PUBLIC

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

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

RESPONDENTS' PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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PROPOSED FINDINGS OF FACT

I. INTRODUCTION

A. Illumina

1. Overview

1. Illumina is the global leader in sequencing- and array-based solutions for genetic and genomic analysis. (PX0061 (Illumina) at 5; PX0091 (Illumina) at 4.) Illumina's focus is on next-generation sequencing ("NGS") technology. NGS technology is a much higher throughput type of sequencing that allows for the simultaneous sequencing of millions or even billions of sequences in a single run. (Aravanis (Illumina) Tr. 1841.)

2. Illumina was incorporated in California in April 1998 and reincorporated in Delaware in July 2000. (PX0061 (Illumina) at 5.) Its principal executive offices are located in San Diego, California. (PX0061 (Illumina) at 5.)

3. 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 5; *see also* Berry (Illumina) Tr. 807–08.) Illumina's customers include leading genomic research centers, academic institutions, government laboratories, and hospitals, as well as pharmaceutineecal, biotechnology, commercial molecular diagnostic laboratories, and consumer genomics companies. (PX0061 (Illumina) at 5; *see also* deSouza (Illumina) Tr. 2313–15; Berry (Illumina) Tr. 807–09; [redacted]

4. Illumina's portfolio of integrated sequencing and microarray systems, consumables, and analysis tools is designed to accelerate and simplify genetic analysis. (PX0061 (Illumina) at 5.) This portfolio addresses the range of genomic complexity, price points, and throughput, enabling customers to select the best solution for their research or clinical application. (PX0061 (Illumina) at 5; PX0091 (Illumina) at 14.)

2. Illumina's Businesses

5. Illumina targets life sciences and clinical genomics segments and customers. (PX0061 (Illumina) at 6; deSouza (Illumina) Tr. 2318.)

6. Life Sciences. Historically, Illumina's core business has been in life sciences research. (PX0061 (Illumina) at 6.)

6.1 This includes laboratories associated with universities, research centers, and government institutions, along with biotechnology and pharmaceutical companies. (PX0061 (Illumina) at 6; *see also* deSouza (Illumina) Tr. 2312–13; [redacted]

6.2 Researchers at these institutions use Illumina's products and services for basic and translational research across a spectrum of scientific applications, including targeted, exome, and whole-genome sequencing, genetic variation; gene expression,

epigenetics, and metagenomics. (PX0061 (Illumina) at 6; *see also* deSouza (Illumina) Tr. 2313–15; [redacted]

6.3 Next-generation sequencing (NGS) technologies are being adopted due to their ability to sequence large sample sizes quickly, accurately, and cost-effectively, generating vast amounts of high-quality data. (PX0061 (Illumina) at 6.)

7. Illumina's products also serve various applied markets including consumer genomics and agrigenomics. (PX0061 (Illumina) at 6; *see also* deSouza (Illumina) Tr. 2318.)

7.1 For example, in consumer genomics, Illumina's customers use Illumina's technologies to provide personalized genetic data and analysis to individual consumers. (PX0061 (Illumina) at 6; PX0091 (Illumina) at 24.)

7.2 In agrigenomics, government and corporate researchers use Illumina's products and services to explore the genetic and biological basis for productivity and nutritional constitution in crops and livestock. (PX0061 (Illumina) at 6; *see also* Berry (Illumina) Tr. 807.) Researchers can identify natural and novel genomic variation and deploy genome-wide, marker-based applications to accelerate breeding and production of healthier and higher-yielding crops and livestock. (PX0061 (Illumina) at 6.)

8. Clinical Genomics. Illumina is focused on enabling translational and clinical markets through the introduction of best-in-class sequencing technology. (PX0061 (Illumina) at 6; *see also* [redacted]; PX0091 (Illumina) at 18.) Further, Illumina is developing sample-to-answer solutions to catalyze adoption in the clinical setting, including in reproductive and genetic health and oncology. (PX0061 (Illumina) at 6; *see also* PX7072 (deSouza (Illumina) IHT at 157–58).)

9. *Reproductive Health.* In reproductive health, Illumina's primary focus is driving the adoption of noninvasive prenatal testing (NIPT) globally through Illumina's technology, which identifies fetal chromosomal abnormalities by analyzing cell-free DNA in maternal blood. (PX0061 (Illumina) at 6; RX2264 (Illumina) at 50); PX0091 (Illumina) at 20–21.)

10. *Rare and Undiagnosed Disease.* Illumina's NGS technology is also accelerating rare and undiagnosed disease research to discover the genetic causes of inherited disorders by assessing many genes simultaneously. (PX0061 (Illumina) at 6; *see also* deSouza (Illumina) Tr. 2326–27, PX0091 (Illumina) at 22.) Using NGS can reduce costs compared to traditional methods of disease diagnosis, which are often expensive and inconclusive while requiring extensive testing. (PX0061 (Illumina) at 6.)

11. *Oncology.* Cancer is a disease of the genome, and the goal of cancer genomics is to identify genomic changes that transform a normal cell into a cancerous one. (PX0061 (Illumina) at 6.) Understanding these genomic changes will improve diagnostic accuracy, increase understanding of the prognosis, and enable oncologists to target therapies to individuals. (PX0061 (Illumina) at 6; *see also* Aravanis (Illumina) Tr. 1828.)

11.1 There are a variety of NGS applications in oncology including: research applications where people sequence cancer cells to understand cancer biology, how

cancer is behaving and how to treat it; therapy selection applications where a tumor is sequenced to understand whether or not any of the mutations that are present might be targetable by a drug, monitoring or minimal residual disease where the goal is to look for cancer signals in the blood in order to determine how effective a treatment is and early cancer detection where cancer is detected in asymptomatic patients. (Aravanis (Illumina) Tr. 1843.)

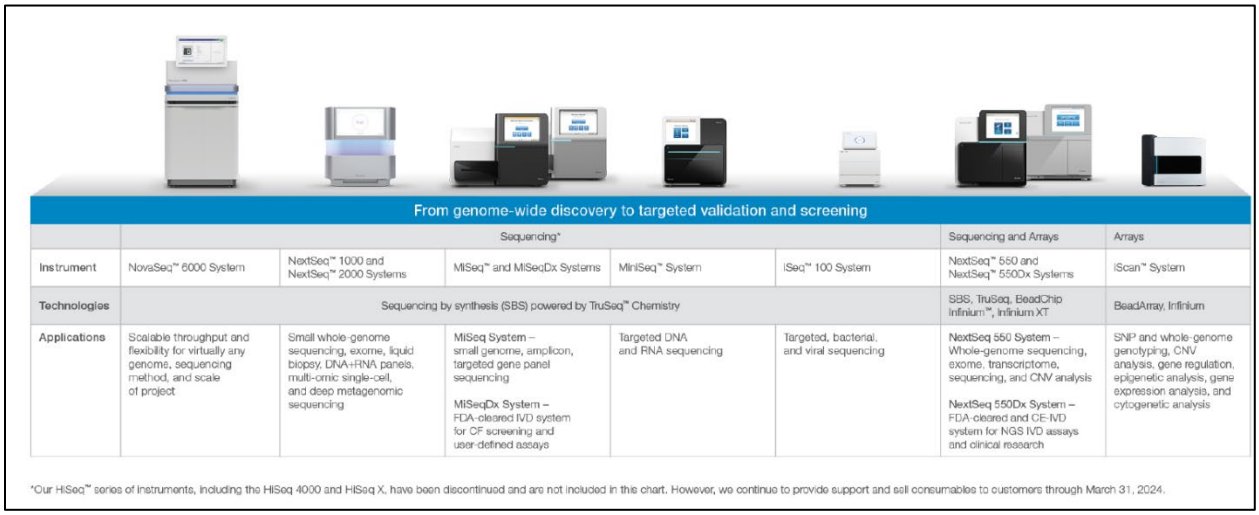
11.2 Customers in the translational and clinical oncology markets use Illumina's products to perform research that may help identify individuals who are genetically predisposed to cancer and to identify molecular changes in a tumor. (PX0061 (Illumina) at 6; *see also* Berry (Illumina) Tr. 814–22; PX0091 (Illumina) at 17; **{PX2035 (Illumina) at 16, 18–19.)}** Illumina believes that circulating tumor DNA (ctDNA) will become an important clinical tool for managing oncology patients during all stages of tumor progression. (PX0061 (Illumina) at 6–7; [redacted]

11.3 Illumina's technology is being used to research the implications of ctDNA in treatment determination, treatment monitoring, minimal residual disease, and asymptomatic screening. (PX0061 (Illumina) at 7; *see also* Aravanis (Illumina) Tr. 1843; PX0091 (Illumina) at 19.)

3. Principal Products, Services and Technologies

12. Illumina's unique technology platforms support the scale of experimentation necessary for population-scale studies, genome-wide discovery, target selection, and validation studies. (PX0061 (Illumina) at 7; Berry (Illumina) Tr. 823–26.)

Figure 1: Illumina Platform Overview



13. Customers use Illumina's products to analyze the genome at all levels of complexity, from targeted panels to whole-genome sequencing. (PX0061 (Illumina) at 7.) A large and dynamic Illumina user community has published tens of thousands of customer-authored scientific papers using Illumina's technologies. (PX0061 (Illumina) at 7.) Through rapid innovation, Illumina is changing the economics of genetic research, enabling projects that

were previously considered impossible, and supporting clinical advances towards precision medicine. (PX0061 (Illumina) at 7.)

14. Most of Illumina's product sales consist of instruments and consumables, which include reagents, flow cells, and microarrays, based on Illumina's proprietary technologies. (PX0061 (Illumina) at 7; *see also* Aravanis (Illumina) Tr. 1844–47; Berry (Illumina) Tr. 826–28.)

15. Illumina also performs various services for its customers. (PX0061 (Illumina) at 7; *see also* [redacted], 865–66; PX7076 (Berry (Illumina) Dep. at 87–92); PX7063 (Berry (Illumina) IHT at 35–36.) In 2020, 2019, and 2018, instrument sales represented 13%, 15%, and 17%, respectively, of total revenue; consumable sales represented 71%, 68%, and 65%, respectively, of total revenue; and services represented 16%, 17%, and 18%, respectively, of total revenue. (PX0061 (Illumina) at 7.)

16. Sequencing. DNA sequencing is the process of determining the order of nucleotide bases (A, C, G, or T) in a DNA sample. (PX0061 (Illumina) at 7; *see also* Aravanis (Illumina) Tr. 1828.)

16.1 Illumina's portfolio of sequencing platforms represents a family of systems that Illumina believes set the standard for productivity, cost-effectiveness, and accuracy among NGS technologies. (PX0061 (Illumina) at 7; deSouza (Illumina) Tr. 2327–2328; Berry (Illumina) Tr. 809–811.)

17. Customers use Illumina's platforms to perform whole-genome, de novo, exome and RNA sequencing, as well as targeted resequencing of specific gene regions and genes. (PX0061 (Illumina) at 7.)

17.1 Whole-genome sequencing determines the complete DNA sequence of an organism. (PX0061 (Illumina) at 7; RX2264 (Illumina) at 76.)

17.2 In de novo sequencing, the goal is to sequence and assemble the genome of that sample without using information from prior sequencing of that species. (PX0061 (Illumina) at 7.)

17.3 In targeted resequencing, a portion of the sequence of an organism is compared to a standard or reference sequence from previously sequenced samples to identify genetic variation. (PX0061 (Illumina) at 7; RX2264 (Illumina) at 74.)

18. Illumina's DNA sequencing technology is based on its proprietary reversible terminator-based sequencing chemistry, referred to as sequencing by synthesis (SBS) biochemistry. (PX0061 (Illumina) at 7; RX2264 (Illumina) at 154)

18.1 SBS tracks the addition of labeled nucleotides as the DNA chain is copied in a massively parallel fashion. (PX0061 (Illumina) at 7; RX2264 (Illumina) at 154.)

18.2 Illumina's SBS sequencing technology provides researchers with a broad range of applications and the ability to sequence even large mammalian genomes in a few

days rather than weeks or years. (PX0061 (Illumina) at 7–8; *cf.* RX2264 (Illumina) at 156.)

19. Illumina's sequencing platforms can generate between 500 megabases (Mb) and 6.0 terabases (Tb) (equivalent to approximately 48 human genomes) of genomic data in a single run, depending on the instrument and application. (PX0061 (Illumina) at 8; *see also* Aravanis (Illumina) Tr. 1841.)

20. There are different price points per gigabase (Gb) for each instrument, and for different applications, which range from small-genome, amplicon, and targeted gene-panel sequencing to population-scale whole human genome sequencing. (PX0061 (Illumina) at 8; *see also* **{deSouza (Illumina) Tr. 2265.)}**

21. Since Illumina launched its first sequencing system in 2007, its systems have reduced the cost of sequencing by a factor of more than 10,000. In addition, the sequencing time per Gb has dropped by a factor of approximately 12,000. (PX0061 (Illumina) at 8, 14.)

22. In 2018, 2019, and 2020, total sequencing revenue comprised 83%, 87%, and 89%, respectively, of total revenue. (PX0061 (Illumina) at 8; *see also* PX0091 (Illumina) at 11.)

23. [redacted]

24. Arrays. Arrays are used for a broad range of DNA and RNA analysis applications, including SNP genotyping, CNV analysis, gene expression analysis, and methylation analysis, and enable the detection of millions of known genetic markers on a single array. (PX0091 (Illumina) at 15; *see also* PX7072 (deSouza (Illumina) IHT at 55).)

24.1 Arrays are the primary technology used in consumer genomics applications. (PX0061 (Illumina) at 8; *see also* PX7076 (Berry (Illumina) Dep. at 158); *cf.* Berry (Illumina) Tr. 805.)

24.2 Illumina's BeadArray technology combines microscopic beads and a substrate in a proprietary manufacturing process to produce arrays that can perform many assays simultaneously. (PX0061 (Illumina) at 8; *see* PX0091 (Illumina) at 16.) This facilitates large-scale analysis of genetic variation and biological function in a unique, high-throughput, cost-effective, and flexible manner. (PX0061 (Illumina) at 8; *see* PX0091 (Illumina) at 16.)

24.3 In 2018, 2019 and 2020, total array revenue comprised 17%, 13% and 11%, respectively, of total revenue. (PX0061 (Illumina) at 8; *see* PX0091 (Illumina) at 16.)

25. Consumables. Illumina has developed various library preparation and sequencing kits to simplify workflows and accelerate analysis. (PX0061 (Illumina) at 8; *see also* deSouza (Illumina) Tr. 2313, 2355–56; Berry (Illumina) Tr. 826–27, 844–85, 928; PX0091 (Illumina) at 15; [redacted].)

25.1 Illumina's sequencing applications include whole-genome sequencing kits, which sequence entire genomes of any size and complexity, and targeted resequencing kits, which can sequence exomes, specific genes, RNA or other genomic regions of interest. (PX0061 (Illumina) at 8; *see also* [redacted]; Berry (Illumina) Tr. 822–24; Aravanis (Illumina) Tr. 1958–59; [redacted]); PX0091 (Illumina) at 21.)

25.2 Illumina's sequencing kits maximize the ability of its customers to characterize the target genome accurately and are sold in various configurations, addressing a wide range of applications. (PX0061 (Illumina) at 8; *see also* [redacted]; PX7076 (Berry (Illumina) Dep. at 67–68).)

25.3 Customers use Illumina's array-based genotyping consumables for a wide range of analyses, including diverse species, disease-related mutations and genetic characteristics associated with cancer. (PX0061 (Illumina) at 8; *see also* deSouza (Illumina) Tr. 2325–26; PX0091 (Illumina) at 24; PX7076 (Berry (Illumina) Dep. at 158).)

25.4 Customers can select from a range of human, animal, and agriculturally relevant genome panels or create their own custom arrays to investigate millions of genetic markers targeting any species. (PX0061 (Illumina) at 8; *see also* PX7076 (Berry (Illumina), Dep. at 163–64).)

26. Services. Illumina provides whole-genome sequencing, genotyping, NIPT, and product support services. (PX0061 (Illumina) at 9; *see also* Berry (Illumina) Tr. 866–68; [redacted] at 24, [redacted].)

27. Illumina's CLIA-certified, CAP-accredited laboratory provides human whole-genome sequencing services. (PX0061 (Illumina) at 9; *see also* [redacted] PX7073 (Aravanis (Illumina) IHT at 32).) Using Illumina's services, customers can perform whole-genome sequencing projects and microarray projects (including large-scale genotyping studies and whole-genome association studies). (PX0061 (Illumina) at 9; *see also* PX0091 (Illumina) at 24.)

28. Illumina also provides NIPT services through its partner laboratories that direct samples to Illumina on a test send-out basis in Illumina's CLIA-certified, CAP-accredited laboratory. (PX0061 (Illumina) at 9; PX7063 (Berry (Illumina) IHT at 24, 207–08).)

29. In addition, Illumina also offers support services to customers who have purchased its products. (PX0061 (Illumina) at 9; *see also* PX7076 (Berry (Illumina) Dep. at 58–59, 87–88, 108–109); PX7063 (Berry (Illumina) IHT at 14).)

