruments and configurations that are available today in the U.S. do not allow [Guardant] to sequence this many molecules directly from cfDNA" as it needs for its MCED test in development. (Chudova (Guardant) Tr. 1224).

612. [redacted]

613. [redacted]

614. Guardant's cancer screening test "has been optimized to work in an Illumina environment." (PX7105 (Getty (Guardant) Dep.) at 239-40).

615. Guardant believes "Illumina is central to what we do. . . . [W]e built part of our world around the Illumina ecosystem." (PX7090 (Sood (Guardant) Dep.) at 112-13).

616. In Guardant's 2020 Form 10-K filed with the Securities and Exchange Commission, Guardant states:

> We rely on Illumina as the sole supplier of . . . sequencers and as the sole provider of maintenance and repair services for these sequencers. Any disruption in operations of Illumina . . . or termination or suspension of our relationships with them could materially and adversely impact our supply chain and laboratory operations . . . and thus our ability to conduct our business and generate revenue.

(PX0153 at 047 (Guardant, 2020 Form 10-K, Feb. 25, 2021)).

c. Freenome

617. Freenome believes that the high throughput of Illumina's sequencer enables Freenome to achieve "operational efficiency" because it enables Freenome to use a single asset to perform higher-volume testing, as opposed to using multiple assets that require daily, weekly, or monthly maintenance. (Nolan (Freenome) Tr. 2716).

618. To Freenome, apart from Illumina's NGS sequencers, "there is nothing really suitable that . . . meets [Freenome's] throughput . . . requirements" for its MCED test in development. (PX7094 (Nolan (Freenome) Dep.) at 221-23).

619. Freenome has incurred substantial cost savings from using Illumina's high-throughput NovaSeq because of NovaSeq's "greater throughput" compared to other sequencing instruments. (PX7055 (Otte (Freenome) IHT) at 17-19).

620. Freenome believes it does not have a "suitable substitute" to Illumina's NGS platform for its MCED test in development. (PX7094 (Nolan (Freenome) Dep.) at 142-44, 221-23; PX8378 (Freenome) at 002).

621. Freenome believes alternatives to Illumina sequencers are not viable for Freenome to run its cancer screening test because of throughput and cost concerns. (PX7094 (Nolan (Freenome) Dep.) at 222-23; PX7055 (Otte (Freenome) IHT) at 69).

d. Singlera

622. Singlera's PanSeer test uses Illumina's NextSeqDx NGS platform. (Gao (Singlera) Tr. 2875; PX7102 (Gao (Singlera) Dep.) at 26).

623. Singlera chooses to run its cancer screening test on Illumina's NGS platform in part because it is very cost economical in terms of the number of reads per run. (PX7102 (Gao (Singlera) Dep.) at 27).

624. Singlera believes that for its PanSeer test, long-read sequencers are prohibitively expensive compared to Illumina's short-read sequencers. (Gao (Singlera) Tr. 2900-01).

625. Singlera views Illumina's NGS sequencing platform as "easy to use, very accurate, easy to maintain, and cost effective." (PX7102 (Gao (Singlera) Dep.) at 27-28).

626. Singlera believes it does not have a viable alternative to Illumina's NGS sequencers for its PanSeer test. (Gao (Singlera) Tr. 2901).

e. Helio

627. Helio purchases NGS sequencers and reagents from Illumina. (Chahine (Helio) Tr. 1024).

628. Helio cannot use reagents from another company on Illumina's NGS sequencers. (Chahine (Helio) Tr. 1024).

629. Illumina is Helio's "preferred NGS platform" because of "accuracy and cost and scale and throughput." (Chahine (Helio) Tr. 1114-15).

630. Helio believes Illumina provides "a number of . . . technological advantages" compared to other providers, including lower cost. (PX7077 (Chahine (Helio) Dep.) at 26).

631. Helio believes Illumina is the preferred NGS platform because "from a business standpoint . . . it is just considered the top technology with respect to its ability to sequence . . . accurately . . . at larger scales" that create "some [very useful] economies of scale." (Chahine (Helio) Tr. 1044).

f. [redacted]

632. [redacted]

633. [redacted]

634. [redacted]

6. Non-Illumina NGS Platforms

a. Thermo Fisher

635. Thermo Fisher Scientific, Inc. ("Thermo Fisher") offers the Ion Torrent line of NGS platforms. (RX2577 (Thermo Fisher) at 001).

636. Thermo Fisher sequencers are not currently being used for any MCED tests in development. (Felton (Thermo Fisher) Tr. 1987).

637. [redacted]

638. [redacted]

639. Thermo Fisher believes Illumina's NGS sequencers are better suited than Thermo Fisher's NGS sequencers for "any application that requires a very large number of samples . . . like early cancer detection." (Felton (Thermo Fisher) Tr. 2001).

640. Illumina's NovaSeq platform has a significantly higher output than any of Thermo Fisher's NGS sequencers. (Felton (Thermo Fisher) Tr. 2000).

641. Thermo Fisher's NGS platform can read approximately 130 million DNA fragments per run of the instrument. (Chudova (Guardant) Tr. 1218-19)).

642. Thermo Fisher believes its highest throughput sequencer, the GeneStudio, is not an option for MCED developers because "a platform with considerably more output per run than 130 million reads would be . . . preferred. . . . In general, [Thermo Fisher's] system isn't well suited to a kind of test that needs a very large number of samples . . . running through it very quickly." (Felton (Thermo Fisher) Tr. 1987-89).

643. The cost per read of Thermo Fisher's GeneStudio is higher than the cost per read of Illumina's NovaSeq. (Felton (Thermo Fisher) Tr. 2000).

644. [redacted] views Thermo Fisher's Ion Torrent NGS platform as having "significantly lower throughput" and a less favorable "error profile" than Illumina's NovaSeq NGS platform. [redacted] (comparing the NovaSeq's ability to read 10 billion DNA fragments per run to Thermo Fisher's ability to read 130 million DNA fragments per run).

645. [redacted] believes that using Thermo Fisher's NGS platform for its MCED test in development "would be completely impractical from a screening assay standpoint based on the throughput and the error rate of that system." [redacted]

646. [redacted] believes Thermo Fisher's NGS platform could likely process "less than one patient sample[] on a run of the instrument" for its MCED test in development, compared to 400 patient samples per run on the Illumina NovaSeq. [redacted]

647. [redacted] does not believe it can run its MCED test in development on a Thermo Fisher sequencer. [redacted]

648. [redacted] believes that "Thermo Fisher has a very slow – low throughput analyzer that has homopolymer issues where if you have a repeating base, it will make an inaccurate call. It's problematic." [redacted]

649. [redacted] approached Thermo Fisher to discuss whether Thermo Fisher's NGS sequencers would be a good option for [redacted] multicancer early detection test in development but "determined it wasn't suitable . . . [for] the kinds of requirements that they had for their test . . . ." [redacted]

650. After evaluating Thermo Fisher's NGS technology, Singlera concluded Thermo Fisher was "not going to be a viable alternative" to Illumina. (Gao (Singlera) Tr. 2894).

651. [redacted] believes that Thermo Fisher's NGS platform "does not have the through-put or accuracy that Illumina has. So it's not a viable system that you could use in a multi-cancer test." [redacted]

652. [redacted] believes that the "error rate" of Thermo Fisher's NGS platform is "too high." [redacted]

653. [redacted]

654. [redacted]

655. [redacted]

656. [redacted]

b. BGI

657. BGI Genomics Co., Ltd. ("BGI") is a China-based genomics company that supplies next-generation sequencing. (deSouza (Illumina) Tr. 2226).

658. BGI is affiliated with the government of the People's Republic of China. (deSouza (Illumina) Tr. 2311-12; PX5027 (Illumina) at 063 (BGI Review Pre-Read, Aug. 5, 2020)).

659. In 2019 and 2020, Illumina sued BGI in the Northern District of California alleging that BGI's sequencers and reagents infringe Illumina owned patents. (PX0119 at 001 (Illumina Inc. Announces that U.S. Federal Court Issues Preliminary Injunction Against BGI Companies)).

660. Illumina filed additional patent infringement claims against BGI. (PX9232 at 015, 025-027 (Answer and Counterclaim, *Complete Genomic, Inc. v. Illumina, Inc.*, Case 1:19-cv-00970-MN (D. Del.)) (July 25, 2019)).

661. "Due to the risk of that IP and them not being well [e]ntrenched in the US and also not having regulatory clearances in the US, [[redacted] has] decided not to pursue" BGI NGS sequencers. [redacted]

662. On June 6, 2022, BGI announced its intention to "make its CoolMPS sequencing chemistry and DNBSeq-G400 sequencer commercially available in the US starting Aug. 29, the day a certain Illumina patent is set to expire." (RX4062 (BGI) at 001).

663. As of July 2020, Illumina had "11 active IP infringement suits against BGI." (PX2847 (Illumina) at 013 (Project Protego BoD Discussion, July 15, 2020)). On July 14, 2022, Illumina entered into settlement and license agreement with BGI that resolves certain patent and antitrust claims between the two companies. (RX4064 (Illumina)).

664. Singlera believes using BGI for its PanSeer test is "out of the picture" because of the intellectual property dispute involving BGI's sequencers. (Gao (Singlera) Tr. 2895).

665. Singlera does not use BGI sequencers to run its PanSeer test because Singlera believes BGI has a poor reputation for reliability and service. (Gao (Singlera) Tr. 2899).

666. Once Illumina's patents expire, [redacted] will not likely switch to BGI because [redacted] believes that: (1) the performance of the BGI sequencer is not as good as Illumina's; (2) Illumina may have other intellectual property that could hinder BGI; and (3) [redacted] "customers were very concerned about being dependent on a Chinese sequencing system . . . [and] didn't want data to be in the hands of a Chinese company." [redacted]

667. Once Illumina's patents expire, [redacted] does not expect to switch to BGI because of concerns regarding switching costs and because it prefers "to be building something on the dominant installed sequencing systems that are used by the labs around the world." [redacted]

668. [redacted] would not consider using BGI machines because it has "a strict policy not to [have] . . . anyone outside of the United States . . . have access to data of U.S. citizens." [redacted]

669. [redacted] views BGI as "not an option" because it believes "the quality of the products, the quality of the technology, the reproducibility is not where it needs to be." [redacted]

670. [redacted] believes BGI's quality and efficiency "doesn't compare to Illumina . . . ." [redacted]

671. [redacted]

c. PacBio/Omniome

672. Pacific Biosciences of California, Inc. ("PacBio") is a Menlo Park, California-based company that supplies long-read sequencing platforms. (PX8399 (Henry (PacBio) Decl.) ¶ 1).

673. Omniome, Inc. is a biotechnology company located in San Diego, California that was founded in 2013. (PX7071 (Song (Omniome) IHT) at 12-13).

674. [redacted]

675. [redacted]

676. [redacted] believes PacBio's platform is "designed to read much longer molecules and also have much lower throughput in terms of number of molecules that can be analyzed" per run than Illumina's NGS platforms. [redacted]

677. Because long-read NGS platforms are not "capable of reading the amount of molecules that [redacted] typically need[s] to profile in a blood sample," it has not evaluated PacBio as an option for its MCED test in development. [redacted]

678. [redacted] cannot use PacBio's NGS platform for its MCED test in development "because the typical throughput of PacBio is about 4 million reads . . . [which] doesn't match what the libraries are when we prepare them from cfDNA in terms of throughput needs, in terms of number of molecules sequenced." [redacted]

679. In July 2021, PacBio announced it had acquired Omniome for $800M. (RX3947 (PacBio) (Clinical OMICs)).

680. Omniome currently does not have a commercial NGS platform on the market. (deSouza (Illumina) Tr. 2473-74).

681. [redacted] did not consider Omniome's NGS platform as a potential platform because it believed that "[e]ven [Omniome's] speculations on what their final numbers were going to be on the throughput and the cost were prohibitively expensive and not enough throughput for [Omniome's] application." [redacted]

682. [redacted]

683. [redacted]

d. Oxford Nanopore

684. Oxford Nanopore Technologies ("Oxford Nanopore") is a United Kingdom-based supplier of NGS sequencers. (PX7043 (Gunn (Roche) IHT) at 72).

685. [redacted] believes Oxford Nanopore is "designed to read much longer molecules and also have much lower throughput in terms of number of molecules that can be analyzed" per run than Illumina's NGS platforms. [redacted]

686. [redacted] believes it cannot use Oxford Nanopore's NGS platform for its MCED test in development because "[i]t's optimized for long molecules. We don't have . . . long molecules in their native state in cfDNA. [Oxford Nanopore] also has a substantially higher error rate than Illumina and so would require many more copies to be sequenced to be as accurate as Illumina is[.]" [redacted]

687. [redacted] believes Oxford Nanopore "doesn't have the accuracy or throughput needed to be able to run [its MCED test] on that platform." [redacted]

688. [redacted] views Oxford Nanopore's long-read sequencing platform as "not nearly as advanced as . . . Illumina . . . so it's not something necessarily that's suitable" for their cancer screening test. [redacted]

689. Singlera does not believe that Oxford Nanopore's long-read sequencer is a viable option for Singlera's PanSeer test. (PX7042 (Gao (Singlera) IHT) at 66).

690. Illumina believes its NGS technology is "superior in a meaningful way . . . around data accuracy [and] the accuracy of the Oxford Nanopore reads is not as good as the Illumina reads." (PX7065 (Aravanis (Illumina) IHT) at 157-59).

691. Illumina NGS sequencers have higher accuracy than Oxford Nanopore sequencers. (PX7065 (Aravanis (Illumina) IHT) at 158).

e. Singular Genomics

692. Singular Genomics ("Singular") is developing an NGS sequencer called the G4 sequencer. (Velarde (Singular Genomics) Tr. 4513).

693. Singular expects its G4 system to compete with Illumina for sales of sequencers to multicancer early detection test developers. (Velarde (Singular Genomics) Tr. 4536).

694. Singular's target throughput for its sequencer is [redacted] (PX7117 (Velarde (Singular Genomics) Dep.) at 48-49).

695. Singular's throughput goal of [redacted] is less than NovaSeq's 10 billion reads per flow cell. (*See* PX7117 (Velarde (Singular Genomics) Dep.) at 48-49; *see also* PX0085 at 001 (Illumina NovaSeq 6000 System Specifications); *see also* PX2169 (Illumina) at 025 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020)).

696. Singular faces a number of risks related to the development and commercialization of its products. (Velarde (Singular Genomics) Tr. 4549-50).

697. Singular identified as a risk to its investors that "[o]ur limited operating history makes it difficult to evaluate our future prospects . . . ." (PX0068 at 023 (Singular Genomics S-1, May 2021)).

698. Singular represented to investors that it "expect[s] that [its] competitors will, in connection with our launch of our G4 Integrated Solution and our planned PX Integrated Solution and later stage product offerings, assert that we are infringing, or have in the past infringed as part of our research and development activities, their patent and other intellectual property rights and that we are employing their proprietary technology without authorization." (PX0068 at 046 (Singular Genomics S-1, May 2021)).

699. Currently, [redacted] believes it could "absolutely not" switch to Singular as an NGS platform for its MCED test. [redacted]

700. After meeting with Singular, [redacted] concluded Singular was not close to meeting their needs for an MCED test. [redacted]

f. Ultima Genomics

701. Ultima Genomics ("Ultima") is an NGS sequencing platform developer. (PX7119 (Lauer (Ultima) Dep.) at 23-24).

702. According to Ultima, its sequencer has achieved a throughput of approximately [redacted] reads per run in early testing. (PX7119 (Lauer (Ultima) Dep.) at 42-43).

703. Ultima's [redacted] than Illumina's. (PX7119 (Lauer (Ultima) Dep.) at 45-46).

704. [redacted] is currently in the process of running three pilot tests on Ultima's platform. [redacted]

705. Ultima met with [redacted] has not contracted to participate in Ultima's early access program. (PX7119 (Lauer (Ultima) Dep.) at 123-24).

g. Element Biosciences

706. Element Biosciences ("Element"), founded in 2017, is in the process of developing an NGS sequencer, but currently does not have a commercial NGS platform on the market. (PX7124 (He (Element Biosciences) Dep.) at 8; deSouza (Illumina) Tr. 2473).

707. [redacted]

708. [redacted]

709. [redacted]

710. [redacted]

711. [redacted]

712. [redacted]

713. [redacted]

714. [redacted]

715. [redacted]

716. [redacted]

h. [redacted]

717. [redacted]

718. [redacted]

719. [redacted]

720. [redacted]

721. [redacted]

722. [redacted]

7. Barriers to Commercialization for NGS Developers

723. Illumina believes that unproven NGS technologies face a reputational barrier, because "[customers] would look to see that other third part[y customers] have used your [NGS] product and have . . . independently validated the quality of your data. . . . If you couldn't find a single customer that's willing to share [your] data . . . I think you would struggle." (PX7107 (deSouza (Illumina) Dep.) at 259, referring to PX2544 (Illumina) at 025).

724. A February 2020 presentation on NGS use, prepared by a strategy consulting firm focusing on precision medicine, states that "[d]espite increasing competition, Illumina is poised to maintain its leadership position over the next 5+ years" and notes that "NGS users have created an 'Illumina ecosystem' (e.g., bio-informatics pipeline) making it hard for competing technologies." (PX2030 (Illumina) at 006 (UBS/DeciBio, NGS and Spatial Omics Landscape and Trends, Feb. 24, 2020)).

725. A February 2020 presentation on NGS use, prepared by a strategy consulting firm focusing on precision medicine, projects that "Illumina will continue to dominate the space," with other sequencing firms "carving out niches." (PX2030 (Illumina) at 009 (UBS/DeciBio, NGS and Spatial Omics Landscape and Trends, Feb. 24, 2020)).

726. The validation process for evaluating a new sequencer takes months or quarters. (deSouza (Illumina) Tr. 2409-10).

727. Only after observing the sequencer's performance in the market and validating the customer's workflow on the new sequencer will a customer begin selling its tests on a new sequencer. (deSouza (Illumina) Tr. 2409-10).

728. It is "not uncommon" for clinical customers to wait years to adopt a new sequencer – "it could be three-plus years after a new sequencer comes out." (deSouza (Illumina) Tr. 2410).

729. Clinical customers take years to adopt a new sequencer, because they wait to see how it will perform in the real world, and then perform validation. (deSouza (Illumina) Tr. 2450).

8. Switching Costs

730. MCED tests must be "tailor-made" towards an NGS platform, similar to how a key is designed for a lock. [redacted]

731. Grail acknowledges that once a company develops an assay on a sequencer it is "very costly" to move to a different sequencer. (Freidin (Grail) Tr. 3066).

732. Switching an LDT's NGS platform takes approximately six to twelve months. (Febbo (Illumina) Tr. 4325).

733. Switching a test's NGS platform when the test has already received a PMA could take approximately nine to eighteen months. (Febbo (Illumina) Tr. 4325-26).

734. Switching sequencers in the middle of a trial would create a "setback in the timing of FDA approval, of commercial availability, and a waste in the cost the clinical trial leading up to the point in time that you make a change." [redacted]

735. The costs associated with switching to a new NGS platform become more expensive over time because the algorithm for the test will become locked as you get closer to conducting a clinical trial and seeking FDA approval. (Chahine (Helio) Tr. 1070-71).

736. The costs associated with switching to a new NGS platform include training technicians on the use of a new platform and ensuring that the sequencing data generated on the new platform is consistent to the data generated on Illumina's platform. (Chahine (Helio) Tr. 1070).

737. [redacted] believes it is "a high risk" for [redacted] if it has to rely on a new company entering the NGS market to supply materials for running [redacted] in-development MCED test at scale because "any disruption of that [supply] would cause business to stop." [redacted]

738. The minimum steps required to switch [redacted] MCED test in development to a new NGS platform include: adapting its library construction process to make the library compatible with the new platform; generating substantial training data on the new platform using the updated assay; updating the analysis software to mitigate the error rates associated with the new platform; performing analysis steps to adapt the new

sample preparation to be compatible with the new instrument; and locking the new system and redoing the validation of each changed component. [redacted]

739. [redacted] believes that switching its MCED test in development to a new NGS platform would delay the launch of the test. [redacted]

740. After redesigning an MCED test, a test developer would need to revalidate its test on the new platform and, at a minimum, perform "a smaller scale clinical sample analysis." [redacted]

741. Natera represented to investors in its 2020 Form 10-K that it has not "validated any alternative sequencing platform on which our testing could be run in a commercially viable manner. These efforts will require significant resources, expenditures and time and attention of management, and there is no guarantee that we will be successful in implementing any such sequencing platforms in a commercially sustainable way." (PX0155 at 039-40 (Natera 2020 Form 10-K)).

742. [redacted] believes switching from Illumina to BGI would cost millions of dollars and take years. [redacted]

743. To [redacted] switching NGS platforms would be "very difficult" and "extremely challenging." [redacted]

744. For [redacted] switching to another NGS platform "would require change in technology and . . . redeveloping [its] product." [redacted]

745. "It's not that easy" [redacted] to switch sequencing platforms. "[I]t's very cumbersome to revalidate an assay on a new sequencer and particularly if you then need to go back through any form of a regulatory approval, so you can do it but it would take a couple of years and with expense." [redacted]

G. Likelihood of Substantial Lessening of Competition

1. Ability to Harm Grail's Purported Rivals

a. Customer Information

746. In the ordinary course of Illumina's sales and service relationships with its customers, Illumina learns about how customers are using Illumina's products, which provides some insight into customers' research and development activities. F. 747-760.

747. Illumina sales personnel "may from time to time receive information from a customer relating to the NGS products and services the customer is using or expects to use, . . . information relating to the uses of and objectives for using the products offered by Illumina and similar such information. Depending on the customer situation, such

information may pertain to the customer's intended use of the products…; the panel types the customer is running or intends to run . . . ; [and/or] product design attributes in the case of Illumina custom-designed products." (PX6056 (Illumina) at 051 (Illumina, Narrative Response to Second Request, Mar. 1, 2021)).

748. In the course of sales and service interactions with customers, as part of assessing which products are most suitable for the customers' needs, customers may disclose the intended use for Illumina's products. (Berry (Illumina) Tr. 657-58).

749. It is possible for Illumina to glean information about customers' end uses from purchase history because certain Illumina consumables are better suited for certain applications. (PX7063 (Berry (Illumina) IHT) at 220-21; PX7076 (Berry (Illumina) Dep.) at 54-57).

750. Illumina tracks every product that its customers order using databases containing customer order and shipment history and prices. (Berry (Illumina) Tr. 647). Illumina also tracks the services that it provides to customers. (Berry (Illumina) Tr. 647).

751. An increase in the volume of samples that a customer requires and the volume of reagents purchased can indicate that a customer is pursuing a clinical trial or commercializing a product. (Berry (Illumina) Tr. 664-65; PX7076 (Berry (Illumina) Dep.) at 24).

752. Illumina typically "talk[s] to the customer about the various performance attributes that . . . our general-purpose reagents have . . . or our sequencing instruments have, and . . . that conversation could lead to an outcome whereby a particular instrument platform or sequencing kit could be identified as likely to be best suited to their needs." (Berry (Illumina) Tr. 658).

753. Illumina identifies many of its customers that are buying its products for the purpose of developing or performing oncology tests through public information. For example, Illumina reviews company websites and regulatory filings to gather this information. (Berry (Illumina) Tr. 655-56). Illumina's customer database classifies customers based on the market segments in which they participate. Illumina classifies customers in "approximately 10 or 12 segments," including oncology testing. (Berry (Illumina) Tr. 660-61; PX7076 (Berry (Illumina) Dep.) at 54-57).

754. In order for Illumina to provide effective service, customers may share with Illumina certain attributes of their tests or provide information on the expected outcomes of their tests, so that Illumina can determine the underlying cause of the service issue. (PX7076 (Berry (Illumina) Dep.) at 32-34).

755. Illumina can learn the strengths or weaknesses of its customers' businesses through their purchase patterns. As David Daly, a former Thrive Chief Executive Officer and former Illumina executive, testified, "it's generally about business trends." For example, Illumina can see whether Thrive's purchases are increasing or decreasing, which "would be indicators of strength or weakness in [Thrive's] business." (PX7109 (Daly (Singular Genomics) Dep.) at 58).

756. Purchase patterns can disclose "your pricing structure, your volumes, any instrument issues or supply issues you might be encountering, any of that information could potentially be used against you in a competitive situation." (PX7109 (Daly (Singular Genomics) Dep.) at 58-59).

757. Illumina's customers can choose to turn on "Proactive," a performance monitoring system that is embedded in Illumina's instruments. (PX7076 (Berry (Illumina) Dep.) at 27-28, 30).

758. Illumina's Proactive system, if activated by the customer, provides Illumina with information on the number of runs its customers perform on each instrument, whether machines are operable or inoperable, and what errors customers receive from their runs.

[redacted]

759. Illumina learns several types of information from its IVD customers. (Goswami (Illumina) Tr. 3226-27). For example, Illumina learns about its customer's development plans, when a customer will need the local run module for its test, when the customer plans to seek FDA approval, and when the customer plans to commercialize its test. Illumina typically sets up a confidentiality agreement with its IVD customers early in the IVD agreement process. (Goswami (Illumina) Tr. 3226-28).

760. Illumina treats customer information it receives as confidential. This includes, among other things, customer purchase order details and pricing, forecasting information, financial information received in connection with credit terms, service records, and quality management records. (Berry (Illumina) Tr. 849-50).

761. Confidential information received from customers at Illumina is subject to Illumina's data privacy restrictions, including, among other things, regular training of staff and supervision by management, and a "need-to-know" limitation on accessing data outside the purview of an individual's role. Illumina requires staff to sign confidentiality agreements when they are hired. Illumina also separates employee teams that have customers with similar products. (Berry (Illumina) Tr. 853-55; Goswami (Illumina) Tr. 3227-30).

762. If an Illumina employee requests access to confidential material, the person responsible for the material is to obtain and comply with legal guidance regarding whether to allow access. (Goswami (Illumina) Tr. 3229-30).

763. Illumina clearly outlines for employees what is considered confidential information and what the employees' obligations are under their confidentiality agreements. (Goswami (Illumina) Tr. 3232).

764. If an Illumina employee shares confidential information of a test developer with a Grail employee, Illumina's disciplinary procedures allow Illumina to take disciplinary action up to termination of the employee. (Goswami (Illumina) Tr. 3232-33).

765. Illumina's confidentiality practices referenced in F. 761-764 are "fairly industry standard and generally accepted" by companies such as Thermo Fisher that serve multiple clients in the same industry. (Goswami (Illumina) Tr. 3228-29).

b. Price Discrimination

766. Illumina has tools available to price discriminate among customers based on the customers' uses for the instruments and reagents purchased. F. 767-778.

767. Illumina uses a multi-part pricing strategy for its products, pricing separately for its instruments, consumables, and service and support based on a standard pricing list. (PX7123 (Fellis (Illumina) Dep.) at 27-30, 35).

768. Illumina offers discount tables, or pricing grids, which provide volume-based discounts to customers. (PX7076 (Berry (Illumina) Dep.) at 115-16, 169-70; *see* PX7123 (Fellis (Illumina) Dep.) at 53-54).

769. Illumina offers a variety of discounts to customers based on various factors such as customer type, volume, market segment, and mix of business. (*See, e.g.*, PX2306 (Illumina) at 011 (email from N. Berry, Illumina, to L. Leigh et al., Illumina, attaching Guardant Executed Supply Agreement, Jan. 4, 2021); *see* PX2387 (Illumina) at 001-02, (email from WF-BATCH, Illumina, to N. Berry, Illumina, Apr. 19, 2018) [redacted]

770. Illumina has a unique pricing grid used only for oncology clinical testing customers. (Berry (Illumina) Tr. 788-90; PX7076 (Berry (Illumina) Dep.) at 177).

771. Illumina's discount tables are often included in Illumina's supply agreements and can vary based on the customer's application. (PX7076 (Berry (Illumina) Dep.) at 172-73, 177).

772. In addition to standard discount matrices, "Illumina from time to time negotiates customer-specific discounts . . . ." These include "promotional discounts, such as starter pack discounts, new customer discounts, product upgrade discounts and other promotional discounts." (PX6056 (Illumina) at 022 (Illumina, Narrative Response to Second Request, Mar. 1, 2021)).

773. Illumina offers discretionary discounts outside of discounts defined in Illumina's pricing tables. Discounts can be based on the number of instruments a customer purchases, whether customers paid in advance for multiple years on a service contract, or the volume of annual purchases of consumables. (Berry (Illumina) Tr. 775-76).

774. Illumina may offer discretionary discounts separate and apart from pricing in a supply agreement. (Berry (Illumina) Tr. 780).

775. Illumina has used differentiated pricing and discounting based on customer product lines. (PX7081 (George (Invitae) Dep.) at 82-85 ("There's always been a kind of differential pricing for that – the core components of the Illumina sequencing based on what the application was, based on what you were using the sequencing for."); PX7082 (Cooper (Progenity) Dep.) at 124-25 ("[W]e have to buy fancy reagents in a different-colored box to run an NIPT versus cheap reagents for research use in doing [product] discovery purposes.")). [redacted]

776. [redacted]

777. In an offer to Singlera to grant IVD rights, Illumina proposed a "market access fee" that distinguished between a single cancer test like Singlera's ColonES and a multicancer test like Singlera's PanSeer. (PX7042 (Gao (Singlera) IHT) at 78-80; *see* PX8516 (Singlera) at 006 (email from J. Leite, Illumina, to G. Gao, Singlera, attaching Singlera-Illumina Draft IVD NextSeqDX Term Sheet, June 20, 2020) (assigning a payment structure for each cancer indication, capping "pan-cancer Class III claims" at $10 million)).

778. Illumina has used "field of use" restrictions in supply agreements. A field of use restriction limits the use of the products to a specific application area or areas. For example, Illumina included a field of use clause in an agreement in which Illumina was [redacted] (PX7079 (Flatley (Illumina) Dep.) at 127; [redacted]

779. [redacted] Field of use restrictions are "typical in this industry . . . ." (Felton (Thermo Fisher) Tr. 2063). *See also* PX7060 (Naclerio (Illumina) IHT) at 125 ("Field of use" is "a standard term of art that's in practically . . . every license or supply agreement.").

c. Access to New Technology

780. Illumina regularly releases new sequencers, reagents, and upgrades to its NGS technology. F. 573-574, 579-584.

781. Illumina continuously seeks to improve the performance of its products, including through providing customers with periodic software updates. (Berry (Illumina) Tr. 675-76; deSouza (Illumina) Tr. 2383).

782. Illumina has introduced new instrument platforms and new chemistries within instrument platforms "on a very regular basis." (Berry (Illumina) Tr. 714).

783. [redacted]

784. [redacted]

785. [redacted]

786. Illumina updates its sequencers' software from time to time. (deSouza (Illumina) Tr. 2383).

787. When customers seek to upgrade their NGS instruments, Illumina will send a technician to get the new instruments "up and running and to assist in troubleshooting matters." (PX7082 (Cooper (Progenity) Dep.) at 87).

788. Illumina sends an engineer to the customer to install, test, and validate a new Illumina machine, including when Illumina upgrades its NGS equipment to ensure it is performing in accordance with its specifications. (PX7076 (Berry (Illumina) Dep.) 153-54). *See also* PX7076 (Berry (Illumina) Dep.) at 151-52 (Illumina "work[s] with a customer to confirm that the instrument is performing to spec and the general purpose reagents, the sequencing kits that they buy from us to sequence the samples using their assay, are performing to our specifications.").

789. Illumina's new products typically "reduce the cost of sequencing, increase the throughput from a given sequencer . . . and so having early access to the products would be important to start, for example, a revalidation process . . . ." (PX7085 (Harada (Exact) Dep.) at 204-05).

790. Changes to Illumina's products can impact products and clinical trials. As Dr. Lengauer explained: "When [changes to Illumina's products] are big, they could also impact . . . the product that you sought registration for, because if you make changes to the product, you might have to go back to a trial again . . . . [W]e need to always adapt to the changes" that NGS sequencing providers are making. (Lengauer (Exact/Thrive) Tr. 197-98).

791. In or around 2017, while Grail was part of Illumina, Illumina collaborated with Grail on "extraction methodology to improve library yields" and on the development of library prep and sequencing kits, including kits "built specifically for Grail." (PX2541 (Illumina) at 008, 010, 017 (Interim Review: K2-Grail, Feb. 2, 2017)).

792. Illumina does not typically customize, design or modify products for one customer application. As deSouza explained, "If we are going to embark on a substantial undertaking from an engineering team perspective, we want a product that can meet the needs more broadly . . . . We're not a consulting firm[.]" (deSouza (Illumina) Tr. 2434; *see also* deSouza (Illumina) Tr. 2446-47 ("Q: [I]f you made one of these improvements to time, throughput, or reducing cost, is there any way to limit that to one particular user or customer? A: No, there isn't . . . . There isn't technically a way to do that . . . . [T]echnically, I can't imagine how we would give it to just one . . . .")).

793. Illumina is willing to customize its library prep kits for use in an NGS workflow. Library prep kits are "some very specific SKUs" (stock-keeping units) where a customer can specify content they want to interrogate. (Berry (Illumina) Tr. 812).

794. In the Americas, Illumina has "almost never" created a customized version of an instrument or core consumable. (Berry (Illumina) Tr. 844, 881-82).

d. Quality of Supply, Service, and Support

795. To the extent that Illumina is an MCED test developer customer's sole supplier of necessary sequencing instruments and reagents, the test developer's business depends on consistent and reliable supply, service, and support from Illumina. [redacted] ("[W]e are totally dependent upon Illumina as a supplier, and we need a true partnership with them to know that we can get a high-quality product at a good price with incredible support."); PX7109 (Daly (Singular Genomics) Dep.) at 56 ("[I]f there were ever instrument or consumable shortages, my concern is Grail would be supplied and others might have restricted supply."); PX7045 (Chudova (Guardant) IHT) at 105-09 **(**Guardant depends on Illumina "to consistently generate reagents with particular quality characteristics in an uninterrupted way."); Getty (Guardant) Tr. 2684-85 ("Illumina is a sole supplier" for Guardant and its "business rests on [Guardant's] ability to sequence and leverage [Illumina's] services in order to maintain those sequencers.")).

796. In its annual report, Natera expressed, "Illumina is currently the sole supplier of our sequencers and related reagents for [our tests] . . . . Without sequencers and the related reagents, we would be unable to run our tests and commercialize our products." (PX0155 at 039 (Natera 10-K, Feb. 25, 2021)).

797. MCED test developers that purchase Illumina's products rely on Illumina for service and support of those products. (Conroy (Exact) Tr. 1583-84 (Illumina's instruments are "not like a washing machine. . . . [T]hey frequently stop working and you need to call an

Illumina technician to come out and help find out what's wrong with it and get it up and running again."); PX7110 (Conroy (Exact) Dep.) at 72 ("[A]ll of this equipment is highly sophisticated and you need the support."); PX7105 (Getty (Guardant) Dep.) at 61-62 (Guardant relies on Illumina for service and support on a daily basis.); PX7076 (Berry (Illumina) Dep.) at 83-84 (Illumina endeavors to "do [its] best to" quickly resolve any customer issues with a purchase.); PX2601 (Illumina) at 002-04 (Invitae asked for expedited shipment of its purchases and Illumina's team worked to make that happen.)).

798. Sequencing instruments do "break down, and when they do, . . . you need a service engineer to be able to respond and restore that instrument in a timely manner." (PX7094 (Nolan (Freenome) Dep.) at 277-78; Conroy (Exact) Tr. 1584-85).

799. Guardant's Bill Getty estimated that Illumina technicians come to Guardant's lab to work on sequencers on a regular basis, probably weekly. (Getty (Guardant) Tr. 2514). Getty explained that "without [Illumina's] sequencers, [and] without the service that Illumina provides to keep them in good working order, [Guardant] would be unable to run [blood samples of patients] and deliver the final product to patients." (Getty (Guardant) Tr. 2685-86).

800. Illumina services Illumina equipment that customers purchase and provides customers with technical support to resolve any problems with Illumina products. (Berry (Illumina) Tr. 646).

801. Illumina provides customers with field application scientists who train customers after a customer purchases an Illumina instrument and subsequently upon a customer's request. (Berry (Illumina) Tr. 669-70).

802. Illumina provides customers with field service engineers who perform routine maintenance and repair customers' instruments. Field service engineers perform "break/fix service" when instruments experience a failure that prevents customers from operating the instruments. (Berry (Illumina) Tr. 668-69).

803. Some larger customers contract to have Illumina service engineers working on the customer's lab full-time. (Berry (Illumina) Tr. 682-83; PX7094 (Nolan (Freenome) Dep.) at 156-57 (Freenome has onsite Illumina service engineers.)).

804. Illumina's service team offers unique expertise to fix any issues that may arise when customers use its products and, MCED test developer customers "need those experts that are well trained to be able to perform the work on instruments." (PX7094 (Nolan (Freenome) Dep.) at 277-78).

805. Illumina customers expressed concerns that any decline in Illumina's service and support could harm their efforts to develop MCED tests. (*See* PX7110 (Conroy (Exact) Dep.) at 72; PX7105 (Getty (Guardant) Dep.) at 69-71).

2. Incentive to Harm Grail's Purported Rivals

a. Relative Profits

806. Illumina's "core business is to sell sequencers and consumables. That's how [Illumina] make[s] the vast majority of [its] revenue." (deSouza (Illumina) Tr. 2378).

807. To the extent Illumina causes Grail's alleged rivals stop investing in NGS applications on Illumina systems, this could result in the loss of Illumina's NGS sales for MCED and non-MCED applications, and thereby harm Illumina's core business. (deSouza (Illumina) Tr. 2378-80; RX3864 (Carlton Expert Report) ¶¶ 76, 78-80, 86).

808. One potential result of an attempt by Illumina to raise prices or foreclose supply for MCED test developers is that these customers, as well as the non-MCED clinical testing customers who learned of it, would choose to no longer invest in current or future NGS applications on Illumina systems. (Aravanis (Illumina) Tr. 1922; deSouza (Illumina) Tr. 2380-81; Febbo (Illumina) Tr. 4331-32; RX3864 (Carlton Expert Report) ¶ 78).

809. Since Illumina released its first genome analyzer instrument in 2007, sequencing costs have gone down substantially. (RX3515 (National Human Genome Research Institute Sequencing Costs Data)). According to data published by the National Human Genome Research Institute analyzed by Dr. Carlton, since Illumina released its genome analyzer instrument in 2007, sequencing costs have been reduced from roughly $300,000 per gigabase to less than $8 per gigabase today. (RX3864 (Carlton Expert Report) ¶ 77).

810. NGS allowed completion of a sequencing project that would have cost billions of dollars and take over a decade to complete without NGS to now be completed in a single day for under a thousand dollars. (*See* PX0124 at 006-07 (Jon Gertner, *New York Times*, "Genome Sequencing and COVID-19 – How Scientists Are Tracking the Virus," Mar. 25, 2021)).

811. Illumina recognized that acquiring Grail would require Illumina to transform from "a genomics tools & diagnostics company into a clinical testing and data driven healthcare company." (PX2488 (Illumina) at 003 (email from S. Muppaneni, Illumina, to K. Reeves, Illumina, Sept. 29, 2020, attaching final Board of Directors presentation "Project Valor")).

812. Illumina's stated strategy in acquiring Grail was to "[v]ertically integrate into oncology, developing content and providing services at scale, while continuing to serve other segments with [its] existing strategy." (PX2488 (Illumina) at 011 (email from S. Muppaneni, Illumina, to K. Reeves, Illumina, Sept. 29, 2020, attaching final Board of Directors presentation "Project Valor"); *see also* PX2465 (Illumina) at 009 (email from B. Blanchett, Illumina, to S. Samad, Illumina, et al., July 29, 2020, attaching presentation entitled "Project Valor Audit Committee Chair Discussion Materials")).

813. Illumina segments its target NGS customers into three "value chain" components: (1) clinical testing services, (2) library preparation and assays, and (3) instruments and core consumables. (PX2488 (Illumina) at 008 (email from S. Muppaneni, Illumina, to K. Reeves, Illumina, attaching "Project Valor," Sept. 29, 2020)).

814. Illumina's clinical oncology testing segment of its business includes therapy selection, which is for patients that already have cancer; monitoring; and screening, which looks for early markers of cancer in asymptomatic individuals. (PX7087 (Goswami (Illumina) Dep.) at 148).

815. Internal Illumina analyses in 2020 projected revenues from its NGS instruments and core consumables to grow from [redacted] Illumina further projected: "As commercialized screening/monitoring products scale, the clinical testing services market will grow to ~3x larger than" Illumina's product segments combined. Illumina projected a [redacted] revenue market for clinical testing services by 2035, noting that Illumina's "current strategy" does not focus on "direct participation" in that segment. (PX2169 (Illumina) at 042 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020)). *See also* PX2488 (Illumina) at 008 (email from S. Muppaneni, Illumina, to K. Reeves, Illumina, attaching "Project Valor," Sept. 29, 2020); PX2465 (Illumina) at 007 (email from B. Blanchett, Illumina, to S. Samad et al., Illumina, attaching "Project Valor Audit Committee Chair Discussion Materials," July 29, 2020).

816. Illumina's 2021-2025 Strategic Plan projected: "NGS testing in oncology [is] expected to grow rapidly reaching [approximately] $75B by 2035 – screening and monitoring are the largest, fastest growing segments." (PX2169 (Illumina) at 041 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020)). *See also* PX2465 (Illumina) at 006 (email from B. Blanchett, Illumina, to S. Samad, Illumina, attaching "Project Valor Audit Committee Chair Discussion Materials," July 31, 2020).

817. A presentation to Illumina's Board of Directors regarding the proposed acquisition of Grail estimated the total market opportunity for oncology screening at approximately $75 billion by 2035. (PX2488 (Illumina) at 003 (email from S. Muppaneni, Illumina, to K. Reeves, Illumina, et al., Sept. 29, 2020, attaching final Board of Directors Project Valor Presentation)).

818. Illumina's 2021-2025 Strategic Plan projected that "[a]s testing evolves, the clinical testing services component of the value chain in NGS applications becomes substantially larger than other components" and that Illumina's then-current strategy did not focus on direct participation" in the clinical testing services segment. (PX2169 (Illumina) at 042 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020)).

819. [redacted]

[redacted]

820. Illumina's 2021-2025 Strategic Plan advised that "[a] move towards oncology clinical testing services & subsequent data ownership will evolve [Illumina's] business," including by shifting the "[m]ajority of revenue" coming from "hardware and associated consumable sales" to "[redacted] of revenues [coming] from data-intensive clinical services." Illumina's transition strategy included to "[v]ertically integrate into oncology, developing content and providing services at scale, while continuing to serve other segments with existing strategy." (PX2169 (Illumina) at 045 (Illumina Strategic Plan 2021-2025, Board Discussion Document," Oct. 23, 2020)).

821. Illumina predicted in 2020 that the "net margin profit pool" in 2035 would be [redacted] for clinical testing services compared to the [redacted] for "Instruments/Core Cons[umables]," and [redacted] for "L[ibrary] P[rep] and Assays." (PX2488 (Illumina) at 009 (email from S. Muppaneni, Illumina, to K. Reeves, Illumina, Sept. 29, 2020, attaching final Board of Directors presentation "Project Valor")).

822. Illumina estimated in 2020 that acquiring Grail would "add[] [redacted] in 2035 revenue [redacted] and improves [Illumina's compound annual growth rate] to [approximately] [redacted]" (PX2488 (Illumina) at 003 (email from S. Muppaneni, Illumina, to K. Reeves, Illumina, Sept. 29, 2020, attaching final Board of Directors presentation "Project Valor"); PX5030 (Illumina) at 021 (Illumina, Project Valor, Sept. 6, 2020)).

823. Illumina forecasted in 2020 that, in the long run, its revenue and profits would be greater through the acquisition of Grail compared to a smaller ownership stake in Grail. (Flatley (Illumina) Tr. 4096-97; PX2575 (Illumina) at 003 (Illumina, Grail Announcement Q&A, Sept. 20, 2020)).

824. deSouza explained to investors in September 2020 that the acquisition of Grail "positions Illumina to participate in what we expect will be a $75 billion market for NGS-based oncology tests by 2035, $60 billion higher than our oncology TAM [total addressable market] excluding GRAIL." (PX2575 (Illumina) at 069 (Illumina, Investor Call Transcript, Sept. 21, 2020); *see also* PX2031 (Illumina) at 003 (Illumina, Cowen Liquid Biopsy Summit with Francis deSouza, Sept. 24, 2020) (stating that Illumina has "been moving into select clinical applications, and this acquisition adds the largest genomics application to our portfolio – and with it, an incremental $60B TAM")).

825. deSouza told investors in September 2020 that the "early detection of cancer segment is the largest segment in the clinical market we can see for the next decade . . . ." (PX2575 (Illumina) at 060 (Illumina, Illumina Inc at Cowen Liquid Biopsy Summit (Virtual), Sept. 24, 2020); PX2151 (Illumina) at 005 (Illumina, Sands Capital Management Call, Oct. 11, 2020) (stating that "[e]arly cancer detection is the largest opportunity in clinical genomics in our lifetime representing an incremental $60B[illion] market opportunity by 2035")).

826. deSouza explained to investors in September 2020, regarding the acquisition of Grail, "[d]irect participation ensures that our revenue share of these high value clinical applications will be higher than it would be if we are limited to supplying the hardware and consumables only. In short, Illumina's revenue reflects clinical value, not simply the underlying sequencing output." (PX2575 (Illumina) at 016 (Illumina, Cowen Liquid Biopsy Summit with Francis deSouza, Sept. 23, 2020)). *See also* deSouza (Illumina) Tr. 2219 (referring to PX2575 (Illumina) at 060) ("[P]articipating directly in [the clinical testing] segment . . . allows Illumina to get a larger percentage of the value created in that solution rather than just being the platform provider.").

827. In a discussion at the Cowen Liquid Biopsy Summit in September 2020, deSouza stated that "the GRAIL acquisition gives [Illumina] a leading position in this very large market opportunity. And the early detection cancer market dwarfs the clinical markets we see today, NIPT and therapy selection for oncology combined." (deSouza (Illumina) Tr. 2218-19 (referring to PX2575 (Illumina) at 060); *see* PX2564 (Illumina) at 005 (email from J. Ross, Illumina, to F. deSouza, Illumina, Sept. 5, 2020, attaching Draft Project Valor Script) ("[W]e believe that the screening opportunity dwarfs therapy selection and monitoring.")). deSouza acknowledged at trial that he was talking about the market opportunity that the Grail acquisition provided. (deSouza (Illumina) Tr. 2219).

828. Illumina projects that by 2026, it will "lose getting close to [redacted]" from Grail, which will be funded by Illumina's NGS business. Illumina expects that it will begin to generate profits as a result of the acquisition of Grail in [redacted] and will recoup its losses incurred in connection with the acquisition around [redacted] (deSouza (Illumina) Tr. 2291, 2382-83).

829. Illumina does not expect the clinical testing business to yield a profit "for many, many years" and Illumina expects that it "will lose" money on the business, which deSouza described as "very typical in clinical testing businesses." (deSouza (Illumina) Tr. 2386).

830. Illumina expects that "the vast majority of Illumina's revenue in the next ten years will come from [its] . . . sequencers and consumables." (deSouza (Illumina) Tr. 2291).

b. Expert Witness Opinion

831. In an analysis of a vertical merger, it is important to compare the premerger world to the post-merger world to understand the impact of the merger on the merging parties' incentives. (RX6000 (Carlton Trial Dep.) at 92-94).

832. "Illumina's own analysis showed that it believes that there will be more profit to be had in the clinical testing services market – which includes Grail – than in the sale of Illumina's NGS products to all customers, including MCED developers. As such, it would have the incentive to advantage Grail to maximize its share of this large profit pool." (PX6090 (Scott Morton Expert Report) ¶ 201 (relying on PX2169 at 043)).

833. Dr. Scott Morton's opinions on Illumina's economic incentives improperly assume that in the but-for world without the merger, Illumina has no incentive to foreclose Grail rivals. (RX6002 (Guerin-Calvert Trial Dep.) at 20-21, 108-09). Even absent the merger, Illumina would have an incentive to favor Grail. In the world absent the merger, Illumina would own roughly 12% of Grail and, in the event there was a "highly substitutab[le]" product being developed, Illumina would still make more money by favoring Grail over Grail's rivals. (RX6000 (Carlton Trial Dep.) at 45-46). As Dr. Carlton explained:

> Absent this merger, Illumina owns roughly 12 percent of GRAIL. That means if there's a product that does exactly the same thing as GRAIL's product, Illumina already has an enormous incentive to favor GRAIL, and, therefore, there would be no effect from the merger.

(RX6000 (Carlton Trial Dep.) at 46).

834. Dr. Scott Morton included a table in her expert report that purports to quantify Illumina's incentive to harm competition through measures of pre-Acquisition and post-Acquisition profits. Table 2 of her report purports to compare what Illumina would earn from Grail versus two hypothetical Grail rivals in the premerger and post-merger worlds, both of whom pay a royalty to Illumina. (PX6090 (Scott Morton Expert Report) at 104, Table 2; PX7138 (Scott Morton Trial Dep.) at 235 ("[T]his is the relevant calculation of the incentive to harm competition.")).

835. In her analysis of Illumina's incentives, Dr. Scott Morton assumed that, absent the Acquisition, Illumina would charge the same royalties to Grail's rivals as Illumina was entitled to receive from Grail under Grail's supply agreement with Illumina. (PX7138 (Scott Morton Trial Dep.) at 234-37).

836. There is no basis for Dr. Scott Morton's assumption that any rival MCED test developer would pay a royalty similar to the royalty Grail paid Illumina, and the assumption ignores the unique nature of the Grail royalty and the undisputed fact that, other than Grail's supply agreement, no Illumina supply agreement contains such a provision. (RX6000 (Carlton Trial Dep.) at 92-94).

837. Dr. Carlton calculated Illumina's pre-Acquisition and post-Acquisition profits from Grail and from Grail's alleged rivals, including Grail's royalty payment and the assumption that Dr. Scott Morton made, that Illumina would charge 20% higher prices to Grail's alleged rivals. Dr. Carlton did not include in his calculation any royalty payments to Illumina from Grail's alleged rivals on sales of NGS products. This calculation

demonstrates that pre-merger, Illumina already makes five times as much from selling NGS products to Grail than to other customers. Therefore, by Dr. Scott Morton's reasoning, an incentive to foreclose already exists, absent the Acquisition. (RX3864 (Carlton Expert Report) ¶¶ 148-49 and Table 4).

838. Dr. Scott Morton failed to quantify the per-test gross profits Illumina earns from selling sequencing products used by any hypothetical MCED rival for non-screening tests, or the gross profits that Illumina would lose if Illumina's conduct toward an MCED test developer customer caused Illumina to lose the developer's entire clinical testing business, including non-MCED tests. (PX7138 (Scott Morton Trial Dep.) at 242-45).

839. The extent of Illumina's incentive to foreclose or disadvantage MCED rivals depends in part on the degree of diversion between any foreclosed rival and Grail. (*See* PX7138 (Scott Morton Trial Dep.) at 248-49).

840. Dr. Carlton explained that "if products are very different from one another, it suggests that they're unlikely to be close substitutes, and if they're not close substitutes, then the diversion of sales from the rival – to in this case GRAIL . . . [is] likely to be low or nonexistent," and "if it's low or nonexistent, then the incentive – the profit incentive to engage in the raising rivals' cost strategy . . . will also be low or nonexistent." (RX6000 (Carlton Trial Dep.) at 40-41; RX3864 (Carlton Expert Report) ¶ 50).

841. Illumina's incentive to raise rivals' costs is diminished the greater the downstream tests are different from each other, because the greater the differentiation is between Grail and rivals' MCED tests, the less diversion would be expected if Illumina attempted to raise rivals' costs. (RX3697 (Carlton, Transaction Costs and Competition Policy, 2019) at 007-09; RX3864 (Carlton Expert Report) ¶ 87).

842. To the extent important differences exist between MCED tests, Grail's MCED test and those of other MCED test developers would not be good substitutes for each other, and the less the substitutability there is among the downstream products, the lower will be the diversion from rivals to Grail; this reduces or eliminates any incentive to raise rivals' costs. (RX3864 (Carlton Expert Report) ¶ 87).

843. Dr. Scott Morton acknowledged that if products "are sufficiently differentiate[d], then what you would get is the inability to recapture. . . . [T]he combined firm would not recapture any of those profits" and "that would be not a very successful strategy." "That's what highly differentiated means, that diversion is limited." (RX3852 (Scott Morton Dep.) at 173, 174).

844. Dr. Scott Morton agreed that one cannot "put aside diversion" in a foreclosure analysis and that if there is "no way to . . . recapture the sales, then yes, raising price above the optimal level will harm Illumina." (PX7138 (Scott Morton Trial Dep.) at 227).

845. Because Galleri is the only NGS-based MCED test that is commercially available, current diversion between Galleri and other tests is impossible. (F. 201; RX6000 (Carlton Trial Dep.) at 46).

846. Dr. Scott Morton failed to evaluate the ability of Illumina to raise rivals' costs, impose harm, or foreclose rivals under the Open Offer. (RX6002 (Guerin-Calvert Trial Dep). at 23-24).

3. The Open Offer

847. Illumina's products and services serve customers in a wide range of markets, including in research and clinical settings. Illumina's customers include genomic research centers, academic institutions, government laboratories and hospitals. They also include pharmaceutical companies, biotechnology companies, commercial molecular diagnostic laboratories, and consumer genomics companies. (PX0061 (Illumina) at 005).

848. Illumina customers that do not have a pricing agreement typically begin the process of purchasing a sequencing instrument or core consumable by initiating a conversation with their Illumina sales representative. After consulting with the customer and determining which products are most suitable, Illumina will provide a price quote, as well as Illumina's standard terms and conditions. The customer might sign the purchase order as is or negotiate the terms and conditions. This process will often culminate in a customer-specific supply agreement. (Berry (Illumina) Tr. 840-42).

a. Development of the Open Offer

849. On or around October 9, 2020, Illumina's commercial team followed up its pre-Acquisition telephone outreach to certain prior customers (F. 514-516) with letters of intent ("LOIs"), which sought to formalize and document the specifics of the assurances that had been provided by Illumina to its customers over the telephone. (Berry (Illumina) Tr. 755-57, 857).

850. In summary, the LOIs outlined assurances by Illumina that, post-Acquisition, customers will be able to purchase Illumina's products on terms and conditions "substantially similar" to those under which the customers had purchased Illumina's products prior to the acquisition; that customers will receive commercial terms similar to other "similarly situated customers" based on factors such as "region, customer type, volume, and mix of business"; and that Illumina will continue to make its sequencing platforms, product services and support, "consistent with Illumina's customary practices." (*See, e.g.*, RX1940 (Illumina) at 002; RX2135 (Illumina) at 002).

851. After some customers raised concerns about Illumina's protecting customers' confidential business information post-Acquisition, on October 20, 2020, Illumina sent out a revised LOI adding that Illumina will not share any customer confidential or proprietary information or data with Grail, any subsidiary of Grail, or any "employees of Illumina who work" within the same division as Grail post-Acquisition. (PX7063 (Berry

(Illumina) IHT) at 134-35; Berry (Illumina) Tr. 757; *see, e.g.*, RX1942 (Illumina) at 002-03; RX1940 (Illumina) at 002-03).

852. Illumina's amended letter of intent was "sent out . . . to everybody who received the first one." (Berry (Illumina) Tr. 755-57).

853. In total, 14 companies received LOIs from Illumina including, among others, Guardant, Freenome, FMI, Natera, Thrive, and Exact. (Berry (Illumina) Tr. 936-37; PX2653 (Illumina); PX2655 (Illumina); RX1651 (Illumina); RX1938 (Illumina); RX1940 (Illumina); RX1942 (Illumina); RX1951 (Illumina); RX2135 (Illumina); RX2138 (Illumina); RX2140 (Illumina); RX2157 (Illumina); RX2159 (Illumina); RX3918 (Illumina); RX3919 (Illumina)).

854. In connection with receiving the LOIs, some customers began, or continued, negotiations with Illumina for a long-term supply agreement. (Berry (Illumina) Tr. 758-59; [redacted] These negotiations were either part of ongoing negotiations in the normal course of business or were triggered by Illumina's invitation in the outreach to execute such an agreement. (Berry (Illumina) Tr. 758-59).

i. Negotiations with [redacted]

855. [redacted]

856. [redacted]

857. [redacted]

858. [redacted]

859. [redacted]

860. The MFN provision in the [redacted] supply agreement amendment came about because [redacted] wanted a provision to ensure that [redacted] was not treated unfavorably both relative to Grail but also relative to [redacted] peers. [redacted] and Illumina discussed the issue and ultimately agreed on language. (Berry (Illumina) Tr. 941-43; RX2476 at 011 (providing that customer will have access to overall commercial terms for products "that are substantially similar to those of similarly situated customers" considering primarily "region, customer type, volume, market segment, and mix of business")).

861. In the negotiations over the supply agreement amendment with Illumina, [redacted] wanted a term to ensure that neither Grail nor [redacted] peers would obtain access to new products and, in particular, to pre-release products, in a way that would give them an advantage relative to [redacted] (Berry (Illumina) Tr. 942).

862. The [redacted] supply agreement amendment provides for [redacted] "access to any Pre-Release Sequencing Product" to which Grail is offered access, and on terms "no less favorable" than those offered to Grail. (RX2476 (Illumina) at 012).

863. The [redacted] supply agreement amendment contains a term that prohibits Illumina from ceasing supply of products in the event of an alleged intellectual property ("IP") infringement. (Berry (Illumina) Tr. 945; RX2476 (Illumina) at 010).

864. The [redacted] supply agreement amendment prohibits Illumina from sharing any confidential [redacted] information with Grail, any subsidiary of Grail, or any "employees of Illumina who work" within the same division as Grail post-Acquisition. In addition, the [redacted] supply agreement amendment limits Illumina's use of customer confidential information and requires establishing a "firewall designed to prevent any" Grail personnel or Illumina personnel involved with Grail's business or products from accessing [redacted] confidential information. Compliance with the firewall is secured by Illumina's obligation, upon no more than quarterly request, to provide a written certification of compliance. (RX2476 (Illumina) at 009-10).

ii. Negotiations with [redacted]

865. [redacted]

866. [redacted]

867. [redacted]

868. [redacted]

869. [redacted]

870. [redacted]

871. [redacted]

872. [redacted]

873. [redacted]

874. [redacted]

b. Relevant Provisions of the Open Offer

i. Overview

875. Illumina used the information gained from its customer outreach discussions and what it learned in negotiations with customers such as [redacted] and [redacted] to develop a standardized supply contract to offer to all of its U.S. oncology customers (the "Open Offer"). (Berry (Illumina) Tr. 857, 941-46). For example, the term prohibiting Illumina from ceasing supply of products in the event of an alleged intellectual property infringement claim is in the Open Offer because of feedback Illumina received from [redacted] (Berry (Illumina) Tr. 945-46). Working with [redacted] on developing provisions for equivalent access to pre-release products (F. 862) helped Illumina develop similar terms for the Open Offer. (Berry (Illumina) Tr. 942-43).

876. The Open Offer, dated March 29, 2021, was made available on Illumina's website on March 30, 2021. The form contract posted on the website recites Illumina's purpose as: "to allay any concerns relating to the [then-proposed Grail acquisition] including that Illumina would disadvantage GRAIL's potential competitors after the [acquisition] by increasing their sequencing prices or by withholding access to Illumina's latest innovations in" NGS. (PX0064 (Illumina) at 001; PX0087 (Illumina); PX0088 (Illumina); PX0089 (Illumina); RX4003 (Illumina's Oncology Contract Terms Website) at 001; deSouza (Illumina) Tr. 2338-39, 2401-02).

877. The Open Offer is available to all for-profit U.S. oncology customers who purchase NGS products for developing and/or commercializing oncology tests. (PX0064 (Illumina) at 001; RX4003 (Illumina's Oncology Contract Terms Website) at 001; deSouza (Illumina) Tr. 2401-02).

878. Illumina made the Open Offer available in an effort to address concerns raised by both FTC Complaint Counsel and certain customers that the Illumina-Grail transaction would allow Illumina to disadvantage Grail rivals. (*See* Berry (Illumina) Tr. 688-89, 709-10; deSouza (Illumina) Tr. 2338-39, 2401; Goswami (Illumina) Tr. 3207).

879. Illumina has made the terms of the Open Offer available to any existing or new customer of Illumina that is a "For-Profit Entity"[11] and purchases NGS products for developing and/or commercializing oncology tests. (PX0064 (Illumina) at 003).

880. Existing or new customers of Illumina may sign the Open Offer at any time until six years after the close of Illumina's acquisition of Grail, which is August 18, 2027. (PX0064 at 001; Berry (Illumina) Tr. 861-62).

[11] The Open Offer defines "For-Profit Entity" as "a for-profit company in the United States that purchases Supplied Products for performing sequencing for liquid biopsy cancer screening or diagnostic tests for clinical oncology purposes, on human samples received from, and delivered to, unaffiliated health care professionals, health care organizations or other laboratories for clinical oncology purposes." (PX0064 (Illumina) at 003). A For-Profit Entity excludes governments, government agencies, hospitals, research institutes, academic institutions, nonprofits and Illumina Affiliates (including Grail). (PX0064 (Illumina) at 003).

881. Under the Open Offer, the customer has a "unilateral right to terminate its supply relationship with Illumina at any time for any reason" without liability for the termination, "upon ninety (90) days' prior written notice to Illumina, provided, however, that Customer shall honor all invoices . . . ." issued for items shipped under a purchase order. "Illumina cannot terminate th[e] Supply Agreement for convenience during the [12 year] Term." (PX0064 (Illumina) at 010; Berry (Illumina) Tr. 862-63; deSouza (Illumina) Tr. 2402).

882. The Open Offer is "not contingent on any purchase commitments by Customer, nor does it affect Customer's existing unilateral right to terminate its supply relationship with Illumina at any time and for any reason." (PX0064 (Illumina) at 009; *see also* Berry (Illumina) Tr. 864-65).

883. "Supplied Products" under the Open Offer is defined as: "Illumina's NextSeq, NextSeqDx and NovaSeq instruments, and any future sequencing instruments launched by Illumina or its Affiliates, or Sequencing Consumables, that are purchased by Customer for any Customer Use pursuant to the Supply Agreement." (PX0064 (Illumina) at 004-05).

884. "Sequencing Consumables" under the Open Offer means "those consumables intended by Illumina to be used to perform a sequencing process on Illumina's NextSeq, NextSeqDx and NovaSeq instruments and any future sequencing hardware launched by Illumina or its Affiliates, and includes core consumables that are (i) commercialized or otherwise made available by Illumina to customers or Affiliates of Illumina and (ii) intended by Illumina to be used to perform a sequencing process on any such system. Sequencing Consumables do not include products that were at the 'end of life' or 'end of sale' or were announced (before January 1, 2021) to customers as a planned 'end of life' or 'end of sale.' Sequencing Consumables are limited to products that are shipped to and used in the United States." (PX0064 (Illumina) at 004).

885. The Open Offer is irrevocable, binding on Illumina, and governed by New York law. (PX0064 (Illumina) at 001, 011).

886. On September 8, 2021, Illumina added additional terms to the Open Offer stating in part "Illumina is irrevocably offering additional terms to further allay any concerns relating to Illumina's" acquisition of Grail. (RX3935 (Illumina) at 001; deSouza (Illumina) Tr. 2405-06).[12]

887. All of the provisions of the Open Offer are publicly posted and are publicly available on Illumina's website. (deSouza (Illumina) Tr. 2401-02; RX4003 (Illumina's Oncology Contract Terms Website) at 001; PX0064 (Illumina); PX0087 (Illumina); PX0088 (Illumina); PX0089 (Illumina); PX7076 (Berry (Illumina) Dep.) at 275-76).

[12] In summary, the September 8, 2021 additions to the Open Offer reduced certain waiting periods from 45 days to 5 days, specified additional arbitration provisions, and increased the frequency of audits from yearly to biannual. (RX3935 (Illumina)).

888. If signed, the Open Offer becomes a supply agreement, which is effective for twelve (12) years from the date of the Acquisition, or August 18, 2033, "regardless of the date either party signs this Supply Agreement." (PX0064 (Illumina) at 005).

889. A 12-year duration is longer than Illumina's typical supply agreements; however, Illumina believed this duration would convey to customers that Illumina was invested in maintaining positive relationships as the technology provider to these customers. (Berry (Illumina) Tr. 862).

ii. Services

890. Under the Open Offer, Illumina must provide customers with the same access to services to which Grail or any other for-profit entity has access, or to which the customer had access before the Acquisition, at the same prices. (Rabinowitz (Natera) Tr. 420-21; Berry (Illumina) Tr. 865-66; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 006 ("Customer shall have access to the same product services and support services for purchase relating to the Supplied Products to which Grail or any For-Profit Entity has access, or which Customer had access before" the Acquisition); RX3935 (Illumina) at 002 (providing further that "[f]or such services, Customer shall have access to the same volume-based pricing that GRAIL has access to for the equivalent level of service, or to which Customer had access before the [Acquisition], at the Customer's option")).

891. To comply with the access-to-services provisions referenced in F. 890, and ensure consistency in treatment between customers, Illumina keeps track of services that customers order using service contract SKUs. When a customer purchases a service SKU, there is an agreement that describes aspects of the service relationship such as turnaround time and the number of preventative maintenances to which a customer is entitled. As with products, there is a standard list of orderable service SKUs, each associated with a standard U.S. list price. (Berry (Illumina) Tr. 866-69).

892. Illumina offers for purchase three levels of service agreements, known as service level agreements, or "SLAs" – gold, silver, or bronze. The different levels of service agreements determine matters such as technician response time and frequency of proactive maintenance visits. (Berry (Illumina) Tr. 681-82).

893. In order to ensure that it satisfies its obligations when a customer orders a service SKU, Illumina measures its customer support using what Illumina refers to as "key performance indicators," or "KPIs," which assess such metrics as instrument downtime or the length of time between when a case is opened to when it is closed. These KPIs enable Illumina to compare how it performs in terms of service and support across individual customers or groups of customers. (Berry (Illumina) Tr. 867-68).