30. Clinical Applications. Through its Lab Services division, Illumina offers clinical sequencing services, including NIPT testing, direct-to-consumer ("DTC") genomic testing, more recently, COVID testing, and its TruSight series of therapy selection tests, including TSO-500. (*See* PX0091 (Illumina) at 17–24.)

30.1 The first COVID-19 viral sequence was on an Illumina machine and now genomic surveillance has emerged as a critical tool in the global fight against the pandemic, with over 70 countries now using Illumina platforms for COVID-19 variant tracking. (PX0377 (Illumina) at 2; *see also* Aravanis (Illumina) Tr. 1950–51; [redacted]

4. Research and Development, Marketing and Distribution

31. Research and Development. Illumina has historically made substantial investments in research and development. (PX0061 (Illumina) at 9; Aravanis (Illumina) Tr. 1949–50; deSouza (Illumina) Tr. 2354–55.) Illumina's research and development efforts prioritize continuous innovation coupled with product evolution. (PX0061 (Illumina) at 9; deSouza (Illumina) Tr. 2328–30, 2353; Aravanis (Illumina) Tr. 1948.)

31.1 Illumina's research and development expense in 2020, 2019, and 2018 was $682 million, $647 million, and $623 million, respectively. (PX0061 (Illumina) at 9; Aravanis (Illumina) Tr. 1948; deSouza (Illumina) Tr. 2354.)

31.2 Illumina expects research and development expense to increase during 2021 to support business growth and continuing expansion in research and product-development efforts. (PX0061 (Illumina) at 9.)

31.3 Illumina's research and development efforts have enabled Illumina to dramatically lower the cost of sequencing over time. (deSouza (Illumina) Tr. 2327–31.)

32. Marketing and Distribution. Illumina markets and distributes its products directly to customers in North America, Europe, Latin America, and the Asia-Pacific region. (PX0061 (Illumina) at 9; *cf.* deSouza (Illumina) Tr. 2373–74; PX7076 (Berry (Illumina) Dep. at 50).) In addition, Illumina sells through life-science distributors in certain markets within Europe, the Asia-Pacific region, Latin America, the Middle East, and Africa. (PX0061 (Illumina) at 9; *see also* PX7107 (deSouza (Illumina) Dep. at 79–80).)

5. Competition

33. Illumina faces intense competition, which could render is products obsolete, result in significant price reductions, or substantially limit the volume of products that Illumina sells. (PX0061 (Illumina) at 10; *see also* deSouza (Illumina) Tr. 2331–32, 2385–86; Aravanis (Illumina) Tr. 1855–58; [redacted]

34. Illumina competes with third parties that manufacture and market products and services for analysis of genetic variation and biological function. (PX0061 (Illumina) at 10, 14.) For instance, these competitors offer products and services for sequencing, SNP genotyping, gene expression, and molecular diagnostics markets, including PCR platforms, microarray platforms and proteomics platforms. (PX0061 (Illumina) at 10; *see also* deSouza (Illumina) Tr. 2318–20; *cf.* Berry (Illumina) Tr. 813.)

35. In some cases, Illumina competes for the resources its customers allocate for purchasing a wide range of sequencing and non-sequencing products used to analyze genetic

variation and biological function, some of which are complementary or adjacent to Illumina's own; in other cases, Illumina's products face direct competition as customers choose among sequencing and non-sequencing products that are designed to address the same use case or answer the same biological question. (PX0061 (Illumina) at 10; *see also* deSouza (Illumina) Tr. 2323–26;).)

36. Some of Illumina's competitors have, or will have, substantially greater financial, technical, research, and other resources than Illumina does, along with larger, more established marketing, sales, distribution, and service organizations. (PX0061 (Illumina) at 10; *see also* deSouza (Illumina) Tr. 2311–12; *cf.* Aravanis (Illumina) Tr. 1857–61.) In addition, they may have greater name recognition than Illumina does in the markets Illumina addresses, and in some cases a larger installed base of systems. (PX0061 (Illumina) at 10.)

37. Illumina expects new competitors to emerge and the intensity of competition to increase as existing companies develop new or improved products and as new companies enter the market with new technologies. (Aravanis (Illumina) Tr. 1860–61, 1866; Berry (Illumina) Tr. 813; PX7079 (Flatley (Illumina) Dep. at 57–58); PX2017 (Illumina) at 40, 43; ; PX0061 (Illumina) at 10, 15.) One or more of Illumina's competitors may render one or more of Illumina's technologies obsolete or uneconomical. (PX0061 (Illumina) at 15; *see also* Aravanis (Illumina) Tr. 1854–58.)

38. In the NGS space in particular, Illumina expects there will be intensifying competition in the near future both from incumbent players and new entrants. (deSouza (Illumina) Tr. 2318–20.)

B. GRAIL

1. Overview

39. GRAIL is a healthcare company focused on saving lives and improving health by pioneering new technologies for early cancer detection. (PX0043 (GRAIL) at 4.) Using its platform technology, GRAIL has developed a multi-cancer early detection blood test that has demonstrated in clinical studies the ability to detect more than 50 types of cancer, across all stages, and localize the cancer signal with a high degree of accuracy, from a single blood draw. (PX0043 (GRAIL) at 4.)

2. Formation

40. In February 2013, Illumina acquired Verinata, a company that had developed a noninvasive prenatal test ("NIPT") for fetal chromosomal abnormalities using a blood sample. (RX3337 (Illumina) at 1.) In the first 100,000 women that received the non-invasive prenatal test from Verinata, some unusual signs were identified: in a handful of cases, a signal was detected in the mother's blood that was initially believed to be a false signal indicating a genetic abnormality in the fetus. (Aravanis (Illumina) Tr. 1868–69; *see generally* RX2547 (Bianchi et al., 2015).)

41. Meredith Halks-Miller, the laboratory director at Illumina, approached Illumina's leadership about these unusual signals. (PX7048 (Klausner (GRAIL) IHT at 49–50.) Illumina

formed a team and a program to evaluate these signals to follow up with patients and prescribing physicians and discovered that these women had undiagnosed cancer. (Aravanis (Illumina) Tr. 1868–69, 1873–74; PX7079 (Flatley (Illumina) Dep. at 35–37; PX7048 (Klausner (GRAIL) IHT at 49–50.) This discovery led to the realization that early cancer could be detected in the blood. (Aravanis (Illumina) Tr. 1868–69, 1873–74; PX7079 (Flatley (Illumina) Dep. at 35–37; PX7048 (Klausner (GRAIL) IHT at 49–50.)

42. At the same time, Illumina was developing a liquid biopsy technology to look at cancer signals in late-stage cancer for the purposes of therapy selection for advanced cancer patients. (Aravanis (Illumina) Tr. 1869.) There was data from that project which applied to some early-stage cancer samples that also suggested early-stage cancer detection might be possible. (Aravanis (Illumina) Tr. 1869.)

43. Because of the aforementioned discoveries, Illumina decided to pursue the early detection of cancer in the blood. (Aravanis (Illumina) Tr. 1868–69; PX7079 (Flatley (Illumina) Dep. at 35–37; PX7048 (Klausner (GRAIL) IHT) at 49–50.)

44. In 2015, 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; PX0036 (GRAIL) at 5; PX7079 (Flatley (Illumina) Dep. at 35–37); PX7104 (Aravanis (Illumina) Dep. at 159–160).)

45. It was a "moonshot" ambition—as Illumina's then-CEO, Jay Flatley (Illumina), put it at the time, "GRAIL is going after a much more daunting technology, scientific and biological problem that [no other companies] to [Illumina's] knowledge . . . have even begun to address". (RX3970 (Illumina) at 10.)

46. By forming GRAIL, Illumina hoped to "[a]ccelerat[e] development of the ctDNA cancer screening market by 10 years". (RX1914 (Illumina) at 7.) Thus, from the start, Illumina viewed GRAIL as an extension of its core goal of expanding and accelerating adoption of NGS technology in new applications, paving the way for NGS-based screening tests and spurring innovation. (Aravanis (Illumina) Tr. 1870–71, 1905–1907; *cf.* [redacted]

47. To position GRAIL for its moonshot objective, Illumina seeded GRAIL with the talent, R&D capabilities, development plans and data it would need to investigate how to use NGS technology for multi-cancer early detection through foundational, population-scale trials. (PX7107 (deSouza (Illumina) Dep. at 182–83).)

48. However, GRAIL would also require a substantial amount of capital to conduct the foundational clinical trials necessary to build the data sets for its machine learning algorithm. (PX7079 (Flatley (Illumina) Dep. at 92–94); PX7065 (Aravanis (Illumina) Dep. at 62–64).)

49. Given the high risks of failure at this early stage, 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 "moonshot" objective. (Aravanis (Illumina) Tr. 1772–73; PX7079 (Flatley (Illumina) Dep. at 92–94).)

49.1 To that end, in February 2017, Illumina completed a capital raise in connection with which Illumina reduced its stake in GRAIL to less than 20%. (RX3972 (Illumina) at 2; RX3984 (Illumina) at 14; *see* deSouza (Illumina) Tr. 2202.)

50. Although Illumina reduced its investment in GRAIL in 2017, Illumina remained heavily invested in GRAIL's success. In addition to its equity stake in GRAIL (around 12% of GRAIL's outstanding shares on a fully diluted basis before the transaction closed), Illumina has a long-term agreement to supply GRAIL with NGS instruments and reagents for its genomic testing needs, and also had the right to receive approximately **{7%}** of future net sales of any GRAIL oncology products or services. [redacted]; *see also* Aravanis (Illumina) Tr. 1876–77; RX3984 (Illumina) at 14–15.)

3. **GRAIL Today**

51. By late 2020, GRAIL had built a multi-disciplinary organization of scientists, engineers, and physicians to use the power of next-generation sequencing (NGS), population-scale clinical studies, and state-of-the-art computer science and data science to overcome one of medicine's greatest challenges: detecting cancer early, when it can be cured. (PX0043 (GRAIL) at 4; *see also* Aravanis (Illumina) Tr. 1907; deSouza (Illumina) Tr. 2334–35.)

52. Using GRAIL's platform technology, GRAIL developed a multi-cancer early detection blood test that has demonstrated in clinical studies the ability to detect more than 50 types of cancer, across all stages, and localize the cancer signal with a high degree of accuracy, from a single blood draw. (PX0043 (GRAIL) at 4; *see also* Aravanis (Illumina) Tr. 1892, 1897; deSouza (Illumina) Tr. 2335; PX7104 (Aravanis (Illumina) Dep. at 238).)

53. GRAIL undertook a rigorous, comprehensive, multi-omic discovery approach to explore and identify the most promising biological hallmarks of cancer. (PX0043 (GRAIL) at 4, 96; *see also* Aravanis (Illumina) Tr. 1880–81, 1916–18.)

53.1 GRAIL invested significant capital and resources in its foundational studies, which have collectively enrolled approximately 115,000 participants, to build what GRAIL believes are the largest linked datasets of genomic and clinical data in the cancer field. (PX0043 (GRAIL) at 4, 96; *see also* PX7083 (Bishop (GRAIL) Dep. at 63); PX7069 (Bishop (GRAIL) IHT at 191–92).)

54. In order to determine the optimal means of cancer detection, GRAIL compared the performance of three different NGS approaches—mutations, chromosomal alterations and methylation patterns—in head-to-head studies. (PX0043 (GRAIL) at 96; *see also* Aravanis (Illumina) Tr. 1880–81; [redacted]

55. While all three markers were capable of detecting cancer, GRAIL found that methylation profiling yielded significantly better results for cancer detection than was observed by interrogating mutations or chromosomal alterations, alone or in combination. (PX0043 (GRAIL) at 96; *see also* Aravanis (Illumina) Tr. 1881; Ofman (GRAIL) Tr. 3291–92.)

56. After comprehensive analysis of whole-genome methylation patterns, GRAIL discovered highly informative and low-noise methylation regions for cancer signal detection and localization, leading it to develop a targeted methylation approach with superior performance and lower costs than whole-genome methylation. (PX0043 (GRAIL) at 96; *see also* Aravanis (Illumina) Tr. 1891; Bishop (GRAIL) Tr. 1373; PX7104 (Aravanis (Illumina) Dep. at 182–83, 188); PX7072 at 55,

57. This approach helps solve a core problem in detecting cancer early in asymptomatic individuals: the low level of cancer signal circulating in the blood. (PX0043 (GRAIL) at 96;); *see also* PX0036 (GRAIL) at 7.)

58. While methylation profiling is the approach GRAIL is using with Galleri, it continues to evaluate multi-omic approaches including evaluation of additional analytes and biofluids. (PX0043 (GRAIL) at 96; ; Ofman (GRAIL) Tr. 3301, 3303–04;

4. **GRAIL's Galleri Test**

59. GRAIL's multi-cancer early detection test, Galleri, is designed as a screening test for asymptomatic individuals over 50 years of age. (PX0043 (GRAIL) at 96; PX7083 (Bishop (GRAIL) Dep. at 25); PX7069 (Bishop (GRAIL) IHT at 149).) GRAIL commercially launched Galleri in May 2021 as a laboratory developed test (LDT.) (Aravanis (Illumina) Tr. 1892; Freidin Tr. 2968–69.)

60. Galleri has the potential to transform cancer care and population health. (PX0043 (GRAIL) at 5, 97; *see also* Ofman (GRAIL) Tr. 3279–80; PX7092 (Ofman (GRAIL) Dep. at 22.)

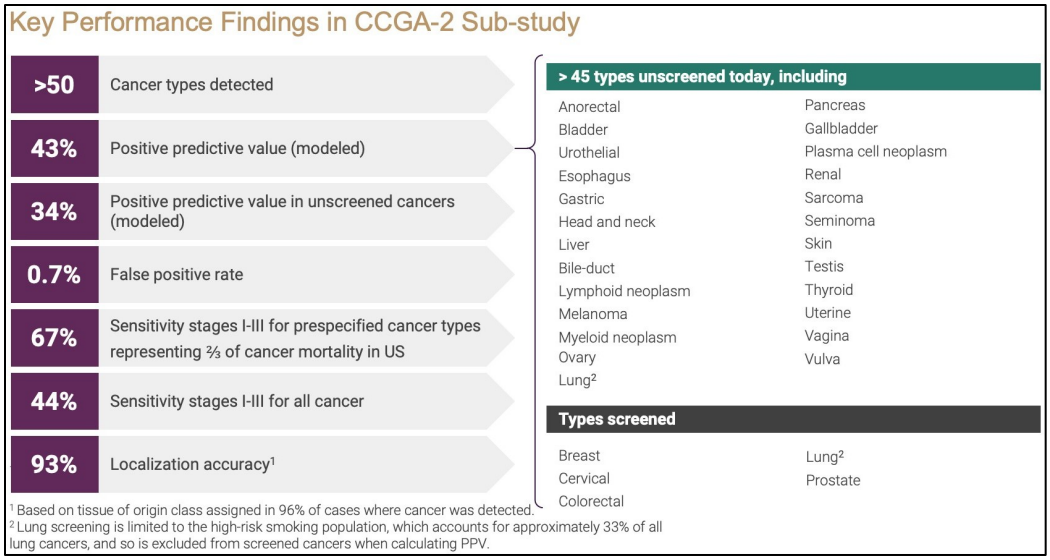
61. GRAIL has demonstrated that the Galleri test can identify over 50 types of cancers, over 45 of which lack recommended screenings. (PX0043 (GRAIL) at 97, 5; *see also* Ofman (GRAIL) Tr. 3312; Section I.A *infra*).)

62. Data shows that when Galleri detects cancer, it is also able to localize the cancer signal with high accuracy. (*See* Bishop (GRAIL) Tr. 1387, .)

62.1 In the second sub-study (CCGA-2) of GRAIL's foundational Circulating Cell-Free Genome Atlas Study (CCGA), when a cancer signal was detected, an earlier version of Galleri localized the cancer signal in 96% of the samples, and of these, Galleri correctly localized the cancer signal in 93%. (PX0043 (GRAIL) at 5, 97;

62.2 Early data also suggested that indolent cancers are unlikely to be detected by Galleri, potentially reducing the problem of treating over-diagnosed cancers. (PX0043 (GRAIL) at 97, 5; *see also* Ofman (GRAIL) Tr. 3289–3290.)

62.3 Below is a summary of the results from the CCGA study (GRAIL S-1 Registration Statement) at 97, 5):

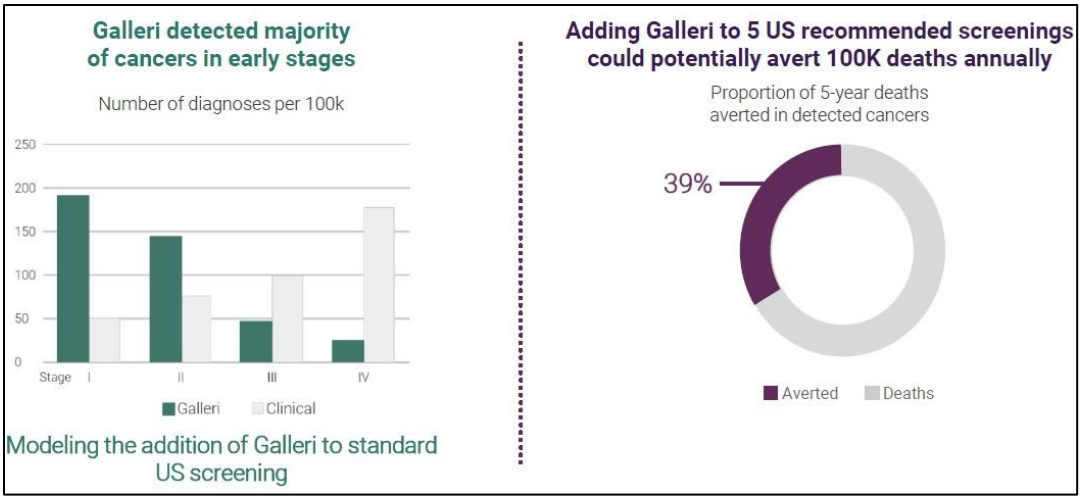


62.4 In those over age 50, Galleri demonstrated a 66% detection rate of Stage II cancers for which there are no current recommended screenings. (PX0043 (GRAIL) at 98.)