894. Illumina trains its service technicians to help ensure consistent service among technicians. Illumina can track individual cases to determine whether there is any gap in performance between service engineers. (Berry (Illumina) Tr. 869-71).

895. Illumina understands that if it delayed or refused to service an instrument that belonged to a customer who had signed the Open Offer, Illumina would be in breach of the agreement. Illumina also understands it would be in breach if it provided worse services to a customer-laboratory who did not also purchase Galleri. (Berry (Illumina) Tr. 871, 879). In addition, Illumina has a disincentive to encourage or allow delayed or suboptimal service to Grail's alleged rivals because instrument downtime means that customer is not using consumables or buying consumables from Illumina. (Berry (Illumina) Tr. 872 ("[W]hen instruments are down, customers aren't buying kits from us. They're not using kits from us and they're not buying kits from us, and so there's absolutely a disincentive for us to be . . . supporting or . . . looking for any situation where there's extensive downtime, whether it be related to a technician issue or, you know, any other issue.")).

iii. Products

896. The Open Offer requires Illumina to provide customers the same access to purchase sequencing instruments and core consumables as provided to Grail. (Rabinowitz (Natera) Tr. 421; deSouza (Illumina) Tr. 2433-35 ("[W]e commit that any product we give GRAIL, everyone will have access to it, so it won't be a product specifically for GRAIL. It will be a product for everyone. . . . We are not allowed to make a product just available for GRAIL . . . . [I]n this offer letter we're saying that any product that's available for GRAIL will be available for everyone."); PX0064 (Illumina) at 006; RX3935 (Illumina) at 002).

897. The Open Offer requires Illumina to provide customers the same access to purchase sequencing instruments and core consumables as any for-profit entity. (Rabinowitz (Natera) Tr. 421; deSouza (Illumina) Tr. 2438; PX0064 (Illumina) at 006; RX3935 (Illumina) at 002).

898. The Open Offer requires that "Customer shall have access to the Supplied Products for purchase that GRAIL or any For-Profit Entity has access, within 5 days of when GRAIL or such For-Profit Entity, as applicable, is offered such access (if not earlier) for purchase." (RX3935 (Illumina) at 002; deSouza, Tr. 2438 (stating that the provision requires that "any product that GRAIL gets, everybody will get within five days")). Illumina had originally proposed such access within 45 days, but Illumina revised this time period down to 5 days in its September 8, 2021 additions to the Open Offer. (PX0064 (Illumina) at 006; RX3935 (Illumina) at 002).

899. The Open Offer requires Illumina to provide customers, within 5 days, with the same information that Grail receives about final product specifications of any new sequencing instruments or core consumables. This provision was introduced by Illumina in the September 8, 2021 additions to the Open Offer. (RX3935 (Illumina) at 002 (amending Section 4 to add: "Customer shall have access to the same information about final product specifications of any new Supplied Product, any new version of a Supplied

Product or any Pre-Release Sequencing Product within 5 days of when GRAIL is provided such information")).

900. Under the Open Offer: "'Pre-Release Sequencing Product' means Illumina sequencing hardware or Sequencing Consumables[13] that are not available for purchase in Illumina's product catalogue. Such sequencing hardware or Sequencing Consumables shall include any re-designed or modified products made available to any For-Profit Entity or to GRAIL that optimize, in any material respect, a product's interoperability, capabilities, or performance." (PX0064 (Illumina) at 004; Berry (Illumina) Tr. 877 (While Illumina typically launches a product by adding it to its sales catalogue, for certain products Illumina "seek[s] customer feedback in the form of making customers – or making these pre-release sequencing products accessible to limited numbers of customers prior to launch for the purposes primarily of that customer providing us with feedback.")).

901. The Open Offer requires that "Customer shall have access for purchase to any Pre-Release Sequencing Product to which GRAIL or any For-Profit Entity is offered access" within 5 days of when Grail or such for-profit entity "is offered such access (if not earlier), and for the same categories of uses . . . ." (PX0064 (Illumina) at 006; RX3935 (Illumina) at 002).

902. When Illumina launches a product, Illumina's practice is to make the product available to all customers at once. It is unusual for Illumina to provide sequencing products to external customers prior to their launch, but Illumina might do so for a limited number of customers in order to obtain feedback. Because it is unusual to offer pre-release products, Illumina can effectively manage complying with the pre-release product provisions of the Open Offer. (Berry (Illumina) Tr. 877, 880).

903. Clinical customers do not necessarily adopt new products promptly upon launching but wait for the product to be on the market, to determine if modifications get made and to get a sense of how the product is performing in the real world. Clinical customers typically begin by acquiring a single sequencer and validate its performance and train staff before rolling out production tests on the new sequencer. Adoption cycles for new sequencers in clinical markets are typically measured in months or years. (deSouza (Illumina) Tr. 2409-10).

904. The NovaSeq was released in the first half of 2017, but a substantial portion of Illumina's NovaSeq customers are only now bringing the NovaSeq into their environments. (deSouza (Illumina) Tr. 2409-11).

[13] Under the Open Offer, "Sequencing Consumables" includes those consumables intended by Illumina to be used to perform a sequencing process on Illumina's NextSeq, NextSeqDx, and NovaSeq instruments and any future sequencing hardware launched by Illumina or its Affiliates, and includes "core consumables that are (i) commercialized or otherwise made available by Illumina to customers or Affiliates of Illumina and (ii) intended by Illumina to be used to perform a sequencing process on any such system." (PX0064 (Illumina) at 004).

iv. Supply Assurances

905. The Open Offer includes a "No Obsolescence" clause providing that "Illumina shall not discontinue any Supplied Product so long as [the] Customer continues to purchase that Supplied Product. Illumina may discontinue a Supplied Product that Customer has not purchased in more than one year." (PX0064 (Illumina) at 006).

906. Illumina's plan to comply with the no-obsolescence provision is through Illumina's comprehensive recording of what customers purchase and continue to purchase, on a part number basis, as well as the quantity and the price. (Berry (Illumina) Tr. 885).

907. Illumina understands that if Illumina manipulates supply by providing lower quality instruments or consumables or by delaying a purchase order, Illumina would be in breach of the Open Offer. (Berry (Illumina) Tr. 878-79).

908. The Open Offer requires that "[i]n the event Illumina is experiencing a supply shortage of the applicable Supplied Product (or components therein), Illumina will allocate the existing supply in an equitable manner among its customers (including Affiliates[14]) based on expiring lots, and which shall not favor Affiliates over other customers." (PX0064 (Illumina) at 009). *See also* Berry (Illumina) Tr. 885-86 (Illumina acknowledges that "in the event of a short supply," Illumina has obligated itself under the Open Offer that Illumina "will not disadvantage any customers.")).

909. Under the Open Offer, Illumina agrees that: "In no event will Illumina have the right to cease shipping" a product "solely on the basis of any alleged claim of infringement of any intellectual property rights of Illumina. (PX0064 (Illumina) at 009; Berry (Illumina) Tr. 864; deSouza (Illumina) Tr. 2405).

910. To the extent that developers' tests have unique features that are less compatible with new products, the Open Offer requires Illumina to enter into development agreements, on a customer's request, to design or modify Illumina's products to optimize interoperability with the customer's tests. (Berry (Illumina) Tr. 844-47, 881; PX0064 (Illumina) at 006 (Illumina shall "enter into, upon Customer request, a separate development agreement with Customer on commercially reasonable terms, relating to the design or modification of any Supplied Product, in a manner that optimizes interoperability with Customer's tests, including, without limitation, capabilities, performance, speed, efficiency, cost, convenience, accuracy, specificity, precision, ease of use and user experience.")).

911. Illumina typically has not entered into agreements with customers to customize a core consumable or instrument. (Berry (Illumina) Tr. 844, 881-82).

912. While Illumina engages in post-sale support for its products, such as troubleshooting and addressing instrument failures, Illumina typically does not provide support in the

[14] "Affiliate" is defined in the Open Offer to mean "with respect to a party, any entity that, directly or indirectly, controls, is controlled by or is under common control with such Party for so long as such control exists." Grail is included as an "Affiliate" under the Open Offer. (PX0064 (Illumina) at 003, 004).

development or commercialization of its customers' products. (Berry (Illumina) Tr. 846-47).

913. Customers typically purchase Illumina equipment and reagents "off the shelf" and do not commission Illumina to make custom sequencing equipment. ([redacted]; Berry (Illumina) Tr. 845).

914. The development agreement provision (F. 910) was included in the Open Offer based on a request from [redacted] to incorporate this type of clause into [redacted] supply agreement. (Berry (Illumina) Tr. 881; *see* [redacted]).

v. Pricing

915. Under the Open Offer, customers may select one of two options for each product purchased: the pricing that they received before Illumina's acquisition of Grail closed ("Grandfathered Pricing") or pricing under a "universal" pricing grid ("Universal Pricing"). (PX0064 (Illumina) at 006 ("Customer may elect to receive the Grandfathered Pricing that Customer received before the close of the Transaction under 5.a. . . . Alternatively, Customer may elect to switch over to receiving Universal Pricing under 5.b, under which Customer purchases each Supplied Product under the pricing in Appendix 1.")).

916. "Grandfathered Pricing" under the Open Offer is "any pricing (either under a quote of duration longer than 30 days or a supply agreement) that is operative for the Customer for use of the Supplied Products at the time that the Transaction closes, provided that this pricing is for ongoing, ordinary course purchases of Supplied Products." (PX0064 (Illumina) at 004).

917. If a customer chooses Grandfathered Pricing, it will have the option of maintaining the pricing it had prior to the Acquisition for the duration of the 12-year term of the Open Offer. (PX0064 (Illumina) at 007 ("Customer may continue to receive the benefit of any Grandfathered Pricing for the Term."); Berry (Illumina) Tr. 902-03). This is a result of the interaction between the Grandfathered Pricing provision and the no-obsolescence provision (F. 905). The no-obsolescence provision prohibits Illumina from discontinuing or rendering obsolete any Supplied Product, and the Grandfathered Pricing provision ensures that customers can continue to receive their legacy pricing over the full 12-year term. (Berry (Illumina) Tr. 902-03; PX0064 (Illumina) at 006-07).

918. Under the Open Offer, a customer choosing Universal Pricing for any given product receives "the Volume-Based Net Price[15] for that Supplied Product in accordance with Appendix 1" which provides the Universal Pricing grid. (PX0064 (Illumina) at 007 ("The [U]niversal Pricing Grid in Appendix 1 contains all currently available universal

[15] "Volume-Based Net Price" under the Open Offer refers to "the actual list price of a Supplied Product less the applicable discount for a customer's volume under a volume-based discount schedule." The greater the volume of Illumina's products purchased, the lower the price. (PX0064 (Illumina) at 005; Fiedler (FMI) Tr. 4484).

pricing, including list prices and volume-based discount tiers, for currently available Supplied Products, and such Appendix 1 will be updated as additional pricing tiers or new Supplied Products (including new versions of existing Supplied Products) become available."); *see also id.* at 012-27 (Appendix 1 Universal Pricing grid)).

919. If a customer chooses Universal Pricing, that customer will receive the standard pricing in Illumina's Universal Pricing grid. (PX0064 (Illumina) at 007).

920. If a customer is receiving Universal Pricing under the Open Offer, the customer will receive "most favored nation" (MFN) pricing protections relative to "Equivalent" customers. [16] Specifically, the Open Offer requires that "[i]f Customer is not currently receiving Grandfathered Pricing for Supplied Product, . . . Customer shall have access to Volume-Based Net Prices (under Appendix 1) for that Supplied Product that are no less favorable (*i.e.*, the same or better) than the Volume-Based Net Prices provided by Illumina to an Equivalent customer" for that product, after the date of the Acquisition. (PX0064 (Illumina) at 008; Berry (Illumina) Tr. 893).

921. If a customer chooses Universal Pricing, it will also receive MFN pricing protections specifically relative to Grail. The Open Offer requires that "[i]f Customer is not currently receiving Grandfathered Pricing for Supplied Product, Customer shall have access to Volume-Based Net Prices (under Appendix 1) for that Supplied Product that are no less favorable (i.e., the same or better) than the Volume-Based Net Prices provided to GRAIL (including of transfer pricing, portability fees, and royalties)" for that product, after the date of the Acquisition. (PX0064 (Illumina) at 008; Berry (Illumina) Tr. 893).

922. Customers can pick Grandfathered Pricing for some products and Universal Pricing for others. (PX0064 (Illumina) at 006-07; Berry (Illumina) Tr. 892).

923. Since the Acquisition, Grail receives pricing under the Universal Pricing grid. (Berry (Illumina) Tr. 894).

924. If Grail or an Equivalent customer receives more favorable pricing than another customer, the Open Offer requires Illumina to notify the other customer promptly and to refund any difference between the price paid by the customer and the applicable reduced price. (Berry (Illumina) Tr. 894, 914; PX0064 (Illumina) at 008 (stating that in the event that Grail or an Equivalent customer receives more favorable pricing, "Illumina will notify Customer promptly, and no later than 45 days after the end of the applicable Illumina fiscal quarter, and the pricing made available to Customer for the applicable Supplied Products will be reduced, effective as of the date on which GRAIL or the Equivalent customer received the triggering pricing, and Customer will receive such

[16] Under the Open Offer, "'Equivalent' means, with respect to the comparison of Customer to another customer, that (a) the aggregate volume of all Supplied Products purchased by such other customer from Illumina in the immediately preceding year (measured in U.S. dollars) is not more than 10% greater than the volume purchased by Customer in prior year, (b) such other customer is a For-Profit Entity, and (c) such other customer is not currently receiving Grandfathered Pricing." (PX0064 (Illumina) at 003; *see also* Berry (Illumina) Tr. 895).

reduced pricing for the period of time that the triggering pricing is available to GRAIL or the Equivalent customer. With respect to units of Supplied Product ordered and invoiced pursuant to a Purchase Order accepted after the date the triggering purchase was made, and for which Customer has paid the applicable invoice, Illumina will refund to Customer the difference between the pricing made available to Customer and the triggering pricing, multiplied by the number of affected units of Supplied Product.")).

925. Illumina understands the Open Offer to require that any discretionary discounts offered to Grail or any other For-Profit Entity must be made available to all other Open Offer customers. Thus, if Grail received a discretionary discount higher than the discounts in the Appendix 1 Universal Pricing grid for equivalent volume or a price that is lower than the prices in Appendix 1 for an equivalent volume, then Illumina would be obligated to reduce the price for other customers at the same volume levels to match the prices under such discretionary discount to Grail. (Berry (Illumina) Tr. 893-94, 914).

926. The Open Offer includes a "no price increase" provision, in which Illumina commits not to increase prices beyond inflation for the 12-year term of the agreement. This applies to Grandfathered Pricing and Universal Pricing. The provision states that "[t]he inflation-adjusted (based on the Bureau of Labor Statistics' Analytical Laboratory Instrument Manufacturing Index in the Producer Price Index ("PPI")) Volume-Based Net Price (under Appendix 1) that Customer has access to for each Supplied Product purchased under this Supply Agreement over the twelve (12) year term of this Supply Agreement shall not increase. To the extent Illumina's costs of goods sold for a Supplied Product materially increase due to factors beyond Illumina's control, then the Volume-Based Net Price (under Appendix 1) may increase solely to reflect that cost increase and solely for the duration of that cost increase." (PX0064 (Illumina) at 007; Berry (Illumina) Tr. 899-900).

927. Under the Open Offer, Illumina cannot release a new version of a Supplied Product at a higher price than the previous version, unless the new version results in a material improvement in performance or capability. (Berry (Illumina) Tr. 901-02; PX0064 (Illumina) at 007 (requiring that "[t]o the extent that Illumina launches a new version of any Supplied Product (*e.g.*, a sequencing instrument of similar throughput, or a Sequencing Consumable of the same sequencing read length and similar number of sequencing reads per flow cell), the inflation-adjusted" price cannot be higher than the price of the prior version "provided that the new version of the Supplied Product does not result in any material improvements in performance or capability")).

928. The Open Offer requires that "[t]he price for a new Supplied Product or a new version of a materially improved Supplied Product must be commercially reasonable" taking into account "the value of the improvement." Disputes are to be resolved by an arbitrator, expressly "empowered to determine the reasonableness of the price, including the value of . . . any improvement in performance or capability, and to require that Illumina charge a price that is commensurate with the improvement, as well as require any associated refunds to Customer." (RX3935 (Illumina) at 002; deSouza (Illumina) Tr. 2408).

929. Under the Open Offer, Illumina agrees to reduce the pricing of sequencing by at least 43% by 2025. (PX0064 (Illumina) at 007 (providing that "by 2025, Illumina commits that, under this Supply Agreement, the Volume-Based Net Price (under Appendix 1) to Customer per gigabase of sequencing using the highest throughput Illumina instrument then available, with the highest throughput, best-performance flow cell and kit then available, at full capacity, will be at least 43% lower than the inflation-adjusted (based on the PPI) Volume-Based Net Price (under Appendix 1 as of March 26, 2021), per gigabase of sequencing using the NovaSeq instrument, with an S4 300 flow cell, at full capacity"); Berry (Illumina) Tr. 712 ("[T]his paragraph is specifically committing Illumina to a 43 percent price reduction, whether or not we introduce new products."), 903-04).

930. Sequencing flow cells are described in terms of the number of gigabases of DNA or RNA that can be sequenced. Thus, describing the price reduction using a price per gigabase nomenclature allows for an "apples-to-apples basis" between flow cells with different capacities when comparing different kits. (Berry (Illumina) Tr. 904-05).

931. While the number of gigabases refers to a number of DNA or RNA bases, a "read" refers to the processing of a fragment of DNA or RNA. (*See* Berry (Illumina) Tr. 818-20; PX8399 (Henry (PacBio) Decl.) at 001-02). As an example, if Illumina reduced the price per gigabase of the S4 300 flow cell by 43%, it would also reduce the price per read by 43% because the given number of reads in that S4 300 flow cell kit is constant. (Berry (Illumina) Tr. 922-23).

932. Illumina selected the 43% number for the price reduction in the Open Offer because that is the price Illumina assumed in its deal model that Grail would pay in 2025. (deSouza (Illumina) Tr. 2338; PX5042 (Illumina)).

933. A customer who signs the Open Offer can receive short-term project pricing that is the same or better than pricing extended to Grail or equivalent customers for similar projects. (PX0064 (Illumina) at 008 ("Customer shall have access to Short Term Project pricing that is no less favorable (*i.e.*, the same or better) than pricing extended to Equivalent customer or GRAIL for a Short Term Project of substantially similar size (*i.e.*, using between 90% and 110% of the volume of Sequencing Consumables) and duration (*i.e.*, for a period of not more than 3 months longer than the other Short Term Project), provided that Customer has requested such pricing. If Illumina offers GRAIL pricing for a Short Term Project under this section, Illumina shall make Customer aware of such pricing promptly, but in no event later than 45 days after the end of the applicable Illumina fiscal quarter.")).

934. The Short Term Project pricing provision was added because in certain discrete situations there is a good reason for a customer to pay less than the pricing in the universal grid or grandfathered pricing agreements. These are discretionary discounts. (Berry (Illumina) Tr. 909-10). As an example, Short Term Project pricing was provided in connection with certain Covid-19 studies. (Berry (Illumina) Tr. 910-13).

935. No customer, including Grail, can receive Short Term Project pricing for more than two consecutive years or for ordinary course purchases. (Berry (Illumina) Tr. 913; deSouza (Illumina) Tr. 2440; PX0064 (Illumina) at 008). Special Project pricing applies only when products are used in nonstandard ways, *i.e.*, uses beyond the normal course of the customer's business. (Berry (Illumina) Tr. 925).

vi. IVD Agreements and FDA Documentation

936. FDA approval is required for a distributed, or kitted, in-vitro diagnostic test. (PX7044 (Stahl (Invitae) IHT) at 51-52; PX7045 (Chudova (Guardant) IHT) at 76-77).

937. To get FDA clearance for a distributed IVD test, the FDA typically requires an agreement between a test developer and the sequencing company being used. (PX7049 (Bailey (PGDx) IHT) at 43). As an example, for Roche to have an FDA approved distributed kit on an Illumina instrument "would require Illumina to both provide certain information to the FDA and implement a more controlled change process for the sequencing platform on which the IVD assay would run." (PX8351 (Roche) at 003 (Roche, Distributed NGS Kits Group Level Discussions with Illumina Presentation, Sept. 2019); PX7068 (Perettie (FMI/Roche) IHT) at 81).

938. As Megan Bailey, CEO of PGDx, explained, "traditionally when you take a product through the FDA you need to be able to demonstrate control around quality across what is considered the device, and so in our case 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 [Illumina] sequencer, [the FDA] want[s] 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." (PX7049 (Bailey (PGDx) IHT) at 42-43).

939. Illumina requires customers to enter into an IVD agreement to run a test on Illumina's diagnostic ("Dx") instruments. A test developer needs an IVD agreement with Illumina to distribute its test to third-party labs. (Goswami (Illumina) Tr. 3261-62, 3268).

940. An "IVD agreement" "[w]ithin the context of Illumina . . . generally refers to a grant of rights by Illumina to the [agreement] partner to develop IVD tests on the Illumina platform and leveraging the installed base of Illumina Dx-designated instruments." (PX7052 (Leite (Illumina) IHT) at 52).

941. "IVD Agreements" are co-development agreements or collaboration agreements where Illumina provides access to its NGS platform so that the IVD test provider can validate its assays on Illumina's instruments, and then secure the necessary agreements with Illumina to supply the IVD test developer during the development period. (Leite (Illumina) Tr. 2081).

942. An IVD agreement between Illumina and a third party does not mean the two entities are "actively codeveloping or designing experiments together, but they're exchanging

documentations around the parameters of the software that needs to be developed." (PX7052 (Leite (Illumina) IHT) at 53-54).

943. Dr. Goswami explained Illumina's role in IVD kit development: Illumina provides a diagnostic platform, is responsible for FDA approval of that Dx platform and provides a local run module ("LRM"), which is a software module Illumina transfers to the test developer to use with the test. The developer maintains responsibility for conducting the clinical trials, analytically and clinically validating the test for FDA approval and manufacturing and distributing the test kit in accordance with FDA guidelines. (Goswami (Illumina) Tr. 3188-91).

944. Only Illumina can provide the sequencing and reagent information for their products, or the control change processes, required by the FDA. (PX7068 (Perettie (FMI/Roche) IHT) at 82).

945. The Open Offer provides that, for six years after the closing of the Illumina-Grail transaction (*i.e.*, until August 18, 2027), customers may enter into one or more separate agreements with Illumina to develop IVD test kits for use on Illumina's platforms. (deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 008).

946. The types of IVD agreements available under the Open Offer, attached to the Open Offer as Exhibit B, are posted on Illumina's website. (Goswami (Illumina) Tr. 3204-07).

947. IVD agreements under the Open Offer allow developers to create test kits for all oncology applications, including cancer screening generally and multicancer screening specifically. (Goswami (Illumina) Tr. 3233-35; PX0064 (Illumina) at 034).

948. The Open Offer requires Illumina to provide customers with standard terms for IVD agreements "to develop and commercialize IVD test kits on one or all of Illumina's Dx sequencing platforms" and to "provide any documentation or information reasonably required for Customer to seek FDA approval or FDA marketing authorization to sell a for-profit, clinical test using the Supplied Products." (PX0064 (Illumina) at 008; PX7093 (Young (Illumina) Dep.) at 67-68).

949. IVD agreements under the Open Offer include a right for Illumina's IVD partners to refer to any relevant Illumina regulatory documentation. Under this right, an IVD partner developing on Illumina systems may reference Illumina's files in their regulatory submission. (Leite (Illumina/InterVenn) Tr. 2156-57; PX0064 (Illumina) at 039; PX7093 (Young (Illumina) Dep.) at 111-12). Illumina also provides participation in regulatory meetings together with the customer if required and desired by the customer. (PX7093 (Young (Illumina) Dep.) at 111-12).

950. The Open Offer provides three template agreement options for customers interested in IVD test kit agreements: an All-Platforms Agreement, a NextSeq Agreement, and a NovaSeq Agreement. These options give customers access to all of Illumina's platforms

that are currently available, as well as platforms that Illumina plans to develop in the future. (Goswami (Illumina) Tr. 3207-08; PX0064 (Illumina) at 028-40).

951. The Open Offer lays out the summary of the terms for the different types of IVD agreements. (Goswami (Illumina) Tr. 3208; PX0064 (Illumina) at 028-40).

952. Dr. Joydeep Goswami, Illumina's Chief Strategy and Corporate Development Officer, worked at Thermo Fisher for 16 years and led its clinical oncology and NGS division. (Goswami (Illumina) Tr. 3180-81). Dr. Goswami confirmed that the Open Offer's IVD agreement terms reflect industry standards. (Goswami (Illumina) Tr. 3210, 3212, 3215, 3228-29; *see also* [redacted]

953. A customer can develop an unlimited number of IVD test kits under the All-Platforms Agreement. For the NextSeq Agreement and the NovaSeq Agreement, customers can develop up to three tests. Illumina determined the number of tests that customers could develop on each platform based on what Illumina had agreed to with previous IVD partners. (Goswami (Illumina) Tr. 3208-09; PX0064 (Illumina) at 028).

954. The All-Platforms Agreement has a 15-year term, from the date of the Acquisition (or August 18, 2026). The NextSeq Agreement and the NovaSeq Agreement have 10-year terms. For the NextSeq Agreement, the Open Offer provides for a term of 10 years from the date of the Acquisition. For the NovaSeq Agreement, the Open Offer provides for a term of 10 years from the later of (i) the date of the Acquisition or "(ii) the date NovaSeqDx is listed with FDA in the U.S. pursuant to applicable law." (PX0064 (Illumina) at 029).

955. Developers may commercialize their tests beyond the term lengths stated for IVD agreements under the Open Offer. (Goswami (Illumina) Tr. 3210; PX0064 (Illumina) at 029 ("After expiration of the Term, Customer may continue commercializing IVD Test Kits that were launched before expiration of the Term for so long as Illumina is still commercializing the applicable Sequencing Consumables and servicing and supporting" the applicable instruments in the applicable territory.)).

956. Illumina selected the 10 and 15-year terms for the IVD agreements under the Open Offer based on industry standards and in order to give customers enough time to develop kits on the relevant platforms. (Goswami (Illumina) Tr. 3210).

957. The Open Offer's IVD agreement templates include three types of financial considerations: (1) a technology access fee, paid upfront; (2) milestone payments, due when a test developer progresses towards development of a kit; and (3) a 6% revenue share, due only after the developer launches the kit. (PX0064 (Illumina) at 029-30).

958. The financial components of the IVD agreement templates referenced in F. 957 are standard in the industry. (Goswami (Illumina) Tr. 3212; *see also* [redacted]

[redacted]

959. The technology access fee for the All-Platforms Agreement is $25 million; the technology access fee for the NextSeq Agreement is $3 million; and the technology access fee for the NovaSeq Agreement is $15 million. (PX0064 (Illumina) at 029). The technology access fees were selected based on recovering Illumina's upfront investment in its platforms and on feedback from negotiations from IVD agreements reached with [redacted] (Leite (Illumina/InterVenn) Tr. 2162-63; Goswami (Illumina) Tr. 3213-14).

960. The 6% revenue share was chosen based on it being a point in between 4% and 10%, which is the fairly common range for revenue sharing in the life sciences and diagnostic industry. (Goswami (Illumina) Tr. 3215).

961. Illumina selected the milestone payments based on obtaining a return on Illumina's initial and continued investment in its platforms, as well as on previous successful negotiations for IVD agreements. (Goswami (Illumina) Tr. 3215-16).

962. The Open Offer provides for customers to submit proposed "IVD Plans" to Illumina, which Illumina may not unreasonably reject. (PX0064 (Illumina) at 034-35 ("Each IVD Test Kit, and the parties' specific development obligations and timelines with respect to each IVD Test Kit," to be described in a "development plan to be negotiated in good faith (each, an 'IVD Plan'). Customer [may] propose potential IVD Plans. Illumina may not unreasonably reject any proposed IVD Plan.")).

963. Illumina provides two categories of information to customers during the IVD agreement process: (1) Illumina provides an overview of countries where Illumina has regulatory approval and the number of instruments in each region or country, so the developer can plan for how they will introduce and commercialize a test; and (2) in connection with seeking regulatory approval, Illumina provides technical information about the instrument as required for the regulatory process and authorization to access the device master file when the customer requires it for FDA approval. (Goswami (Illumina) Tr. 3223-24).[17]

964. Illumina does not receive access to proprietary information from test developers through the IVD agreement process. (Goswami (Illumina) Tr. 3227).

vii. Intellectual Property

965. Customers who sign the Open Offer receive a right under Illumina's core intellectual property ("Core IP") to use the relevant products. (deSouza (Illumina) Tr. 2405; PX0064

[17] Device Master File means materials that may be used to provide detailed information to the FDA about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of the Products or Material. https://www.fda.gov/medical-devices/premarket-approval-pma/master-files.

(Illumina) at 009 ("Customer's purchase of Supplied Products under this Supply Agreement confers upon Customer the non-exclusive, non-transferable, personal, non-sublicensable right solely under Illumina's Core IP to use the Supplied Products, only with Illumina hardware and software, and only in Customer facilities.")).

966. Under the Open Offer, "Core IP" means "Illumina Intellectual Property Rights that pertain to or cover aspects or features of any Supplied Product (or use thereof), or software embedded in or installed on Illumina hardware (or use thereof), or software that Illumina hardware is designed to communicate or interact with (or use thereof), that are common to such Supplied Product in all applications and all fields of use." (PX0064 (Illumina) at 003). "Illumina Intellectual Property Rights" means all intellectual property rights "owned or controlled by Illumina or Affiliates of Illumina during the Term of this Agreement. Application Specific IP and Core IP are separate, non-overlapping, subsets within the Illumina Intellectual Property Rights." (PX0064 (Illumina) at 004).

967. "Intellectual Property Rights" under the Open Offer means "all rights in patent, copyrights (including rights in computer software), trade secrets, know-how, trademark, service mark and trade dress rights and other industrial or intellectual property rights under the laws of any jurisdiction, whether registered or not and including all applications therefor and registrations thereto." (PX0064 (Illumina) at 004).

968. Under the Open Offer, Illumina agrees that it will not have the right to cease shipments of the products "solely on the basis of any alleged claim of infringement of any intellectual property rights of Illumina." (PX0064 (Illumina) at 009; Berry (Illumina) Tr. 864; deSouza (Illumina) Tr. 2405).

viii. Firewalls and Protection of Confidential Information

969. The Open Offer prohibits Illumina from sharing any customer confidential information with Grail or its subsidiaries or employees, or with Illumina employees who work with Grail. (Berry (Illumina) Tr. 916-17; PX0064 (Illumina) at 009 ("To the extent that Illumina may have access to confidential information ('Confidential Information') of Customer in connection with this Supply Agreement or the provision of Supplied Products by Illumina to Customer, Illumina shall in no event share such Confidential Information of Customer with GRAIL or any subsidiary of GRAIL, or any employees who work within GRAIL.")).

970. The Open Offer requires Illumina to "establish a firewall designed to prevent any GRAIL personnel (and any Illumina personnel carrying out activities with respect to the GRAIL business or products) from accessing any Confidential Information obtained by or made available to Illumina relating to Customer or its business or products, whether pursuant to this Supply Agreement or otherwise." (PX0064 (Illumina) at 009-10).

971. Under the Open Offer, if Illumina becomes aware of a breach of confidentiality of any kind, it is required to notify the other party of the breach. Illumina will also conduct a

biannual audit to identify any breaches that might have been missed. (Goswami (Illumina) Tr. 3232-33; PX0064 (Illumina) at 010; RX3935 (Illumina) at 003).

972. [redacted]

973. After Illumina closed its acquisition of Grail, Illumina added a new account manager specifically to handle the Grail account. (Berry (Illumina) Tr. 931-32).

974. High-level executives at Illumina generally do not have access to customer databases. (Berry (Illumina) Tr. 918-19; *see also* Goswami (Illumina) Tr. 3232 (confirming that upper-level executives and Illumina and Grail will have no need to have access to sensitive customer information and won't access such information).

975. The firewall provision of the Open Offer (F. 970) can be effectively implemented. (F. 976; *see also* RX6002 (Guerin-Calvert Trial Dep.) at 80-85).

976. Illumina is familiar with how to set up and operate confidentiality procedures because Illumina has already set up and implemented such procedures for use with other customers in similar fields, such as in connection with IVD agreements. (Goswami (Illumina) Tr. 3231). *See* F. 760-764.

ix. Monitoring and Enforcement

977. The Open Offer requires Illumina to publish and update information about the products and services Grail purchases, as well as the pricing grids used for those purchases. Illumina is required to make necessary updates to the website "within 5 days of entry of" any Grail purchase order or service contract relating to the products being supplied to the customer under the Open Offer. (RX3935 (Illumina) at 002 ("Illumina shall publish, on the 'Oncology Contract Terms' website, (i) the Supplied Products, by SKU, that GRAIL is purchasing; (ii) the service plans, by SKU, that GRAIL is purchasing; and (iii) the pricing grid for both products and services under which GRAIL is purchasing Supplied Products and services. To the extent necessary, Illumina shall update this website within 5 days of entry of any purchase order for Supplied Products or any service contract relating to the Supplied Products by GRAIL."); RX4003 (Illumina) at 001; RX3960 (Illumina)).

978. The Open Offer contains enforcement provisions including a biannual audit and a commitment to binding arbitration in the event of a dispute. (deSouza (Illumina) Tr. 2405, 2438; PX0064 (Illumina) at 010-11; RX3935 (Illumina) at 003; F. 979-988).

979. The Open Offer requires Illumina to conduct a biannual audit of its compliance with the Open Offer using "an independent third-party auditor selected by Illumina from among

the 'Big 4' accounting firms . . . ."[18] (deSouza (Illumina) Tr. 2405, 2438; PX0064 (Illumina) at 010; RX3935 (Illumina) at 003).

980. In addition to the biannual audits referenced in F. 979, if a customer has a "good faith basis for alleging that Illumina is in breach" of any commitment in the Open Offer, Illumina must "engage an auditor to assess [the] Customer's allegation separate from and in addition to" the biannual audits. (PX0064 (Illumina) at 010; RX3935 (Illumina) at 003).

981. Illumina must "provide cooperation, including access to necessary books and records, in support of any audit conducted." (PX0064 (Illumina) at 010).

982. Illumina is obligated to provide customers with a written report "confirming compliance with the commitments" in the Open Offer. (PX0064 (Illumina) at 010; PX7076 (Berry (Illumina) Dep.) at 286-87).

983. If upon auditing there is "any finding of potential noncompliance with Illumina's performance" of the terms of the Open Offer, Illumina must notify customers within 10 days. (RX3935 (Illumina) at 003).

984. The Open Offer provides for binding arbitration of any disputes. The Open Offer provides that "[i]f any dispute arises from or relates to this Supply Agreement, including as a result of a dispute over terms in a separate agreement that incorporates the terms herein (the "Dispute"), other than claims involving infringement, validity, or enforceability of Intellectual Property Rights (whether Illumina's or Customer's), or about the scope of Intellectual Property Rights in an agreement, Illumina and Customer (each a "party" and together the "parties") shall submit the matter to confidential binding arbitration to determine final terms and conditions of the supply agreement, or to settle the dispute as to the terms of a supply agreement." (PX0064 (Illumina) at 010).

985. The Open Offer provides for an immediate dispute resolution process, prior to going to arbitration, stating: "Prior to submitting any matter to arbitration, Illumina and Customer shall each designate a contact having the proper authorization to resolve the Dispute in a final and binding fashion, who shall meet in person or by telephone for a period of thirty (30) days (or such other period of time as Illumina and the Customer shall mutually agree) in an attempt to resolve the Dispute in good faith." (PX0064 (Illumina) at 010).

986. Illumina's deSouza confirmed Illumina wants to use "as accelerated a process as available" and is willing to solicit feedback and improve the arbitration process to make it more expeditious to the extent possible. (deSouza (Illumina) Tr. 2460-61).

[18] "The Big Four is the nickname used to refer collectively to the four largest professional services networks in the world, consisting of the global accounting networks Deloitte, Ernst & Young (EY), KPMG and PricewaterhouseCoopers (PwC)." https://en.wikipedia.org/wiki/Big_Four_accounting_firms# :~:text = The%20Big%20Four%20is%20the,KPMG%20and%20PricewaterhouseCoopers%20(PwC).

987. Under the Open Offer, if the arbitrator determines that Illumina "has breached any provision of the Supply Agreement, the Arbitrator may order any relief necessary to restore the status quo prior to Illumina's breach, including monetary and/or injunctive relief." In addition, the arbitrator must follow the Commercial Arbitration Rules of the AAA. (PX0064 (Illumina) at 010-11; RX3935 (Illumina) at 003).

988. The Open Offer requires the arbitrator to resolve disputes in accordance with the purpose of the agreement, stating that "[i]n resolving any dispute under the Supply Agreement, the Arbitrator shall take into account, and the Arbitrator's decision shall reflect, that the purpose of the Supply Agreement is to allay any concerns relating to the Transaction, including that Illumina would disadvantage GRAIL's potential competitors after the Transaction by increasing their sequencing prices or by withholding access to Illumina's latest innovations in NGS." (RX3935 (Illumina) at 003).

c. Status of the Open Offer

989. Of Grail's alleged rivals to develop an MCED test, [redacted] have signed the Open Offer. [redacted] have signed amendments to their existing supply agreements that incorporate the relevant terms of the Open Offer. [redacted] Additionally, [redacted] has stated its intent to sign the Open Offer soon. [redacted]

990. Illumina has agreed to enter into a consent order providing the same protections as the Open Offer. On February 26, 2021, Illumina presented the FTC with a set of unilateral behavior commitments in the form of consent principles ("the Consent Principles"). (RX3155 (Illumina)). These Consent Principles include authorizing the FTC to appoint a monitor trustee to monitor any "disputes, claims or controversies," to require an annual verified written report of Illumina's manner and form of compliance, and to access Illumina's books, records, directors, officers, and employees. (RX3155 (Illumina) at 004-05).

991. The Consent Principles in essence represent the terms of the Open Offer in a consent order format and are consistent with the Open Offer. (RX6002 (Guerin-Calvert Trial Dep.) at 95-96).

992. Illumina has engaged Deloitte Consulting to assist Illumina in implementing systems to put into operation the terms of the Open Offer in order to enable Illumina to "administer those terms in a way that maximizes compliance" and ensures that Illumina "is prompt in upholding [its] obligations under the agreement." (Berry (Illumina) Tr. 800, 896).

993. Illumina is currently implementing the confidentiality provisions of the Open Offer by operating Grail as a separate organization and by thoroughly reviewing any interface points with Grail. For example, the account manager at Illumina who used to be

responsible for Grail no longer handles Grail matters, and that responsibility has been reassigned to an individual who has no oncology testing for-profit entities in that person's territory. (Berry (Illumina) Tr. 917-18).

994. Kevin Conroy, the Chairman and Chief Executive Officer of Exact, was aware of the Open Offer's general terms, but, as of the time of trial, had not read it and was not familiar with many specific terms beyond what counsel had described to him. These include the Open Offer terms providing the ability to purchase any Pre-Release Sequencing Product to which Grail or any For-Profit Entity has access, the ability to enter into a separate development agreement on commercially reasonable terms, including for the design or modification of any Supplied Product, and the requirement to equitably allocate supply in the event of a shortage. (Conroy (Exact/Thrive) Tr. 1725-27). Conroy was also unaware of the substance of the Open Offer's intellectual property provisions. (Conroy (Exact/Thrive) Tr. 1728-29).

995. [redacted]

996. [redacted]

d. Expert Witness Opinion

i. Generally

997. In evaluating the competitive efficacy of the Open Offer, the relevant economic issue for evaluation is whether the Open Offer sufficiently prevents Illumina from acting on any incentive to harm Grail's alleged rivals caused by the Acquisition. (*See* RX6002 (Guerin-Calvert Trial Dep.) at 21, 108-09).

998. Illumina's complying with the Open Offer will reflect favorably on Illumina as adhering to its legal commitments and will avoid the cost and time of enforcement actions by customers. (PX7138 (Scott Morton Trial Dep.) at 299-300).

999. The Open Offer provides the economically necessary set of terms to prevent such harm in both the short term and the long term. (RX3865 (Guerin-Calvert Expert Report) at 006; RX6002 (Guerin-Calvert Trial Dep.) at 21-22).

1000. The Open Offer provides a comprehensive set of protections for Illumina's customers for all aspects of conduct and competition including access to products, pricing, and quality of products and services, and rights to develop distributable IVD kits on Illumina's FDA-regulated systems. (RX3865 (Guerin-Calvert Expert Report) at 006; RX6002 (Guerin-

Calvert Trial Dep.) at 21-22, 94-95). The Open Offer also provides for effective monitoring and enforceability mechanisms. (RX6002 (Guerin-Calvert Trial Dep.) at 22).

1001. The Open Offer "creates a framework to enable a competitive playing field as the upstream and downstream segments evolve over the duration of the Open Offer." (RX3865 (Guerin-Calvert Expert Report) at 006).

ii. Term of the Agreement

1002. The 12-year term of the Open Offer enables long-term protections and certainty about price, quality, access, and conduct for the next 12 years. (RX6002 (Guerin-Calvert Trial Dep.) at 28-29).

1003. Based on Margaret Guerin-Calvert's review of government consent decrees, a 12-year term is consistent with what is normally provided in consent decrees that the FTC and the DOJ have approved historically. (RX6002 (Guerin-Calvert Trial Dep.) at 28).

1004. Under the theory of incomplete contracts, which recognizes that contracts cannot foresee every possible circumstance that may arise under the life of a contract, economists can still evaluate the terms and conditions of the Open Offer to determine whether the terms and conditions provide customers with adequate protection. (RX6002 (Guerin-Calvert Trial Dep.) at 99-102).

iii. Supply and Support Assurances

1005. The no-obsolescence provision of the Open Offer (F. 905) adequately addresses the concern often raised by economists in vertical transactions that an upstream firm could advantage its affiliate and disadvantage a rival by simply discontinuing a product being purchased by a purported rival. (RX6002 (Guerin-Calvert Trial Dep.) at 71-72).

1006. The short supply provision of the Open Offer (F. 908) addresses the concern that Illumina will be able to allocate short supply to Grail by providing for an equitable manner of allocation. Moreover, customers with the greatest need – those whose existing products ("lots") are expiring the earliest – will receive allocations of short supply first. (RX6002 (Guerin-Calvert Trial Dep.) at 76-77).

1007. The provisions of the Open Offer requiring customer access to supplied products and pre-release sequencing products provided to Grail (F. 896-901) directly address the concern that products would be developed and supplied to Grail and withheld from other customers by requiring equivalent access within a very short time frame. (RX6002 (Guerin-Calvert Trial Dep.) at 59-60).

1008. The access to services provision of the Open Offer (F. 890) addresses the concern that Illumina will delay support services to Grail's rivals by requiring that customers receive the same quality and type of services as Grail or any for-profit customer. (RX6002 (Guerin-Calvert Trial Dep.) at 58-59; RX3865 (Guerin-Calvert Expert Report) ¶ 64 ("The

access to services commitment restricts Illumina's ability to delay servicing or to provide poor service to disadvantage oncology screening customers relative to GRAIL . . . .")).

1009. The development agreement provision of the Open Offer, which requires Illumina on request of a customer to enter into an agreement to customize or optimize the use of Illumina's products with the customer's tests (F. 910), addresses the potential foreclosure concerns that have been raised because it affirmatively requires Illumina to act in a particular way to support the ability of rivals to further their own, potentially competitive products. (RX6002 (Guerin-Calvert Trial Dep.) at 67-68).

1010. The Open Offer provisions on IVD agreements and FDA documentation (F. 945-949) address the anticompetitive concern that if, in the future, an MCED test developer seeks to develop and receive FDA approval for a kitted IVD MCED test, Illumina could withhold support because the Open Offer requires Illumina, upon request of the customer, to enter into an IVD agreement, on standard terms, and to provide necessary information and documents required for FDA approval. (RX6002 (Guerin-Calvert Trial Dep.) at 74).

1011. The Open Offer's provisions on the right to use the supplied products under Illumina's Core IP (F. 965-967) address the potential anticompetitive concerns that have been raised by ensuring that there will be no concern or confusion about whether the Core IP rights will be provided to customers going forward. (RX6002 (Guerin-Calvert Trial Dep.) at 77-79).

1012. The fact that the Open Offer prohibits Illumina from ceasing supply to a customer based on an alleged intellectual property claim (F. 968) effectively addresses the alleged anticompetitive concern that Illumina can use intellectual property rights to foreclose or disrupt supply to Grail's alleged rivals. (*See* RX6002 (Guerin-Calvert Trial Dep.) at 77-79).

1013. Dr. Scott Morton acknowledged that under the Open Offer, Illumina can cease supplying products on the basis of infringement only if a court has found that infringement of Illumina's intellectual property has occurred. (PX7138 (Scott Morton Trial Dep.) at 290).

iv. Pricing Protections

1014. The Open Offer's pricing provisions (F. 915-935), in their totality, address the anticompetitive concerns that have been raised. The pricing provisions address foreclosure concerns by preventing price increases (except for inflation), including relative to Grail. (RX6002 (Guerin-Calvert Trial Dep.) at 34-36). The pricing provisions commit to potential MCED test developers that they will receive fair pricing from Illumina vis-a-vis Grail and any equivalent customer, in the short term, medium term, and long term. (RX6002 (Guerin-Calvert Trial Dep.) at 53).

1015. Dr. Scott Morton acknowledged that, in the world without the merger, sequencing prices could decrease by less than 43% by 2025. (PX7138 (Scott Morton Trial Dep.) at 282).

v. Confidentiality and Firewalls

1016. The confidentiality and firewall provisions directly address the potential anticompetitive concerns that have been raised regarding Illumina's ability to make use of customer confidential information to disadvantage Grail rivals. (*See* RX6002 (Guerin-Calvert Trial Dep.) at 79-80).

1017. Based on Dr. Guerin-Calvert's review of government consent decrees using firewall and confidentiality provisions, the firewall in the Open Offer between Illumina and Grail will provide at least the essential features common to past accepted firewalls; specifically, provisions for monitoring and auditing, methods to report violations, and consequences for violations. (RX6002 (Guerin-Calvert Trial Dep.) at 85).

1018. While "no process is 100 percent certain," "the auditor can go a long way to identifying breaches and violations of the firewall." (RX6002 (Guerin-Calvert Trial Dep.) at 133).

1019. Dr. Scott Morton acknowledged that firewalls are not novel or unusual. (PX7138 (Scott Morton Trial Dep.) at 294).

vi. Monitoring and Enforcement

1020. The Open Offer provides effective mechanisms for monitoring and enforcement that will maximize compliance, and which are bolstered by extrinsic factors. (RX3865 (Guerin-Calvert Expert Report) ¶ 7; RX6002 (Guerin-Calvert Trial Dep.) at 22-23). As an example of an extrinsic factor, the fact that the Open Offer is available to the broad category of all clinical oncology customers and not just MCED test customers, aids in the enforceability of the Open Offer because it ensures a broad base beyond MCED test developers to exert pressure on Illumina to comply. This fact also makes the Open Offer easier to implement because it applies to a class of customers who are readily identifiable. In addition, the public nature of the offer exerts additional pressure on Illumina to comply. (RX6002 (Guerin-Calvert Trial Dep.) at 22-23, 26-27).

1021. The audit and arbitration provisions of the Open Offer (F. 978-988) play complementary roles to address the potential anticompetitive concerns that have been raised. The audit provision assures customers that they will have access to the necessary information to ensure that Illumina abides by its obligations, and the arbitration provision provides a mechanism to resolve any disputes that could arise. (RX6002 (Guerin-Calvert Trial Dep.) at 89-90).

1022. The arbitration provisions in the Open Offer (F. 984-988) address the concerns that have been raised by providing for an independent entity to judge disputes that arise under the Open Offer. (RX6002 (Guerin-Calvert Trial Dep.) at 88-91).

1023. This immediate, pre-arbitration dispute resolution mechanism of the Open Offer, referenced in F. 985, helps address any concern about the time and expense of arbitration. (RX6002 (Guerin-Calvert Trial Dep.) at 90-91).

1024. The Open Offer's audit provisions (F. 978-983) allow for effective audits of Illumina's compliance with the Open Offer's requirements. (RX6003 (Rock Trial Dep.) at 29-32, 44-46, 50-72).

1025. Audits of the Open Offer's provisions on pricing and access to products and services will expose flaws in Illumina's procedures and enable improvement, which will further minimize the risk of harm to Illumina's customers. (RX6003 (Rock Trial Dep.) at 62-63, 65-67).

1026. Illumina can follow several steps to ensure that the Open Offer audits are effective: (1) establish evaluation criteria, (2) develop and document systems for tracking and reporting, (3) develop a reporting framework to evaluate compliance, (4) develop an internal audit program to monitor and test compliance, (5) engage the independent auditor, (6) establish a data room to allow customers to review information on a more timely basis, (7) establish an Open Offer compliance hotline, (8) develop agreed-upon procedures to address the concerns that have been raised, (9) allow the independent auditor to perform the procedures and publish their findings, and (10) engage an auditor to address alleged breaches outside of regular audits. (RX6003 (Rock Trial Dep.) at 50-56).

1027. Independent auditors are fully capable of assisting Illumina in developing the appropriate procedures and controls and reporting to allow Illumina and contracting customers the ability to monitor compliance with the terms of the Open Offer. (RX6003 (Rock Trial Dep.) at 31).

1028. An independent auditor can successfully audit the confidentiality provisions by obtaining a list of Illumina employees working with Grail and ensuring the list is complete and accurate, obtaining a list of all Illumina and Grail employees who are authorized to receive confidential information, executing employee compliance certifications regularly, examining reports of violations, performing keyword email searches, creating and testing electronic barriers, testing for noncompliance with respect to hard-copy information, and interviewing select personnel. (RX6003 (Rock Trial Dep.) at 67-71).

1029. Large Certified Public Accountant (CPA) firms like the Big Four have the relevant knowledge and experience to conduct an effective compliance audit. Additionally, CPAs very frequently review compliance with contract provisions and audit the effectiveness of internal controls. This experience can increase the effectiveness and value of an audit over time. (RX6003 (Rock Trial Dep.) at 45).

1030. Independent auditors can be effective in (1) examining an entity's compliance with the various terms of contracts, (2) performing agreed-upon procedures related to an entity's compliance with specific terms, and (3) performing agreed-upon procedures related to an

entity's internal controls over compliance with specified terms. (RX6003 (Rock Trial Dep.) at 29-30).

1031. The Public Company Accounting Oversight Board (PCAOB) has published standards to ensure quality for compliance audits like those provided for in the Open Offer. (RX6003 (Rock Trial Dep.) at 45). An auditor's report would likely be prepared consistent with PCAOB standards for agreed-upon procedures. (RX3870 (Rock Expert Report) ¶ 19; *see also* PX0347 at 002[19] (PCAOB Agreed-Upon Procedures Engagements)).

vii. Incentives to Comply

1032. Under Dr. Scott Morton's theory of economic incentives, Illumina should have a financial incentive to favor Grail even absent the merger, given Grail's positioning and the close economic ties between Grail and Illumina prior to the Acquisition. (RX3865 (Guerin-Calvert Expert Report) ¶ 14).

1033. Compliance with the Open Offer will have a favorable impact on Illumina's reputation, by demonstrating that Illumina honors its commitments. (PX7138 (Scott Morton Trial Dep.) at 300).

1034. Knowing that there will be audits acts as a deterrent to non-compliance by Illumina and encourages compliance. Compliance audits also serve a "detective" function by revealing acts of non-compliance. (RX6003 (Rock Trial Dep.) at 44-46).

III. ANALYSIS

A. Summary of Background Facts

1. The Parties and the Acquisition

This case challenges the vertical merger between Illumina, Inc. ("Illumina"), a provider of next-generation sequencing ("NGS") platforms, and GRAIL, Inc. ("Grail"), a company that recently launched a cancer screening test designed to detect many cancers at an early stage.

[19] "An agreed-upon procedures engagement is one in which a practitioner is engaged by a client to issue a report of findings based on specific procedures performed on subject matter. The client engages the practitioner to assist specified parties in evaluating subject matter or an assertion as a result of a need or needs of the specified parties. Because the specified parties require that findings be independently derived, the services of a practitioner are obtained to perform procedures and report his or her findings. The specified parties and the practitioner agree upon the procedures to be performed by the practitioner that the specified parties believe are appropriate." (PX0347 at 002).

Founded in 1998, Illumina makes and sells sequencing instruments and consumables[20] for NGS systems. F. 1, 4, 5. NGS is a method of DNA (deoxyribonucleic acid) sequencing, the process of determining the order of nucleotides in DNA molecules. F. 521. Illumina's NGS platforms may be used for a variety of applications, including genetic disease testing, non-invasive prenatal testing ("NIPT"), and early cancer screening. F. 522; *see also* F. 6.

Illumina founded Grail in 2016, with the goal of developing an early screening test for multiple cancers. F. 21, 27. Illumina seeded Grail with talent, research and development ("R&D") capabilities, development plans, and data needed to investigate how to use NGS technology for early detection of multiple cancers. F. 22.

At Grail's founding, Illumina retained 55 percent ownership of Grail. F. 29. However, Grail required substantial capital to conduct the foundational clinical trials necessary to build the data sets for its machine-learning algorithm that differentiates abnormal tumor patterns. F. 37. Thus, Illumina brought in outside investors to provide Grail with the necessary capital to move from concept through clinical trials and the freedom of a biotech startup to experiment in pursuit of its objective. F. 38. To that end, in February 2017, Illumina completed a capital raise, in connection with which Illumina "spun off" Grail by reducing its own investment in Grail to less than 20 percent. F. 40. Thereafter, Illumina's share was reduced to approximately 12 percent. F. 40.

Since the time of its spinoff, Grail succeeded in developing a multicancer early detection ("MCED") test that detects early signs of multiple cancers in asymptomatic patients. F. 48-51. MCED tests detect cancer by looking for biomarkers[21] within a patient's blood sample that are consistent with cancer. F. 114, 135. NGS technology enables MCED tests to simultaneously screen for thousands of biomarkers that potentially signal cancer within the body. F. 541-542.

[20] The term consumables refers to the "materials that are actually consumed in a sequencing run," such as library preparation reagents and flow cells. F. 5, 14-15.

[21] A biomarker is a molecule in the body that is present when cancer is present and not present when cancer is not present. F. 116.

Grail launched its MCED test, called Galleri, in the United States in April 2021, as a laboratory developed test ("LDT").[22] F. 52. As an LDT, because Galleri is not approved for reimbursement by insurance, Grail targets as potential purchasers of Galleri large, self-insured employers; concierge medicine practices; executive health programs; and progressive healthcare institutions that focus on preventative health. F. 53. As of August 2021, Grail had sold around 3,000 Galleri tests. F. 55.

On September 20, 2020, Respondents entered into an Agreement and Plan of Merger for Illumina to acquire the approximately 85.5% of Grail voting shares that Illumina did not already own for a combination of cash and stock consideration valued at about $8 billion ("Acquisition"). F. 57-58. Grail closed the Acquisition on August 18, 2021. F. 60.

2. Industry Background

a. Cancer Screening and MCED Tests

Cancer is the second-leading cause of death in the United States. F. 65. The American Cancer Society estimates that over 1.7 million new cancer cases are diagnosed annually in the United States, and every year approximately 630,000 Americans die from cancer. F. 65-66. A significant reason for the high death toll is that most cancers are not detected until after the cancer has grown or spread, when treatment is more difficult and survival rates are lower. F. 80-81. By some estimates, patients with cancers diagnosed "early" have an 89 percent survival rate, compared to a 21 percent survival rate if diagnosed "late." F. 82. Early cancer screening improves patient survival rates by increasing effective treatment options. F. 83-85. Today, single cancer screening exists for only a few types of cancer – lung, breast, colorectal, and cervical. F. 69. While existing screening methods are highly effective at detecting these cancers in patients, the vast majority of cancers have no screening options. F. 68.

Although Grail is the only company that has a commercially available MCED test, several cancer screening companies are developing or planning to develop cancer screening tests designed to detect multiple cancers at early stages, before the cancer has grown or spread in the

[22] A laboratory developed test is a test developed on-site at a single clinical laboratory, which uses components from multiple suppliers to put together a specific test that is then validated in that laboratory. F. 52.

body. *Infra* III.D.1. The objective is for these tests to be offered to asymptomatic patients through a blood draw as part of a routine physical examination. F. 131, 132, 208.

Generally, MCED tests detect cancer by looking for biomarkers within a patient's blood sample that are consistent with cancer. F. 132, 134. Nearly all cells, including cancer cells, contain DNA. F. 95. DNA resides in the nucleus of most cells in the form of long molecules called chromosomes. F. 98. When a cell dies, the chromosomal DNA from the nucleus naturally disintegrates into small fragments that spill into the bloodstream, at which point it is known as cell-free DNA ("cfDNA"). F. 99. Cancerous tumor cells go through the same process; when cancer cells die, they shed their chromosomal DNA into the bloodstream in the form of short cfDNA fragments. F. 101. cfDNA originating from cancerous tumor cells is called circulating tumor DNA ("ctDNA"). F. 102. The levels of ctDNA in a person's blood varies by the type of cancer, the stage of cancer,[23] and the size of the person's tumor. F. 106.

The objective of MCED tests is to analyze cfDNA in a patient's blood to determine whether there is any ctDNA consistent with cancer. F. 132, 134. Detecting cancer signals in the blood of otherwise healthy individuals is difficult because finding ctDNA in the blood is like finding a needle in a haystack of normal cfDNA. F. 105. The earlier the stage of the cancer, the more difficult it is to detect ctDNA. F. 108.

b. Next-Generation Sequencing

To analyze cfDNA in a patient's blood, cancer screening test developers utilize next-generation sequencing. F. 541-544. The NGS process involves fragmenting DNA/RNA ("ribonucleic acid") into multiple pieces, adding adapters, sequencing the libraries, and reassembling them to form a genomic sequence. F. 523.

There are two types of NGS platforms, short-read and long-read, which differ in the number of DNA fragments that can be sequenced simultaneously and the length of those fragments. F. 527-528. For short-read NGS, sequencers prepare each DNA sample into a library

[23] Stage of cancer describes the extent or spread of cancer at the time of diagnosis. F. 76. Stages of cancer range from Stage 0 to Stage IV. F. 77. The higher the stage number, the larger the cancer tumor and the more it has spread into nearby tissues. F. 77.

of short fragments that are typically 350 base pairs or less in length and replicate and sequence the fragments in parallel on a glass chip known as a flow cell. F. 529. Short-read sequencing provides high read count and low cost per read relative to long-read sequencing. F. 532.

Key performance parameters of an NGS platform are throughput, accuracy, and cost. F. 546. Throughput is measured by the number of samples that can be processed simultaneously in a given period. F. 547-548. Cost is closely related to throughput, as it is measured on a per-sample basis in the context of MCED tests. F. 548, 564. Accuracy refers to the error rate and the type of errors produced by the sequencer. F. 556.

c. Regulatory Requirements for MCED Tests

The United States Food and Drug Administration ("FDA") classifies MCED tests as Class III medical devices, which are considered the riskiest type of medical device. F. 173-174. The FDA typically requires a developer of a Class III medical device to submit an application for Premarket Approval ("PMA") that includes clinical and analytical validation data to determine safety and efficacy. F. 171-172. An in-vitro diagnostic ("IVD") test is a test of human tissue or blood samples that is performed outside the body. F. 187. An IVD test for cancer screening requires premarket approval from the FDA. F. 188.

There are two types of IVD tests: single-site IVD tests and distributed, "kitted" IVD tests. F. 189-190. A single-site, or centralized, IVD test is approved by the FDA to run in a single approved lab, typically the developer's own lab. F. 189. The PMA process involves validating the test developer's lab where the developer must run the test. F. 188-189. A distributed, or kitted, IVD test is approved by the FDA to be sold as a standalone kit that can be sent to and processed in third-party labs. F. 190. Because a distributed IVD test must ensure consistent quality in each lab that runs it, a distributed IVD test developer must follow FDA guidelines and submit to regular FDA audits after obtaining Premarket Approval. F. 195.

Under the existing regulatory framework, a lab may run in-house clinical tests, known as laboratory-developed tests ("LDTs"), without obtaining FDA approval. F. 161, 165. Typically, the medical community is significantly slower to adopt LDTs than FDA-approved tests. F. 166. FDA approval is seen as a requirement for an MCED test to receive broad-based reimbursement

from payers. F. 169-170. Obtaining reimbursement coverage expands the MCED test developer's customer base by providing access to patients who otherwise could not afford to pay the out-of-pocket price of a test. F. 199. Thus, to gain widespread commercialization and reimbursement of an MCED test, developers need FDA approval for their tests. F. 198.

B. Applicable Legal Standards

1. Mergers in General

Section 7 of the Clayton Act prohibits acquisitions "where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly." 15 U.S.C. § 18.[24] Section 7 thereby prohibits acquisitions that would "substantially lessen competition within the area of effective competition." *Brown Shoe Co. v. United States*, 370 U.S. 294, 324 (1962) (internal quotations omitted).

"Congress used the words '*may be* substantially to lessen competition' to indicate that its concern was with probabilities, not certainties." *Brown Shoe*, 370 U.S. at 323; *accord FTC v. H.J. Heinz Co.*, 246 F.3d 708, 713 (D.C. Cir. 2001). "Section 7 does not require 'certain' harm, but instead permits courts to use predictive judgment to 'arrest anticompetitive tendencies in their "incipiency."'" *United States v. AT&T, Inc.*, 310 F. Supp. 3d 161, 189 n.16 (D.D.C. 2018), *aff'd*, 916 F.3d 1029 (D.C. Cir. 2019) (quoting *United States v. Penn-Olin Chem. Co.*, 378 U.S. 158, 171 (1964)).

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[24] Section 5(a)(2) of the FTC Act gives the Commission jurisdiction "to prevent persons, partnerships, or corporations . . . from using unfair methods of competition in or affecting commerce . . . ." 15 U.S.C. § 45(a)(2); *Kaiser Aluminum & Chem. Corp. v. FTC*, 652 F.2d 1324, 1327 n.2 (7th Cir. 1981). Section 11 of the Clayton Act vests jurisdiction in the FTC to determine the legality of a corporate acquisition under Section 7. 15 U.S.C. § 21(b); *In re R.R. Donnelley & Sons Co.*, 1995 FTC LEXIS 450, at *11 (July 21, 1995). Corporations are included within the definition of "persons" that are subject to jurisdiction under the Clayton Act, 15 U.S.C. § 12(a), and the FTC Act, 15 U.S.C. § 44. Both Illumina and Grail are corporations and engage in activities in or affecting commerce, within the meaning of Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12. F. 1-3. Thus, the Commission has jurisdiction over this matter pursuant to Section 5 of the FTC Act, 15 U.S.C. § 45, and Sections 7 and 11 of the Clayton Act, 15 U.S.C. § 18, 21(b).

The allegation that an acquisition is a Section 5 violation, as well as a Section 7 violation, "does not require an independent analysis . . . . " *In re Chicago Bridge & Iron Co.*, 2005 FTC LEXIS 215, at **8 n.23 (Jan. 6, 2005); *accord FTC v. PPG Indus., Inc.*, 798 F.2d 1500, 1501 n.2 (D.C. Cir. 1986) (stating that Section 5 of the FTC Act "may be assumed to be merely repetitive of [Section] 7 of the Clayton Act").

For the government to prevail, "the Court *must* conclude that the Government has introduced evidence sufficient to show that the challenged 'transaction is likely to lessen competition substantially.'" *AT&T, Inc.*, 310 F. Supp. 3d at 189 (emphasis in original) (citing *United States v. Baker Hughes, Inc.*, 908 F.2d 981, 985 (D.C. Cir. 1990)). As part of satisfying that burden, Section 7 "demand[s] that a plaintiff demonstrate that the substantial lessening of competition will be 'sufficiently probable and imminent' to warrant relief." *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 115 (D.D.C. 2004) (quoting *United States v. Marine Bancorporation*, 418 U.S. 602, 623 n.22 (1974)); *FTC v. CCC Holdings Inc.*, 605 F. Supp. 2d 26, 35 (D.D.C. 2009). "Of course the word 'may' [in Section 7] should not be taken literally, for if it were, every acquisition would be unlawful. But the statute requires a prediction, and doubts are to be resolved against the transaction." *FTC v. Elders Grain, Inc.*, 868 F.2d 901, 906 (7th Cir. 1989).

Courts and the Commission have traditionally analyzed Section 7 claims under a burden shifting framework. *See, e.g., United States v. Anthem, Inc.*, 855 F.3d 345, 349 (D.C. Cir. 2017); *Baker Hughes*, 908 F.2d at 982-83; *In re ProMedica Health Systems, Inc.*, 2012 WL 2450574, at *30 (F.T.C. June 25, 2012). In *AT&T*, the district court recited the traditional *Baker Hughes* burden shifting framework as follows:

> [T]he Government must first establish its prima facie case by 1) identifying the relevant product and geographic market and 2) showing that the proposed merger is likely to "substantially lessen competition" in that market. [*Baker Hughes*, 908 F.2d] at 982, 991; *see also Arch Coal*, 329 F.Supp.2d at 117; Gov't PCOL ¶ 24. If the Government satisfies its prima facie burden, the burden then shifts to defendants to "provide sufficient evidence that the prima facie case 'inaccurately predicts the relevant transaction's probable effect on future competition.'" *United States v. Anthem, Inc.*, 855 F.3d 345, 349 (D.C. Cir. 2017) (quoting *Baker Hughes*, 908 F.2d at 991) . . . . If the defendants put forward sufficient evidence to rebut plaintiff's prima facie case, "the burden of producing additional evidence of anticompetitive effect shifts to the [government], and merges with the ultimate burden of persuasion, which remains with the [government] at all times." *Anthem*, 855 F.3d at 350 (quoting *Baker Hughes*, 908 F.2d at 983).