62.5 Galleri could be integrated directly into the existing healthcare pathways delivered to 40 million patients a year who are already going to a physician for their standard-of-care cancer screening. (PX0043 (GRAIL) at 98.)

63. GRAIL has developed a cancer epidemiology forecast model to estimate the potential impact of multi-cancer early detection testing on cancer stage shift and mortality reduction. (PX0043 (GRAIL) at 6, 98.)

64. Based on the performance of Galleri in the CCGA-2 study and using 2006 to 2015 SEER data for ages 50–79, GRAIL estimates that by adding Galleri to diagnosis by usual care, there is potential to detect nearly 70% of cancers resulting in death within five years at an earlier stage (excluding cancers that grow too quickly to be detected by any screening program), which would translate to averting potentially 100,000 deaths annually, or 39% of the five-year deaths expected if not for early detection by Galleri. (PX0043 (GRAIL) at 6, 98; [redacted])



65. Galleri has the potential to dramatically increase population early cancer detection, reducing the attendant morbidity, mortality and costs of late-stage cancer diagnoses. (PX0043 (GRAIL) at 6, 98; *see also* Ofman (GRAIL) Tr. 3280–81; PX7069 (Bishop (GRAIL) IHT at 24, 204.)

66. It has been estimated that a 1% reduction in cancer mortality in the United States would be worth $695 billion in today's dollars from increased quality of life, productivity and survival. (PX0043 (GRAIL) at 6, 98.)

66.1 This estimate does not include intangible benefits such as the decreased emotional burden to family, friends and caregivers. (PX0043 (GRAIL) at 6, 98.)

5. **Barriers to Commercial Success**

67. While GRAIL has enormous promise, it must overcome several barriers to achieve success as it shifts its focus from research and development to commercialization. (PX0043 (GRAIL) at 20–69; Bishop (GRAIL) Tr. 1413–14; PX7069 (Bishop (GRAIL) Dep. at 186).)

68. GRAIL is subject to numerous business and industry risks. For example:

68.1 GRAIL is operating in a rapidly evolving field and has a limited operating history, which makes it difficult to evaluate GRAIL's current business and predict GRAIL's future performance. (PX0043 (GRAIL) at 11, 20; *see also* Bishop (GRAIL) Tr. 1414.)

68.2 GRAIL may not be successful in transitioning its products to a new or enhanced version or iteration, since product development involves a lengthy and complex process and GRAIL may be unable to commercialize, validate, or improve performance of any of its products on a timely basis, or at all. (PX0043 (GRAIL) at 11, 20; *see also* Bishop (GRAIL) Tr. 1415.)

68.3 GRAIL has only limited sales and marketing infrastructures and no experience as a company in the sale, marketing, and distribution of screening or diagnostic tests. (PX0043 (GRAIL) at 35; *see also* Bishop (GRAIL) Tr. 1420–21.)

68.4 Factors that may inhibit GRAIL's efforts to broadly commercialize any of its products include:

- GRAIL's inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to persuade adequate numbers of customers, including healthcare systems and healthcare providers, to use GRAIL's products;
- the inability to price GRAIL's products at a price point sufficient to ensure an adequate and attractive level of profitability;
- GRAIL's inability to effectively market to, collaborate with, and secure coverage and reimbursement from third-party payors;
- GRAIL's failure to comply with applicable regulatory requirements governing the sale, marketing, reimbursement, and commercialization of its products; and
- unforeseen costs and expenses associated with creating an independent commercial organization. (PX0043 (GRAIL) at 35; *see also* Bishop (GRAIL) Tr. 1420–21.)

68.5 GRAIL is at a delicate and risky inflection point as it transitions from a company that up until recently was exclusively an R&D company; GRAIL will need to build different types of teams; serve customers; continue to develop technologies, including screening technologies and other new types of tests. (Bishop (GRAIL) Tr. 1367–68.)

68.6 GRAIL has incurred significant net losses in each period since GRAIL's inception and anticipate that it will continue to incur net losses for the foreseeable future. (PX0043 (GRAIL) at 11, 20.)

68.7 But for the Transaction, GRAIL may have failed to obtain additional financing and may be unable to expand its commercialization efforts with respect to Galleri and DAC and develop additional products. (PX0043 (GRAIL) at 29; Bishop (GRAIL) Tr. 1372; 1418; Freidin (GRAIL) Tr. 3052–53.)

68.8 [redacted]

68.9 Clinical trials are necessary to validate GRAIL's investigational products to launch them as LDTs and to support future product submissions to FDA. (PX0043 (GRAIL) at 11, 22.) The clinical trial process is lengthy and expensive with uncertain outcomes, and often requires the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. (PX0043 (GRAIL) at 11, 22; *see also* Aravanis (Illumina) Tr. 1878–80; PX7130 (Deverka Dep. at 72, 89, 92); *cf.* [redacted]

68.10 GRAIL has encountered delays and may encounter substantial delays in its clinical studies, including due to COVID-19, and may therefore be unable to complete its clinical studies on the timelines it expects, if at all, which could materially and adversely impact its ability to launch its products and seek regulatory clearance or approval. (PX0043 (GRAIL) at 11, 22; [redacted]; PX7104 (Aravanis (Illumina) Dep. at 75–76, 268–69); [redacted]

68.11 GRAIL is building a new laboratory to ensure capacity to meet future demand and reduce the cost of its test; is investing in robotics and other improvements and will need to obtain regulatory approval for these processes. (Bishop (GRAIL) Tr. 1368–69.)

68.12 Even if GRAIL commercially launches its products, it may fail to achieve the degree of market acceptance necessary for commercial success. (PX0043 (GRAIL) at 11, 24; PX7066 (Freidin (GRAIL) IHT at 97).)

68.13 GRAIL has never generated revenue from product sales, does not expect any near-term revenue to offset its ongoing operating expenses, and may never be profitable. (PX0043 (GRAIL) at 11, 25–26; PX7069 (Bishop (GRAIL) IHT at 191); [redacted]

68.14 GRAIL may be unable to develop and commercialize new products. (PX0043 (GRAIL) at 11, 26–27; *see also* Bishop (GRAIL) Tr. 1414–15.)

68.15 One of the key elements of GRAIL's strategy is to expand access to GRAIL's tests by pursuing reimbursement and coverage from third-party payors. (PX0043 (GRAIL) at 27; *see also* Bishop (GRAIL) Tr. 1416–17.)

68.16 If GRAIL's products do not receive adequate coverage and reimbursement from third-party payors, its ability to expand access to its tests beyond its initial sales channels and its overall commercial success will be limited. (PX0043 (GRAIL) at 27; Bishop (GRAIL) Tr. 1416–18.)

68.17 If GRAIL's competitors' products do not perform as intended, the market for GRAIL's products could be impaired. (PX0043 (GRAIL) at 28.)

69. GRAIL is subject to regulation and legal compliance risks. For example:

69.1 GRAIL launched Galleri initially as an LDT. (PX0043 (GRAIL) at 41; *see also* Ofman (GRAIL) Tr. 3317, [redacted]; PX7108 (Freidin (GRAIL) Dep. at 96); PX7069 (Bishop (GRAIL) Dep. at 65).)

69.2 If FDA were to end or modify its current policy of enforcement discretion on LDTs, or if Congress were to enact legislation that changes the current requirements for LDTs, GRAIL may no longer be able to market Galleri without FDA premarket approval, which could result in substantial costs and delays. (PX0043 (GRAIL) at 41; *see also* Ofman (GRAIL) Tr. 3317–20; *cf.* Bishop (GRAIL) Tr. 1323, 1345.)

69.3 The regulatory clearance or approval processes of FDA and comparable foreign regulatory authorities are lengthy, time-consuming, and unpredictable. (PX0043 (GRAIL) at 43; *see also* Bishop (GRAIL) Tr. 1411); PX7069 (Bishop (GRAIL) IHT at 64–65); PX7048 (Klausner (GRAIL) IHT at 119–20); *cf.* [redacted])

69.4 If GRAIL is ultimately unable to obtain any necessary or desirable regulatory approvals or clearances, or if such approvals or clearances are significantly delayed, its business will be substantially harmed. (PX0043 (GRAIL) at 43; PX7104 (Aravanis (Illumina) Dep. at 289); [redacted]

69.5 GRAIL's multi-cancer detection tests are a new approach to cancer screening, which present a number of novel and complex issues for FDA review. (PX0043 (GRAIL) at 21, 44; [redacted]) Because FDA has never cleared or approved a multi-cancer detection test, it is difficult to predict what information GRAIL will need to submit to obtain pre-market approval (PMA) from FDA for a proposed intended use, or if GRAIL will be able to obtain such approval on a timely basis or at all. (PX0043 (GRAIL) at 21, 44; [redacted]); PX7065 (Aravanis (Illumina) IHT at 177); Bishop (GRAIL) Tr. 1421.)

69.6 GRAIL's use and disclosure of personal information, including individually identifiable health information, biologic samples and related data are subject to federal, state and foreign privacy and security regulation. (PX0043 (GRAIL) at 45.) Data privacy rules are evolving and new legislation concerning privacy and data use may limit GRAIL's ability to use such data and specimens. (PX0043 (GRAIL) at 45.) GRAIL's failure to comply with privacy and security requirements or to adequately secure such information could result in significant liability, administrative or governmental penalties, and/or reputational harm and, in turn, substantial harm to its business and results of operations. (PX0043 (GRAIL) at 45.)

69.7 If GRAIL or its partners fail to comply with federal, state, and foreign laboratory and other applicable licensing and registration requirements, GRAIL could be prevented from performing its tests or experience disruptions to its business. (PX0043 (GRAIL) at 47; Ofman (GRAIL) Tr. 3317–18; PX7092 (Ofman (GRAIL) Dep. at 178–79); PX7069 (Bishop (GRAIL) Dep. at 196); *cf.* PX7104 (Aravanis (Illumina) Dep. at 74–76).)

69.8 Any product for which GRAIL obtains regulatory clearance or approval will be subject to extensive ongoing regulatory requirements, and GRAIL may be subject to penalties if it or its partners fail to comply with regulatory requirements or if GRAIL experiences unanticipated problems with its products. (PX0043 (GRAIL) at 49.)

69.9 To obtain and maintain FDA approvals or clearances, GRAIL's products will need to be manufactured in accordance with federal and state regulations, and it could be forced to recall its devices or terminate production if it or its partners fail to comply with these regulations. (PX0043 (GRAIL) at 50–51.)

69.10 Healthcare reform measures, including recently enacted legislation reforming the U.S. healthcare system, and data protection measures, could significantly harm GRAIL's business, operations and financial condition. (PX0043 (GRAIL) at 51.)

C. The Transaction

1. Overview

70. On September 21, 2020, Illumina and GRAIL announced they had entered into a definitive agreement under which Illumina would acquire GRAIL for cash and stock consideration of $8 billion upon closing of the transaction. (PX0122 (Illumina) at 1; RX3349 (GRAIL) at 1; RX3971 (Illumina) at 293; PX0378 (Illumina) at 3–4.)

70.1 In addition, GRAIL stockholders were to receive future payments representing a tiered single digit percentage of certain GRAIL-related revenues. (PX0122 (Illumina) at 1; RX3349 (GRAIL) at 1; RX3971 (Illumina) at 293; PX0378 (Illumina) at 3.)

70.2 The Boards of Directors of Illumina and GRAIL approved the agreement. (PX0122 (Illumina) at 1; RX3349 (GRAIL) at 1; RX3971 (Illumina) at 293.)

71. Under the terms of the agreement, at closing, GRAIL stockholders (including Illumina) were to receive 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. (PX0122 (Illumina) at 2; RX3349 (GRAIL) at 2; PX0061 (Illumina) at 30.)

71.1 Illumina currently holds 14.5% of GRAIL's shares outstanding, and approximately 12% on a fully diluted basis. (PX0122 (Illumina) at 2; RX3349 (GRAIL) at 3.)

71.2 The collar on the stock consideration was to ensure that GRAIL stockholders excluding Illumina would receive a number of Illumina shares equal to approximately $4 billion in value if the 20 trading-day volume weighted average price of Illumina stock as of 10 trading days prior to closing is between $295 and $399. (PX0122 (Illumina) at 2; RX3349 (GRAIL) at 2; RX3971 (Illumina) at 2, 294.)

71.3 GRAIL stockholders excluding Illumina were to receive approximately 9.9 million Illumina shares if the 20 trading-day volume weighted average price of

Illumina stock as of 10 trading days prior to closing was above $399 and approximately 13.4 million Illumina shares if the 20 trading-day volume weighted average price of Illumina stock as of 10 trading days prior to closing was below $295. (PX0122 (Illumina) at 2; RX3349 (GRAIL) at 3; RX3971 (Illumina) at 294.)

71.4 Upon closing of the transaction, current Illumina stockholders are expected to own approximately 93% of the combined company, while GRAIL stockholders are expected to own approximately 7% based on the mid-point of the collar. (PX0122 (Illumina) at 2; RX3349 (GRAIL) at 3; RX3971 (Illumina) at 294.)

72. In connection with the transaction, GRAIL stockholders were also to receive contingent value rights, which would entitle holders to receive future payments representing a pro rata portion of certain GRAIL-related revenues each year for a 12 year period. (PX0122 (Illumina) at 3; RX3349 (GRAIL) at 3; RX3971 (Illumina) at 6; PX0061 (Illumina) at 66.)

72.1 This will reflect a 2.5% payment right to the first $1 billion of revenue each year for 12 years. (PX0061 (Illumina) at 66). Revenue above $1 billion each year would be subject to a 9% contingent payment right during this same period. (PX0122 (Illumina) at 3; RX3349 (GRAIL) at 3; RX3971 (Illumina) at 4, 143, 295; PX0061 (Illumina) at 5, 31, 36, 66.)

72.2 Illumina offered GRAIL stockholders the option to receive additional cash and/or stock consideration, in an amount to be determined prior to closing, in lieu of the contingent value rights. (PX0122 (Illumina) at 3; RX3349 (GRAIL) at 3; RX3971 (Illumina) at 2, 295; PX0061 (Illumina) at 36, 66.) Forty percent of shares outstanding have opted for the CVR Consideration. [redacted]

2. **Strategic Benefits**

73. There are numerous strategic benefits of the transaction, including (1) saving of thousands of lives, (2) acceleration of market access to Galleri, (3) R&D efficiencies, (4) reduction of GRAIL's royalty burden, (5) elimination of double marginalization and (6) supply chain efficiencies, operational efficiencies and acceleration of international expansion of Galleri. (*See* deSouza (Illumina) Tr. 2341–80; Aravanis (Illumina) Tr. 1934–70; Febbo (Illumina) Tr. 4332–72; Qadan (Illumina) Tr. 4158–63; Flatley (Illumina) Tr. 4082–89; Bishop (GRAIL) Tr. 1415–32; Ofman (GRAIL) Tr. 3283–84; 3307–08; 3320–21; [redacted]; Freidin (GRAIL) Tr. 2973–74; 2986, 2999, 3007–08.)

3. **Consummation of the Deal**

74. On August 18, 2021, Illumina consummated the transaction, but committed to holding GRAIL as a separate company during the European Commission's ongoing regulatory review. (PX0377 (Illumina) at 1; *see also* deSouza (Illumina) Tr. 2234–38.)

75. Regulators in the EU were still reviewing the transaction, but a decision was projected after the deal expires. (PX0377 (Illumina) at 1; *see also* deSouza (Illumina) Tr. 2235–38, 2475–77.)

76. GRAIL has no business in the EU, and Illumina believes that the European Commission does not have jurisdiction to review the merger as the EU merger thresholds are not met, nor are they met in any EU member state. (PX0377 (Illumina) at 1; *see also* deSouza (Illumina) Tr. 2235–38, 2339–40; PX0378 (Illumina) at 3–4.)

76.1 The General Court of the European Union is expected to decide Illumina's jurisdictional challenge some time in 2022. (PX0377 (Illumina) at 1; *see also* deSouza (Illumina) Tr. 2235–38, 2339–40; PX0378 (Illumina) at 4.)

77. There was no legal impediment to Illumina acquiring GRAIL in the US. Illumina believes the reasons to reunite the two companies are compelling:

77.1 The deal will save lives. Cancer kills around 10 million people annually worldwide and 600,000 people in the US alone. (PX0377 (Illumina) at 1; *see also* deSouza (Illumina) Tr. 2372.)