310 F. Supp. 3d at 191. However, "unlike horizontal mergers, the government cannot use a short cut to establish a presumption of anticompetitive effect through statistics about the change in market concentration, because vertical mergers produce no immediate change in the relevant market share." *United States v. AT&T, Inc.*, 916 F.3d 1029, 1032 (D.C. Cir. 2019).

Given that the ultimate burden rests with the Government, debates over the nuances of burden shifting are somewhat academic. *AT&T*, 310 F. Supp. 3d at 191 n.17. In reality, courts recognize that, in practice, evidence is often considered all at once and the burdens are often analyzed together. *Chicago Bridge & Iron Co. v. FTC*, 534 F.3d 410, 424-25 (5th Cir. 2008) (citing *FTC v. Univ. Health*, 938 F.2d 1206, 1218-19 (11th Cir. 1991)). "The Ninth and Eleventh Circuits interpret *Baker Hughes*' burden-shifting language as describing a flexible framework rather than an air-tight rule." *Chicago Bridge*, 534 F.3d at 424; *see also Baker Hughes*, 908 F.2d at 984 (stating that "[t]he Supreme Court has adopted a totality-of-the-circumstances approach to the statute, weighing a variety of factors to determine the effects of particular transactions on competition"); *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1111 (N.D. Cal. 2004) (noting that the Supreme Court and appellate courts acknowledge the need to adopt a flexible approach in determining whether anticompetitive effects are likely to result from a merger).

2. Vertical Mergers

In *Brown Shoe*, 370 U.S. 294 (1962), the Court held that Congress intended vertical mergers to be subject to the Clayton Act. *Brown Shoe* explains that "[t]he primary vice of a vertical merger or other arrangement tying a customer to a supplier is that, by foreclosing the competitors of either party from a segment of the market otherwise open to them, the arrangement may act as a 'clog on competition' which 'deprive[s] . . . rivals of a fair opportunity to compete.'" *Brown Shoe*, 370 U.S. at 323-24 (citations omitted). However, the Court continued, the fact of foreclosure "will seldom be determinative." *Id.* at 328:

> If the share of the market foreclosed is so large that it approaches monopoly proportions, the Clayton Act will, of course, have been violated; but the arrangement will also have run afoul of the Sherman Act. And the legislative history of [Section] 7 indicates clearly that the tests for measuring the legality of any particular economic arrangement under the Clayton Act are to be less stringent than those used in applying the Sherman Act. On the other hand, foreclosure of a *de minimis* share of the market will not tend "substantially to lessen competition."

Brown Shoe, 370 U.S. at 328-29; *see also Fruehauf Corp. v. FTC*, 603 F.2d 345, 352 (2d Cir. 1979) ("The Supreme Court's insistence that each merger challenged under [Section] 7 be 'viewed . . . in the context of its particular industry,' and that the Clayton Act protects

'Competition, not Competitors,' contravenes the notion that a significant level of foreclosure is itself the proscribed effect.").

"In dealing with vertical acquisitions under Section 7, as amended, the United States Supreme Court has relied on several functional factors as indicia of the requisite anti-competitive effect." *United States Steel Corp. v. FTC*, 426 F.2d 592, 599 (6th Cir. 1970). These include:

> (1) foreclosing of the competitors of either party from a segment of the market otherwise open to them; (2) the 'nature and purpose' of the vertical arrangement; (3) actual and reasonable likely adverse effects upon local industries and small businesses; (4) the level and trend of concentration in the market shares of participating companies, including any trend towards domination by a few leaders; (5) the existence of a trend towards vertical integration and consolidation in previously independent industries; and (6) the ease with which potential entrants may readily overcome barriers to full entry and compete effectively with existing companies.

Id. Similarly, in *Fruehauf*, the court identified as the "[m]ost important among the factors" to consider in determining probable effects of a merger:

> the nature and economic purpose of the arrangement, the likelihood and size of any market foreclosure, the extent of concentration of sellers and buyers in the industry, the capital cost required to enter the market, the market share needed by a buyer or seller to achieve a profitable level of production (sometimes referred to as "scale economy"), the existence of a trend toward vertical concentration or oligopoly in the industry, and whether the merger will eliminate potential competition by one of the merging parties. To these factors may be added the degree of market power that would be possessed by the merged enterprise and the number and strength of competing suppliers and purchasers, which might indicate whether the merger would increase the risk that prices or terms would cease to be competitive. This list, with some variations, has been the standard framework for analysis of the legality of a vertical merger.

603 F.2d at 353.

Further complicating vertical merger analysis "is the recognition among academics, courts, and antitrust enforcement authorities alike that 'many vertical mergers create vertical integration efficiencies between purchasers and sellers.'" *AT&T*, 310 F. Supp. 3d at 193 (citing Michael H. Riordan & Steven C. Salop, Evaluating Vertical Mergers: A Post-Chicago Approach, 63 Antitrust L.J. 513, 519 (1995)); *see also* 4A Areeda & Hovenkamp, Antitrust Law ¶ 1000a

("[T]he basic economic reason for limiting horizontal mergers is well-founded and rather generally accepted: horizontal mergers increase market concentration, and high market concentration can substantially lessen competition among rivals, particularly with respect to price. Unfortunately, there is no comparable theoretical basis for dealing with vertical mergers."); *AT&T*, 310 F. Supp. 3d at 193 n.19 (quoting Robert H. Bork, The Antitrust Paradox 227 (2d ed. 1993) ("Vertical mergers may cut sales and distribution costs, facilitate the flow of information between levels of the industry . . . [,] create economies of scale in management, and so on."); Ernest Gellhorn et al., Antitrust Law and Economics 411 (5th ed. 2004) (discussing the "[v]arious efficiency rationales" that "can motivate vertical mergers"); *cf. National Fuel Gas Supply Corp. v. FERC*, 468 F.3d 831, 840 (D.C. Cir. 2006) ("[V]ertical integration creates efficiencies for consumers.").

C. Summary of Arguments

Complaint Counsel argues that the Acquisition has a reasonable probability of substantially lessening competition in an alleged relevant market for the research, development, and commercialization of MCED tests. Complaint Counsel asserts the evidence proves that Illumina is the sole viable supplier of NGS products and that Grail, although the first MCED test developer to commercialize an MCED test, faces current and future competition from other cancer screening companies that are each working on developing an MCED test to compete with Galleri. Complaint Counsel argues, in summary, that the asserted position of Illumina as sole viable supplier of NGS, combined with alleged current and future competition to Grail, results in Illumina having both the ability and incentive post-Acquisition to harm Grail's alleged rivals and advantage Grail, including by raising the alleged rivals' costs and/or by withholding or limiting critical NGS products and services. As a result of such harm to the alleged rivals, Complaint Counsel argues, the Acquisition is likely to harm innovation and potentially raise prices or deprive consumers of choice and quality in MCED tests, in violation of Section 7. As a remedy for the alleged violation, Complaint Counsel seeks an order requiring Illumina to divest the Grail business and assets acquired in the Acquisition, which are currently being held separate, and thereby return Illumina's ownership stake to the 12% held by Illumina prior to the Acquisition.[25]

[25] A provision allowing for Illumina to retain the 12% ownership stake in Grail it had prior to the Acquisition is contained in Complaint Counsel's Proposed Order Section II.C, CCB Attachment A.

Respondents argue that the evidence fails to prove a Section 7 violation. Respondents first argue that Complaint Counsel failed to prove a relevant product market. Respondents further argue that Complaint Counsel failed to prove that the Acquisition is likely to substantially lessen competition. Respondents dispute most, if not all, of the factual assertions underlying Complaint Counsel's arguments. Respondents also affirmatively rely on the effects of what is referred to herein as the "Open Offer," a long-term supply agreement being offered by Illumina to all its United States oncology testing customers, discussed more fully below, which Respondents contend effectively constrains Illumina's alleged ability and incentive to harm Grail's purported rivals or to advantage Grail. Respondents further claim that Complaint Counsel's case fails to account for asserted procompetitive effects of the Acquisition, including the acceleration of market access to a life-saving test, the creation of various research and development efficiencies, and the elimination of double marginalization, and argue that the procompetitive effects of the Acquisition outweigh the alleged likely harm from the Acquisition.

As summarized above, Complaint Counsel's argument depends on proof of several disputed factual propositions, including that Illumina is the sole viable provider of the NGS products required for MCED test development; Grail and its alleged rivals are currently competing in the research, development, and commercialization of an MCED test; and, future competition through the launch of new MCED tests to compete with Galleri is imminent or likely in the near future. A summary of findings on these issues is included in section D. Also included in section D is a summary of the terms of the Open Offer. The current competition evidence is further addressed in section E on the relevant market. Section F addresses the likelihood of harm to competition, including Illumina's asserted post-Acquisition ability and incentive to harm Grail's rivals, and the constraining effects of the Open Offer.

D. Summary of Central Findings

1. Grail and Purported Rivals

Today, several companies, along with Grail, are working on developing blood-based early detection cancer tests. Complaint Counsel argues that "Grail and its rivals are competing vigorously to develop the best performing test, and are poised to compete head-to-head

commercially as Grail's rivals begin to market and sell their tests." CCB at 18. The evidence shows that various companies are working to develop single cancer screening tests, with hopes to expand to combine single cancer tests to create a test that detects multiple cancers, and a few companies are working to develop tests that screen for several cancers; however, no company is close to being able to "begin to market and sell" a test that screens for as many cancers as Galleri and that determines the tissue of origin[26] as Galleri does, without also requiring further diagnostic tests. These companies' efforts to develop MCED tests are detailed in Findings of Fact II.E and summarized below.[27] An assessment of the likelihood that the companies with in-development tests may launch an MCED test that will compete with Galleri follows.[28]

a. Status of MCED Test Development

i. Grail

Grail is the only company that has developed an MCED test that is available for sale. F. 201. Prior to selling Galleri as a laboratory developed test ("LDT"), Grail undertook a rigorous five-year development process, involving four clinical studies with a combined total of over 130,000 participants in North America and the United Kingdom. F. 215. Grail's first clinical study, the Circulating Cell-Free Genome Atlas Study ("CCGA"), started in August 2016. F. 216.

The CCGA involved the collection of de-identified biospecimens (blood and tissue samples) and clinical data from 142 clinical networks in the United States and Canada, involving the enrollment of 15,254 participants, and cost about $30 million. F. 220. Grail used the samples it had collected – across 50+ cancer types at all stages – to look at over a million methylation sites in the genome and train a machine learning algorithm to distinguish a cancer signal from a

[26] Tissue of origin, also called signal of origin or tumor of origin, indicates where in the human body the detected cancer is located. F. 155.

[27] Definitions and additional information regarding the medical and scientific terms used herein are also detailed in the Findings of Fact, II.B-F.

[28] This section focuses principally on whether the evidence proves Complaint Counsel's contentions that Grail's alleged rivals will launch MCED tests that will compete commercially with Galleri in the near future. Complaint Counsel's related contention, that there is current competition between Grail and its alleged rivals as they work towards researching, developing, and commercializing MCED tests, is addressed in section III.E on the relevant product market.

noncancer signal. F. 212, 220. If a cancer signal gets detected, the patterns are then analyzed through another classifier, which looks and weighs different features from these patterns to predict where the cancer signal came from in the body. F. 213.

The CCGA study comprises three sub-studies: CCGA-1, CCGA-2, and CCGA-3. F. 221. Grail used the CCGA-3 study to assess the current version of Galleri that Grail launched as an LDT in 2021. F. 229. The CCGA-3 study reported that the Galleri test achieved a specificity of 99.5% across more than 50 cancer types, a false-positive rate of 0.5%, sensitivity of 51.5% for all cancers, and a signal of origin prediction accuracy of 88.7%. F. 231.

In addition to the CCGA study, Grail is in the midst of conducting three additional studies: STRIVE, a prospective, observational study assessing Galleri's performance in approximately 100,000 women undergoing mammography (F. 233); SUMMIT, a prospective, observational study to evaluate Galleri's performance in a 13,000-participant population at high risk for lung cancer (F. 235-236); and PATHFINDER, a 6,662-participant prospective interventional trial in which Galleri results were returned to participants and their clinicians to allow them to undertake any necessary diagnostic steps necessary for a proper cancer diagnosis. F. 239, 241. The interim results of the PATHFINDER study showed that the Galleri test detected seven types of Stage One through Stage Three cancer in an asymptomatic screening population. F. 245.

Galleri is not approved by the FDA. F. 238, 260. [redacted]

ii. Exact/Thrive

Exact Sciences Corp. ("Exact") is headquartered in Madison, Wisconsin with locations across the United States and in Europe. F. 270. In January 2021, Exact acquired Thrive Earlier Detection Corp. ("Thrive"). F. 272. Exact, through Thrive, ("Exact/Thrive") is developing an MCED test called CancerSEEK, which analyzes both DNA and proteins. F. 273-277.

Exact/Thrive has conducted clinical trials on CancerSEEK and published two studies in peer-reviewed articles. F. 282. The data from these studies report that the original version of CancerSEEK identified ten types of cancer, using a three-step testing process: (1) a baseline blood test, (2) a confirmation blood test, given to participants that scored positive on the baseline blood test, and (3) imaging using a positron emission tomography-computerized tomography ("PET-CT") scan to confirm the results of CancerSEEK and localize the potential cancer. F. 292. Thus, CancerSEEK does not identify tissue of origin through the liquid biopsy alone. F. 292-294. If a patient receives a positive cancer result, CancerSEEK uses a PET-CT scan to identify the tissue of origin. F. 294.

[redacted]

iii. [redacted]

[redacted]

[redacted]

iv. Freenome

Freenome Holdings, Inc. ("Freenome") is a biotech company headquartered in San Francisco, California. F. 348. [redacted]

v. Guardant Health

Guardant Health, Inc. ("Guardant") is a clinical diagnostics company that is developing blood-based tests for oncology applications. F. 381-382. Guardant is currently developing an NGS-based blood biopsy early cancer screening test using genomic and methylation signatures called LUNAR-2. F. 386.

The initial version of Guardant's LUNAR-2 test will screen for colorectal cancer ("CRC"). F. 387. Guardant's business strategy involves first creating a CRC test that it hopes will be rapidly adopted, then moving to a test that detects more than one cancer. F. 388.

[redacted]

[redacted]

vi. Helio Health

Helio Health, Inc. ("Helio") is a healthcare company focused on the early detection of cancer using blood specimens. F. 424. Helio is developing a test for the early detection of liver cancer named the "HelioLiver" test. F. 424. The HelioLiver test has not yet been approved by the FDA. *See* F. 432.

[redacted]

vii. [redacted]

[redacted] Minimal residual disease tests are used to determine

whether remnants of cancer remain in a patient who has been treated for cancer. F. 267 n.9. [redacted] tracks the mutations associated with a patient's cancer and monitors the recurrence of that cancer. F. 454. Because MRD tests are typically used in patients who have already been diagnosed with cancer, they are distinct from early cancer detection tests in asymptomatic persons. F. 267 n.9.

[redacted]

viii. Singlera

Singlera Genomics, Inc. ("Singlera") is headquartered in Shanghai, China and has offices in La Jolla, California. F. 481. Singlera is developing a blood-based early detection test called ColonES for colorectal cancer that uses DNA methylation to detect colorectal cancer. F. 485. Singlera is far from starting FDA clinical trials for ColonES in the United States, believes it will take at least three to four years to conduct such trials, and expects it will be several years before ColonES obtains FDA approval. F. 487-488.

Singlera is also developing a test, called PanSeer, which is a blood-based early detection test designed to detect multiple cancers using the same methylation analysis, assay, and software and algorithm as used in ColonES. F. 484, 491. Singlera does not expect to launch PanSeer until after it has launched ColonES. F. 490. Singlera has not begun designing a clinical trial plan for PanSeer and is a long way from starting clinical trials for PanSeer in the United States. F. 501-

502. Even if it started now, Singlera believes it would need approximately ten years to do the clinical trial work to get FDA approval for a screening test that screens for ten cancers. F. 502.

Singlera completed a proof-of-concept study of its PanSeer test in the People's Republic of China, called the Taizhou Longitudinal study, and published a paper based on data from that study. F. 493-494. The study reported on PanSeer's sensitivity and specificity at detecting five different cancers (lung, esophageal, liver, colorectal, and gastric cancers). F. 496.

b. Conclusion

As addressed further in section III.E below, the evidence demonstrates that there are cancer screening companies in addition to Grail that are engaged in research and development of MCED tests. However, the evidence falls far short of proving Complaint Counsel's factual assertions that "Grail's rivals are poised to imminently launch their products commercially in direct competition with Grail[,]" CCB at 83, *see also* CCB at 129 ("[c]ommercial competition between Grail's Galleri and its MCED Test rivals is imminent"), or that such competition will commence in the "near future." CCB at 135, 141, 143.

Galleri is the only MCED test commercially available for patients to purchase today.[29] F. 201. As summarized above, most of the companies who are pursuing the goal of creating an MCED test do not expect to launch a screening test for more than one cancer type for many years. F. 203. Representatives from some companies testified that they "hoped to" or "aspired to" or "planned to" launch an MCED test, some within three years. [redacted] (a hope to launch a single cancer screening test first, by the end of 2023, and then a hope to launch future undeveloped tests for additional cancers); [redacted] (a plan to launch a single cancer screening test first and then a hope to add one or two other cancers by 2024 and 2027); [redacted] (a vision to get FDA approval for a single cancer screening test first, then obtain FDA approval for other single cancers, then combine two tests into a single screening test, which would take a minimum of three years); [redacted] (an expectation to begin a registrational clinical trial in the middle of 2022; to complete the trial in the middle of 2024; and a hope for FDA approval between 2025 and 2027). Representatives from

[29] The prices of yet-to-be marketed MCED tests have not yet been determined. F. 205.

other companies projected launching an MCED test in about ten years. [redacted] (a projection of launching a planned multicancer screening test "towards the end of the decade"); F. 505, 506 (Singlera does not intend to launch its multicancer screening test until it has FDA approval and believes it will take at least seven to ten years before its test is submitted to the FDA for approval.).

Whatever probative value there may be of a company's expressed intent to launch an MCED test in three years is diminished by facts that the company has not yet: obtained approval for a single cancer screening test, determined which cancer(s) it intends to add to its intended single cancer screening test, begun designing clinical trials, or conducted any clinical trials beyond trials conducted for a single cancer screening test.

Developing a cancer screening test that can detect more than one type of cancer is challenging and requires many years of research, development, and clinical validation. As explained by Respondents' expert witness, Dr. Richard Cote[30]: *First*, a test developer must undertake sample collection, research, and biomarker discovery. RX3869 (Cote Expert Report) ¶ 104. Biomarker discovery involves efforts by the test developer to identify which biomarkers are the best at predicting that an individual has cancer, particularly if that biomarker may be used to distinguish between an individual who has cancer and a healthy subject, and can take anywhere from 18 months to three years, and in some cases much longer. RX3869 (Cote Expert Report) ¶ 105; Cote Tr. 3785-86. *Second*, after selecting the biomarkers for the assay, a test developer enters the "development" stage and focuses on optimizing the assay across different metrics, including costs, quality control and other performance characteristics. RX3869 (Cote Expert Report) ¶ 107. *Third*, after completing the initial research and development steps, test developers must clinically validate their test to ensure its efficacy in detecting cancer and to

[30] Dr. Richard Cote is highly qualified to offer opinions for this case. Dr. Cote is a Professor and Chair at the Department of Pathology and Immunology, Washington University School of Medicine at St. Louis, Missouri and the Pathologist-in-Chief at Barnes-Jewish Hospital of St. Louis, Missouri. RX3869 (Cote Expert Report) ¶ 1. Dr. Cote is a board-certified pathologist, serving over 25 years in senior academic, consultative, director and clinical roles with leading universities, hospitals, and healthcare enterprises. *Id.* at ¶ 2. Dr. Cote's research is focused on the elucidation of cellular and molecular pathways of tumor progression and response to therapy. *Id.* at ¶ 6. He has led three of the largest clinical trials in breast, lung, and bladder cancer, all based on discoveries from his research. *Id.* Dr. Cote is also the author of over 300 publications and serves as a member and advisor to a large number of national and international study groups, and cancer programs and societies, including the National Cancer Institute. *Id.* at ¶ 7.

identify the cancers that the test is intended to detect at an early stage. RX3869 (Cote Expert Report) ¶ 108. In comparison to other oncology tests, MCED tests require multi-year, large-scale clinical studies to receive FDA approval. F. 185-186. Between planning, recruiting participants at multiple sites, testing and analyzing samples, diagnostic follow-up, further therapeutic intervention, and multiple additional follow ups, a large, prospective, interventional study in asymptomatic patients takes between five and seven years. RX3869 (Cote Expert Report) ¶ 119. Accounting for all of these steps in the development process, Dr. Cote opined that most of the MCED developers identified by Complaint Counsel were at least five to seven years away from launching any kind of MCED test. Cote Tr. 3727, 3857, 3869, 3901. Dr. Cote's opinions are well supported by the record evidence and are persuasive.

Even if the tests in development could be expected to launch earlier than a 5 to 7-year range, the evidence fails to prove Complaint Counsel's assertions that the MCED tests under development are "reasonably interchangeable" with Galleri, CCRB at 54-57, or "will be close substitutes to Galleri." CCB at 2, 92, 122. Presently, most of the in-development tests are focused solely on detecting a single cancer, with companies aspiring to add screening capabilities for additional cancers, after conducting additional clinical trials. *E.g.*, [redacted] Respondents' expert witness, Dr. Richard Abrams,[31] opined that "[t]ests that are capable of screening for two or three cancer types" are unlikely to be suitable substitutes for a test that can screen for many cancer types. PX6097 (Abrams Expert Report) ¶ 42. Dr. Cote concurs. Cote Tr. 3874-75 ("[C]learly the majority of cancer mortality would not be assessed with the two or three-cancer screen."); *see also* F. 520 (It is "unlikely" Galleri will compete with a test that screens for fewer than ten cancers.). For the general population, a test that detects only two types of cancer is not a reasonable substitute for a test that detects seven or more types of cancers.[32] F. 206.

[31] Dr. Richard Abrams is qualified to offer opinions for this case. Dr. Abrams is a primary care physician and founder of Colorado Preventative Medicine, where he has practiced Internal Medicine. He also serves on the clinical faculty at the University of Colorado School of Medicine. During the 44 years Dr. Abrams has practiced medicine, he has regularly performed physical exams and treated a wide spectrum of common illnesses in adults. A large portion of his current practice is devoted to identification and management of risk factors for cardiovascular disease and early detection of cancer. PX6097 (Abrams Expert Report) ¶¶ 1, 4.

[32] Whether Galleri has been clinically proven to detect 50 cancers is not dispositive. Even if Galleri has been clinically proven to detect only seven cancers, the only other MCED test that has been clinically shown to detect more than seven cancers requires a PET-CT scan to determine tissue of origin. F. 294.

Most of the tests in development are too underdeveloped to permit a meaningful comparison of their features, and at present are being actively developed as single cancer tests. But, as explained below, the three for which there are data – Galleri, Exact/Thrive, and Singlera – are distinguishable.

- The data from Grail's CCGA study showed that Galleri achieved a specificity of 99.5% across more than 50 cancer types, sensitivity of 51.5% for all cancers, and a signal of origin. F. 231. The data from Grail's PATHFINDER study showed that the Galleri test detected seven types of Stage One through Stage Three cancer in an asymptomatic screening population. F. 245. The Galleri test consists of a single blood draw that may be performed in a primary care physician's office. F. 208.

- The data from Exact/Thrive's DETECT-A study showed that CancerSEEK identified ten types of cancer, using a three-step testing process, each collected at a different time: (1) a baseline blood test, (2) a confirmation blood test, and (3) imaging using a PET-CT scan to confirm the results of CancerSEEK and localize the potential cancer. F. 292. The data showed CancerSEEK achieved specificities of 95.3% in its baseline blood test, 98.9% with both baseline and confirmational blood tests, and 99.6% with both blood tests and PET-CT imaging; and sensitivities of 30.2% in its baseline blood test, 27.1% with both baseline and confirmational blood tests, and 15.6% with both blood tests and PET-CT imaging. F. 298.

- The data from Singlera's Taizhou Longitudinal study showed that PanSeer identified five different cancers and showed that PanSeer achieved 96.1% specificity and 94.9% sensitivity. F. 496. The FDA has stated that a specificity of 95% "will result in an unacceptably high number of false positive results. A high specificity is needed to minimize the potential harms from false positive results." F. 145. In order to minimize the potential harms from a false positive result, the FDA recommends that for reasonable assurance of clinical success, the specificity for a screening test should exceed 99%. F. 145. PanSeer's 96.1% specificity is below the FDA's recommended standards for reasonable assurance of clinical success.[33]

Moreover, none of the MCED tests being developed and planned, using only a single blood draw, matches the tissue of origin determination available with Galleri. Singlera envisions that any patient testing positive on PanSeer would undergo an additional blood test and/or

[33] CancerSEEK's specificity from the single blood draw of 95.3% is also below the FDA's recommended standard. It is only with two blood tests and the PET-CT scan that CancerSEEK's specificity is 99.6%, essentially equivalent to Galleri's. *Compare* F. 298 *with* F. 231.

follow-up imaging to allow tissue of origin mapping. F. 497. Exact/Thrive has not demonstrated that CancerSEEK can identify the cancer signal of origin without the aid of a whole-body PET-CT scan. F. 294, 308.[34]

Tissue of origin refers to the tissue or location in the body from which the cancer signal originates. F. 155. Tissue of origin is "a necessary component" of an MCED test for the test "to be clinically useful." F. 155. Without tissue of origin, doctors would "be on an endless diagnostic odyssey to figure out where the positive [cancerous] signal is coming from." F. 155. Indeed, the FDA has stated that an MCED test will have "limited clinical utility in the absence of reporting" the cancer signal of origin. F. 158; *see also* F. 159 (A survey conducted of 12 primary care physicians and 12 radiologists found that a tissue of origin reporting is a "highly desirable feature that is a must-have to defend [a] competitive market position," and a "very helpful and, in most cases, critical part" of an MCED test.). Based on the differences in performance of the MCED tests in development and the timeframe in which such MCED tests may become available, the evidence fails to prove that the MCED tests under development will be close substitutes to Galleri.

Complaint Counsel next contends that a "better-quality test could allow a competitor to leapfrog existing competition and take market share from Grail or other MCED Test rivals." CCB at 112. Relying on her background in empirical industrial organization, Complaint Counsel's economic expert witness, Dr. Fiona Scott Morton,[35] opined that although Grail was first to reach the market with an LDT of its Galleri MCED test, "there is no guarantee that Grail will remain in the lead. Grail's rivals continue to invest in alternative approaches, and one of those approaches *might* turn out to be superior in the future. A rival *might* make a discovery or

[34] A PET-CT scan is a form of imaging technology that is not recommended for early cancer screening due to its additional cost and potential harm from exposing patients to radiation. F. 288, 295, 296.

[35] Dr. Fiona Scott Morton's qualifications to give opinions for this case are minimal. Dr. Scott Morton is a Professor of Economics at Yale University and a researcher in the field of empirical industrial organization. PX6090 (Scott Morton Expert Report) ¶¶ 1, 6. Dr. Scott Morton is not an expert in MCED tests, clinical trials, any field of chemistry or biological studies, or cancer screening technologies; nor is she a biochemist, molecular biologist, pathologist or medical doctor. PX7138 (Scott Morton Trial Dep.) at 96-97. Dr. Scott Morton does not have medical training or direct experience with cancer screening or MCED tests; lacks scientific expertise to compare and contrast the features of the Galleri test with other MCED tests in development; and lacks the clinical expertise to dispute whether or not it would be improper for a physician to use Galleri as a substitute for another test. *Id.* at 96-98, 111-12, 177.

advancement at any time, and leapfrog ahead of Grail." PX6090 (Scott Morton Expert Report) ¶ 159 (emphasis added). Dr. Scott Morton further opined: "Grail's rivals continue to invest in alternative approaches (including approaches that [redacted] and one of those approaches *might* turn out to be superior in the future. . . . A rival *might* make a discovery or advancement at any time, and leapfrog ahead of Grail, or provide an alternative test that allows more cases of cancer to be detected or a subset of cancers to be detected with more accuracy." PX6090 (Scott Morton Expert Report) ¶ 222 (emphasis added).

"[T]o be probative in a particular case, expert testimony must incorporate assumptions that are 'reasonable' in light of the record evidence." *AT&T, Inc.*, 310 F. Supp. 3d at 221 (citations omitted) ("When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable record facts contradict or otherwise render the opinion unreasonable, it cannot support a jury's verdict."). The record evidence shows there is substantial uncertainty around the MCED tests in development: it is unclear when clinical trials for many of the MCED tests in development might be started; it is unclear whether any of the MCED tests in development will get FDA approval; it is unclear if the MCED tests in development will launch; it is unclear how many cancers many of the tests in development will screen for; and it is unclear what features the MCED tests in development may have. Under these circumstances, the assertion that it is likely that a "leapfrog" product "could" appear in the reasonably near future, much less "imminently," is unsupported and is rejected.

Relying on his background in pathology and immunology and experience in leading clinical trials in cancer,[36] Respondents' expert witness, Dr. Cote, reviewed the record evidence in this case and opined that there is no basis to conclude that these in-development MCED tests will be adopted for the same indications as Galleri anytime in the foreseeable future. RX3869 (Cote Expert Report) ¶ 150. Dr. Cote further explained that most multicancer screening test developers are more than five years away from commercializing a test that is capable of screening for more

[36] Dr. Cote has experience in cancer screening as he has led three large clinical trials in cancer, works in a laboratory focused on technology development, including nanoscale technologies for cancer diagnostic applications, and has founded several technology companies, including several focused on cancer testing and analysis. RX3869 (Cote Expert Report) ¶¶ 6, 8, 9; *see also* footnote 30.

than one cancer type; tests in development by [redacted] are not being studied in clinical trials for more than one cancer; tests in development by [redacted] are years away from completing an assay that is capable of screening for more than one cancer simultaneously; and, at this time, it is impossible to predict how different screening tests that may be launched in the future will compete with each other, if at all. RX3869 (Cote Expert Report) ¶¶ 152, 153, 156. The greater weight of the evidence supports the opinion of Respondents' expert, Dr. Cote. Based on the evidence in the record, Complaint Counsel has failed to persuade that it is likely that a better-quality test is on the horizon in any reasonable timeframe.[37]

2. Role of Illumina NGS and Availability of Alternatives

NGS technology allows for the detection of a broad range of DNA mutations within a blood sample, which in turn allows for the analysis of many mutations associated with cancer. F. 541. NGS can simultaneously screen for thousands of biomarkers (such as mutations or methylation patterns) that potentially signal cancer within the body. F. 542. Cancer screening companies depend on NGS to detect several biomarkers. F. 544. Furthermore, MCED tests require high-accuracy, high-throughput, cost-effective NGS platforms. F. 545.

Complaint Counsel asserts that Illumina is the only supplier of NGS platforms that are suitable for MCED test developers. Respondents assert that there are other viable NGS platforms that can currently be used for cancer screening, namely Thermo Fisher Scientific, Inc. ("Thermo Fisher"), Oxford Nanopore Technologies ("Oxford Nanopore"), BGI Genomics Co., Ltd. ("BGI") and Ultima Genomics ("Ultima"). As explained below, the evidence proves that currently only Illumina offers NGS instruments with the characteristics needed by MCED test developers. The evidence fails to prove Respondents' assertions that there are currently other viable NGS platforms for use with MCED tests.

Illumina currently sells 11 models of NGS instruments, with the NovaSeq being its high-throughput platform and the NextSeq being its mid-throughout platform. F. 567-568, 575.

[37] Whether the evidence proves Complaint Counsel's related claim, that, irrespective of whether Grail is likely to have commercial competition in the near future from another MCED test, Grail and its alleged rivals are currently "competing vigorously to develop the best performing test," is addressed in the context of the relevant product market, section III.E.

Illumina's customers include Grail, Exact, [redacted] Guardant, Freenome, Singlera, and [redacted] F. 588. Illumina holds various patents for its technology and has pending intellectual property applications for its NGS platforms. F. 9.

Key representatives from [redacted] Guardant, Freenome, Singlera, Helio and [redacted] explained how they depend on NGS supply from Illumina to run the MCED tests that they are developing, or plan to develop, because of Illumina's uniquely superior performance parameters. F. 601-634. For example, [redacted] depends on Illumina's high throughput and accuracy. F. 601. Similarly, Darya Chudova of Guardant testified that Guardant requires Illumina's highest throughput NGS, the NovaSeq, because it is "the only one that comes with the throughput, accuracy, cost, and turnaround time that meets [its] criteria." F. 608. In addition, Michael Nolan of Freenome testified that Freenome can only use Illumina NGS because of throughput and cost requirements (F. 621), and [redacted] testified that Illumina is a "critical supplier" and that without it, [redacted] "couldn't perform [its] tests." [redacted]

The few NGS platforms other than Illumina's that are available in the United States, sold by Thermo Fisher, Oxford Nanopore, BGI, and Ultima, are not as suitable for MCED test use as Illumina's NGS platforms. Multiple MCED test developers credibly testified that Thermo Fisher's lower accuracy precluded its use for their MCED tests in development. F. 644-645, 651-653. Similarly, MCED test developers testified that the combination of Oxford Nanopore's long-read technology and higher error rate makes it unsuitable for MCED tests. F. 686-689. Thermo Fisher's Vice President of Product Management, Dr. Mark Felton, admitted that Thermo Fisher's NGS platforms are not well suited for MCED tests because of their lower throughput and higher cost, a sentiment echoed by many MCED test developers. F. 637, 642, 644-646, 651.