77.2 Cancers responsible for nearly 71% of cancer deaths have no recommended early detection screening, and most cancers are detected when chances of survival are lower. (PX0377 (Illumina) at 1; *cf.* Aravanis (Illumina) Tr. 1904.)

77.3 Illumina believes there is a moral obligation to have the deal decided by a thoughtful and full review by the EU regulators and the US courts; this can only be done if Illumina acquires GRAIL now. (PX0377 (Illumina) at 1; *see also* deSouza (Illumina) Tr. 2339–40.)

77.4 Otherwise, the company is locked into a situation where the deal terms will expire before there is a chance for full review; the clock will just run out. (PX0377 (Illumina) at 1; *see also* deSouza (Illumina) Tr. 2475–77.)

77.5 Right now, the Galleri test is available but costs $950 because it is not covered by insurance. (PX0377 (Illumina) at 1; *see also* deSouza (Illumina) Tr. 2342.)

77.6 Reuniting the two companies is the fastest way to make the test broadly available and affordable. (PX0377 (Illumina) at 1; *see also* deSouza (Illumina) Tr. 2341–43.)

77.7 Illumina's expertise in market development and access has resulted in coverage of genomic testing for over 1 billion people around the world already. (PX0377 (Illumina) at 2; *see also* deSouza (Illumina) Tr. 2342–43.)

77.8 This experience will help lead to coverage and reimbursement for the Galleri test. (PX0377 (Illumina) at 2; *see also* deSouza (Illumina) Tr. 2341–43.)

77.9 GRAIL and Illumina have a long history. Illumina formed GRAIL and spun it out in 2016. (PX0377 (Illumina) at 2; *see also* deSouza (Illumina) Tr. 2195–96.)

77.10 GRAIL's first employees were part of Illumina, which still owns 12 percent of the company. (PX0377 (Illumina) at 2; *see also* Flatley (Illumina) Tr. 4094; [redacted] 152–53, [redacted].)

77.11 GRAIL and Illumina are not competitors. (PX0377 (Illumina) at 2; PX7073 (Aravanis (Illumina) IHT at 80).)

77.12 Based on past experience, when Illumina enters a market, the market expands. (PX0377 (Illumina) at 2; *see also* deSouza (Illumina) Tr. 2392–94.) When Illumina entered the non-invasive prenatal testing space, prices dropped, reimbursement expanded, the number of providers increased, and more expectant parents had access to testing. (PX0377 (Illumina) at 2; *see also* deSouza (Illumina) Tr. 2392–94.)

77.13 Illumina's acquisition of GRAIL is driven by the belief that Galleri should be available to as many people as possible as quickly as possible. (PX0377 (Illumina) at 2; *see also* deSouza (Illumina) Tr. 2342.) From fighting the COVID-19 pandemic to matching cancer patients to therapies, Illumina's mandate is to save lives and transform healthcare. (PX0377 (Illumina) at 2.)

II. BACKGROUND

A. Oncology Overview

1. Cancer and Cancer Stages

78. Cancer affects one in three people in the United States. (RX3035 (ACS) at 1.) As the second leading cause of death in the U.S., behind only heart disease, cancer leads to one in every four deaths in the U.S. (RX3103 (CDC); *see also* Cote Tr. 3728–29.)

79. Cancer has been found in all organs of the human body and is typically named for the part of the body where the cancer originated. (*See* RX3103 (CDC); RX3035 (ACS).)

80. Breast, prostate, lung, and colorectal are the most common cancer types. (RX3103 (CDC).)

81. Cancer is characterized by the development of abnormal cells that divide uncontrollably. (RX3449 (Mayo Clinic) at 2; RX3869 (Cote Expert Report) ¶ 26). Cancers are understood to be caused by accumulated changes or mutations to the DNA inside cells. (RX3449 (Mayo Clinic) at 1–2; RX3869 (Cote Expert Report) ¶ 26.)

81.1 Often these changes are to genes that control cellular functions, such as those controlling cell growth and division, or DNA repair. (RX3449 (Mayo Clinic) at 1–2.)

82. Increasing evidence suggests that cancer may be caused by genomic and epigenomic changes to DNA, including DNA methylation. (RX3401 (Kamel and Bagader Al-Amodi 2016) at 3; Cote Tr. 3733.)

82.1 Such changes may be inherited from our parents, or may be accumulated as a result of various factors, including from improper DNA repair and from the environment, such as exposure to smoking, radiation, viruses, and carcinogens. (RX3449 (Mayo Clinic) at 2; (RX3506 (National Cancer Institute) at 3; RX3869 (Cote Expert Report) ¶ 26.)

83. DNA stands for deoxyribonucleic acid and is a molecule made up of four chemical bases: adenine, guanine, cytosine and thymine, abbreviated A, G, C and T. Each of these bases are known as "nucleotides"; RNA stands for ribonucleic acid, which comprises uracil, abbreviated U, instead of thymine; together, DNA and RNA are referred to as "nucleic acids." (Cote Tr. 3736; PX7131 (Cote Dep. at 137–138); RX3869 (Cote Expert Report) ¶ 26, n.21.)

84. As a result of the genomic and epigenomic changes to the DNA, cancer cells differ from normal cells in that they undergo rapid and uncontrolled growth. (RX3449 (Mayo Clinic) at 2.) Such uncontrolled growth leads to the formation of tumors. (RX3869 (Cote Expert Report) ¶ 27; *see also* RX3449 (Mayo Clinic).)

85. As these abnormal cells continue to grow and divide, cancer cells may spread (metastasize) to other parts of the body from where the cancer originated. (RX3449 (Mayo Clinic) at 4; RX3869 (Cote Expert Report) ¶ 27.)

86. As cancers progress, the cancer cells can enter the blood stream and the lymphatic system (lymph nodes), in a process called "metastasis". (RX3869 (Cote Expert Report) ¶ 27; RX3506 (National Cancer Institute).)

87. As cancer cells first enter the blood, they are called circulating tumor cells ("CTC"); as these CTC enter other organs and grow, they form metastases, which is the major cause of cancer death. (Cote Tr. 3733; PX7131 (Cote Dep. at 59–61); RX3869 (Cote Expert Report) ¶ 27.)

88. The American Joint Committee on Cancer (AJCC) and the Union for International Cancer Control (UICC) maintain the TNM (Tumor, Node, Metastasis) classification system, which characterizes the tumor by size and amount of spread into nearby tissue, its spread into lymph nodes, and metastatic status. (RX3031 (ACS); Cote Tr. 3730–33; RX3869 (Cote Expert Report) ¶ 28, n.25.)

89. Stages of cancers are determined based on how much cancer there is in a patient's body and where it's located. (RX3031 (ACS) at 1; (Cote Tr. 3730–3732; RX3869 (Cote Expert Report) ¶ 28.) Cancer is commonly divided into five stages:

89.1 Stage 0 can also refer to a cancer that has not yet invaded into surrounding normal tissue, which is also called carcinoma in *situ*. (Cote Tr. 3730–31; RX3869 (Cote Expert Report) ¶ 28.) Stage 0 can also refer to when a cancer has been treated prior to surgical removal (neoadjuvant therapy) and that cancer can no longer be found. (Cote Tr. 3730–31; RX3869 (Cote Expert Report) ¶ 28, n.26.)

89.2 Stage I, which is also called early-stage cancer, means there is cancer present, but it is small and only in one area, where the cancer originated. (Cote Tr. 3731; RX3869 (Cote Expert Report) ¶ 28.)

89.3 Stage II is still an early stage cancer, but the cancer is larger, and it may also have metastasized to regional lymph nodes. (Cote Tr. 3731; RX3869 (Cote Expert Report) ¶ 28.)

89.4 Stage III means the cancer is larger, has penetrated more deeply in to the organ of origin, and has spread to lymph nodes. (Cote Tr. 3730–32; RX3869 (Cote Expert Report) ¶ 28.)

89.5 Stage IV, which is also called advanced or metastatic cancer, means the cancer has spread (metastasized) to other parts of the body. (Cote Tr. 3731; RX3869 (Cote Expert Report) ¶ 28.)

90. At its earliest stages, particularly Stages 0, I and II, cancer generally does not cause symptoms. (RX3869 (Cote Expert Report) ¶ 29; *see also* Cote Tr. 3730–3732.) By the time symptoms develop, the cancer has very often progressed to Stages III or IV. (RX3869 (Cote Expert Report) ¶ 29; *see also* Cote Tr. 3730–30.)

91. Cancer staging also helps oncologists determine the best treatment options, such as surgery, radiation, chemotherapy, targeted drug therapy, and immunotherapy, many of which are either invasive, or cause significant harm to normal cells in the body. (RX3031 (American Cancer Society, Cancer Staging) at 1; RX3869 (Cote Expert Report) ¶ 30.)

92. The earlier a cancer can be detected, the higher the cure rate. [redacted]; Cance (ACS) Tr. 600–01, 606–08; PX7086 (Cance (ACS) Dep. at 81, 97) RX3869 (Cote Expert Report) ¶ 31.) Because of this, detecting cancer at earlier stages has been the focus of intense research by the scientific community. [redacted]; Cote Tr. 3719–21; RX3869 (Cote Expert Report) ¶ 31.)

92.1 Depending on the type of cancer, patients with Stage 0, I and II cancers can often be cured by surgery alone, or by a combination of surgery and other therapies, such as chemo- or radiation therapy. (Cote Tr. 3731–32; RX3869 (Cote Expert Report) ¶ 31). Stage III cancer has a much lower cure rate. (Cote Tr. 3731–32; RX3869 (Cote Expert Report) ¶ 31).

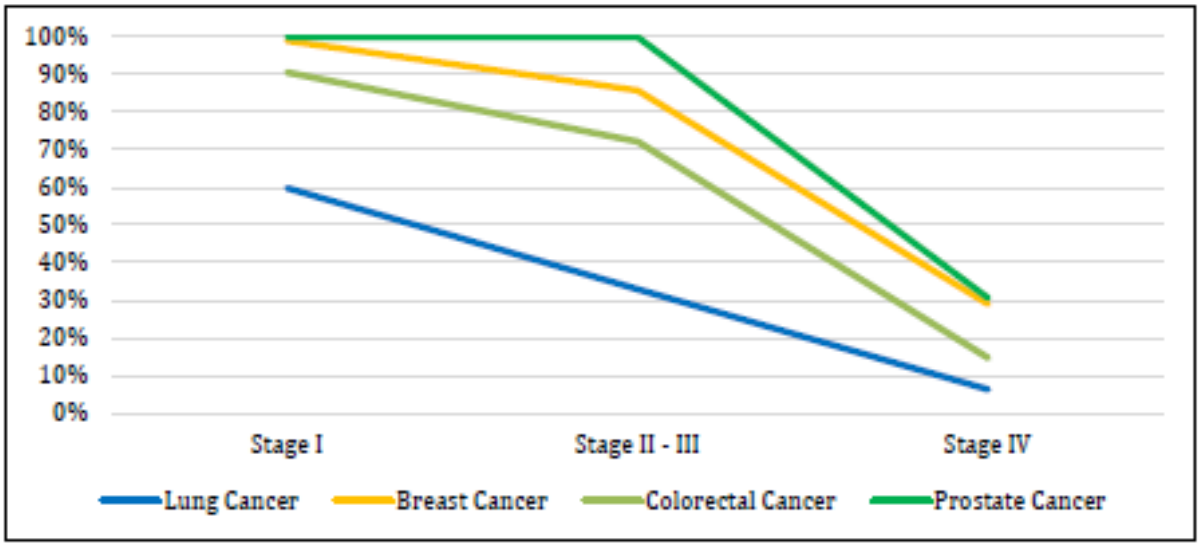
92.2 While Stage IV cancer may be treated (resulting in prolongation of life), it is almost always incurable and will eventually result in the death of the patient. (Cote Tr. 3731; RX3869 (Cote Expert Report) ¶ 31.) Patients diagnosed with Stage IV cancer only account for approximately 18% of total cancer cases, but represent up to 48% of deaths caused by cancer within five years of diagnosis. (RX3178 (Hubbell et al., 2020) at 1.)

93. Epidemiologically speaking, a cancer patient's survival rates and prognosis correlates to the stage of cancer at the time of the diagnosis. (Cote Tr. 3730–32; RX3869 (Cote Expert Report) ¶ 32.) That is, the earlier the cancer is detected, the higher the likelihood that the patient will recover from cancer, and the longer the patient is likely to survive after the diagnosis.

[redacted]; Cance (ACS) Tr. 600–01, 606–08; PX7086 (Cance (ACS) Dep. at 81, 97; Cote Tr. 3730–32; RX3869 (Cote Expert Report) ¶ 32.)

93.1 In breast, colorectal, and prostate cancer, patients diagnosed at Stages I–III have average five-year survival rates between 70% and nearly 100%, while patients with the same types of cancer who are diagnosed at Stage IV experience five-year survival rates of only 14-30%. (RX3504 (SEER) at 4–5; RX3503 (SEER) at 4–5; RX3505 (SEER) at 4–5; RX3869 (Cote Expert Report) ¶ 32.)

Figure 2: Five-Year Survival Correlated With Stage At Diagnosis



(RX3869 (Cote Expert Report) Figure 1.)

94. It is well understood that the rate of death for certain cancers, in particular breast, prostate, lung and colon cancer, has declined over the past few decades in the U.S. (RX3033 (ACS) at 2.) This is almost entirely due to earlier detection of these tumor types by routine screening. (RX3869 (Cote Expert Report) ¶ 32; *see also* RX3033 (ACS) at 2.)

95. For tumors that do not have effective screening technologies, such as pancreas, ovary and stomach cancers (to name a few), the rate of death has been largely unaffected, even in the face of advanced therapies. (PX0125 (ACS) at 4, Figure 1, 20, Table 7; RX3869 (Cote Expert Report) ¶ 32.)

96. Most types of cancers do not currently have effective *screening* technologies, again highlighting the need for better methods of early detection. [redacted]; Cote Tr. 3728–3729; RX3869 (Cote Expert Report) ¶ 32.)

2. **Biomarkers for Cancer Testing**

97. Currently, many companies and academic groups are researching methods for early cancer screening. [redacted]; Cote Tr. 3719–21; RX3869 (Cote Expert Report) ¶ 33.) Many of these methods detect biomarkers that indicate or suggest the presence of cancer. (Cote Tr. 3733; RX3869 (Cote Expert Report) ¶ 33.)

98. As a result of the accumulated genomic and/or epigenomic changes in the cancer cells, these cells exhibit uncontrolled cell division and proliferation as well as inhibited apoptosis (cell death). (RX3449 (Mayo Clinic) at 2; PX7131 (Cote Dep. at 60); RX3869 (Cote Expert Report) ¶ 34.)

99. Such uncontrolled cell division and proliferation result in further genomic and epigenomic changes to the cancer cells. (RX3449 (Mayo Clinic) at 2); PX7131 (Cote Dep. at 59–61); RX3869 (Cote Expert Report) ¶ 34.)

100. As cancer cells grow and die, they release their contents, including DNA, RNA, proteins and metabolites into the blood and sometimes other body fluids, such as urine, saliva and sputum. (RX3401 (Kamel, Cancer Biomarkers); Cote Tr. 3733; PX7131 (Cote Dep. at 59–61); RX3869 (Cote Expert Report) ¶ 39.)

101. These released cellular constituents, also called "biomarkers", can be detected by various technologies, and have been the source of intense scientific focus due to their potential to help diagnose cancer earlier, at a more curable stage. (RX3401 (Kamel, Cancer Biomarkers) at 1; Cote Tr. 3733; PX7131 (Cote Dep. at 59–61); RX3869 (Cote Expert Report) ¶ 39.)

102. Similarly, exosomes and their constituent components may also be used as a biomarkers for cancer patients. (RX3165 (Dai, Exosomes: Key Players in Cancer and Potential Therapeutic Strategy) at 2; PX7131 (Cote Dep. at 111–12); RX3869 (Cote Expert Report) ¶ 39.)

103. Many tests in routine use today may be used to detect cancer biomarkers. (RX3869 (Cote Expert Report) ¶ 40). Detection of cancer biomarkers is commonly used to help screen for early stage cancer, for example, detection of Prostate Specific Antigen ("PSA") in the blood for prostate cancer. (Cance (ACS) Tr. 606–07, 622–23; Cote Tr. 3729–30; RX3869 (Cote Expert Report) ¶ 40.)

104. Cancer biomarkers are often used for other applications, such as helping determine specific treatments to which a cancer is likely to respond (*i.e.*, cancer therapy selection), by following the course of cancer therapy to see if the therapy is working, and to help detect recurrence of cancer. (Cote Tr. 3733, 3735–36; RX3869 (Cote Expert Report) ¶ 40.)

105. Cancer biomarkers are most often a very small portion of the DNA, RNA, proteins and metabolites that can be found in the blood and other body fluids. (PX7131 (Cote Dep. at 59–61); RX3869 (Cote Expert Report) ¶ 41.)