Although on June 6, 2022, BGI announced its intention to make its NGS platform commercially available in the United States starting on August 29, 2022, the day after an Illumina patent is set to expire, F. 662, MCED test developers persuasively testified that they would not consider switching to BGI's NGS platform because of the perceived low quality of

BGI's NGS instruments, pending intellectual property disputes with Illumina,[38] and data privacy concerns surrounding BGI's ties to the government of the People's Republic of China. F. 661, 664-666, 668-670.

Respondents point to evidence that on June 21, 2022, Exact/Thrive announced it has entered into a long-term NGS supply agreement with Ultima, arguing this constitutes proof that Ultima is a viable alternative to Illumina. However, the press release issued by Exact/Thrive announcing the agreement does not state that Ultima's NGS products will be used for Exact/Thrive's *MCED* tests, but merely states that Exact/Thrive plans to develop "one or more . . . advanced cancer *diagnostic* tests using Ultima's sequencing technology." RX4063 (Exact) at 001 (emphasis added). Moreover, the evidence fails to show that Ultima's NGS products are appropriate for MCED tests. The [redacted] than Illumina's, which may render Ultima's platform inappropriate for MCED test developers, depending on their varying performance requirements. F. 703.

Respondents further assert that there are companies with NGS platforms currently in development that are likely to become commercially available in the near future and which will be viable platforms for MCED tests, including Singular Genomics ("Singular"), [redacted] Element Biosciences, and Pacific Biosciences of California, Inc. ("PacBio")/Omniome, Inc. ("Omniome"). The evidence, however, fails to show that these platforms would be appropriate alternatives to Illumina's platforms for MCED tests. Nolan of Freenome testified that neither Omniome nor Singular provides the performance specifications Freenome seeks. F. 681, 700. [redacted] projects its [redacted] platform will have lower accuracy than Illumina's NovaSeq, and Guardant testified that [redacted] platform lacks the characteristics that Guardant needs. F. 721-722.

Moreover, the evidence fails to prove that the asserted alternative NGS platforms are likely to become commercially available in the near future. The evidence shows that these potential NGS platforms are still in an early phase of development and that there are significant

[38] In a Form 8-K filed July 14, 2022, with the United States Securities and Exchange Commission Illumina reported it had entered into a settlement and license agreement with BGI ("July 14 Settlement Agreement"). In the filing, Illumina states that the July 14 Settlement Agreement resolves certain patent and antitrust claims between the two companies. F. 663.

barriers to developing and commercializing an NGS platform suitable for MCED tests. F. 723-729. Because these NGS platforms are in development, their performance has not yet been subject to the verification and testing necessary prior to adoption. As Francis deSouza of Illumina acknowledged, only after observing the sequencer's performance in the market and validating the customer's workflow on the new sequencer will a customer begin selling its tests on a new sequencer. F. 727. It is "not uncommon" for clinical customers to wait years to adopt a new sequencer in order "to see how it will perform in the real world, then perform validation." F. 728-729. Even assuming the performance parameters of these in-development NGS platforms were appropriate for MCED tests, it could take years after their launch for potential platforms to be used by MCED developers.

Finally, even if there were viable alternatives to Illumina NGS, the evidence shows that MCED tests are validated to a particular sequencing platform and that there are significant costs associated with switching NGS platforms. F. 730-745. Grail acknowledges that once a company develops a testing assay on a sequencer, it is "very costly" to move to a different sequencer. F. 731. Even if one of the in-development NGS platforms that Respondents propose as alternatives had appropriate performance parameters and were to become commercially available in the United States in the near future, switching NGS platforms would require redesigning the MCED test, training technicians on the use of a new platform, revalidating the test on the new platform, performing a clinical sample analysis, and potentially obtaining new regulatory approvals, all of which could cost millions of dollars and take years to complete.[39] F. 736, 738, 740, 742-745. MCED test developers convincingly testified that, based on the high costs, switching away from Illumina would be very challenging and could delay the launch of their planned MCED tests. F. 734, 739, 744.

[39] As part of the process for receiving PMA for a distributed or kitted IVD, the test developer must specify its NGS instrument, reagents, and other system components. F. 191. Because NGS platforms and their components are specified as part of the final FDA approval process, an approved distributed IVD test is "locked in" to those systems once clinical trials begin, making switching to new technology platforms difficult. F. 191, 193. Modifying any component of the approved distributed IVD test could require conducting additional clinical trials with the modified component. F. 192.

Based on the foregoing, the evidence demonstrates that currently, and for the near future, Illumina is the only viable supplier of NGS platforms that meet the requirements of MCED test developers.[40]

3. The Open Offer

a. Background

The term "Open Offer" used herein refers to a standardized, long-term supply agreement that is presently available to all of Illumina's for-profit, United States oncology customers who purchase NGS products for developing and/or commercializing oncology tests. F. 875, 877, 886, 888. The Open Offer, dated March 29, 2021, was made available on March 30, 2021, supplemented on September 8, 2021, and posted publicly on Illumina's website. F. 876, 886.

Complaint Counsel notes that the instant litigation began on March 30, 2021, and argues that the significance and sincerity of the Open Offer should be discounted as "made for litigation." CCB at 161-66. The assertion that the Open Offer was made for litigation is unconvincing and is rejected. Illumina began the efforts that led to the Open Offer months before the commencement of this litigation. F. 849. Contrary to Complaint Counsel's position, the Open Offer grew out an effort by Illumina, beginning before the planned acquisition of Grail was announced on September 21, 2020, to assure customers, particularly those developing a multicancer screening test, that the then-pending acquisition would have no impact on their relationship with Illumina. F. 513-514. This effort included telephone outreach, including to [redacted] Freenome, [redacted] Thrive, and Guardant, which Illumina followed with Letters of Intent ("LOIs"), issued on October 9, 2020. F. 516, 849-850. As detailed in section II.G.3 of the Findings of Fact, Illumina used the information that it learned from its customer outreach and what it learned in negotiations with customers such as [redacted] and [redacted] to develop the

[40] Respondents contend that Complaint Counsel had the burden of proving that NGS instruments are a "related product market," as part of Complaint Counsel's burden of proving the relevant market in this case. RB at 73-76. Complaint Counsel contends that it need not prove that NGS platforms constitute a related product market, and that identifying NGS platforms as a "related product" to MCED tests is merely "helpful" to the analysis. CCB at 66-71. Neither side has provided sufficiently clear or applicable legal authority for its position. Moreover, it is unclear that the parties' dispute of law, or semantics, is material – much less dispositive – given the conclusion herein that Complaint Counsel has proven its factual assertions that Illumina NGS is necessary for MCED tests and that there are presently no viable alternatives to Illumina NGS for MCED test development.

Open Offer, and Illumina posted an amendment to the Open Offer on September 8, 2021, adding terms to respond to certain customer feedback on the March 29, 2021 terms. F. 875, 886. The Open Offer itself publicly declares its purpose to be to allay customer concerns that Illumina would disadvantage Grail's potential competitors after the Acquisition "by increasing their sequencing prices or by withholding access to Illumina's latest innovations in" NGS. F. 876, 886.

Of Grail's alleged rivals, [redacted] signed the Open Offer on October 7, 2021, and [redacted] signed the Open Offer on July 29, 2022. F. 989. [redacted] each signed amendments to their existing supply agreements in early 2021 that incorporate the relevant terms of the Open Offer. F. 989; *see also* F. 855-874. [redacted] has stated its intent to sign the Open Offer. F. 989.

b. Summary of Material Terms

Existing or new customers of Illumina may sign the Open Offer at any time until six years after the close of Illumina's acquisition of Grail, which is August 18, 2027. F. 880. Once signed, the Open Offer becomes the customer's supply agreement, and is effective for 12 years from the date of the Acquisition, or August 18, 2033. F. 888. The Open Offer is irrevocable and, once signed by a customer, is binding on Illumina. F. 885. A customer signing the Open Offer supply agreement is not obligated to purchase any supplies from Illumina. F. 882. Illumina cannot terminate the agreement for convenience; however, the customer has a "unilateral right to terminate its supply relationship with Illumina at any time for any reason" upon advance notice without penalty. F. 881.

c. Supply Assurances

The Open Offer requires that, in the event Illumina experiences a supply shortage, "Illumina will allocate the existing supply in an equitable manner among its customers" and "Affiliates," defined to include Grail, based on expiring lots and that the allocation "shall not favor" Grail over other customers. F. 908. Furthermore, the Open Offer prohibits Illumina from discontinuing a supplied product, so long as the customer continues to purchase it and until the product has not been purchased by the customer for one year. F. 905.

Customers who sign the Open Offer receive a right under Illumina's core intellectual property to use the relevant products, covering all Illumina's intellectual property rights that "pertain to or cover aspects or features of any" supplied product. F. 965-967. Illumina also agrees under the Open Offer that "in no event will Illumina have the right to cease shipments" of a product "solely on the basis of any alleged claim of infringement of any intellectual property rights of Illumina." F. 968.

d. Pricing

Under the Open Offer, customers may select one of two options for each product purchased: the pricing that they received before Illumina's acquisition of Grail closed ("Grandfathered Pricing") or pricing under a "universal" pricing grid ("Universal Pricing"). F. 915. "Grandfathered Pricing" refers to the customer's price for ongoing, ordinary course supplied products operative at the time of the closing of the Acquisition. F. 916. If a customer chooses Grandfathered Pricing, it will have the option of maintaining the pricing it had prior to the Acquisition for the duration of the 12-year term of the Open Offer. F. 917. Universal Pricing refers to "the Volume-Based Net Price" for the product[41] as set forth in Illumina's Universal Pricing grid, which is attached to the Open Offer. F. 918-919. Since the Acquisition, Grail receives pricing under the Universal Pricing grid. F. 923. Customers purchasing under the Open Offer can pick Grandfathered Pricing for some products and Universal Pricing for others. F. 922.

If a customer is receiving Universal Pricing to purchase a product under the Open Offer supply agreement, the customer will receive "most favored nation" (MFN) pricing protections relative to Grail, and to any customer of Illumina's that is "equivalent" to the purchasing customer, as judged by prior purchase volumes "not more than 10% greater than the volume purchased by Customer in prior year." F. 920-921 and n.16. The equivalent customer must also be a for-profit entity. F. 921 n.16. Specifically, the MFN protections require that the purchasing customer be given prices "that are no less favorable (*i.e.*, the same or better) than" the prices provided by Illumina to Grail, or to an equivalent customer, after the date of the Acquisition.

[41] "Volume-Based Net Price" under the Open Offer refers to "the actual list price of a Supplied Product less the applicable discount for a customer's volume under a volume-based discount schedule." The greater the volume of Illumina's products purchased, the lower the price. F. 918 n.15.

F. 920-921.[42] If Grail or an equivalent customer receives more favorable pricing than another customer, the Open Offer requires Illumina to notify the other customer promptly and to refund any difference between the price paid by the customer and the applicable reduced price. F. 924.

The Open Offer includes a "no price increase" provision, pursuant to which Illumina commits not to increase prices beyond inflation for the 12-year term of the agreement. This applies to Grandfathered Pricing and Universal Pricing. F. 926. Illumina also cannot release a new version of a supplied product at a higher price than the previous version unless the new version results in a material improvement in performance or capability. F. 927. Increased prices for new products, based on material improvement, must be commercially reasonable, and take into account the value of the improvement, with disputes resolved by an arbitrator applying those standards. F. 928. Furthermore, the Open Offer obligates Illumina to reduce the pricing of sequencing by at least 43% by 2025. F. 929.

e. Products and Services

The Open Offer requires Illumina to provide customers with the ability to purchase any sequencing instruments and core consumables that are offered to Grail, or to any for-profit entity, no later than 5 days of when Illumina offers the product to Grail or other for-profit entity. F. 896-898. Illumina understands this provision to prevent Illumina from creating a product specifically for Grail and withholding it from other customers. F. 896 ("We are not allowed to make a product just available for GRAIL. . . . In this offer letter we're saying that any product that's available for GRAIL will be available for everyone."). Similarly, Illumina must provide customers the ability to purchase any "pre-release" sequencing product[43] that is offered to Grail or any for-profit entity within 5 days. F. 900. In addition, Illumina must, within 5 days, provide customers the same information that Grail receives about final product specifications of any new

[42] The MFN provisions in the Open Offer grew out of the supply agreement negotiations with [redacted] that took place in the wake of the issuance of the LOI. F. 855-856, 860. The MFN provisions in [redacted] were added in response to [redacted] request for assurance that [redacted] would not be treated unfavorably, both relative to Grail and to [redacted] peers. [redacted] and Illumina discussed the issue and agreed on the language. F. 860.

[43] When Illumina launches a product, Illumina's practice is to make the product available to all customers at once. It is unusual for Illumina to provide sequencing products to its external customers prior to their launch, but Illumina might do so for a limited number of customers in order to obtain feedback. F. 902.

sequencing instruments or core consumables. F. 899. Under the Open Offer, Illumina also must provide customers with the ability to obtain the same product services and support services as Grail or any other for-profit entity, at the same prices. F. 890.

f. Development Support

To the extent that a customer's tests have unique features that are less compatible with any future Illumina products, the Open Offer requires Illumina, upon a customer's request, to enter into development agreements, on "commercially reasonable terms," to design or modify Illumina's products to optimize interoperability with the customer's tests. F. 910.[44]

The Open Offer also provides that, for six years after the closing of the Illumina-Grail transaction (*i.e.*, until August 18, 2027), customers may enter into one or more separate agreements with Illumina to develop IVD test kits for use on Illumina's platforms. F. 945. FDA approval is required for a distributed, or kitted, in-vitro diagnostic test.[45] F. 936. To get FDA clearance for a distributed IVD test, the FDA typically requires an agreement between a test developer and the sequencing company being used. F. 936-937. Illumina also requires customers to enter into an IVD agreement to run a test on Illumina's diagnostic instruments. F. 939.

The Open Offer lays out the summary of the terms for different types of IVD agreements in an attachment to the Open Offer posted on Illumina's website. F. 946, 951. Illumina is required to provide standard terms for the IVD agreements. F. 948. The types of agreements offered reflect common terms such as 10 to 15-year development timelines, milestone payments, fees, and royalties. F. 952-958. The available IVD agreements will allow developers to create test kits for all oncology applications, including cancer screening generally and multicancer screening specifically. F. 947. They will also require Illumina to provide "any documentation or

[44] The development agreement term (F. 910) was included in the Open Offer based on a request from [redacted] to incorporate this type of clause into [redacted] supply agreement. [redacted]

[45] An in-vitro diagnostic ("IVD") is a test of human tissue or blood samples that is performed outside the body. F. 187. A distributed or kitted IVD is an IVD test that has received a premarket authorization from the FDA permitting analysis by independent testing providers, such as hospitals or large reference labs like LabCorp or Quest Diagnostics. F. 190. IVD agreements are co-development agreements or collaboration agreements where Illumina provides access to its NGS platform so that the IVD test provider can validate its assays on Illumina's instruments, and then secure the necessary agreements with Illumina to supply the IVD test developer during the development period. F. 941.

information reasonably required for Customer to seek FDA approval or FDA marketing authorization to sell a for-profit, clinical test" using the supplied products. F. 948.

g. Protection of Confidential Customer Information

Illumina acknowledges that post-integration of Illumina and Grail, there will likely be some collaboration between Illumina's and Grail's clinical affairs teams. However, there will be separate organizations reporting to different people. This is also true post-integration for Illumina's and Grail's respective sales, market access, and regulatory affairs teams. F. 972. The Open Offer prohibits Illumina from sharing any customer confidential information with Grail or its subsidiaries or employees, or with Illumina employees who work with Grail. F. 969. Illumina is also required to establish a firewall designed to prevent "any GRAIL personnel (and any Illumina personnel carrying out activities with respect to the GRAIL business or products)" from accessing any confidential information "obtained by or made available to Illumina" relating to the customer's business or products. F. 970.

If Illumina becomes aware of a breach of confidentiality of any kind, it is required to notify the other party of the breach. F. 971. Illumina will also conduct a biannual audit, explained more fully below, to identify any breaches that might have been missed.

h. Monitoring and Enforcement

The Open Offer requires Illumina to publish and update information about the products and services Grail purchases, as well as the pricing grids used for those purchases. Illumina is required to make necessary updates to the website "within 5 days of entry of" any Grail purchase order or service contract relating to the products being supplied to the customer under the Open Offer. F. 977.

In addition, the Open Offer requires Illumina to conduct a biannual audit of its compliance with the Open Offer using "an independent third party auditor selected by Illumina from among the 'Big 4' accounting firms."[46] F. 979. Moreover, if a customer has a "good faith basis for alleging that Illumina is in breach" of any commitment in the Open Offer, Illumina

[46] The so-called "Big 4" accounting firms are Deloitte, Ernst & Young, KPMG, and PricewaterhouseCoopers. F. 979 n.18.

must "engage an auditor to assess" the customer's allegation "separate from and in addition to" the biannual audits. F. 980. Illumina must "provide cooperation, including access to necessary books and records, in support of any audit conducted." F. 981. Illumina is obligated to provide customers with a written report "confirming compliance with the commitments" in the Open Offer. F. 982. If upon auditing there is "any finding of potential noncompliance with Illumina's performance" of the terms of the Open Offer, Illumina must notify customers within 10 days. F. 983.

Disputes under the Open Offer are first submitted to a dispute resolution process between Illumina and the customer. F. 985. If unsuccessful, the dispute is submitted to confidential binding arbitration, under the Commercial Arbitration Rules of the American Arbitration Association ("AAA"), "to determine final terms and conditions of the supply agreement, or to settle the dispute as to the terms of a supply agreement." F. 984, 987. If the arbitrator finds a breach of "any provision" of the supply agreement, the arbitrator "may order any relief necessary to restore the status quo prior to Illumina's breach, including monetary and/or injunctive relief." F. 987. The arbitrator is specifically directed to resolve disputes in accordance with the purpose of the agreement, stating that "in resolving any dispute under the Supply Agreement, the Arbitrator shall take into account, and the Arbitrator's decision shall reflect, that the purpose of the Supply Agreement is to allay any concerns relating to the Transaction, including that Illumina would disadvantage GRAIL's potential competitors after the Transaction by increasing their sequencing prices or by withholding access to Illumina's latest innovations in NGS." F. 988.

E. Relevant Market

1. Applicable Legal Standards

The first step in evaluating whether an acquisition may substantially lessen competition in any "line of commerce" in any "section of the country" is to determine the "line of commerce" and the "section of the country"; in other words, to determine the relevant product market and the relevant geographic market. *Oracle Corp.,* 331 F. Supp. 2d at 1110. "The 'relevant product market' identifies the product and services with which the defendants' products compete," while "the 'relevant geographic market' identifies the geographic area in which the defendants compete

in marketing their products or services." *CCC Holdings*, 605 F. Supp. 2d at 37. Complaint Counsel bears "the burden of proving a relevant market within which anticompetitive effects are likely . . . ." *Id.*

As the Clayton Act makes clear, the purpose of market definition is to illuminate the competitive effects of an acquisition. 15 U.S.C. § 18. In order to "measure [the defendant's] ability to lessen or destroy competition . . . the relevant market is defined as 'the area of effective competition.'" *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2285 (2018) (citing *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 177 (1965)). "Typically this is the 'arena within which significant substitution in consumption or production occurs.'" *Am. Express*, 138 S. Ct. at 2285 (quoting Areeda & Hovenkamp § 5.02). "But courts should 'combin[e]' different products or services into 'a single market' when 'that combination reflects commercial realities.'" *Am. Express*, 138 S. Ct. at 2285 (citing *United States v. Grinnell Corp.*, 384 U. S. 563, 572 (1966); *Brown Shoe*, 370 U.S. at 336-37 (pointing out that "the definition of the relevant market" must "'correspond to the commercial realities' of the industry")).

Further, "it is improper 'to require that products be fungible to be considered in the relevant market.'" *United States v. Cont'l Can Co.*, 378 U.S. 441, 449 (1964) (quoting *United States v. E. I. du Pont De Nemours & Co.*, 351 U.S. 377, 394 (1956)). Indeed, it is not uncommon for courts to define relevant product markets that include products or services that most customers would not consider to be reasonable substitutes. For example, the market for hospital services may include heart transplants, brain tumor surgery, and appendectomies, which patients and doctors would not consider to be interchangeable. *See, e.g., FTC v. Penn State Hershey Medical Center*, 838 F.3d 327, 338-45 (3d Cir. 2016) (including local hospitals that constrain the defendants' pricing of general acute care services and incorporating new economic learning for determining relevant geographic markets); *FTC v. Advocate Health Care Network*, 841 F.3d 460, 468, 471-73 (7th Cir. 2016) (including "abdominal surgeries, childbirth, treatment of serious infections, and some emergency care" in the relevant product market and adopting new economic learning for relevant market definition). "Interchangeability of use and cross-elasticity of demand are not to be used to obscure competition but to 'recognize competition where, in fact, competition exists.'" *Cont'l Can*, 378 U.S. at 454 (quoting *Brown Shoe*, 370 U.S. at 326).

"Since the purpose of delineating a line of commerce is to provide an adequate basis for measuring the effects of a given acquisition, its contours must, as nearly as possible, conform to competitive reality." *Cont'l Can*, 378 U.S. at 457. In defining the product market, courts "must recognize meaningful competition where it is found to exist." *Id*. at 449.

2. Geographic Market

In this case, the relevant geographic market is not contested. The Complaint alleges that the relevant market is "the market for the research, development, and commercialization of MCED tests in the United States[.]" Complaint ¶ 31. Respondents do not dispute that the relevant geographic market is the United States of America ("United States or U.S."). Respondents' Response to Proposed Conclusions of Law 32-35. Thus, the relevant geographic market in this case is the United States.

3. Product Market

The nature and contours of the relevant product market in this case are highly contested. The issue is made more complicated by Complaint Counsel's muddled and varying approach to the relevant product market. Complaint Counsel contends that the relevant product market is "the research, development, and commercialization of MCED tests," as alleged in the Complaint. CCB at 49 ("The research, development, and commericalization of MCED tests is a relevant product market"); Complaint ¶ 31. However, Complaint Counsel confuses the issue by abbreviating this alleged "research, development, and commercialization" market as "MCED Tests" or the "MCED Test Market," CCB at 1, while also using the term "MCED Tests" to refer to a market for MCED tests themselves. *See* CCRB at 20-21 n.10 ("[T]he relevant question is whether other MCED tests compete with Grail's Galleri test.").

The confusion over the relevant product market at issue is compounded by the fact that Complaint Counsel undertook to prove an "MCED tests" market (as opposed to the alleged "research, development, and commercialization of MCED tests" market). Complaint Counsel presents argument and evidence under the Brown Shoe practical indicia that MCED tests are distinct from other oncology tests, such as tests used for symptomatic patients or patients already diagnosed with cancer, therapy selection tests, minimal residual disease ("MRD") tests, and

single cancer screening tests.[47] CCB at 50-57.[48] Complaint Counsel also relies on its proffered economic expert witness, Dr. Scott Morton, who conducted analysis purporting to show that MCED tests are a relevant product market because (1) it is unlikely that customers would switch from an MCED test to one or more currently available cancer screening tests, a liquid biopsy-based single cancer screening test, or to a test developed for a different non-screening application; and (2) a hypothetical monopolist of all MCED products would likely be able to profitably impose a small but significant non-transitory increase in the price ("SSNIP") on at least one MCED product above the price that would prevail if there were multiple MCED rivals (or profitably impose a significant reduction in quality or test availability).[49] CCB at 57-59; PX6090 (Scott Morton Expert Report) ¶¶ 12(b), 132-37.

The conclusion that MCED tests are a distinct product from other oncology tests borders on the obvious. As stated by Respondents, "[n]o one contests that Galleri [an MCED test] is not in the same market as single cancer screening tests, therapy selection tests or MRD [minimal residual disease] tests." RRB at 16; RRCCFF 826.[50] The fact that MCED tests themselves could constitute a relevant product market does not answer the question whether there is a relevant market for the "research, development, and commercialization" of MCED tests.[51]

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[47] In defining markets, courts often identify and rely on "practical indicia" set forth in *Brown Shoe*: industry or public recognition of the market as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors. 370 U.S. at 325; *see, e.g.*, *FTC v. Staples*, 970 F. Supp. 1066, 1075-80 (D.D.C. 1997); *FTC v. Cardinal Health*, 12 F. Supp. 2d 34, 46-48 (D.D.C. 1998); *FTC v. Swedish Match*, 131 F. Supp. 2d 151, 159-64 (D.D.C. 2000).

[48] Specifically, Complaint Counsel presents evidence that: MCED tests have unique characteristics that set them apart from other oncology tests; MCED tests have distinct customers because they are targeted towards patients who do not have symptoms of cancer; and the industry recognizes MCED tests are distinct from other oncology tests. CCB at 50-57.

[49] Courts may also rely on testimony from experts in the field of economics to support a relevant product market. *United States v. Aetna, Inc.*, 240 F. Supp. 3d 1, 21 (D.D.C. 2017); *FTC v. Sysco Corp*., 113 F. Supp. 3d 1, 33 (D.D.C. 2015).

[50] Thus, no findings of fact are necessary to establish that MCED tests are not reasonably interchangeable with non-MCED tests.

[51] Although it asserts its product market is the "research, development, and commercialization" of MCED tests, Complaint Counsel also argues that the putative MCED tests are reasonably interchangeable with Galleri. CCRB at 21-24. If Complaint Counsel were required to prove the interchangeability of the tests themselves to prove a relevant product market, it would not be able to meet its burden, because as explained in III.D.1.b, with the possible exception of Exact/Thrive, the MCED tests currently being developed or planned for by other companies are not reasonably interchangeable with Galleri and will not be in any reasonable timeframe.

Complaint Counsel did not undertake to apply the *Brown Shoe* factors to demonstrate that any of the MCED tests being developed or planned for by Grail's purported rivals would be in the same product market as Galleri. CCB at 50-57. Because no MCED developer other than Grail has brought an MCED test to market, Complaint Counsel's economic expert witness, Dr. Scott Morton, admitted that she did not and could not consider: any data describing past purchase patterns of consumers and their responses to price changes regarding the pricing of MCED tests; any evidence of switching in response to price changes; or any normal course of business documents describing how Galleri customers or any MCED test customer responded to a price increase. PX7138 (Scott Morton Trial Dep.) at 100-01. Dr. Scott Morton admitted that she did not perform a quantitative hypothetical monopolist test, quantitative SSNIP analysis, critical loss analysis, or any analysis of whether a SSNIP for one MCED test would result in customers (*i.e.*, patients, healthcare providers and payers) switching to another MCED test. PX7138 (Scott Morton Trial Dep.) at 100-06. An economic expert witness' opinion does not need to be based on quantitative information to be probative. *See, e.g.*, *United States v. Philadelphia Nat'l Bank*, 374 U.S. 321, 362 (1963); *United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 88 (D.D.C. 2011) (finding that an expert's opinion (even when limited by lack of data) can be helpful to corroborate other evidence in the record like "documents, testimony, and other evidence"); *Sysco Corp.*, 113 F. Supp. 3d at 37. However, this lack of quantitative analysis undermines the probative value of the expert witness' opinion, and weakens Complaint Counsel's relevant product market argument.

Notwithstanding the foregoing, it is important to note that "'Congress prescribed a pragmatic, factual approach to the definition of the relevant market and not a formal, legalistic one.' This is because '[t]he 'market,' as most concepts in law or economics, cannot be measured by metes and bounds.'" *U.S. v. Anthem, Inc.*, 236 F. Supp. 3d 171, 193 (D.D.C. 2017) (internal citations omitted). Given that the purpose of market definition is to provide an adequate basis for measuring the effects of a given acquisition on competition and that courts must recognize meaningful competition where it is found to exist, *Cont'l Can*, 378 U.S. at 449, 457, for purposes of the alleged research, development, and commercialization market, the relevant inquiry is

whether there is current, meaningful competition among the companies engaged in research, development, and commercialization of MCED tests.[52]

The evidence in this case demonstrates that Grail and other cancer screening companies are presently competing to develop the best performing cancer screening test, with an objective of screening for multiple cancers. All MCED tests are intended to detect cancer in asymptomatic patients by looking for unique biomarkers in patients' blood. F. 130-134. MCED test developers have discovered that a number of DNA mutations and methylation biomarkers are common across many different cancers. F. 135. Accordingly, MCED test developers are assembling panels of biomarkers intended to detect a large number of early-stage cancers. *See* F. 278 (Exact/Thrive's CancerSEEK is intended to detect all cancers that shed cancer-related DNA into the blood or secrete proteins at high levels.); [redacted] F. 491 (Singlera has developed PanSeer technology, which is designed to detect multiple cancers.).

In terms of the technical approaches used by cancer screening companies engaged in the research and development of MCED tests, some companies focus on methylation sites in DNA found in blood samples, and others combine a multiomic approach, which focuses on genomics, proteomics, and metabolomics. F. 129, 136, 351; *e.g.*, F. 50, 350, 386, 429, 491. The differentiated technical approaches of MCED test developers can be seen as facets of competition, particularly in a nascent market subject to innovation. *See* PX7132 (Willig Trial Dep.) at 84 ("[P]roducts can compete on the basis of differentiated features."); RX6004 (Katz

[52] Market definition is critical in a horizontal merger case, where the government can establish a presumption of liability by defining a relevant product and geographic market and showing that the transaction will lead to undue concentration in that market. *Baker Hughes*, 908 F.2d at 982-83. But in a vertical merger case, "unlike horizontal mergers, the government cannot use a short cut to establish a presumption of anticompetitive effect through statistics about the change in market concentration, because vertical mergers produce no immediate change in the relevant market share." *AT&T*, 916 F.3d at 1032. Thus, in the instant vertical merger case, an analysis of market share and concentration in the market is not necessary.

Trial Dep.) at 106 (Companies may compete during research and development by differentiating their product to compete on different features or function.).

Cancer screening companies have spent hundreds of millions of dollars in the research and development of multicancer early detection screening tests. F. 274, 373, 403-404, 472, 498. Furthermore, cancer screening companies are currently continuing to improve their tests under development, including by validating additional cancers and trying to add tissue of origin capabilities. *E.g.*, F. 281, 405, 461. As they improve their tests, cancer screening companies expect such features such as sensitivity, specificity, or PPV (positive predictive value) to be a facet of competition in the research, development, and commercialization of MCED tests. *See* F. 281, 362, 405, 499. For instance, as part of its development efforts, Exact/Thrive assessed the data generated and published or made available by Grail to try to improve its MCED test and hopes to "bring the very best test that we can bring, the most accurate test, the one that discovers the most cancers as early as possible." F. 315, 319. Other cancer screening companies similarly are continually engaged in research and are making modifications to improve their planned MCED tests.

Exact/Thrive is currently competing against Grail in "prelaunch activities," associated with bringing a new medical test to market such as "competing for mindshare with physicians, with health systems, with payers." F. 316. Exact/Thrive is competing with Grail for scientists and talent for its research and development efforts because individuals working in early cancer detection have a specialized skill set and there are a limited number of companies requiring those specialized skills. F. 317. [redacted]

Market definition must "take into account the realities of competition." *FTC v. Whole Foods Mkt.*, 548 F.3d 1028, 1039 (D.C. Cir. 2008). Ordinary course of business documents reveal the contours of competition from the perspective of the parties, who may be presumed to "have accurate perceptions of economic realities." *Whole Foods*, 548 F.3d at 1045 (concurring

op.) (quoting *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 218 n.4 (D.C. Cir. 1986)).[53] In the instant case, Grail's ordinary course of business documents show existing competition in the research, development, and commercialization of MCED tests. Grail assessed its potential competitors, by tracking, analyzing, and reporting on competitor activities to gain insight into competitor strategies and develop competitive strategies. F. 261-262, 265-265. Grail's competitive intelligence analysis team evaluated potential competitors according to three categories: viable technology approach, clinical studies, and commercial capabilities. F. 264. Grail's competitive intelligence team was involved in "evaluating all of the advances going on in our spaces" and was "intended to understand how [the multiple cancer early detection] field is advancing," including "events, progression, and new data." F. 263. To achieve this, the competitive intelligence team "track[s] to various degrees many potentially competitive technologies, academic projects, small companies that span the gamut in terms of development stage, indication, biomarker type, technology platform, cancer type, and other factors." F. 263. In an internal presentation titled "Competitive Threats to Galleri After Launch," Grail identified Exact, Thrive, Guardant, Singlera, and Freenome among the "Top Tier" threats. F. 267.[54] In addition, Grail formed a competitive intelligence "Thrive Red Team," specifically targeting Exact/Thrive, which evaluated Thrive's "product, regulatory, reimbursement, clinical and commercial strategy, and . . . recommend[ed] GRAIL mitigations" to the competitive threats from Thrive. F. 329; *see also* F. 326-328, 330-331.