106. This is particularly true when cancer is at its earliest, most curable stages, because the total amount of cancer cells in the body at these stages is very small. (PX7131 (Cote Dep. at 59); Cote Tr. 3734–36; RX3869 (Cote Expert Report) ¶ 41.) Thus, detection of biomarkers that

indicate the presence of an early stage, potentially curable cancer, has been technically very challenging. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 41.)

a. DNA Biomarkers

107. DNA biomarkers, also called *genomic* biomarkers, are among the most common biomarkers for cancer used by researchers and test developers today. (RX3869 (Cote Expert Report) ¶ 42.) DNA biomarkers from cancer cells may be identified in various types of samples from a cancer patient. [redacted]; Cance (ACS) Tr. 609–10; RX3869 (Cote Expert Report) ¶ 42.)

107.1 DNA biomarkers may be extracted and evaluated directly from tissue biopsy samples. (RX3869 (Cote Expert Report) ¶ 43). DNA biomarkers may also be found in bodily fluids, such as blood, urine, saliva and sputum samples. (Cance (ACS) Tr. 609–10; RX3869 (Cote Expert Report) ¶ 43).

107.2 DNA biomarkers obtained from blood and other body fluids are known as cell-free DNA ("cfDNA") and more specifically, when detected in the blood, where they are known as circulating tumor DNA ("ctDNA"). (Cance (ACS) Tr. 609; RX3869 (Cote Expert Report) ¶ 43.)

107.3 DNA biomarkers may be used to identify both genomic and epigenomic changes that may be relevant for cancer. (Cote Tr. 3733; RX3869 (Cote Expert Report) ¶ 44.) Genomic changes include gene mutations, amplifications, and chromosomal rearrangements. (Cote Tr. 3733; RX3869 (Cote Expert Report) ¶ 44.)

107.4 Epigenomic changes are those things that occur to specific DNA molecules, or to proteins that regulate DNA function, but are not structural changes in the DNA sequence or copy number, and include histone modifications and DNA methylation. (Cote Tr. 3733; RX3869 (Cote Expert Report) ¶ 45.)

107.5 These epigenomic changes have been of intense interest in the scientific community, and are now believed to be crucial in cancer formation and progression. [redacted]; Cance (ACS) Tr. 612–13; Cote Tr. 3733; RX3869 (Cote Expert Report) ¶ 45.)

108. Many technologies have been used to detect these genomic and epigenomic changes in cancer DNA biomarkers (including DNA methylation), including polymerase chain reaction ("PCR"), sequencing (such as next-generation sequencing), and microarray, as well as fluorescence *in situ* hybridization ("FISH"). (Cote Tr. 3736–37; RX3869 (Cote Expert Report) ¶ 46.)

b. RNA Biomarkers

109. RNA biomarkers are another type of biomarker, which are also called *transcriptomic* biomarkers. [redacted]; Cance (ACS) Tr. 609; Cote Tr. 3733; RX3869 (Cote Expert Report) ¶ 47.)

110. As with DNA biomarkers, RNA biomarkers may also be extracted and evaluated from tissue and liquid biopsy samples. (RX3869 (Cote Expert Report) ¶ 48.) As with ctDNA and cfDNA, bodily fluids may contain circulating cell free RNA ("cfRNA"), which in individuals with cancer, may contain circulating tumor RNA ("ctRNA"). (Cote Tr. 3733; RX3869 (Cote Expert Report) ¶ 48.)

111. Often, the genomic and epigenomic changes to the DNA in cancer cells may be reflected in the RNA biomarkers. (Cote Tr. 3733; RX3869 (Cote Expert Report) ¶ 48.)

112. As with DNA biomarkers, many technologies have been used to detect the genomic and epigenomic changes in cancer RNA biomarkers. (Cote Tr. 3736–37; RX3869 (Cote Expert Report) ¶ 49).

113. Such changes in RNA biomarkers may be detected directly using microarray, RNA *in situ* hybridization ("RNA ISH") and circulating cancer cell RNA imaging. (Cote Tr. 3736–3737; RX3869 (Cote Expert Report) ¶ 49).

114. Alternatively, messenger RNAs ("mRNAs") may be first reverse-transcribed into complementary DNA ("cDNA"), and then the genomic and epigenomic changes may be detected using the same methods for DNA biomarkers, such as RT-PCR, and sequencing. (Cote Tr. 3736–37; RX3869 (Cote Expert Report) ¶ 49.)

114.1 The epigenomic changes like methylation to DNA and RNA may be directly detected by Oxford Nanopore's nanopore sequencers or indirectly detected by short-read sequencers using a method like bisulfite conversion. (Cote Tr. 3753–54; PX7131 (Cote Dep. at 124–26, 205–06); RX3869 (Cote Expert Report) ¶ 49 n.38.)

114.2 Bisulfite conversion is a process in which potentially methylated DNA is treated with sodium bisulfite, leading to conversion of unmethylated cytosines (C) into uracils (U), while methylated cytosines (both 5–methylcytosine and 5–hydroxymethylcytosine) remain unchanged, thus allowing determination of DNA methylation at the singe nucleotide level. (Cote Tr. 3745; RX3869 (Cote Expert Report) ¶ 49 n.38.)

114.3 Another non-bisulfite method to determine DNA methylation has also been developed. (RX3431 (Liu et al., 2019) at 2–3; RX3869 (Cote Expert Report) ¶ 49, n.38.)

c. Protein Biomarkers

115. Protein biomarkers, also called *proteomic* biomarkers, are also commonly used as cancer biomarkers. (Cance (ACS) Tr. 612–13, 632; Cote Tr. 3736–37; RX3869 (Cote Expert Report) ¶ 51.)

116. Some of the genomic and epigenomic changes to the DNA in cancer cells can be reflected in the protein biomarkers, such as point mutations, truncations, fusions, loss of functions, and in the levels, or presence/absence, of protein biomarkers. (RX3869 (Cote Expert Report) ¶ 52).

117. Protein biomarkers may be examined in bodily fluids, or at a cell, tissue, organ, system, or the whole-body level. (Cance (ACS) Tr. 632; Cote Tr. 3733; RX3869 (Cote Expert Report) ¶ 52.)

118. The approach of using protein biomarker signatures for cancer early screening is an active area of academic and commercial interest, and studies have already determined that by using combinations of protein biomarkers, early cancer can be detected. (RX3274 (Gorelik et al., 2005) at 3; RX3412 (Kozak et al., 2003) at 1; RX3466 (Mor et al., 2005) at 1; Cote Tr. 3735–37.)

119. Protein biomarkers are often used for following the course of treatment for patients with higher stage cancer, and to detect for recurrence in patients who have been treated for cancer. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 53.)

d. Metabolite Biomarkers

120. Metabolite biomarkers, also called *metabolomic* biomarkers, are presently used less frequently than DNA, RNA and protein biomarkers. (RX3869 (Cote Expert Report) ¶ 54). Metabolite biomarkers are direct representations of cancer phenotypes and how a cell's metabolic pathways or processes change can have direct implications on whether the cell is cancerous. (RX3869 (Cote Expert Report) ¶ 54.)

120.1 Metabolite biomarkers include lipids, carbohydrates, nucleotides, and many other low-molecular-weight chemicals, and can be detected in tissue biopsy samples, body fluids, and even in breath through detection of cancer volatile organic compounds ("VOC") markers. (Cance (ACS) Tr. 609–10, 612–13; PX7131 (Cote Dep. at 112); RX3869 (Cote Expert Report) ¶ 54.)

e. Exosome Biomarkers

121. Exosomes are best defined as small (40–100 nm) extracellular vesicles that are released from cells, whose membranes (walls) are composed of the plasma membrane of the cell and contain a variety of cellular components, including DNA, RNA, proteins and metabolites. (RX3184 (Edgar 2016) at 1)

121.1 Because they are abundant, found in virtually all body fluids (including blood) and are representative of the cells from which they are derived, there is increasing interest by the academic and commercial communities in using exosomes as cancer biomarkers. (RX3745 (Wong, et al., 2019) at 2, 5; PX7131 (Cote Dep. at 111–12); RX3869 (Cote Expert Report) ¶ 56.)

B. Clinical Oncology Tests and Testing Modalities

122. While there are many technologies that may be used for early cancer screening, only a few of them are currently in use in commercial tests today. (Cote Tr. 3728–30, 3736–37; RX3869 (Cote Expert Report) ¶ 57.)

1. Types of Clinical Oncology Tests

123. Cancer screening and other tests using blood samples are referred to as "liquid biopsy" tests, even though tests of other body fluids (*e.g.*, urine) can sometimes also be referred to as liquid biopsy. [redacted]; Cance (ACS) Tr. 608–09; [redacted]; RX3869 (Cote Expert Report) ¶ 59.)

124. Because of the minimal invasiveness and ease of use of liquid biopsy from a small sample of blood, blood-based clinical oncology tests have become a standard and essential part of oncology management, and there is enormous interest in developing blood-based cancer screening tests. [redacted]; Cance (ACS) Tr. 608–09; [redacted]; RX3869 (Cote Expert Report) ¶ 59.)

125. Based on intended use and target patient populations, multiple types of clinical oncology tests have been developed to aid in the management of cancer at different stages of the "cancer continuum," including: (1) early cancer screening tests; (2) diagnostic aid to cancer tests; (3) therapy selection tests; (4) treatment response or acquired resistance monitoring tests; (5) minimal residual disease ("MRD") tests; and (6) hereditary risk assessment tests. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 60.)

a. Early cancer screening tests

126. Early cancer screening tests are used in asymptomatic individuals to detect cancer at the earliest, most treatable stage. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 61.) There are several types of tests for detecting single types of cancer at early stage, including imaging (mammography for breast and CT for high risk lung cancer screening), blood (PSA for prostate), or stool (colorectal cancer). (Cance (ACS) Tr. 606–07, 622–23; Cote Tr. 3729–30; RX3869 (Cote Expert Report) ¶ 61.)

127. Work on the development of cancer screening tests has primarily focused on the interrogation of DNA, RNA, proteins, metabolites or exosomes. (Cance (ACS) Tr. 609–10; RX3869 (Cote Expert Report) ¶ 61.)

128. Because blood-based cancer screening tests are designed to detect cancer at early stages, they must be very sensitive in order to detect the small amounts of analytes that small tumors release, though there are potential tradeoffs between sensitivity and specificity in early cancer screening, as well as the importance of detecting the cancer signal of origin. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 61.)

b. Diagnostic aid to cancer ("DAC") tests

129. Once a cancer is suspected or has been detected, it is sometimes difficult to confirm the cancer and determine the type of cancer. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 62.)

130. DAC tests are used to help confirm the presence of cancer or to better specify the type of cancer in an individual who has cancer. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 62.)

c. Therapy selection tests

131. Therapy selection tests examine biomarkers (*e.g.*, known types of somatic mutations, hormone receptor status, oncogene protein expression) in individuals who have already been diagnosed with cancer to help select the particular anti-cancer therapies to which the patient is most likely to respond. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 63.)

132. Because a patient's cancer has already been diagnosed via tissue biopsy or excision at this stage, therapy selection tests are more likely to rely on tissue biopsy samples as there is a much higher amount of cancer cells and other cancer biomarkers in the cancer tissue than are circulating in the body and available for testing. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 63.)

133. However, there is growing use of blood-based testing for cancer biomarkers to help select therapy in patients diagnosed with cancer. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 63.) Particularly in the case of tissue-based cancer biomarker analysis, lower sensitivity testing methods may be used for therapy selection tests than for early cancer screening or diagnostic aid to cancer tests. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 63.)

d. Treatment response or acquired resistance monitoring tests

134. Treatment response or acquired resistance monitoring tests test cancer patients while treatment is ongoing to determine whether the patient has responded to or has acquired resistance to the treatment. (Cote Tr. 3735–36; RX3869 (Cote Expert Report) ¶ 64.)

135. These tests can include imaging, and increasingly liquid biopsy tests for proteins or circulating tumor cells ("CTC"). (RX3869 (Cote Expert Report) ¶ 64.)

e. Minimal residual disease ("MRD") tests

136. 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).

137. There are two types of MRD tests, those that are "tumor-informed" and those that are "tumor-naïve": tumor-informed MRD tests may use information about a patient's cancer, *i.e.*,

the specific mutations/modifications that were present in the patient's original tumor biopsy, while tumor-naïve MRD tests are capable of detecting the recurrence of cancer without information about a given patient's cancer. (RX3869 (Cote Expert Report) ¶ 65.)

f. Hereditary risk assessment tests

138. Hereditary risk assessment tests examine healthy individuals' germline (*i.e.*, inherited) mutations/variants in cancer susceptibility genes to assess risks of hereditary cancer, based on personal and family history. (Cote Tr. 3734; RX3869 (Cote Expert Report) ¶ 66.) These tests do not test any cancer that has actually developed in the individual being tested. (Cote Tr. 3734; RX3869 (Cote Expert Report) ¶ 66.)

139. Because hereditary risk assessment tests are based on DNA collected from any tissue (for example, a mouth swab) or from saliva or blood, they do not have the sensitivity required for early cancer screening. (RX3869 (Cote Expert Report) ¶ 66.)

2. The State of Early Cancer Screening Tests Today

140. The most pressing unmet need in cancer early detection is to identify cancers for which there are no existing recommended screening tests. (PX0043 (GRAIL) at 97, 5; *see also* Ofman (GRAIL) Tr. 3308–09; Aravanis (Illumina) Tr. 1937.)

141. There are no standard of care screening tests for most types of cancer, including some of the major causes of cancer mortality, such as cancers of the pancreas, ovary, stomach, bone marrow, lymph nodes, etc. [redacted]; Cote Tr. 3728–30; RX3869 (Cote Expert Report) ¶ 69.)

142. In most of these cases, the cancers are not diagnosed before a patient exhibits symptoms, which generally will not occur until the cancer has progressed to a late and often incurable stage. [redacted]; RX3869 (Cote Expert Report) ¶ 69.)

143. The United States Preventive Services Task Force ("USPSTF") is an independent panel of experts that makes recommendations about clinical preventive services (such as cancer screening) which influence the coverage and adoption of medical services. (*See* RX3867 (Expert Report) ¶ 39.)

144. USPSTF recommends screening for four cancer types: breast, cervical, lung and colorectal. (RX3723 (USPSTF) at 2–3, 7; Cote Tr. 3728–29.)

145. Other organizations, such as the American Cancer Society, also recommend screening for prostate cancer. (Cance (ACS) Tr. 606; Cote Tr. 3730; RX3869 (Cote Expert Report) ¶ 67.) Below is an overview of the cancer screening tests that are recommended as the "standard of care":

145.1 Breast Cancer. USPSTF recommends biennial screening via mammography for women ages 50 to 74. (RX3723 (USPSTF, A and B Recommendations) at 2; Cance (ACS) Tr. 606; Cote Tr. 3729–30).

145.1.1 A mammogram is an X-ray of the breast, which has the associated risk of having repeated exposure to a small amount of radiation. (RX3104 (CDC).)

145.1.2 When suspicious results are obtained, the patients will undergo either a needle biopsy or fine needle aspiration ("FNA"), or a more extensive removal of tissue, to rule out a diagnosis of cancer. (RX3869 (Cote Expert Report) ¶ 67.)

145.2 Cervical Cancer. For women ages 21 to 29, USPSTF recommends screening every 3 years with cervical cytology (*i.e.*, a pap test) alone; for women ages 30 to 65, every 3 years with cervical cytology alone, every 5 years with high-risk human papillomavirus (hrHPV) testing alone, or every 5 years with hrHPV testing in combination with cytology (cotesting). (RX3723 (USPSTF, A and B Recommendations) at 3; Cance (ACS) Tr. 606; Cote Tr. 3729–30.)

145.2.1 Both pap tests and hrHPV testing are invasive procedures which include gynecological examination of the vagina and the cervix, and collection of cells and mucus from the cervix and the area around it, while samples for hrHPV testing are subsequently analyzed using PCR. (RX3106 (CDC, What Should I Know About Screening?) at 1; Cance (ACS) Tr. 606; Cote Tr. 3729–30; RX3869 (Cote Expert Report) ¶ 67.)

145.3 Colorectal Cancer. USPSTF recommends screening for colorectal cancer in all adults aged 50 to 75 years. (RX3723 (USPSTF, A and B Recommendations) at 3; Cance (ACS) Tr. 606; Cote Tr. 3729–30).

145.3.1 Recommended stool-based tests include the high-sensitivity guaiac fecal occult blood test ("gFOBT"), fecal immunochemical test ("FIT"), and stool DNA test ("sDNA-FIT"). (RX3730 (USPSTF, Screening for Colorectal Cancer) at 2–3.) Recommended direct visualization tests to screen for colorectal cancer include colonoscopy, CT colonography, and flexible sigmoidoscopy. (RX3730 (USPSTF, Screening for Colorectal Cancer) at 3.)

145.3.2 Colonoscopy is the gold standard for colorectal cancer screening and need only be done every ten years, but it is invasive and requires bowel preparation, anesthesia or sedation. (Cance (ACS) Tr. 606; Cote Tr. 3729–30.)

145.4 Lung Cancer. Lung cancer represents the most common killer among cancers, but USPSTF recommendations for lung cancer screening are limited to the high-risk smoking population—adults aged 50 to 80 years who have a 20 pack-a-year smoking history and currently smoke or have quit within the past 15 years. (PX0043 (GRAIL) at 97, 110; *see also* Bishop (GRAIL) Tr. 1392[redacted]; RX3723 (USPSTF, A and B Recommendations) at 7; Cance (ACS) Tr. 606; Cote Tr. 3729–30.)

145.4.1 This high-risk population accounts for only 33% of all lung cancers, meaning there is no effective screening in place for the vast majority of

lung cancer diagnoses. (PX0043 (GRAIL) at 97, 110; *see also* Bishop (GRAIL) Tr. 1392; [redacted]

145.4.2 USPSTF recommends annual screening for lung cancer with low-dose computed tomography ("LDCT"), which carries non-negligible radiation risk and is expensive. (RX3723 (USPSTF, A and B Recommendations) at 7; RX3107 (CDC, Who Should Be Screened for Lung Cancer?); RX3869 (Cote Expert Report) ¶ 67.)

145.5 Prostate Cancer. Although not listed by the USPSTF, screening for prostate cancer involves a serum test (most commonly) for serum PSA, digital rectal examination ("DRE"), and when suspicious results are obtained, "sextant" prostate needle biopsies (6 biopsies per side, 12 or more total biopsies) that are now often done under radiographic guidance to determine the most suspicious areas. (RX3034 (American Cancer Society, Recommendations for Prostate Cancer Early Detection) at 1; Cance (ACS) Tr. 606; Cote Tr. 3729–30.)

145.5.1 A problem with the PSA test is that many factors can affect PSA levels, including non-malignant conditions that affect the prostate, while DRE is uncomfortable, invasive and lacks specificity for cancer. (RX3105 (CDC, What Is Screening for Prostate Cancer?) at 1–2; RX3869 (Cote Expert Report) ¶ 67.)

146. Standard, recommended screening tests nearly all come with major issues in their use, interpretation and follow-up. (Cote Tr. 3813–14; RX3869 (Cote Expert Report) ¶ 68.) The standard of care cancer screening tests and their follow-up to rule out a cancer diagnosis (generally, a surgical procedure) currently recommended by the USPSTF are either invasive, burdensome, or carries potential risks to patients, creating a need for blood-based single cancer screening tests. [redacted]; Cote Tr. 3813–14; RX3869 (Cote Expert Report) ¶ 68.)

147. Importantly, nearly all recommended screening tests are often "positive"—that is, signal the possible presence of cancer, in many more cases compared to the times they actually detect cancer, which affects what is known as the "Positive Predictive Value" of such tests. (RX3869 (Cote Expert Report) ¶ 68 *see infra* PFF ¶ 174.)

3. **Modalities Used for Cancer Screening**

148. Several types of technologies are being used for screening tests today or are being studied for screening tests in development. (PX7095 (Hill (Emory) Dep. at 27–28); [redacted]; Cance (ACS) Tr. 612–13.) Scientists and doctors recognize today that it is impossible to speculate which modality for cancer screening will be the most successful. [redacted]; Cance (ACS) Tr. 620; PX7086 (Cance (ACS) Dep. at 102); RX3869 (Cote Expert Report) ¶ 70.)

a. Imaging

149. For over half a century, imaging technologies have been the standard of care for early-stage cancer detection and screening in the United States. (RX3869 (Cote Expert Report) ¶ 71.) Over the years, imaging technologies progressed from standard x-rays for mammography and lung to low-energy X-rays, 3–D mammography, ultrasound, MRI (Magnetic Resonance Imaging), CT (Computed Tomography), and PET-CT (Positron Emission Tomography), etc. (RX3869 (Cote Expert Report) ¶ 71.)

150. Imaging technologies provide direct or indirect views of structures inside the body, which allow doctors to detect, locate and stage a tumor. (RX3869 (Cote Expert Report) ¶ 71.) Imaging technologies thus may be used for cancer screening, diagnosis, and monitoring. (RX3869 (Cote Expert Report) ¶ 71.) Imaging technologies are currently the most commonly used and commercially available technique for cancer screening. (RX3869 (Cote Expert Report) ¶ 71.)

150.1 For example, both the National Cancer Institute and the American Cancer Society recommend mammograms or MRIs along with mammograms for breast cancer screening, and a low-dose CT scan for lung cancer screening. (RX3502 (National Cancer Institute, Screening Tests) at 2; RX3029 (American Cancer Society, Guidelines for the Early Detection of Cancer) at 1, 3; Cance (ACS) Tr. 606; Cote Tr. 3729–30; RX3869 (Cote Expert Report) ¶ 71.)

151. Although traditional imaging screenings are typically focused on screening for cancer in a single organ of the body, PET, 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. (RX3624 (Schöder & Gonen 2007) at 9.)

152. However, 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 & Gonen 2007) at 9–10; Cote Tr. 3812–13; RX3869 (Cote Expert Report) ¶ 72.)

152.1 Diagnostic PET-CT will necessitate further evaluation of true-positive or false-positive finding and therefore impose downstream costs on the health care system as a whole. (RX3624 (Schöder & Gonen 2007) at 9–10.)

152.2 A diagnostic PET-CT exposes an individual to 62 times more radiation than a mammogram and 12 times more than a low-dose computed tomography (LDCT), which is only approved in high-risk smokers. (RX0661 (GRAIL) at 36.)

153. The cost (or reimbursement) for imaging-based cancer screening is relatively low. (RX3869 (Cote Expert Report) ¶ 73.) The national average total reimbursement for breast cancer screening is only about $353 per person screened, taking into consideration follow-up ultrasonography, biopsy and MRI costs. (RX3414 (Kunst et al., 2020) at 2.)

154. Similarly, the average annual reimbursement of low-dose CT scan for lung cancer screening under Medicare is about $241 per person screened. (RX3593 (Pyenson et al., 2014) at 2; RX3869 (Cote Expert Report) ¶ 73.)

b. Proteomics

155. Protein biomarkers have also been used for many years for early stage cancer detection and screening. (Cance (ACS) Tr. 606; Cote Tr. 3730; RX3869 (Cote Expert Report) ¶ 74.)

155.1 Protein biomarkers are commonly analyzed using antibodies that specifically bind to the protein and covalently link with certain modifiers for easy detection. (RX3869 (Cote Expert Report) ¶ 74.)

155.2 For example, enzyme or fluorescent dye-linked antibodies specific to cancer biomarkers are also used to detect the presence of such antigens in bodily fluids in technologies called ELISA (enzyme-linked immunosorbent assay) and immunochemistry ("IC"), which are used for both cancer diagnosis and screening. (Cote Tr. 3736–37, 3872; RX3869 (Cote Expert Report) ¶ 74.)

156. Proteomics is currently used in a variety of early screening tests for several cancers. (Cance (ACS) Tr. 606; Cote Tr. 3729–30, 3736–37, 3872; RX3869 (Cote Expert Report) ¶ 75.)

156.1 For example, a blood-based ELISA test for the level of PSA has been recommended by both the National Cancer Institute and the American Cancer Society for early stage screening of prostate cancer. (RX3502 (National Cancer Institute); RX3029 (ACS) at 4; Cance (ACS) Tr. 606; Cote Tr. 3729–30; RX3869 (Cote Expert Report) ¶ 75.)

157. The costs for proteomics tests are fairly low. (RX3869 (Cote Expert Report) ¶ 76.) Quest Diagnostics offers the PSA prostate cancer screening test for $75, while, according to the 2021 Fee Schedule, the Centers for Medicare & Medicaid Services ("CMS") reimburses PSA prostate cancer screening for $19.31. (RX3595 (QuestDirect) at 1; RX3869 (Cote Expert Report) ¶ 76.)

c. Polymerase Chain Reaction

158. Polymerase Chain Reaction ("PCR") is a DNA amplification method that can be used for many different types of applications, including to detect specific genomic mutations or methylation biomarkers known to be associated with cancer. (Cote Tr. 3736–37; RX3869 (Cote Expert Report) ¶ 77.)

158.1 Using PCR, copies of very small amounts of DNA sequences are exponentially amplified in a series of temperature changes. (RX3869 (Cote Expert Report) ¶ 77.) PCR tests can be used to evaluate all types of samples, including cancer biopsy tissue, urine, stool, saliva or blood plasma. (RX3869 (Cote Expert Report) ¶ 77).

158.2 PCR can use either DNA, such as cell-free DNA present in the blood plasma, or, through a reverse transcription process that first reverse-transcribes RNA into complementary DNA ("cDNA"), use RNA as templates for the genomic amplification in RT-PCR (real time-PCR). (Cote Tr. 3736–37; RX3869 (Cote Expert Report) ¶ 77.)

158.3 PCR is highly sensitive and requires only minimal amount of sample for detection and amplification of specific sequences. (RX3869 (Cote Expert Report) ¶ 77.)

159. Since its invention in 1983, many improved PCR techniques have been developed and used in clinical cancer testing. (RX3869 (Cote Expert Report) ¶ 78.) Multiplex PCR allows simultaneous detection of multiple targets in a single test, with a different pair of primers for each target. (RX3686 (Thermo Fisher) at 1–2; RX3869 (Cote Expert Report) ¶ 78.)

159.1 Multiplex PCR can generate higher throughput than traditional (single-plex) PCR and obtains more information with less sample. (RX3686 (Thermo Fisher) at 1–2; RX3869 (Cote Expert Report) ¶ 78.)

159.2 For example, Thermo Fisher's Ion AmpliSeq Exome RDY Kit enables ultrahigh-multiplex PCR exome enrichment of approximately 294,000 primer pairs across 12 primer pools, or about 24,500 primer pairs in each PCR pool, showing the ultrahigh capability of the new PCR technology. (RX3686 (Thermo Fisher) at 2; RX3869 (Cote Expert Report) ¶ 78.)

160. Another category of new PCR technology is digital PCR (dPCR). (Cote Tr. 3872; RX3869 (Cote Expert Report) ¶ 79.)

160.1 For example, Thermo Fisher's microfluidic digital PCR OpenArray system uses a microscope slide-sized plate with 3,072 through-holes, on a system that can run up to four OpenArray plates simultaneously, allowing for generation of over 12,000 data points in a single run. (RX3692 (Thermo Fisher).)

160.2 Combinati is developing an Absolute Q Microfluidic Array Partitioning (MAP) dPCR system with 20,000 microchambers, pushing the microfluidic digital PCR technology forward even further. (RX3147 (Combinati) at 3; RX3869 (Cote Expert Report) ¶ 79.)

161. Because of its high sensitivity, PCR is currently used in a variety of early screening tests for several cancers. (Cote Tr. 3736–3737; RX3869 (Cote Expert Report) ¶ 80.) For example, both the National Cancer Institute and the American Cancer Society recommend a stool-based PCR test for early stage screening of colorectal cancer and human papillomavirus ("HPV") PCR test for early stage screening of cervical cancer. (RX3502 (National Cancer Institute) at 2; RX3029 (ACS) at 1–2; RX3869 (Cote Expert Report) ¶ 80.)

162. Many PCR-based cancer screening tests have low costs, though some are reimbursed at higher costs. (RX3869 (Cote Expert Report) ¶ 81.) For example, while the maximum cost of Cologuard could be $649, the CMS 2021 Fee Schedule for an HPV PCR test is only $35.09. (RX3306 (Healthline Media) at 2; RX3869 (Cote Expert Report) ¶ 81.)

d. Microarrays

163. A microarray is an orderly arrangement of many individual fragments of probes, such as DNAs, RNAs, or proteins, attached to a solid support called chips. (RX3869 (Cote Expert Report) ¶ 82.)

163.1 Microarray-based genomic tests may be used to detect the presence or absence of specific genomic mutations and/or methylations in a sample, because mutated and/or methylated DNA bind to the probes differently than normal DNA. (Cote Tr. 3736–37; RX3869 (Cote Expert Report) ¶ 82.)

163.2 Researchers, *e.g.*, the Cancer Genome Atlas and the Human Tumor Atlas Network, are continually generating data and improving algorithms to identify new associations that may be incorporated into microarray-based tests. (RX3869 (Cote Expert Report) ¶ 82.)

164. Microarrays provide a high-throughput platform for simultaneously screening tens of thousands of biomolecular interactions. (RX3869 (Cote Expert Report) ¶ 83; *see also* Cote Tr. 3736–37).

164.1 For example, Thermo Fisher's GeneChip Human Genome U133 Plus 2.0 Array allows for analysis of over 47,000 human genes and transcripts at one time. (RX3682 (Thermo Fisher) at 1; Cote Tr. 3876.)

164.2 Thermo Fisher's Genome-Wide Human SNP Array 6.0 chip features 1.8 million genetic markers for single nucleotide polymorphisms (SNPs) and copy number variations (CNVs). (RX3684 (Thermo Fisher) at 2.)

164.3 Agilent Technologies' SurePrint G3 Human Gene Expression Microarrays allow for analysis of over 56,600 genes and transcripts at one time. (RX3019 (Agilent Technologies).)

164.4 Agilent Technologies' Human Genome CGH Microarrays offers up to 1 million probes for genome-wide CNV identification and characterization. (RX3869 (Cote Expert Report) ¶ 83; RX3020 (Agilent Technologies).)

164.5 Agilent Technologies' Human DNA Methylation Microarrays use 60–oligomer probes for 28,500 CpG islands in human, representing 237,227 unique probes for DNA methylation. (RX3018 (Agilent Technologies) at 2; RX3869 (Cote Expert Report) ¶ 83.)

e. Next Generation Sequencing

165. Sequencing is the process of determining the order of nucleotides, *i.e.*, the sequence, in genomic materials, such as DNA and RNA. (Cote Expert Report) ¶ 85.) The first generation of sequencing technology was based on the chain termination method developed by Dr. Frederick Sanger in 1975, often known as "Sanger Sequencing". (RX3407 (Kircher et al., 2010) at 2; RX3869 (Cote Expert Report) ¶ 85.)

165.1 Applied Biosystems (ABI, now part of Thermo Fisher) introduced the automated ABI Prism 3700 DNA Analyzer in the 1990s, which allowed parallel sequencing of 96 samples of between 600 and 1,000 nucleotides in length, or a maximum of 100,000 nucleotides per run, and a very low error rate at an average of one error per 10,000–100,000 nucleotides. (RX3869 (Cote Expert Report) ¶ 85, n.75.)

165.2 The human genome consists of approximately 3,200,000,000 basepairs (3,200 Mbp (mega-basepairs) or 3.2 Gb (giga-basepairs)) of nucleotides in about 30,000 to 40,000 genes. (RX3869 (Cote Expert Report) ¶ 85, n.75). Many genes are thousands or tens of thousands of basepairs in length, making whole genome sequencing using Sanger sequencers a difficult task. (RX3407 (Kircher et al., 2010) at 2; RX3869 (Cote Expert Report) ¶ 85, n.75.)

166. Next-generation sequencing, also known as NGS, allows parallel sequencing of millions of small DNA fragments that are combined by software into longer, full-length sequences . (Cote Tr. 3750–51; RX3869 (Cote Expert Report) ¶ 86.) With bisulfite conversion and similar techniques, NGS sequencing can be used not only to detect genomic mutations and fragmentations, but also epigenomic modifications such as methylation. (Cote Tr. 3745; RX3869 (Cote Expert Report) ¶ 86.)

166.1 Bisulfite conversion is a process in which potentially methylated DNA is treated with sodium bisulfite, leading to conversion of unmethylated cytosines (C) into uracils (U), while methylated cytosines (both 5–methylcytosine and 5–hydroxymethylcytosine) remain unchanged, thus allowing determination of DNA methylation at the singe nucleotide level. (Cote Tr. 3745; RX3869 (Cote Expert Report) ¶ 86, n.76.)

167. Because cancer is caused by accumulated changes to genes that control cellular functions, a possible approach to cancer screening would be to identify all changes to such genes by interrogating all relevant gene sequences through sequencing. (PX7131 (Cote Dep. at 108–09, 125–27; RX3869 (Cote Expert Report) ¶ 87.)

167.1 With the massive parallel sequencing capability, NGS is scalable and has high throughput, and can systemically study cancer genomes in their entirety, which allows for partial or full characterization of a patient's genomic profile and thus personalized cancer management. (Cote Tr. 3750–51; RX3869 (Cote Expert Report) ¶ 87.)

167.2 However, NGS-based technologies also have their limitations, such as requiring investment in computer capacity and storage to handle the large volume (of tens of gigabytes) of data as well as personnel expertise to skillfully extract and comprehensively analyze and interpret the clinically important information. (RX3869 (Cote Expert Report) ¶ 87.)

168. GRAIL's Galleri is the only NGS-based early cancer screening test currently on the market in the United States and is currently marketed at $949 per test. (Bishop (GRAIL) Tr. 1401; RX3292 (GRAIL).) No NGS-based early cancer screening tests have obtained FDA

approval or mechanisms for reimbursement, either by Medicare or by private payors. (PX7086 (Cance (ACS) Dep.) at 49, 58; RX3869 (Cote Expert Report) ¶ 88.)

f. Multiomics

169. An increasing number of companies are developing "multi-omic" tests which combine information from multiple analytes, including DNA (genome), RNA (transcriptome) and protein (proteome) for increased sensitivity in cancer detection. ({**Cote Tr.}** 3811–12, **{3844, 3871}**; RX3869 (Cote Expert Report) ¶ 89.)