Similarly, Illumina's ordinary course of business documents show that, in connection with determining which of its customers to proactively contact in advance of the Acquisition, Illumina assessed the degree to which oncology testing companies might be developing a multicancer screening test, and identified Guardant, Freenome, Thrive, [redacted] and [redacted] as potential competitors of Grail. F. 513-516. In an April 2020 presentation to Illumina's Board of

[53] In addition to the *Brown Shoe* factors and economic expert witness testimony, courts also pay "close attention to the defendants' ordinary course of business documents." *H&R Block*, 833 F. Supp. 2d at 52.

[54] It should be noted, though, that in the same presentation, Grail assessed the relative features of other developers' tests and commercialization strategies and stated that the other tests (1) are not multiple-cancer early detection tests (*e.g.*, Natera and FMI are identified as developing a MRD test), or (2) do not come close to Galleri in number of cancers detected (*e.g.*, Singlera, Freenome, and Guardant are identified as developing a solely colorectal cancer product). F. 267.

Directors, Illumina's Scientific and Technology Committee noted that "the early movers" in the "early cancer detection space" included Grail, Guardant, Freenome, and Thrive, and noted also that other potential entrants include [redacted] F. 519.

The companies presently engaged in researching and developing MCED tests view Grail as a competitor. *E.g.*, F. 312 (Exact/Thrive considers Grail as its "most direct competitor.");[55] F. 416-417 (Guardant is "really focused" on Grail and considers Grail "the most formidable" competitor to its MCED test under development.); F. 445 (Helio monitors Grail and other companies who are working on developing screening MCED tests to understand what other companies are doing and how the whole field is evolving.); F. 476 [redacted] F. 507 (Singlera believes that cost and accuracy of multicancer screening tests are the main drivers for competition; considers Grail, Freenome, and Thrive as its top competitors; and expects to compete with Grail on additional innovation.).

The facts that the cancer screening companies engaged in the research and development of MCED tests are on varying timelines for developing their tests, and that it cannot be predicted with certainty who will ultimately commercialize a rival test, are not determinative in defining the relevant market where, as here, there is *existing* competition to develop and commercialize a test. In an analogy to a racetrack, where commercialization is the finish line, all the cancer screening companies researching and developing an MCED test are on the same racetrack; some have barely left the starting gates; some are further along; one is approaching the finish line; and one (Grail) has crossed the finish line. But they are all on the same racetrack. They are competing in that they are trying to develop an MCED test and to bring an MCED test to market. This "area of effective competition" is the relevant market in which to assess Illumina's ability to harm competition.

[55] Indeed, Exact/Thrive considers Grail to be its [redacted] relevant competitor in the area of blood-based multicancer screening. F. 312. Although other companies are working towards developing MCED tests, Exact/Thrive does not see [redacted] as close competitors in the area of blood-based multicancer screening. F. 313.

F. Likelihood of Substantial Lessening of Competition

1. Complaint Counsel's Asserted *Prima Facie* Case

Complaint Counsel argues that the Acquisition has a reasonable probability of substantially lessening present and future competition in the research, development, and commercialization of MCED tests, which, according to Complaint Counsel, will result in increased prices and decreased choice and quality for cancer patients. CCB at 79-83, 125-32. Complaint Counsel contends these anticompetitive effects will result from Illumina's taking action to harm Grail's competitors, including through raising the alleged rivals' NGS costs and/or limiting access to NGS products and services. CCB 79-83. The parties and their expert witnesses refer at times to these potential harms to Grail's purported rivals by the shorthand, umbrella term, "foreclosure." *See, e.g.*, CCB at 79; RB at 96-97; *see Yankees Entm't & Sports Network, LLC v. Cablevision Sys. Corp.*, 224 F. Supp. 2d 657, 673 (S.D.N.Y. 2002) (stating that vertical mergers can result in reduced competition where competitors of the purchasing firm in the merger are foreclosed "from access to a potential source of supply, or from access on competitive terms"). Accordingly, the term foreclosure is at times used herein as a shorthand phrase for the harm to competitors asserted in this case.

Complaint Counsel contends that, to meet its *prima facie* burden to show that a merger is likely to substantially lessen competition, it is sufficient to prove that Illumina has an ability and incentive to take action to harm Grail's rivals post-Acquisition. CCB at 84 (stating that a fact-specific showing of a reasonable probability of substantially lessening competition "can be established by showing that the merged firm has the ability and incentive to foreclose, or offer inferior terms to, rivals in the relevant market"); *see also* CCB at 119 (asserting *prima facie* burden has been met by proof of "ability and incentive to disadvantage" Grail's alleged competitors; and *Brown Shoe* factors "bolster" that *prima facie* case). Such a minimalist formulation of the *prima facie* burden is unsupported by applicable legal precedent. As previously explained in section III.B above, evaluating whether a vertical merger is likely to substantially lessen competition requires consideration of numerous factors, including:

> the nature and economic purpose of the [transaction], the likelihood and size of any market foreclosure, the extent of concentration of sellers and buyers in the industry, the capital cost required to enter the market, the market share needed by

> a buyer or seller to achieve a profitable level of production (sometimes referred to as "scale economy"), the existence of a trend toward vertical concentration or oligopoly in the industry, and whether the merger will eliminate potential competition by one of the merging parties. To these factors may be added the degree of market power that would be possessed by the merged enterprise and the number and strength of competing suppliers and purchasers, which might indicate whether the merger would increase the risk that prices or terms would cease to be competitive.

Fruehauf, 603 F.2d at 353; *see also U.S. Steel*, 426 F.2d at 599; *United States v. American Cyanamid Co.*, 719 F.2d 558, 566 (2d Cir. 1983). As the court stated in *Fruehauf*, the above list of considerations, "with some variations, has been the standard framework for analysis of the legality of a vertical merger." 603 F.2d at 353.

One of the cases relied upon by Complaint Counsel is *AT&T*, 310 F. Supp. 3d at 243-25. While the court in *AT&T* considered the government's argument that the merger created an incentive and ability for AT&T – after acquiring Turner networks – to leverage its control of Turner to obtain increased content prices and affiliate fees in distributor negotiations, the court did not express or imply that proof of an incentive and ability to do so would constitute *prima facie* proof of a merger's likely anticompetitive effect. To the contrary, the court held that showing that the effect of a merger is likely to be anticompetitive is "'necessarily both highly complex'" and specific to the facts of the case. *AT&T*, 310 F. Supp. 3d at 192 (quoting David T. Scheffman & Richard S. Higgins, Vertical Mergers: Theory and Policy, 12 Geo. Mason L. Rev. 967, 967 (2004)). Unlike horizontal mergers, which permit the government to meet its *prima facie* burden with a statistical presumption based on market concentration, "there is no comparable theoretical basis for dealing with vertical mergers." *Id.* (quoting 4A Areeda & Hovenkamp, *Antitrust Law* ¶ 1000a).

Complaint Counsel also relies on the initial decision in *In re Union Carbide Corp.*, 1961 WL 65409, at *19 (F.T.C. Sept. 25, 1961) for the proposition that the relevant inquiry is not whether an acquisition creates actual foreclosure, but whether it confers the power to do so. CCB at 81, 84. In *Union Carbide*, the hearing examiner determined that the merger between the largest supplier (Union Carbide) and largest purchaser (Visking) of film-grade polyethylene resins gave "Union Carbide, when it acquired Visking, . . . the power to remove from the market and allocate to itself exclusively the purchasing power of the largest single customer in the

market for film-grade polyethylene resins." 1961 WL 65409, at *18. The hearing examiner found it "beside the point" that, since the merger was consummated, Visking had been purchasing resins from respondent's competitors in increasing proportions. *Id.* at *19. The court reasoned that, through the acquisition, Union Carbide acquired the power to foreclose its competitors from those sales, and "it is the power that counts, not its exercise." *Id.* at *19. On appeal, the Commission agreed that, by acquiring Visking, Union Carbide "secured the power to foreclose . . . ." *Id.* at *31. However, in determining that the acquisition would substantially lessen competition, the Commission relied on a variety of factors, including the substantial amount of sales that were foreclosed to Union Carbide's competitors by virtue of the merger, barriers to entry in the market for manufacturing polyethylene resins, and trends toward market concentration. *Id.* at *32-34. Nothing in *Union Carbide* indicates that a Section 7 violation can be inferred simply from proof of "ability" and "incentive" to harm competitors. Accordingly, Complaint Counsel's contention is rejected.

It is well established that Section 7 protects competition, "rather than any particular competitor." *Aetna*, 240 F. Supp. 3d at 18 (quoting *Baker Hughes*, 908 F.2d at 988, 990 n.12); *see also Brown Shoe*, 370 U.S. at 320 (stating that the Clayton Act protects "competition, not competitors"). Thus, it is not legally sufficient for Complaint Counsel to demonstrate that the Acquisition is likely to harm Grail's rivals. *See Fruehauf*, 603 F.2d at 352 (holding that Supreme Court precedent "contravenes the notion that a significant level of foreclosure is itself the proscribed effect"). Under Complaint Counsel's theory, however, as explained above, likely harm to Grail's rivals is a necessary factual predicate for finding that the Acquisition is likely to substantially lessen competition. Accordingly, the analysis must first resolve the likelihood that the Acquisition will harm Grail's alleged rivals. *See AT&T*, 310 F. Supp. 3d at 199 (referring to the plaintiff's assertion that the acquisition would increase acquirer's bargaining leverage in cable package contract negotiations as the "first hurdle" in establishing potential for anticompetitive effects from the merger); *see also id.* at 206 (describing the factual question presented as "whether the Government has carried its Section 7 burden to show, through proof at trial, that Time Warner will gain increased bargaining leverage in affiliate negotiations on account of the proposed merger and, if so, whether that increased bargaining leverage would

result in increased distributor or consumer costs that would constitute a substantial lessening of competition under Section 7").

As factual support for the conclusion that the Acquisition is likely to harm Grail's rivals, Complaint Counsel asserts that Illumina, post-Acquisition, has the ability to harm MCED test developers, and that Illumina has a strong incentive to harm its MCED test developer customers. Respondents argue that Complaint Counsel has failed to prove either assertion, but that, in any event, the Open Offer effectively constrains Illumina from harming Grail's rivals.

2. Ability to Harm MCED Test Developer Customers

Complaint Counsel argues that Illumina's status as the only viable supplier of NGS instruments appropriate for MCED tests gives Illumina the ability, post-Acquisition, to disadvantage these MCED test developer customers and/or to advantage Grail. As explained in section D.2 above, the evidence proves that Illumina is currently the dominant provider of NGS, which is a necessary component for MCED test development, and the evidence fails to prove that Illumina's MCED test developer customers will have a viable alternative to Illumina NGS in the reasonably near future. These facts support the conclusion that Illumina possesses an ability to affect price, supply, and quality of NGS products and services.

Complaint Counsel further asserts that Illumina has a variety of tools at its disposal to harm MCED test developers, such as completely or partially foreclosing NGS supply, increasing prices, or diminishing service or support, among other tools. As detailed in the Findings of Fact, section II.G.1, the evidence proves that Illumina has a variety of tools through which it could adversely impact its MCED test developer customers, including through price and supply impacts. For example, it is possible for Illumina: to use confidential business information received from its customers to price-discriminate between customers, F. 746-759, 766-775; to withhold, delay, or limit the quantity or quality of NGS supply or services, F. 795-804; and/or to withhold, delay, or limit access to new or improved NGS products. F. 780-790.

Based on the foregoing, the evidence proves that – absent the Open Offer – Illumina has the ability to use its control as a dominant provider of NGS to adversely impact MCED test developers. However, such proof is less significant to this case than Complaint Counsel's

extensive briefing on the issue would suggest. Illumina's status as the only viable supplier of a necessary input for MCED test development existed before the Acquisition, and therefore, Illumina's asserted abilities to raise prices, withhold supply, or decrease the quality of products or services, also existed before the Acquisition.[56] The evidence fails to prove these abilities are a function of the Acquisition, or have changed as a result of the Acquisition. In *AT&T*, by contrast, it was the planned merger itself that gave AT&T, through its control of Turner, the asserted ability to threaten to withhold Turner networks content, which the Government claimed would increase AT&T's bargaining power in distributor negotiations and lead to higher content prices and affiliate fees. *See* 310 F. Supp. 3d at 198-99, 201; *see also Union Carbide*, 1961 WL 65409, at *31 (holding that the merger between the largest seller and the largest purchaser of film-grade resins secured for seller the power to foreclose competitors from a substantial share of market).

3. Incentive to Harm Grail's Purported Rivals

Complaint Counsel asserts that, as a result of the Acquisition, Illumina has a "strong incentive to harm" its MCED test developer customers and give an advantage to Grail. CCB at 104. As grounds for this assertion, Complaint Counsel claims the evidence shows that (1) the volume and profit from anticipated future MCED test sales are expected to "dwarf" sales and profits related to NGS sequencing products; and (2) a new or better MCED test could emerge to overtake, or "leapfrog," Grail's Galleri test, which would necessarily divert sales away from Galleri. As explained below, the evidence fails to demonstrate that Illumina has a "strong incentive to harm" Grail's purported rivals.

a. Relative Profits of NGS and MCED Tests

Illumina segments its target NGS customers into three "value chain" components: clinical testing services, library preparation and assays, and NGS instruments and core consumables. F. 813. Today, Illumina's "core business," from which Illumina makes "the vast majority of [its] revenue," is the sale of NGS sequencers and consumables. F. 7, 806. In 2018, 2019, and 2020,

[56] Complaint Counsel conceded in closing argument that Illumina "absolutely" could have foreclosed Grail's rivals prior to the Acquisition. Tr. 4619-20.

total sequencing revenue comprised 83%, 87%, and 89%, respectively, of total revenue. F. 7. In 2020, Illumina's consumable sales accounted for 71% of Illumina's total revenue. F. 14.

Internal Illumina analyses from 2020 projected Illumina's revenues from its NGS instruments and core consumables would grow from [redacted] F. 815. Illumina further projected: "As commercialized screening/monitoring products scale, the clinical testing services market will grow to ~3x larger than" Illumina's product segments combined. F. 815. Illumina estimated that the market for clinical services could grow to $75 billion by 2035, with screening and monitoring projected to grow the fastest, and that acquiring Grail would add [redacted] in 2035 revenue [redacted] F. 816, 822. Illumina also predicted in 2020 that the "net margin profit pool" in 2035 would be [redacted] for clinical testing services compared to the [redacted] for instruments and core consumables and [redacted] for library preparation and assays. F. 821. Illumina recognized that acquiring Grail would enable Illumina to receive the majority of its revenue from "data-intensive clinical services" instead of from instrument and consumable sales. F. 820. However, the evidence further proves that Illumina does not expect the clinical testing business to yield a profit "for many, many years," which deSouza described as "very typical in clinical testing businesses." F.829. Illumina still expects the vast majority of its revenue in the next ten years to come from its core business of NGS sequencers and consumables. F. 830. Illumina expects to lose nearly [redacted] due to the Grail Acquisition, which loss will be funded by Illumina's NGS business. F. 828. Illumina does not expect to generate profits as a result of the Acquisition of Grail until [redacted] and does not expect to recoup its losses incurred in connection with the Acquisition until approximately [redacted] F. 828. Under these facts, the potential for profit more than 12 years in the future fails to demonstrate that Illumina has a current or near-term incentive to harm Grail's rivals, which undermines any conclusion that resulting harm to competition is "probable and imminent." *See Arch Coal*, 329 F. Supp. 2d at 115 (citing *Marine Bancorp.*, 418 U.S. at 623 n.22).

Furthermore, the desire to participate in the long-term, future profit pool expected for clinical testing services does not necessarily translate into an incentive for Illumina to harm its MCED test developer customers out of the fear that they might potentially launch a competing MCED test for sale in the future. MCED test developers are not Illumina's only customers.

Illumina sells its products and services to a wide range of customers in research and clinical settings. F. 6. Illumina's stated strategy in acquiring Grail was to "[v]ertically integrate into oncology, developing content and providing services at scale, while continuing to serve other segments with [its] existing strategy." F. 812. A potential result of an attempt by Illumina to raise prices or otherwise foreclose or harm its MCED test developer customers is that these customers, as well as the non-MCED clinical testing customers who learned of any such attempt, would choose to no longer invest in current or future NGS applications on Illumina systems. F. 808. This could result in the loss of Illumina's NGS sales for both MCED and non-MCED applications and would be contrary to Illumina's stated strategy with the Acquisition to continue serving the NGS segment. F. 807. Complaint Counsel's evidence does not sufficiently account for these counterincentives of Illumina, but merely assumes that, because Illumina recognizes that sequencing revenue will decline in the long term, and because Illumina seeks to shift toward more profitable clinical testing services, Illumina is motivated to harm its existing and future NGS customers in order to advantage Grail.

In support of its argument that Illumina has a strong incentive to harm alleged MCED test developers, Complaint Counsel also relies on the calculations and opinions of its economic expert witness, Dr. Scott Morton. CCFF 3174-88; PX6090 (Scott Morton Expert Report) at 104, Table 2. Dr. Scott Morton undertook to calculate the profits Illumina would receive on the sale of an MCED test by Grail and compared those to the profits Illumina would receive on the sale of an MCED test by two hypothetical other MCED test developers using Illumina's NGS platform, pre-Acquisition and post-Acquisition. F. 834. Dr. Scott Morton's calculations support the conclusion that Illumina, by virtue of owning all of Grail post-Acquisition, will obtain higher profits from selling NGS-based MCED tests through Grail than it received pre-Acquisition on those sales, when Illumina owned only 12% of Grail. However, as noted above, Illumina's incentive to participate in a profitable business does not necessarily translate into an incentive for Illumina to harm its customers.

In addition, Dr. Scott Morton's pre-Acquisition and post-Acquisition profit calculations assumed that Grail and the hypothetical rivals would each pay a royalty to Illumina on their sales of MCED tests, and at the same percentage. However, the Grail royalty payment was a unique feature of Grail's supply agreement with Illumina, in that the payment was not tied to licensing

any intellectual property or particular technology, but instead was designed to provide revenue-sharing to Illumina. No other customer of Illumina pays such a royalty on their sales of tests. F. 42. The foregoing further detracts from the reliability, and hence the probative value, of Dr. Scott Morton's calculations and her opinions based on them.

Moreover, as shown by calculations performed by Respondents' expert witness, Dr. Dennis Carlton,[57] Illumina's pre-Acquisition profits from the sale of MCED tests through Grail are already substantially higher than the profits Illumina would earn on MCED tests sold through another, hypothetical MCED test seller, given Illumina's pre-Acquisition 12% stake. F. 837. In summary, Complaint Counsel and Dr. Scott Morton fail to account for Illumina's pre-merger stake in Grail and make unwarranted assumptions in describing the alleged changes in Illumina's incentives.

b. Diversion

Complaint Counsel acknowledges that the extent of Illumina's asserted "incentive to foreclose or disadvantage MCED Test rivals will depend, in part, on the degree of diversion between any foreclosed rival and Grail." CCB at 113 (citing PX7138 (Scott Morton Trial Dep.) at 248-49). Complaint Counsel first asserts that "diversion *from* any successful rival MCED test *to* Grail's test is likely to be high." CCB at 115 (emphasis added). Complaint Counsel next argues that "[d]ue to the high diversion *from* competing MCED tests *to* Grail's Galleri test,

[57] Dr. Dennis Carlton is well qualified to offer opinions for this case. Dr. Carlton is a Professor of Economics at The University of Chicago Booth School of Business and has served on the faculties of the Law School and the Department of Economics at The University of Chicago and the Department of Economics at the Massachusetts Institute of Technology. RX3864 (Carlton Expert Report) ¶ 1. Dr. Carlton specializes in the economics of industrial organization, which addresses topics in how firms compete, including the study of antitrust economics and of vertical integration. *Id.* at ¶ 2. Dr. Carlton also serves as Co-Editor of the Journal of Law and Economics, a leading journal that publishes research applying economic analysis to industrial organization and legal matters; serves on the Editorial Board of Competition Policy International, a journal devoted to competition policy; and serves on the Advisory Board of the Journal of Competition Law and Economics. *Id.* at ¶ 2. In addition to Dr. Carlton's academic experience, Dr. Carlton previously served as Deputy Assistant Attorney General for Economic Analysis, Antitrust Division, U.S. Department of Justice from October 2006 through January 2008 and served as a Commissioner of the Antitrust Modernization Commission, created by Congress to evaluate U.S. antitrust laws. RX3864 (Carlton Expert Report) ¶ 3. Dr. Carlton has served as a consultant to the Department of Justice and Federal Trade Commission on the Horizontal Merger Guidelines, as a general consultant to the Department of Justice and Federal Trade Commission on antitrust matters, as a member of the American Bar Association advisory committee that advises the incoming President on antitrust policy, as an instructor to judges on antitrust economics at the Federal Judicial Center and as an advisor to the Bureau of the Census on the collection and interpretation of economic data. *Id.* at ¶ 3.

Illumina stands to profit from derailing Grail's rivals in both their development and commercialization efforts." CCB at 110 (emphasis added).

To accept Complaint Counsel's argument requires several unwarranted leaps of logic. As an initial matter, for sales to divert *from* the alleged MCED rivals *to* Grail, the alleged MCED test developers would have to have sales in the first place. Presently, Galleri is the only NGS-based MCED test that is commercially available. F. 201. Thus, current diversion between Galleri and other tests is impossible. F. 845.

Complaint Counsel contends that competing MCED tests "could" leapfrog Galleri "and take market share from Grail." CCB at 110, 112. Complaint Counsel's assertion that a "leapfrog" MCED test will be developed that will divert sales from Galleri in a reasonable time frame has already been rejected as unsupported. As explained in detail in section D.1. above, most of the tests in development are too underdeveloped to permit a meaningful comparison of their features; none of the MCED tests being planned and developed, using only a single blood draw, match the tissue of origin determination available with Galleri; and it is unclear when any other MCED tests might launch, how many cancers the tests will screen for, what features the MCED tests may have, or what the prices of the MCED tests in development might be. In summary, the evidence fails to support the argument that a "leapfrog" product is likely to be developed or launched in the reasonably near future.

Without persuasive evidence that a leapfrog product is likely to take sales *from* Grail in the first place, there is no basis to make the next leap – that the sales from the alleged MCED rivals would then divert *to* Grail if Illumina were to refuse to sell its NGS products to Grail's rivals, as opined by Dr. Scott Morton. To support its claim, that "diversion from any successful rival MCED test to Grail's test is likely to be high," CCB at 115, Complaint Counsel relies on its expert witness, Dr. Scott Morton, who, despite the fact that Grail had commercially launched in April 2021, opined in July 2021: "If Grail is the first to market, it will have 100% share to begin with." PX6090 (Scott Morton Expert Report) ¶ 268. If Grail's rivals were to launch an MCED test and if Illumina were to refuse to sell its NGS products to one of Grail's rivals, Scott Morton opined, "[f]oreclosure of the second MCED test entrant will result in 100% of the entrant's lost sales being captured by Illumina-Grail, as it is the only other competitor." PX6090 (Scott Morton

Expert Report) ¶¶ 264-68. This opinion is mere conjecture based on an assumption lacking in evidentiary support and is not persuasive evidence of Illumina's asserted incentive to foreclose or disadvantage MCED test rivals. *See HTI Health Servs., Inc. v. Quorum Health Grp., Inc*. 960 F. Supp. 1104, 1136 (S.D. Miss. 1997) (rejecting plaintiff's diversion theory because the "testimony and expert opinion regarding a potential shift in patient admissions to ParkView is conjecture that is based on an assumption lacking in evidentiary support").

To the extent important differences exist between MCED tests, Grail's MCED test and the in-development MCED tests detailed above would not be good substitutes for each other. The lower the substitutability there is among the MCED tests, the lower the diversion will be between rivals and Grail. These factors reduce or eliminate any incentive to harm the purported rivals. F. 842. Some of the tests currently being developed by Grail's alleged rivals are minimal residual disease ("MRD") tests that are used to determine whether remnants of cancer remain in a patient who has been treated for cancer or are single cancer screening tests that test only for colorectal cancer. F. 267 n.9, 346, 474. These are not close substitutes for multiple cancer early detection tests. A cancer screening test that screens only two or three cancer types also is not a close substitute for a test that screens for numerous cancer types. F. 206, 269. While Freenome considers itself to be an MCED competitor, its former Chief Executive Officer ("CEO") Gabe Otte testified that "as a patient," he would "take both" Grail's multicancer screening test and Freenome's test, and therefore, views Freenome's multiomics test as "complementary" to Galleri. F. 376.

As Dr. Carlton explained, "if products are very different from one another, it suggests that they're unlikely to be close substitutes, and if they're not close substitutes, then the diversion of sales from the rival – to in this case GRAIL . . . [is] likely to be low or nonexistent," and "if it's low or nonexistent, then the incentive – the profit incentive to engage in the raising rivals' cost strategy . . . will also be low or nonexistent." F. 840. Even Dr. Scott Morton acknowledged that if products "are sufficiently differentiate[d], . . . the combined firm would not recapture any of those profits" by foreclosing, making foreclosure "not a very successful strategy. . . . That's what highly differentiated means, that diversion is limited." F. 843. Accordingly, the evidence

fails to prove Complaint Counsel's claim that the likelihood of high diversion incentivizes Illumina to harm Grail's purported rivals.[58]

4. Effect of the Open Offer

As explained above, while Complaint Counsel has demonstrated that Illumina has the ability to harm Grail's alleged rivals, the evidence fails to prove any strong incentive to do so. At most, Complaint Counsel has demonstrated that it is possible that Illumina could harm Grail's asserted rivals. As explained below, the Open Offer effectively constrains Illumina from harming Grail's alleged rivals and rebuts the inference that future harm to Grail's alleged rivals, and thus future harm to competition, is likely.

a. Constraints Imposed by the Open Offer

The Open Offer is a standardized, long-term supply agreement offered by Illumina to all its United States oncology testing customers who purchase NGS products for developing and/or commercializing oncology tests. F. 875, 877, 888. The provisions of the Open Offer are detailed in section II.G.3 of the Findings of Fact and summarized in section III.D.3 above. A customer who signs the Open Offer receives a 12-year supply agreement that provides:

- Access to Illumina's product services and support services that is equivalent to that provided to Grail or any other for-profit entity (F. 890);
- Access to Illumina's current and future sequencing products (as well as information about final product specifications) that is equivalent to that provided to Grail or any other for-profit entity (F. 896-901);
- Continued supply of all sequencing products purchased by the customer and equitable allocation of supply during any supply shortage (F. 905-908);
- Access to the pricing that the customer received before the Acquisition ("Grandfathered Pricing") and to most-favored-nation ("MFN") pricing protections when using a standardized, volume-based pricing grid (F. 915-922);

[58] Complaint Counsel's contention that Illumina's past behavior when vertically integrated illustrates how Illumina will act on its financial incentives in the future is addressed in footnote 61 below.

- A commitment not to increase beyond inflation over the full 12-year term of the supply agreement and to decrease prices by at least 43% by 2025 (F. 926, 929);

- Rights, under Illumina's core intellectual property, to use the products purchased under the Open Offer, and a commitment not to discontinue supply based solely on a claim of infringement (F. 965-968);

- The opportunity, at any time within the six years after the date of the Acquisition, to enter into separate agreements with Illumina to develop IVD test kits on Illumina's FDA-regulated instruments and to work with Illumina to modify Illumina's products to optimize interoperability with the customer's tests (F. 910, 945);

- Firewall protection against the improper use of customers' competitively sensitive information (F.969-970);

- The unilateral right of the customer to terminate the supply agreement at any time and for any reason (F. 881); and

- Monitoring and enforcement through biannual audits of Illumina's compliance and binding arbitration in the event of any dispute (F. 978-988).

The Open Offer constrains Illumina from using virtually any of the tools that Complaint Counsel asserts will raise rivals' costs or otherwise foreclose Grail's alleged rivals, as illustrated by the following chart.

Claimed ability	**Open Offer Constraint**
Ability to completely withhold or otherwise adversely impact supply to Grail's alleged rivals (e.g., CCB at § II.E.1.a, c)	Illumina is required to supply all Illumina sequencing instruments and core consumables ordered by the customer, including in the event of a supply shortage, product obsolescence, or a pending intellectual property claim. F. 905, 908, 968.
Ability to increase prices (e.g., CCB at § II.E.1.b)	Illumina is prohibited from increasing prices beyond inflation for the entire 12-year term of the Open Offer, until August 18, 2033. F. 926. Illumina is required to decrease sequencing prices by at least 43% by 2025. F. 929. If Illumina offers Grail or any other equivalent customer lower prices, "most favored nation" provisions require Illumina to offer those same lower prices to customers using Illumina's standardized, volume-based pricing grid. F. 921.

Ability to decrease quality of service and support (e.g., CCB at II.E.1.d)	Illumina is required to provide customers with the same access to services to which Grail or any other for-profit entity has access, or to which the customer had access before the Acquisition, at the same prices. F. 890.
Ability to delay or deny access to new technology (e.g., CCB at II.E.1.e)	Illumina is required to provide the customer access to new technology, including within five days of providing access to Grail. F. 899-901.
Ability to advantage Grail by developing products specifically for Grail (e.g., CCB at II.E.1.f)	Upon customer request, Illumina must enter into a development agreement on commercially reasonable terms relating to the design or modification of sequencing products to optimize interoperability with the customer's tests. F. 910.
Ability to deny access to critical information and IVD agreements needed for FDA approvals (e.g., CCB at II.E.1.g)	Illumina is required to enter into IVD agreements on standard industry terms with any customer who desires one and to provide all information reasonably required by FDA. F. 945, 948-949.

The foregoing facts support the economic opinions of Respondents' well-qualified expert witness, Margaret Guerin-Calvert, which are credited herein.[59] *See, e.g.*, F. 997, 999-1012, 1014, 1016-1018, 1020-1023, 1032. In evaluating the competitive efficacy of the Open Offer, the relevant economic issue for evaluation is whether the Open Offer sufficiently prevents Illumina from acting on any incentive to harm Grail's alleged rivals caused by the Acquisition. F. 997. The Open Offer provides a comprehensive set of protections for Illumina's customers for all aspects of conduct and competition including access to products, pricing and quality of products and services, and rights to develop distributable IVD kits on Illumina's FDA-regulated systems. F. 1000. In short, the Open Offer provides the economically necessary set of terms to prevent

[59] Margaret Guerin-Calvert is well qualified to offer opinions for this case. Guerin-Calvert is the President and Senior Managing Director of FTI Consulting, Inc.'s Center for Healthcare Economics and Policy, a business unit that specializes in healthcare economics and applied microeconomics. RX3865 (Guerin-Calvert Expert Report) ¶ 1. She is an industrial organization economist, the branch of economics that involves the study of firms, industries, consumer behavior, and pricing; and is a founding director of Compass (Competition Policy Associates), the predecessor of Compass Lexecon, an independent subsidiary of FTI Consulting, Inc., a firm which specializes in antitrust and applied microeconomics. *Id.* Guerin-Calvert has also served as Assistant Chief of the Economic Regulatory Section of the Antitrust Division, U.S. Department of Justice, where she had primary responsibility for healthcare matters, including market power and regulatory analyses, and served as Economist at the Federal Reserve Board. *Id.* at ¶ 2.

such harm in both the short term and the long term. F. 999. The Open Offer also provides for effective monitoring and enforceability mechanisms. F. 1000, 1020.

Furthermore, the Open Offer is more than just an inchoate promise; the protections of the Open Offer are presently operating in the relevant market to constrain Illumina and prevent harm to Grail's purported rivals. Of the Illumina customers alleged to constitute Grail's rivals in the research, development, and commercialization of an MCED test, as of the date of this Initial Decision, [redacted] have signed the Open Offer; [redacted] have signed amendments to their existing supply agreements that incorporate the relevant terms of the Open Offer; and [redacted] has stated its intent to sign the Open Offer. F. 989. Regardless of whether the Open Offer fails to resolve each and every potential concern of every Illumina MCED test developer customer, as Complaint Counsel argues (CCRB at 160), the fact that Grail's purported rivals have signed the Open Offer is significant and undermines Complaint Counsel's assertions that the Open Offer is illusory, unenforceable, or otherwise ineffective to prevent harm to Grail's alleged rivals.

Case law also supports applying the real-world effects of contractual commitments to the determination of the potential for anticompetitive harm. In *AT&T*, a vertical merger case, Turner had made an irrevocable offer to Turner network distributors that Turner would "engage in AAA arbitration," in the event of a failure to agree to renewal terms. *AT&T*, 310 F. Supp. 3d at 184. The offer further specified that pending arbitration, "Turner must continue to provide carriage on the same terms and conditions," thereby guaranteeing that no blackout of Turner content could occur once arbitration is invoked. *Id*. The district court included this arbitration commitment as a "real-world" fact that further undermined the government's increased bargaining leverage theory. *Id.* at 241 n.51; *see AT&T*, 916 F.3d at 1042-43 ("[T]he district court's finding of the efficacy of Turner Broadcasting's irrevocable offers of no-blackout arbitration agreements means the merger is unlikely to afford Turner Broadcasting increased bargaining leverage."). Also, in *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, 1298 (W.D. Mich. 1996), the court found that the defendant merging hospitals' formal "'Community Commitment,' . . . to reduce costs – and to pass those cost savings on to consumers – rather than to increase prices or unfairly disadvantage payers" together with other evidence, "further undermine[d] the predictive value of the FTC's prima facie case."

b. Complaint Counsel's Criticisms

Complaint Counsel's criticisms of the Open Offer have been reviewed and considered in the process of resolving the material issues in this case, and they are rejected as insubstantial, unconvincing, or against the greater weight of the evidence.[60] Only a few criticisms warrant additional discussion, as set forth below.