169.1 For example, Exact/Thrive's CancerSEEK pipeline screening test assesses levels of nine protein biomarkers as well as mutations in 16 genes for the early detection of cancers of multiple organs: ovary, liver, stomach, pancreas, esophagus, kidney, bladder, colorectum, lung or breast, in addition to a PET-CT step for positive test results. (RX3419 (Lennon et al., 2020) at 6; Cote Tr. 3811–12.)

169.2 Freenome similarly combines data from whole-genome sequencing, DNA methylation, and protein quantification for the early detection of colorectal cancer from a blood test. (RX3426 (Lin et al., 2021) at 1; RX0111 (Putcha et al., 2020) at 1); Cote Tr. 3844.)

169.3 PrognomiQ, a recent spin-off of Seer, is also developing early cancer screening tests by combining proteomic information, obtainable using Seer's Proteograph platform, with genomic, metabolomic, and other health data. (RX3587 (PrognomiQ) at 1–2; RX3869 (Cote Expert Report) ¶ 89.)

C. Features of Cancer Screening Tests

170. The metrics that may be used to assess the performance of oncology tests, including blood-based early stage cancer screening tests include sensitivity, specificity and cancer signal of origin (also known as tissue of origin) analyses. [redacted]; Cote Tr. 3778–82; RX3869 (Cote Expert Report) ¶ 90.)

171. In addition to the number of cancers that a screening test is capable of detecting, these metrics provide further 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.) In addition to these technical metrics, physicians may also evaluate and select tests based on other factors, such as the ease of using the test. (RX3869 (Cote Expert Report) ¶ 90.)

172. Sensitivity. 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.)

172.1 A concept that is related to false negative rate is the Negative Predictive Value ("NPV"), which is the percentage of patients with a negative test who do not have

cancer. (RX3869 (Cote Expert Report) ¶ 91.) NPV represent the probability a patient does not have cancer when the test result is negative. (RX3869 (Cote Expert Report) ¶ 91.)

172.2 Compared with therapy selection tests where the patient has developed tumors, early stage cancer patients have only small amounts of cancer cells in the body and only a minute amount of materials from cancer, including circulating tumor DNA (ctDNA), mRNA, protein, and circulating cancer cells, in the blood. (RX3303 (Haque et al., 2017) at 3); Cote Tr. 3735–36.)

172.3 Therefore, a 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.)

173. Specificity. 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. (Cote Tr. 3778–3781; RX3869 (Cote Expert Report) ¶ 93.) Low specificity leads to high *false positive* rates. (Cote Tr. 3778–3781; RX3869 (Cote Expert Report) ¶ 93.)

173.1 [redacted]

173.2 [redacted]

174. Positive Predictive Value. A concept that is related to false positive rate is the Positive Predictive Value ("PPV"), which is the percentage of patients with a positive test who actually have cancer. (Cote Tr. 3778–81; RX3869 (Cote Expert Report) ¶ 93.)

174.1 PPV represent the probability a patient has cancer when the test result is positive. (Cote Tr. 3779; RX3869 (Cote Expert Report) ¶ 93.) The PPV is a particularly important metric for cancer screening tests. (Cote Tr. 3778–81; RX3869 (Cote Expert Report) ¶ 93.)

175. Because a cancer screening test is a test used in the general population, *i.e.*, healthy individuals, 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. (RX3501 (National Cancer Institute, Cancer Statistics).)

176. Therefore, even if a test is highly specific with a low false positive rate, the likelihood that a person with a positive test result actually has cancer may still be relatively low

given the low baseline rate of cancer in the population. (Cote Tr. 3778–81; RX3869 (Cote Expert Report) ¶ 93).

176.1 For example, a specificity of 99.5% still translates into about a 40– 50% PPV—one of every two individuals with a positive test result would be a false positive. (Cote Tr. 3778–81; RX3869 (Cote Expert Report) ¶ 93.)

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

178. False negative findings 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 results leads to unnecessary follow-ups and even often harmful procedures to rule out cancer, let alone the severe emotional distress to patients and their families. 3778–81, 3814, ; RX3869 (Cote Expert Report) ¶ 94; *see also* PX7086 (Cance (ACS) Dep. at 90–91.)

179. Therefore, high specificity, *i.e.*, low false positive rates, is also important for a cancer screening test. (3778–81, 3814, ; RX3869 (Cote Expert Report) ¶ 94; *see also* PX7086 (Cance (ACS) Dep. at 90–91.)

180. However, there is typically a tradeoff between specificity and sensitivity. (RX3869 (Cote Expert Report) ¶ 95.) Given the same conditions, a test applying cutoff thresholds that minimizes false positives, *i.e.*, higher specificity, may often have a lower sensitivity than a test that results in a higher false positive rate. (RX3869 (Cote Expert Report) ¶ 95.)

180.1 Existing single cancer screening tests typically have very high sensitivity rates and correspondingly lower specificity/higher false positive rates. (RX3869 (Cote Expert Report) ¶ 95.)

180.2 For example, a colonoscopy has a sensitivity of 92.5% and a specificity of 73.2%. (RX3393 (Issa & Noureddine 2017) at 9.) Cologuard has a sensitivity of 92.3% and a specificity of 86.6%. (RX3222 (FDA) at 19.)

180.3 Mammography for breast cancer screening has a sensitivity of 86.9% and a specificity of 88.9%, and the PPV is only 4%, meaning that only 4 of 100 positive tests actually identify breast cancer. (RX3079 (Breast Cancer Surveillance Consortium) at 1; RX3442 (Marcus 2019) at 4.)

180.4 This means that most patients with a "positive" mammography result will have to undergo further invasive testing, but will end up with a negative cancer diagnosis. (RX3079 (Breast Cancer Surveillance Consortium) at 1; RX3442 (Marcus 2019) at 6.)

181. 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.)

181.1 By contrast, 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.) This again points out the fundamental differences in design that are likely to differentiate tests used to detect early stage cancer. (Cote Tr. 3778–81, 3868–69; RX3869 (Cote Expert Report) ¶ 95.)

182. Cancer Signal of Origin. 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.)

182.1 Therefore, for a blood-based multi-cancer screening test to be most effective, identification of the possible cancer signal of origin is highly desirable. (RX3869 (Cote Expert Report) ¶ 96.)

182.2 [redacted]

182.3 Identification of a cancer signal of origin ensures that the necessary follow-up from a positive test result is efficiently directed to a targeted imaging step or a biopsy, such that those patients who receive a positive test result will not suffer undue anxiety waiting for further testing. (RX3869 (Cote Expert Report) ¶ 96.)

182.4 Importantly, 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, would result in a possibly extensive, invasive and expensive workup to rule in or out the presence of cancer. ([redacted] 3782, 3814, [redacted] RX3869 (Cote Expert Report) ¶ 97.)

182.5 No cancer screening test will be perfect, and even at the extremely high PPV of 50%, only one half of the patients with a positive screening test will actually have cancer. (Cote Tr. 3778–81; RX3869 (Cote Expert Report) ¶ 97.)

182.6 In the above example of a test with a PPV of 50%, the workup would likely be even more prolonged, invasive and expensive for the patients who do not have cancer than for a patient who does have cancer, as the patient without cancer would be forced to undergo a particularly extensive workup to definitively rule out cancer. ([redacted] 3782, 3814, [redacted]; RX3869 (Cote Expert Report) ¶ 97.)

182.7 On the other hand, a multi-cancer screening test that *does* indicate the possible cancer signal of origin will require much less extensive and more focused initial follow-up. (Cote Tr. 3782; RX3869 (Cote Expert Report) ¶ 97.)

182.8 Providing accurate cancer signal of origin to facilitate cancer diagnosis will improve clinical utility and patient compliance, 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.)

183. [redacted]

183.1 [redacted]

D. Regulatory Requirements

184. The FDA is charged with protecting the public health by assuring the safety, effectiveness, and security of medical devices, including diagnostic and screening tests. (RX3006 (FDA); PX7099 (Febbo (Illumina) Dep. at 83–84).)

185. 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 1.) Devices are classified as Class I, II or III, where each class corresponds with a differing degree of risk. (RX3326 (FDA) at 2.)

185.1 Class I devices are those that present the lowest risk, with minimal potential for patient harm. (RX3326 (FDA) at 2.)

185.2 Class II devices represent a moderate risk, and Class III devices represent the highest level of risk, used in scenarios where the device is used to sustain or support life, the device is implanted, or the device presents potential unreasonable risk of illness or injury. (RX3326 (FDA) at 2; RX6001 (Deverka Trial Dep. at 39); RX3867 (Deverka Expert Report) ¶ 32.)

186. Depending on the Class of device, the device may require a different level of FDA premarket clearance or approval, or may not require FDA premarket submission at all.' (RX3326 (FDA) at 3; RX3416 (FDA) at 1.)

187. A company can offer a clinical test to patients in three ways: as a Laboratory Developed Test ("LDT"), as a single-site IVD test, or an IVD distributed kit. (Goswami (Illumina) Tr. 3185–87.)

187.1 LDTs are the most common offering and involve a company clinically and analytically validating the test and then running the test in a single laboratory that has received CLIA/CAP certification. (Goswami (Illumina) Tr. 3185, 3195–96.)

187.1.1 While LDTs do not undergo FDA clearance or approval processes, they are regulated by the Clinical Laboratory Improvements Amendments (CLIA) program, which is implemented via a division of the Centers of Medicare and Medicaid Services (CMS) called the Division of Clinical Laboratory Improvement & Quality. (RX3325 (CMS); PX7113 (Rabinowitz (Natera) Dep. at 382); PX7077 (Chahine (Helio) Dep. at 1028); RX3867 (Deverka Expert Report) ¶ 34.)

187.1.2 Despite not being approved or cleared by the FDA, LDTs still must meet rigorous quality and safety standards for clinical diagnostic testing because it must be run in a laboratory with CLIA certification. (RX3325 (CMS); RX3867 (Deverka Expert Report) ¶ 34.)

187.1.3 Labs undergo routine audits in which the clinical data supporting their tests and the claims that they put on their reports are reviewed and put their CLIA license at risk if they don't have sufficient data supporting their tests. (Febbo (Illumina) Tr. 4322–23.).

187.2 Single-site IVDs are tests that have been FDA-approved, but only can only be run in a single lab. (Goswami (Illumina) Tr. 3186.)

187.3 An distributed IVD test or IVD kit involves a kit that is developed and manufactured by a test manufacturer which, after receiving FDA approval, can be run in various labs provided that the labs are CLIA/CAP certified. (Goswami (Illumina) Tr. 3186–87.)

187.3.1 The manufacturer of an IVD distributed test, not the lab running the test, bears the burden of continuing to manufacture, distribute and support the test in accordance with FDA guidelines. (Goswami (Illumina) Tr. 3187.)

187.3.2 IVD kits are most suitable for tests that have precious samples, that present shipping challenges and require fast turnaround times. (Goswami (Illumina) Tr. 3196–3200.)

188. The below table summarizes the minimum required regulatory submission type required for diagnostic tests depending on the type and class of device. (RX3326 (FDA) at 1–4; RX3416 (FDA) at 1; RX3867 (Deverka Expert Report) ¶ 33.)

Table 1

Regulatory Submission	Eligible Devices	Governing Body	Regulatory Terminology
LDT	Tests that are designed, manufactured and used in a single lab (including RUO/IUO kits) do not require FDA premarket submission. LDTs may be widely accessible even though all analysis is conducted in a central lab that meets CLIA certification standards.	CLIA (CMS)	Not currently reviewed by FDA
510(k)	Required for some Class I and most Class II devices. Manufacturers must demonstrate that the device is substantially equivalent (SE) to (i.e. as safe and effective as) a legally marketed predicate device.	FDA	FDA cleared
De Novo Classification	Provides pathway for Class I and II devices for which there is no legally marketed predicate device.	FDA	FDA cleared
PMA	Class III devices and companion diagnostics (CDxs) require a premarket approval (PMA). The PMA must contain sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).	FDA	FDA approved

189. A company seeking FDA approval for an in-vitro diagnostic (IVD)—i.e., a test of human tissue or blood samples that is performed outside the body—for any test of a life threatening disease, such as cancer, would need premarket approval. (RX3867 (Deverka Expert Report) ¶ 35.)

190. Galleri would be classified as a Class III device requiring premarket approval before it could be commercialized as an FDA-approved test. (Febbo (Illumina) Tr. 4445.)

191. Premarket approval (PMA) is the "most stringent type of device application required by FDA." (RX3585 (FDA Approval) at 10.) It often requires significant preparation and voluminous amounts of data, including in-depth review of the technical features of a device and extensive data from clinical trials to demonstrate the efficacy and safety of the device. (RX3867 (Deverka Expert Report) ¶ 35.)

192. PMA submissions not only take significant time, investment and resources to prepare, but they also take time for the FDA to review. (RX3867 (Deverka Expert Report) ¶ 35.) PMA submission requires a rigorous evidence review. (RX3569 (FDA) at 1; RX3867 (Deverka Expert Report) ¶ 35.)

E. Market Access: Key Factors and Stakeholders

193. The commercial availability of a novel medical device, however promising, will not result in broad patient access without reimbursement by payors and adoption by stakeholders. (RX6001 (Deverka Trial Dep. at 30–31); RX3867 (Deverka Expert Report) ¶ 29.) Test manufacturers must engage in a multi-pronged campaign to obtain reimbursement of a new test before it can obtain widespread adoption. (RX6001 (Deverka Trial Dep. at 30–31); RX3867 (Deverka Expert Report) ¶ 29.)

194. Test manufacturers must take into account a range of considerations when bringing a new test to market, including reimbursement by payors, development of clinical evidence, obtaining regulatory approvals, and adoption by relevant stakeholders. (RX6001 (Deverka Trial Dep. at 31–32, 33–34); RX3867 (Deverka Expert Report) ¶ 30.)

195. The table below provides an overview of each factor, which is described in more detail below. (RX6001 (Deverka Trial Dep. at 31–32, 33–34); RX3867 (Deverka Expert Report) ¶ 30.)

Table 2

Factor	**Key Components**
Evidence	Analytical Validity Evidence
Development	Clinical Validity Evidence
	Clinical Utility Evidence
	Health Economic Evidence
	Engagement with Payors
Regulatory	Approval or Clearance by the FDA or Appropriate Regulatory Framework
Adoption	Physician Education Campaigns
	Engagement with Medical Specialty Societies and Patient Advocacy Groups
	Incorporation of Technology into Specialty Society Guidelines
	Engagement with Health Technology Assessment (HTA) and Advisory Groups that Provide Treatment Recommendations
Reimbursement	Coverage
	Coding & Payment Assignment
	Payment & Contracting

1. **Evidence Development**

196. Public payors—such as Medicare and Medicaid—and private payors consider numerous factors when deciding whether to cover a new test, including evidence of effectiveness, safety, the product's indication, the product's appropriate use population, and cost. In particular, the following types of evidence are considered:

196.1 Analytic Validity. How well the test predicts the presence or absence of a particular biomarker. (RX6001 (Deverka Trial Dep. at 33–34); RX3867 (Deverka Expert Report) ¶ 31.)

196.2 Clinical Validity. How well an analyzed biomarker is related to the presence, absence, or risk of a specific disease. (RX6001 (Deverka Trial Dep. at 33–34); RX3867 (Deverka Expert Report) ¶ 31.)

196.3 Clinical Utility. The ability of a screening or diagnostic test to prevent or ameliorate adverse health outcomes (e.g., mortality, morbidity, or disability) by enabling the clinician to identify and adopt appropriate treatments or to otherwise alter clinical care decisions that lead to improved health outcomes, while also accounting for the harms of testing. (RX6001 (Deverka Trial Dep. at 34); RX3867 (Deverka Expert Report) ¶ 31.)

196.4 Health Economic Evidence. The budgetary impact or cost-effectiveness of adopting or covering a new test on a health plan or the health care system at large. (RX6001 (Deverka Trial Dep. at 34–35); RX3867 (Deverka Expert Report) ¶ 31.)

197. Generating this evidence is a costly and time-intensive endeavor, often requiring extensive clinical trials to get the amount and quality of data to satisfy public and private payors. (RX3867 (Deverka Expert Report) ¶ 31.)

2. **Regulatory**

198. Payors will also consider the regulatory status of a new test. Payors 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 a FDA-cleared test treated as an intermediate preference between the two. [redacted]; PX7090 (Sood (Guardant) Dep. at 124); PX7077 (Chahine (Helio) Dep. at 41–42); PX7116 (Dolan (Quest) Dep. at 66); RX3867 (Deverka Expert Report) ¶ 36.)

199. Medicare is currently statutorily prohibited from covering most preventive services including cancer screening tests, unless carved out as a legislative exemption, which may be influenced based on regulatory status. (RX3646 (Social Security Act § 1833, 42 U.S.C. § 1395I).) Private payors are not prohibited from covering LDTs, however, payors may prefer to cover a screening test that is FDA approved. (RX3867, (Deverka Expert Report) ¶ 36.)