Complaint Counsel criticizes the Open Offer as a "flawed behavioral remedy," asserting that "a remedy to a Section 7 violation must 'restore the competitive intensity' lost from the [A]cquisition." CCRB at 161-62. This argument applies the wrong standard to assessing the effectiveness of the Open Offer. Holding the Open Offer to the standard of a remedy for a violation puts the proverbial cart before the horse. As explained above, Complaint Counsel's theory that the Acquisition is likely to substantially harm competition depends on the likelihood of harm to Grail's alleged rivals, and the issue is whether the Open Offer rebuts that likelihood.

i. Incentives

Complaint Counsel, relying on its expert witness Dr. Scott Morton, contends that the Open Offer does not change Illumina's incentives to favor Grail to the detriment of Grail's alleged rivals, which arise from the fact that Illumina owns Grail. As shown in section III.F.2 above, however, Complaint Counsel's proof regarding Illumina's post-Acquisition incentive is weak, including because of the failure to prove likely diversion between Grail's Galleri test and alleged future MCED tests. Complaint Counsel failed to prove its assertion that Illumina has a strong incentive to advantage Grail to the disadvantage of Grail's alleged rivals. In addition, economic theory regarding changes in incentive due to the Acquisition are rendered largely

[60] For example, the Open Offer requires Illumina to provide customers with the same information that Grail receives about final product specifications of any new, or new version of, sequencing instruments or core consumables, and the ability to purchase any sequencing instruments and core consumables that are offered to Grail, each within 5 days of Grail. F. 898-899. Complaint Counsel criticizes the 5-day allowance, asserting that advance notice to Grail is a competitive advantage. *See, e.g.*, Getty (Guardant) Tr. 2518-19 (testifying that notice of information about a new sequencer in development from Illumina could give Grail a "significant head start" on developing the next version of its MCED assay; *see also* PX8400 (Vogelstein (John Hopkins University) Decl. ¶ 9 (declaring that advanced knowledge of "future product developments and refinements" from Illumina "could substantially alter research and development in the field and the nature of the test products that are eventually produced"). This criticism of the Open Offer is insubstantial. As explained in section III.D.1 above, developing an MCED test takes many years of research, development, and clinical validation. Against this backdrop, the 5-day allowance provided under the Open Offer is inconsequential.

irrelevant insofar as Illumina is constrained from acting on the purported incentive. *See AT&T*, 916 F.3d at 1041 (holding that because the post-merger arbitration agreements would prevent the blackout of Turner Broadcasting content while arbitration is pending, "the government's challenges to the district court's treatment of its economic theories becomes largely irrelevant"). Dr. Scott Morton failed to evaluate the ability of Illumina to raise rivals' costs, impose harm, or foreclose rivals under the terms of the Open Offer. F. 846.[61]

Furthermore, there are a number of factors that operate as counterincentives and drive Illumina to comply with the Open Offer, which also helps ensure that the Open Offer will have the real-world effect of constraining Illumina. *AT&T*, 310 F. Supp. 3d at 241 n.51 (concluding that Turner's commitment to arbitrate will be honored by AT&T and therefore the commitment will have real-world effects). Indeed, the fact that Illumina made the terms of the Open Offer available is itself evidence of Illumina's motivation to maintain its customers, rather than to foreclose or otherwise disadvantage them.

First, all of the terms of the Open Offer are publicly available on Illumina's website, as is the cover letter enclosing the Open Offer, which expressly states that its purpose is to allay customer concerns that Illumina might disadvantage Grail's potential rivals. F. 876, 886. Illumina is also a publicly traded company. F.1. Given that Illumina is under scrutiny by its customers as well as the government, it is logical that Illumina would not want any backlash from failing to follow through on the Open Offer's commitments. As Complaint Counsel's

[61] Complaint Counsel contends that Illumina's past behavior when vertically integrated "illustrates" Illumina's post-Acquisition incentives. CCB at 116. Complaint Counsel argues that Illumina's prior conduct constitutes proof that Illumina will act in accordance with its financial incentives in the future. Complaint Counsel asserts that Illumina provided Grail with special pricing and other benefits when Grail was wholly owned by Illumina and that Illumina withheld NGS supply and IVD rights from companies making testing products that Illumina deemed to be competitive with Illumina's products. It should be noted that the Grail example from the past is readily distinguishable from extant circumstances. At the time of Grail's formation, no other oncology testing companies were developing liquid biopsy cancer screening tests. F. 30. Illumina believed that "no customer ha[d] the ability to implement a pan-cancer screening test responsibly and economically anytime in the next 5 years" and Illumina's goal was to accelerate the development of the cancer screening space. F. 32-34. Illumina believed it would have been difficult for Grail to develop its MCED test without discounts. F. 35. The circumstances present today are very different: Grail has now brought an MCED test to market; the costs of sequencing have come down; and Illumina has committed to be bound by the terms of the Open Offer. F. 36, 201, 789, 810, 879, 885-886. Moreover, regardless of Illumina's past behavior, as explained above, the Open Offer effectively constrains the ability of Illumina to act on any incentive to favor Grail at the expense of Grail's alleged rivals. Under these circumstances, Illumina's past conduct when it was vertically integrated is not probative evidence that Illumina will harm Grail's alleged competitors post-Acquisition.

expert witness, Dr. Scott Morton, acknowledged, Illumina's compliance with the Open Offer will have a favorable impact on Illumina's reputation, by demonstrating that Illumina honors its commitments. F. 1033.

Second, Illumina representatives put themselves on the record, testifying under oath at trial, regarding their understanding of the Open Offer and Illumina's commitments thereunder. For example, Nicole Berry, Illumina's Senior Vice President and General Manager of the Americas Commercial Region, testified that Illumina understands that if it delayed or refused to service an instrument that belonged to a customer who had signed the Open Offer, Illumina would be in breach of the agreement. F. 895. She also testified to the understanding that Illumina would be in breach if it provided worse services to a customer laboratory who did not also purchase Galleri. F. 895.[62] Similarly, Berry acknowledged that it would be a breach of the Open Offer for Illumina to manipulate supply by providing lower quality instruments or consumables or by delaying a purchase order. F. 907. Berry also testified to Illumina's understanding that, under the Open Offer, any discretionary discounts offered to Grail (or any other for-profit entity) must be made available to all other Open Offer customers. F. 925. Moreover, Illumina states that it is prepared to have the Open Offer converted into a consent decree, monitored by the FTC, which further undermines any conclusion of a desire by Illumina to evade its commitments. RB at 178; RRB at 120-21.

Third, according to the qualified, persuasive expert opinion of Respondents' expert witness Robert Rock,[63] Illumina's knowledge that there will be audits itself acts as a deterrent to non-compliance and also encourages compliance. F. 1034. Compliance audits also serve a "detective" function by revealing acts of non-compliance. F. 1034.

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[62] It should also be noted that Illumina has a disincentive to encourage or allow delayed or suboptimal service to Grail's alleged rivals because instrument downtime means that the customer is not using consumables and then buying more consumables from Illumina. F. 895.

[63] Robert Rock is well qualified to offer opinions for this case. Rock is a Managing Director at AlixPartners, LLP ("AlixPartners") where he has been for approximately 27 years. RX3870 (Rock Expert Report) ¶ 1. Prior to joining AlixPartners, he was with PricewaterhouseCoopers for 18 years. *Id.* Rock has been a Certified Public Accountant since 1978. *Id.* at ¶ 2. He has directed audit engagements of public and private companies and provided professional business consulting services to companies in a variety of industries. *Id.* at ¶ 3. Rock has been engaged by the U.S. Department of Justice and the U.S. Securities and Exchange Commission as a litigation consultant or expert witness on numerous matters and has been appointed as a Receiver, Arbitrator, Special Master or Funds Custodian by federal judges in seven different matters. *Id.* at ¶ 5.

All the foregoing facts and circumstances support the conclusion that Illumina is committed to complying with the Open Offer, and weigh against a conclusion that Illumina is intending to evade its requirements.

ii. Protection of Confidential Customer Information

The Open Offer prohibits Illumina from sharing any confidential customer information with Grail or its subsidiaries or employees, or with Illumina employees who work with Grail. F. 969. The Open Offer further requires Illumina to "establish a firewall designed to prevent any GRAIL personnel (and any Illumina personnel carrying out activities with respect to the GRAIL business or products) from accessing any Confidential Information obtained by or made available to Illumina relating to Customer or its business or products, whether pursuant to this Supply Agreement or otherwise." F. 970. After the integration of Illumina and Grail there will be separate organizations reporting to different people. F. 972. This is also true post-integration for Illumina's and Grail's respective sales, market access, and regulatory affairs teams. F. 972.

Complaint Counsel argues that a firewall is inadequate to keep confidential customer information received by Illumina from being shared with Grail, including because Illumina's former Chief Operations Officer is now CEO of Grail and Grail's CEO will report to Illumina's CEO. However, high-level executives at Illumina generally do not have access to customer databases. F. 974. If any Illumina employee requests access to confidential material, the person responsible for the material is to obtain and comply with legal guidance regarding whether to allow access. F. 762. In addition, contrary to Complaint Counsel's argument, the firewall provision can be effectively implemented. F. 975. Illumina is familiar with how to set up and operate confidentiality procedures because Illumina already has set up and implemented such procedures for use with other customers in similar fields, such as in connection with IVD agreements. F. 976. Confidential information received from customers at Illumina is already subject to Illumina's data privacy restrictions, including, among other things, regular training of staff and supervision by management, and a "need-to-know" limitation on accessing data outside the purview of an individual's role. F. 760-761. Illumina requires staff to sign confidentiality agreements when they are hired. F. 761. Illumina also separates employee teams that have customers with similar products. F. 761. If an Illumina employee shares confidential information

of a test developer with a Grail employee, Illumina's disciplinary procedures allow Illumina to take disciplinary action up to termination of the employee. F. 764. These confidentiality practices are fairly typical and generally accepted in the industry. F. 765.

The evidence further supports the opinions of Respondents' expert witness, Guerin-Calvert, that the confidentiality and firewall provisions of the Open Offer directly address the concern regarding Illumina's ability to use confidential customer information in an anticompetitive manner. F. 1016. Based on Guerin-Calvert's review of government consent decrees using firewall and confidentiality provisions, the firewall in the Open Offer between Illumina and Grail will provide at least the essential features common to past accepted firewalls; specifically, provisions for monitoring and auditing, methods to report violations, and consequences for violations. F. 1017. In addition, while no process is "100 percent certain," the auditor can "go a long way" toward identifying any violations. F. 1018.

iii. Monitoring and Enforcement

Complaint Counsel contends that the Open Offer's provisions for monitoring and enforcement are inadequate. Complaint Counsel asserts that the customer will not promptly know if Illumina has breached the terms and that arbitration is time consuming, costly, and creates an uncomfortable situation for customer and supplier. These criticisms do not warrant the conclusion that the monitoring and enforcement provisions of the Open Offer are inadequate.

The Open Offer requires Illumina to publish and update information about the products and services Grail purchases, as well as the pricing grids used for those purchases. F. 977. Illumina is required to make necessary updates to the website "within 5 days of entry of" any Grail purchase order or service contract that relates to products being supplied to the customer under the Open Offer. F. 977. There is no basis for concluding this information will not be prompt or accurate. In addition, Illumina is subject to biannual audits by one of the "Big Four" accounting firms, and any customer with a good faith basis can ask for additional audits, with which Illumina must cooperate. F. 979-980. Furthermore, customers are given a report of all audits and must be notified within 10 days of any potential noncompliance found by the auditor. F. 982-983. Based on the foregoing, Complaint Counsel's contention that customers will not promptly know of a potential breach is rejected.

The facts also support the conclusion, further reflected in qualified, persuasive expert opinion, that the Open Offer provides effective mechanisms for monitoring and enforcement that will maximize Illumina's compliance. F. 1020. The audit and arbitration provisions of the Open Offer play complementary roles – the audit provision assures customers that they will have access to the necessary information to ensure that Illumina abides by its obligations, and the arbitration provision provides a mechanism for resolution of disputes by an independent entity. F. 1021.

Contrary to Complaint Counsel's assertions, audits of the Open Offer provisions on pricing and access to products and services will expose flaws in Illumina's procedures and enable improvement, which will further minimize the risk of harm to Grail's alleged rivals. F. 1025. Independent auditors are fully capable of assisting Illumina in developing the appropriate procedures and controls and reporting to allow Illumina and contracting customers the ability to monitor compliance with the terms of the Open Offer. F. 1027. For example, an independent auditor can successfully audit the confidentiality provisions by obtaining a list of Illumina employees working with Grail and ensuring the list is complete and accurate, obtaining a list of all Illumina and Grail employees who are authorized to receive confidential information, executing employee compliance certifications regularly, examining reports of violations, performing keyword email searches, creating and testing electronic barriers, testing for noncompliance with respect to hard-copy information, and interviewing select personnel. F. 1028. Large Certified Public Accountant firms ("CPAs") such as the Big Four have the relevant knowledge and experience to conduct an effective compliance audit. F. 1029. Additionally, CPAs very frequently review compliance with contract provisions and audit the effectiveness of internal controls. F. 1029. This experience can increase the effectiveness and value of an audit over time. F. 1029.

To the extent arbitration can be time consuming, costly, or create an uncomfortable situation for customer and supplier, such facts would not compel the conclusion that the arbitration provisions of the Open Offer are ineffective to protect customers' interests or will fail to deter Illumina from breaching the Open Offer. Disputes under the Open Offer are first submitted to a dispute resolution process between Illumina and the customer, F. 985, which

could lead to an early resolution at minimal cost. Illumina's CEO, Francis deSouza, testified that Illumina wants to use "as accelerated a process as available" and is willing to solicit feedback and improve the arbitration process to make it more expeditious to the extent possible. F. 986.

If the parties proceed to arbitration, and the arbitrator finds a breach of "any provision" of the supply agreement, the arbitrator "may order any relief necessary to restore the status quo prior to Illumina's breach, including monetary and/or injunctive relief." F. 987. The arbitrator is specifically directed to resolve disputes in accordance with the purpose of the agreement, which states that "[i]n resolving any dispute under the Supply Agreement, the Arbitrator shall take into account, and the Arbitrator's decision shall reflect, that the purpose of the Supply Agreement is to allay any concerns relating to the Transaction, including that Illumina would disadvantage GRAIL's potential competitors after the Transaction by increasing their sequencing prices or by withholding access to Illumina's latest innovations in NGS." F. 988.

Taken together, the foregoing provisions in the Open Offer provide effective monitoring and enforcement mechanisms to prevent or redress potential violations.

iv. Customer Concerns

Complaint Counsel relies on testimony from MCED test developer witnesses, who depend on Illumina for NGS supply, that the Open Offer fails to address all their concerns about the Acquisition. Most of the concerns reflect, in essence, a fear that Illumina might breach its contractual commitments and a preference that Illumina not own Grail, so as to eliminate any possibility that Illumina uses its position to disadvantage them. The court is not unsympathetic to the concerns of these witnesses; however, it cannot, and will not, be assumed that Illumina will evade its commitments or operate in bad faith. To ignore the commitments in the Open Offer, and find instead that evasion or bad faith is likely, based on fears expressed by certain MCED test developers, is not justified.

In addition, the customer witness testimony regarding concerns over the Open Offer was not uniform. For example, [redacted] testified that the MFN pricing protections would help mitigate [redacted] concerns with the Acquisition if the provisions were properly implemented. [redacted] Similarly,

[redacted] testified that he trusted that his company would receive equitable pricing relative to Grail. [redacted] further testified that, if properly implemented, the firewall provision in the Open Offer would help mitigate the risk of Illumina's sharing sensitive information with Grail. [redacted] testified that [redacted] which is similar to the Open Offer, is sufficient for his company's business needs and agreed that the agreement adequately addressed the concerns about the Acquisition that it previously expressed to the FTC. [redacted] no longer has any objections to the Acquisition and has no further edits that it would like to make to its current supply agreement with Illumina. [redacted] Complaint Counsel fails to persuasively explain why greater weight should be given to the opinions of certain customers over others, or why the opinions of some customers should be determinative of whether, as an economic and legal matter, the Open Offer constrains Illumina from harming the alleged rivals.

Finally, the self-interest and potential bias of Grail's alleged rivals as witnesses in the government's effort to undo the Acquisition cannot be ignored. As the court stated in *AT&T*, Section 7 is not aimed at "protecting AT&T's rivals from any and all competitive pressures they would experience should the merger go through . . . Caution is therefore necessary in evaluating the probative value" of third-party competitor testimony. *AT&T*, 310 F. Supp. 3d at 211. "In evaluating the likely competitive consequences of proposed mergers, competition authorities and courts properly weigh the totality of the evidence, refusing to take the views expressed by customers at face value and insisting that customer testimony be combined with economic evidence providing objective support for those views . . . ." *Id.* (quoting Ken Heyer, *Predicting the Competitive Effects of Mergers by Listening to Customers*, 74 Antitrust L.J. 87, 127 (2007)).[64]

[64] As an example of such potential bias, Respondents note that prior to the fall of 2020, when Illumina and Grail entered into their merger agreement, [redacted] did not have a supply agreement with Illumina. F. 995. [redacted] testified that he decided, after learning of the proposed acquisition and the FTC investigation, that this would be a good time to negotiate a supply agreement with Illumina, because it would "bring it all to daylight" and enable "terms that are more conducive." [redacted]

5. Evidence Allegedly Bolstering *Prima Facie* Case

As shown above, and contrary to Complaint Counsel's argument, Complaint Counsel has failed to prove its asserted *prima facie* case that the Acquisition is likely to result in "competitive harm due to [Illumina's post-Acquisition] unbridled ability and incentive to disadvantage" Grail's alleged rivals. CCB at 119. As shown below, Complaint Counsel has also failed to prove the additional factors that it contends bolster its *prima facie* case.

In *United States Steel Corp. v. FTC*, 426 F.2d 592 (6th Cir. 1970), the court synthesized the "several functional factors as indicia of the requisite anti-competitive effect" relied upon by the Supreme Court in "dealing with vertical acquisitions under Section 7":

> (1) foreclosing of the competitors of either party from a segment of the market otherwise open to them; (2) the 'nature and purpose' of the vertical arrangement; (3) actual and reasonable likely adverse effects upon local industries and small businesses; (4) the level and trend of concentration in the market shares of participating companies, including any trend towards domination by a few leaders; (5) the existence of a trend towards vertical integration and consolidation in previously independent industries; and (6) the ease with which potential entrants may readily overcome barriers to full entry and compete effectively with existing companies.

Id. at 599 (citing, *inter alia*, *Brown Shoe*, 370 U.S. 294). Complaint Counsel argues its *prima facie* case is bolstered by: (1) the power to foreclose; (2) the "nature and purpose" of the transaction; and (3) the creation or increase in entry barriers. CCB at 119-25.

The first factor in *U.S. Steel*, is "foreclosure," which the court defined as when "[a] segment of the market otherwise open to the competing members of the two industries is removed from the open market." 426 F.2d at 599. This factor considers to what extent, if any, a merger "will cause market foreclosure." *Crouse-Hinds Co. v. InterNorth, Inc.*, 518 F. Supp. 416, 433 (N.D.N.Y. 1980). It does not, as Complaint Counsel contends, evaluate whether the Acquisition will give Illumina "the power to foreclose." The court in *U.S. Steel* explained:

> Immediately after the merger, nearly one-half of the entire cement market and two-thirds of cement sales to ready-mix concrete producers were foreclosed by three vertically integrated concerns. A prospective entrant to the cement industry must assume the risk of competing for the business of the remaining one-half of

> the cement market's demands and one-third of the ready-mixers' demands not already foreclosed.

U.S. Steel, 426 F.2d at 605. In the instant case, by contrast, it is not alleged, and the evidence fails to show, that the Acquisition is removing *any* NGS products from the market. Complaint Counsel's case is based on the theory the Acquisition confers the incentive and ability to foreclose in the future, rather than actual foreclosure.

Furthermore, Complaint Counsel's "power to foreclose" argument is merely a restatement of its argument that Illumina has the ability to foreclose, and relies on the same evidence that MCED test developers depend on Illumina as the sole viable source of NGS. Recasting the "ability to foreclose" claim as a "power to foreclose" claim does not add any evidentiary weight. Moreover, as explained in section III.F.2, the Acquisition did not give Illumina the power to foreclose; Illumina's ability to foreclose existed *before the Acquisition*. *Compare AT&T*, 310 F. Supp. 3d at 198-199, 201, in which it was the acquisition of Turner by AT&T that conferred on the combined entity the purported ability to threaten to withhold Turner content, and thereby increase AT&T's bargaining leverage in affiliate negotiations. Furthermore, as explained in section III.F.4 above, Illumina's ability to foreclose is effectively constrained by the Open Offer. *See United States v. Hammermill Paper Co.*, 429 F. Supp. 1271, 1293-94 (W.D. Pa. 1977) (finding that "the United States has not carried its burden of proof that the effect of the [vertical] acquisition . . . may be substantially to lessen competition" in the relevant market because "[t]he possibility of foreclosure of access by manufacturers is barred by" other factors).

Complaint Counsel states that it is also appropriate to consider the "nature and purpose" of the Acquisition. CCB at 122, citing *e.g.*, *Brown Shoe*, 370 U.S. at 329 ("A most important such factor to examine is the very nature and purpose of the arrangement."). Complaint Counsel asserts that the nature and purpose of the Acquisition is to enable Illumina to shift its business from NGS sales toward clinical testing services, in order to earn profits that Illumina projected would, by 2035, substantially exceed profits from NGS sales. Therefore, Complaint Counsel argues, "Illumina has every incentive to ensure its investment is successful to the detriment of Grail's competitors." CCB at 122. This is essentially a restatement of Complaint Counsel's incentive argument, relying on the same evidence and logic. *See* section III.F.3.a above. As explained in section III.F.3.a, Illumina's goal to participate in the long-term, future profit pool

expected for clinical testing services does not necessarily translate into an incentive for Illumina to harm Grail's rivals, particularly where, as here, the evidence fails to prove likely diversion between Grail's Galleri test and alleged future MCED tests. Moreover, as explained in section III.F.4, free-floating "incentive" without a meaningful ability to act upon it (due to the Open Offer) renders the economic theories about incentive "largely irrelevant." *See AT&T*, 916 F.3d at 1041. For all these reasons, the "nature and purpose" factor does not add any evidentiary weight to support Complaint Counsel's claim.

Complaint Counsel next argues that the Acquisition has, or will, create or increase barriers to entry. Complaint Counsel asserts that, given the high cost of developing an MCED test, existing and future MCED test developers, particularly smaller ones, will be deterred or will pull back from MCED test development to avoid being in the position of relying on Illumina as a supplier of NGS, while also competing with Grail. In *U.S. Steel*, the court noted that prior to the vertical merger at issue, there existed "formidable" barriers to entry into the relevant markets, financial and otherwise, and that such barriers were "stiffened" by the merger, including because of the extensive foreclosure caused by the merger. 426 F.2d at 604-05. Among other things, the court referred to "psychological 'fears' of smaller rivals competing with large integrated concerns" as a barrier to entry. *Id.* at 605. Analogizing to *U.S. Steel*, Complaint Counsel cites testimony from [redacted] that he "had concerns that we were in a position of having a platform provider that we rely on now moving into a position of directly competing with us" [redacted] and from [redacted] who testified that his company was "currently evaluating to see what happens with the Illumina GRAIL acquisition because that's obviously a very big concern." [redacted] cited in CCB at 123-24. This evidence carries scant probative weight in proving that the Acquisition will create or exacerbate entry barriers as asserted by Complaint Counsel.

The court in *U.S. Steel* noted that, in holding the merger unlawful, the Commission had "very substantial evidence" to support its findings with regard to all six factors. *Id.* at 605. In the instant case, Complaint Counsel's brief does not argue the existence of three of the factors and the record has not proved the other factors by a preponderance of evidence. Based on the

foregoing, Complaint Counsel's additional arguments and evidence based on the *Brown Shoe* factors are rejected as unsupported and unpersuasive.

G. Conclusion

In conclusion, Complaint Counsel has failed to prove its asserted *prima facie* case that Illumina's post-Acquisition ability and incentive to advantage Grail to the disadvantage of Grail's alleged rivals is likely to result in a substantial lessening of competition in the relevant market for the research, development, and commercialization of MCED tests. Among other relevant findings:

- the evidence proves that whatever ability Illumina has to harm Grail's alleged competitors post-Acquisition, such as by raising their costs or restricting supply or service (in shorthand, "foreclosure"), existed prior to the Acquisition and is not a result of it;

- the evidence fails to demonstrate that the Acquisition gives Illumina a strong incentive to harm Grail's alleged rivals post-Acquisition, including because of a lack of proof of likely high diversion between Grail's Galleri and other MCED tests in the reasonably near future; and

- the Open Offer effectively constrains Illumina from acting on the asserted ability and incentive post-Acquisition to harm Grail's alleged rivals, including by raising rivals' costs or foreclosing supply or services.

In short, the evidence fails to prove the Acquisition is likely to harm Grail's alleged rivals during the 12-year term of the Open Offer. Absent proof of a likelihood of harm to Grail's alleged competitors in the reasonably near future, Complaint Counsel's argument that such harm will further result in likely harm to existing innovation and future commercial competition is deprived of its factual premise. As stated in *Arch Coal*, 329 F. Supp. 2d at 116, "antitrust theory and speculation cannot trump facts . . . ." Furthermore, to sustain a Section 7 claim, the alleged substantial lessening of competition must be "probable and imminent." *See Arch Coal*, 329 F. Supp. 2d at 115 (citing *Marine Bancorp.*, 418 U.S. at 623 n.22). The evidence fails to prove that a likelihood of harm to Grail's alleged rivals is probable or imminent, and therefore cannot properly support a finding that a resulting substantial lessening of competition is probable or imminent.

Because Complaint Counsel has failed to sustain the "first hurdle" of its asserted *prima facie* burden, the case will be dismissed, and it is not necessary to determine whether foreclosure harm to Grail's alleged rivals would in fact lessen competition in the relevant market. *See AT&T*, 310 F. Supp. 3d at 199 (denying preliminary injunction where government's evidence "failed to clear the first hurdle of showing that the proposed merger is likely to increase Turner's bargaining leverage in affiliate negotiations" and holding that therefore the court "need not consider the separate legal question of whether any effects associated with the Government's increased-leverage theory would result in a substantial lessening of competition for purposes of the Clayton Act's prohibitions").

For all the foregoing reasons, the Complaint is DISMISSED.

IV. SUMMARY OF CONCLUSIONS OF LAW

1. The Commission has jurisdiction over Respondents and the Acquisition pursuant to Section 5 of the FTC Act, 15 U.S.C. § 45, and Sections 7 and 11 of the Clayton Act. 15 U.S.C. §§ 18, 21(b).

2. Section 7 of the Clayton Act prohibits mergers or acquisitions "where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly." 15 U.S.C. § 18.

3. To show a reasonable probability of anticompetitive effects, the evidence must show that the alleged loss of competition is a sufficiently probable and imminent result of the merger or acquisition.

4. In evaluating the likely competitive consequences of proposed mergers, competition authorities and courts properly weigh the totality of the evidence, refusing to take the views expressed by customers at face value and insisting that customer testimony be combined with economic evidence providing objective support for those views.

5. Congress intended vertical mergers to be subject to the Clayton Act.

6. Under the traditional burden shifting framework in Section 7 cases, the government must first establish its *prima facie* case by: 1) identifying the relevant product and geographic market and 2) showing that the proposed merger is likely to substantially lessen competition in that market.

7. In a vertical merger case, unlike horizontal mergers, the government cannot use a short cut to establish a presumption of anticompetitive effect through statistics about the change in market concentration.

8. In reality, courts recognize that, in practice, evidence is often considered all at once and the burdens are often analyzed together.

9. The Supreme Court has adopted a totality-of-the-circumstances approach to the Clayton Act, weighing a variety of factors to determine the effects of particular transactions on competition.

10. A flexible approach must be adopted in determining whether anticompetitive effects are likely to result from a merger.

11. For the government to prevail, the court must conclude that the government has introduced evidence sufficient to show that the challenged transaction is likely to lessen competition substantially.

12. The first step in evaluating whether an acquisition may substantially lessen competition in any line of commerce in any section of the country is to determine the line of commerce and the section of the country; in other words, to determine the relevant product market and the relevant geographic market.

13. In order to measure the defendant's ability to lessen or destroy competition, the relevant market is defined as the area of effective competition.

14. Interchangeability of use and cross-elasticity of demand are not to be used to obscure competition, but to recognize competition where competition, in fact, exists.

15. Since the purpose of delineating a line of commerce is to provide an adequate basis for measuring the effects of a given acquisition, its contours must, as nearly as possible, conform to competitive reality.

16. Complaint Counsel bears the burden of proving a relevant market within which anticompetitive effects are likely.

17. Congress prescribed a pragmatic, factual approach to the definition of the relevant market and not a formal, legalistic one. This is because the market, as most concepts in law or economics, cannot be measured by metes and bounds.

18. Courts must recognize meaningful competition where it is found to exist.

19. The relevant geographic market in which to assess the likely effects of the Acquisition is the United States.

20. The relevant product market in which to assess the likely effects of the Acquisition is the research, development, and commercialization of MCED tests.

21. The primary vice of a vertical merger or other arrangement tying a customer to a supplier is that, by foreclosing the competitors of either party from a segment of the market otherwise open to them, the arrangement may act as a clog on competition which deprives rivals of a fair opportunity to compete. However, the fact of foreclosure will seldom be determinative.

22. Whether a vertical merger is likely to substantially lessen competition requires consideration of numerous factors.

23. In dealing with vertical acquisitions under Section 7, the Supreme Court has relied on several functional factors as indicia of the requisite anticompetitive effect. Showing that the effect of a merger is likely to be anticompetitive is necessarily both highly complex and specific to the facts of the case.

24. The foreclosure factor refers to the extent to which a segment of the market otherwise open to the competing members of the two industries is removed from the open market.

25. The most important among the factors to consider in determining probable effects of a vertical merger are: the nature and economic purpose of the arrangement, the likelihood and size of any market foreclosure, the extent of concentration of sellers and buyers in the industry, the capital cost required to enter the market, the market share needed by a buyer or seller to achieve a profitable level of production (sometimes referred to as "scale economy"), the existence of a trend toward vertical concentration or oligopoly in the industry, and whether the merger will eliminate potential competition by one of the merging parties. To these factors may be added the degree of market power that would be possessed by the merged enterprise and the number and strength of competing suppliers and purchasers, which might indicate whether the merger would increase the risk that prices or terms would cease to be competitive. This list, with some variations, has been the standard framework for analysis of the legality of a vertical merger.

26. There is recognition among academics, courts, and antitrust enforcement authorities alike that many vertical mergers create vertical integration efficiencies between purchasers and sellers.

27. The Clayton Act protects competition, not competitors.

28. The Supreme Court's insistence that each merger challenged under Section 7 be viewed in the context of its particular industry, and that the Clayton Act protects competition, not competitors, contravenes the notion that a significant level of foreclosure is itself the proscribed effect.

29. Complaint Counsel's contention that it is sufficient to prove that Illumina has an ability and incentive to take action to harm Grail's rivals post-Acquisition, in order to meet its

prima facie burden to show that a merger is likely to substantially lessen competition, is unsupported by applicable legal precedent.

30. Case law supports applying the real-world effects of contractual commitments to the determination of the potential for anticompetitive harm.

31. Antitrust theory and speculation cannot trump facts.

32. Economic theories about incentive are largely irrelevant absent a meaningful ability to act upon it.

33. The Open Offer effectively constrains Illumina from acting on its asserted ability and incentive to harm Grail's alleged rivals and rebuts the inference that Illumina's post-Acquisition ability and incentive to harm Grail's alleged rivals is likely to result in a substantial lessening of competition.

34. The evidence fails to prove that a likelihood of harm to Grail's alleged rivals is probable or imminent, and therefore the evidence cannot properly support a finding that a resulting substantial lessening of competition is probable or imminent.

35. Complaint Counsel has failed to prove its asserted *prima facie* case – that Illumina's post-Acquisition ability and incentive to advantage Grail to the disadvantage of Grail's alleged rivals is likely to result in a substantial lessening of competition in the relevant market for the research, development, and commercialization of MCED tests.

ORDER

For the reasons stated above, IT IS ORDERED that the Complaint be, and hereby is, DISMISSED.

ORDERED:

D. Michael Chappell
Chief Administrative Law Judge

Date: September 9, 2022