3. **Adoption**

200. In addition to public and private payors, a number of other stakeholders influence the availability of novel medical tests and any MCED test developer must attempt to engage these stakeholders to communicate the value of their test, including health technology assessment (HTA) and advisory bodies, patient advocacy groups, and medical specialty societies. (RX3005 (Deloitte); RX3867 (Deverka Expert Report) ¶ 37.)

201. Each of these stakeholders plays an integral role in shaping treatment pathways and innovation in oncology, thereby influencing coverage in addition to utilization of oncology tests and treatments. (RX3867 (Deverka Expert Report) ¶ 37.)

202. Health Technology Assessment (HTA) and Advisory Bodies. HTAs evaluate the benefits and shortcomings of medical products, including cost, value and expected clinical outcomes, to provide recommendations regarding coverage and adoption of these products. (RX6001 (Deverka Trial Dep. at 43–44); RX3867 (Deverka Expert Report) ¶ 38.)

202.1 Recommendations from HTA bodies may either increase or decrease access to a new test, depending on the final recommendation and indications/populations

that HTAs conclude are most appropriate for a new technology. (RX6001 (Deverka Trial Dep. at 43–44); RX3867 (Deverka Expert Report) ¶ 38.)

202.2 Among the most influential HTA organizations is the USPSTF, which influences coverage and adoption of medical services through a review system that ultimately assigns a letter grade to the reviewed service, indicating positive or negative support. (RX3867 (Deverka Expert Report) ¶ 39.)

202.3 USPSTF recommendations also impact whether a screening test can be covered by Medicare, where Medicare has statutory authority to cover only preventive tests with a USPSTF A or B rating. (RX3646 (Social Security Act § 1833, 42 U.S.C. § 1395I); RX6001 (Deverka Trial Dep. at 50); RX3867 (Deverka Expert Report) ¶ 39.)

203. Medical Specialty Societies. Test manufacturers must engage with specialty societies to communicate the clinical validity and utility of a new test to physicians and pathologists. (RX3867 (Deverka Expert Report) ¶ 40.)

203.1 Medical specialty societies such as the American Medical Association (AMA), the National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO®), and American Clinical Laboratory Association (ACLA), provide a range of services for their members, including providing practice support, participating in relevant lobbying efforts, and considering the role of new technologies in existing care paradigms. (RX3867 (Deverka Expert Report) ¶ 40.)

203.2 Specialty societies such as NCCN and ASCO® develop guidelines that provide screening, diagnostic workup and treatment recommendations based on comprehensive literature reviews. (RX6001 (Deverka Trial Dep. at 44–45); RX3867 (Deverka Expert Report) ¶ 40.)

203.3 For instance, NCCN most recently updated its guidelines in 2021 that detail recommended screening paradigms, including frequency and modalities, for lung cancer and breast cancer, called the "Lung Cancer Screening" and "Breast Cancer Screening and Diagnosis" guidelines, respectively. (RX3867 (Deverka Expert Report) ¶ 40.) Such guidelines heavily influence testing and treatment decisions across U.S. physician practices. (RX3867 (Deverka Expert Report) ¶ 40.)

203.4 Particularly for new technologies such as MCED screening, physicians may be unaware of test indications, appropriate populations for testing, and how to interpret test results. (RX3867 (Deverka Expert Report) ¶ 40.)

203.5 Without engagement of these specialty societies, new technologies may go unused despite a positive reimbursement environment. (RX3516 (Bevers et al., NCCN Breast Cancer Screening and Diagnosis); RX6001 (Deverka Trial Dep. at 44–45); RX3518 (Wood, et al., NCCN Lung Cancer Screening); RX3867 (Deverka Expert Report) ¶ 40.)

204. Patient Advocacy Groups. Patient advocacy groups drive initiatives and promote policy agendas that improve patient outcomes. (RX3867 (Deverka Expert Report) ¶ 42.)

204.1 Advocacy groups are often focused on the treatment and detection of select disease areas, such as oncology. (RX3867 (Deverka Expert Report) ¶ 42.) An oncology advocacy group generally focuses on the treatment and detection of select tumor types. (RX3867 (Deverka Expert Report) ¶ 42.)

204.2 For instance, advocacy groups may drive education regarding the use of MCED screening for select tumor types, including how MCED screening fits into the standard treatment paradigm for that cancer, the risks and rewards of MCED screening for that cancer, and how family history or other risk factors may influence the benefit of MCED screening. (RX6001 (Deverka Trial Dep. at 45–46); RX3867 (Deverka Expert Report) ¶ 42.)

204.3 This is particularly important because while MCED tests screen across many cancer types at once, the patient needs, risks, and existing treatment options across cancers differ. (RX3534 (Putcha G., One Size Does Not Fit All); RX6001 (Deverka Trial Dep. at 45–46); RX3867 (Deverka Expert Report) ¶ 42.)

4. Reimbursement

205. Payor reimbursement is a complex, multi-step effort. Coverage defines the range and extent of services and products for which an insurer will pay. Coding is the language that characterizes services, procedures and products rendered to patients, and insurers rely on that coding to define which products and services will or will not be reimbursed.

206. Payment is the amount and process by which reimbursement is made by an insurer for a covered service and/or technology which may involve development of contracts and associated contracted rates between payor and manufacturer. In addition to each of these components of reimbursement, manufacturers must also secure appropriate regulatory authorization dependent on the type of product. (RX6001 (Deverka Trial Dep. at 47–48); RX3867 (Deverka Expert Report) ¶ 43.)

a. Medicare and Medicaid

(i) Development of Coverage Determinations

207. Positive Medicare coverage is critical for cancer screening test developers to ensure accessibility of tests among individuals who are most at risk. (RX6001 (Deverka Trial Dep. at 48.) Medicare is generally available for individuals 65 or older as well as certain younger people with disabilities. (RX3742 (Who is Eligible for Medicare?) at 1.) Based on the common age ranges in which new cancer cases are identified, Medicare coverage will be critical for widespread access to MCED screening. (RX6001 (Deverka Trial Dep. at 48); RX3867 (Deverka Expert Report) ¶ 44.)

208. SEER data from 2014–2018 indicates that cancer of any site is most frequently diagnosed in individuals aged 65–74, with a median age of 66. (RX3091 (NCI) at 1). The data show that 28.7% of newly diagnosed cancer cases during this time period occurred in individuals aged 65–74, while 24.3% occurred in individuals aged 55–64, aligning with the population for

which Galleri is currently recommended (ages 50+). (RX3091 (NCI) at 1; RX6001 (Deverka Trial Dep. at 48); RX3867 (Deverka Expert Report) ¶ 44.)

209. Medicare's coverage policies are developed in one of two formats: National Coverage Determinations (NCDs) are policies that determine coverage for all Medicare patients nationally, while Local Coverage Determinations (LCDs) are regionally developed policies by Medicare Administrative Contractors (MACs) that specify coverage specific to that MAC's jurisdiction, in the absence of an NCD. (RX3453 (CMS) at 1; RX6001 (Deverka Trial Dep. at 48–49).)

210. When determining coverage for their Medicare Advantage plans, private payors must cover all services with a positive coverage determination across NCDs, and across LCDs within that plan's region. (RX3867 (Deverka Expert Report) ¶ 45.)

211. Pertinent to MCED tests, under § 1862(a)(1)(A) of the SSA, Medicare does not cover experimental or investigational items and services, except in cases of "research conducted pursuant to [Agency for Healthcare Research and Quality (AHRQ) authority]". (RX3648 (Social Security Act § 1862 [42 U.S.C. 1395y]).) § 1142(a)(1) indicates that AHRQ has the authority to "support research with respect to the outcomes, effectiveness, and appropriateness of healthcare services." (RX3645 (Social Security Act § 1142 [42 U.S.C. 1320b–12]).)

211.1 In 2006, Medicare released its initial guidance for the Coverage with Evidence Development (CED) program, which outlined scenarios for limited coverage of experimental and investigational products and services relating to clinical studies, under the statutory basis of § 1862(a)(1)(A) and § 1142(a)(1). (RX3454 (CMS) at 1.)

211.2 CMS finalized the CED policy in 2006 to generate data on the utilization and impact of the item or service evaluated in an NCD so that CMS can: document the appropriateness of use of that item or service in Medicare beneficiaries under current coverage; consider future changes in coverage for the item or service; and generate clinical information that will improve the evidence base on which providers base their recommendations to Medicare beneficiaries regarding the item or service. (RX3454 (CMS) at 1–2; RX3867 (Deverka Expert Report) ¶ 46.)

212. CMS's initial 2006 guidance outlined two arms of the CED program: 1) Coverage with Appropriateness Determination (CAD), which refers to coverage conditioned on specific additional data collection, and 2) Coverage with Study Participation (CSP), which refers to coverage conditioned on care being delivered in a setting with a pre-specified data collection process and additional protections in place, such as those present in some research studies.' (RX3454 (CMS) at 1; RX3867 (Deverka Expert Report) ¶ 47.)

213. While CMS has since removed use of these terms, scenarios outlined by the previous terminology remain appropriate uses of CED. Instead of outlining CED options as falling under CAD or CSP, present CED guidance generally details requirements of CED studies to ensure that such studies are considered to be AHRQ-supported. (RX3867 (Deverka Expert Report) ¶ 47, n.73; RX3454 (CMS).)

214. While the CED program offers alternative coverage options for manufacturers without a clear coverage pathway through the standard LCD/NCD process, coverage is limited in scope and contingent on completion of an AHRQ-supported clinical study. As a result, CED-based coverage bears additional data reporting burdens and setting restrictions, while still requiring development of a formal coverage determination. (RX3867 (Deverka Expert Report) ¶ 48.)

215. While Medicare covers individuals aged 65 and older, private payor or Medicaid coverage must be achieved to ensure coverage for those under 64 years old. (RX6001 (Deverka Trial Dep. at 55–56).)

216. Because low socioeconomic status is correlated with increased cancer incidence and mortality, it is also critical to provide access to MCED screening for the population likely to be covered by Medicaid. (RX3650 (Singh et al., 2017) at 11.)

217. While Medicaid programs differ on a state-by-state basis, § 1905 [42 U.S.C. § 1936d] of the Social Security Act (SSA) sets federal minimum coverage requirements that all state Medicaid programs must adhere to. RX3649 (Social Security Act § 1905 [42 U.S.C. § 1396d]); (RX3867 (Deverka Expert Report) at 49.) Other items and services, including oncology tests, are covered on a state-by-state basis, where coverage determinations typically lag behind coverage from Medicare and other private payors. (RX3150 (OLC, Patient Protection and Affordable Care Act); RX3438 (MACPAC, Mandatory and Optional Benefits) at 2–3; (RX3867 (Deverka Expert Report) ¶ 49.)

218. Manufacturers seeking Medicaid reimbursement for services that fall outside of the scope of the program's national coverage mandates will therefore have to understand how coverage determinations are made on a state-by-state program level, and communicate the value of their test to payors and state-managed Medicaid programs as appropriate. (RX3867 (Deverka Expert Report) ¶ 50.)

(ii) Statutory Limitations to Coverage

219. While Medicare coverage is primarily dictated by development of coverage determination policies, coverage is limited by statute and other requirements. (RX6001 (Deverka Trial Dep. at 49–50).) Regulations as set forth by 45 CFR § 156.100 of the ACA require individual and small group market health plans to cover a pre-established list of itemized Essential Health Benefits (EHBs), including preventive and wellness services. (RX3150 (OLC); RX3380 (CMS) at 1.)

220. As a result, eligible plans are required to cover a number of single-cancer screening tests without cost-sharing, including colorectal cancer screening for adults aged 45–75; lung cancer screening for adults aged 55–80 at high risk for lung cancer due to current or past heavy smoking; breast cancer mammography screenings every 2 years for women over 50; and cervical cancer screenings via pap smear for women aged 21–65. (RX3580 (CMS); RX3581 (HealthCare.gov) at 2–3; RX3867 (Deverka Expert Report) ¶ 51.)

221. However, due to current statutory restrictions, the Medicare program is restricted from providing coverage to preventive services in the vast majority of situations. RX3150 (OLC, Patient Protection and Affordable Care Act; (RX3867 (Deverka Expert Report) ¶ 52.)

222. As such, manufacturers of new preventive services, including cancer screening tests and presumably MCED tests, cannot gain Medicare coverage through standard processes. Instead, MCED tests can only gain Medicare coverage through an exception to these statutory provisions, which will require prolonged and cumbersome coverage efforts. (RX6001 (Deverka Trial Dep. at 50–51); [redacted]

223. Ultimately, a manufacturer seeking coverage of a new preventive service, such as an MCED test, has only two available pathways to coverage:

224. USPSTF Review with NCD Development. This pathway requires that a test manufacturer seek development of a USPSTF evidence report reviewing the product, followed by development of an NCD from Medicare. Developing a USPSTF evidence report requires an initial topic selection, work plan development, development of a draft recommendation statement, an associated vote, and eventually development and release of a final report—all of which can take significant time. (RX3720 (USPSTF); **{RX3867 (Deverka Expert Report) ¶ 52.)}**

224.1 During the initial topic selection stage, USPSTF reviews nominated topics by considering each topic's public health importance and potential for impact (i.e. controversy, timeliness), with an intent to balance USPSTF's review portfolio across populations, types of services and disease types. USPSTF selects and prioritizes topics for review, and is not required to review all nominated topics. (RX3720 (USPSTF); [redacted]

224.2 Next, USPSTF indicates that expected timelines from workplan development to draft recommendation vote is 9–15 months, and then an additional 9 months is typically required between the vote to final recommendation release. (RX3720 (USPSTF).)

224.3 As such, manufacturers with screening tests who seek Medicare coverage through this pathway should not expect approval for at least 1.5 years from the time they apply, followed by development of an NCD for coverage to be established. (RX3720 (USPSTF).) In practice, the USPSTF pathway often takes far longer because of the time it requires up front during the topic selection stage. (RX6001 (Deverka Trial Dep. at 50–51.)

224.4 According to a former USPSTF liaison, it will likely take 5–6 years for the USPSTF to evaluate a novel technology such as MCED tests. (RX3720 (USPSTF); RX1912 (Liquid Biopsy GLG) at 2); [redacted]

225. Amendment of SSA with LCD/NCD Development. Manufacturers of the MCED test supports passage of Congressional legislation that provides Medicare authorization to cover the test based on a newly developed benefit category. (RX6001 (Deverka Trial Dep. at 49–50, 52); [redacted]

225.1 Only a limited number of other preventive services, such as pap smears, mammography, and colon and prostate cancer screening, have successfully used this option. (RX3050 (Balanced Budget Act of 1997 § 4101–04).)

225.2 Further, coverage for these preventive services is limited to the definition of the service used in the added benefit category. Manufacturers interested in using this pathway to gain coverage would require approval of a bill that amends § 1861 and § 1862 of the SSA, followed by development of a Medicare LCD or NCD. (RX3647 (Social Security Act § 1861 [42 U.S.C. 1395x] at Part E- Miscellaneous Provisions); RX3648 (Social Security Act § 1862 [42 U.S.C. 1395y] at Exclusions from Coverage and Medicare as a Secondary Payor); [redacted]

225.3 One such bill, the Multi-Cancer Early Detection Screening Coverage Act (H.R. 1946), was re-introduced by Representative Terri Sewell (D-AL) on March 16, 2021 following its initial introduction as H.R. 8845 during the 116th Congressional session in 2020. (PX0095 (H.R. 8845); RX3602 (H.R. 1946); [redacted]

225.4 The bill would add MCED tests as a Medicare benefit category, where a MCED test is defined as an FDA approved/cleared test for early detection across many cancer types, that is either of the following: 1) A genomic sequencing blood or blood product test that includes the analysis of cell-free nucleic acids, OR 2) Such other equivalent tests (which are based on urine or other sample of biological material) as the HHS Secretary deems appropriate. [redacted]

225.5 H.R. 1946 presents several challenges for MCED test manufacturers. First, manufacturers may expend resources in advocating for a bill that may ultimately lose traction and fail to become law, as seen with the bill's predecessor, H.R. 8845.

225.6 Second, assuming the bill is passed, manufacturers will be required to achieve FDA approval or clearance to qualify as a product under the new benefit category. (RX6001 (Deverka Trial Dep. at 49–50); RX6001 (Deverka Trial Dep. at 52; [redacted]

(iii) Alternative Coverage/Regulatory Pathways

226. CMS has developed several alternative streamlined coverage and reimbursement pathways, although each presents its own set of challenges. Such programs include Parallel Review Pilot Program, which is not currently available to MCED tests, and the recently established Medicare Coverage for Innovative Technologies (MCIT) Pathway, for which the status is unclear and implementation has been delayed until at least December 2021. (RX6001 (Deverka Trial Dep. at 53–55); RX3867 (Deverka Expert Report) ¶ 55.)

227. The Parallel Review Pilot Program. The Parallel Review Pilot Program ("Parallel Review") was established in October 2011 and permanently extended in 2016 to create a mechanism for the FDA and CMS to simultaneously review clinical data, decreasing the time between FDA approval and CMS NCD development. (RX3556 (FDA) at 3; RX3867 (Deverka Expert Report) ¶ 56.)

227.1 Since the program's inception, only two tests, Foundation One CDx and Cologuard, have successfully navigated Parallel Review, despite 26 applications and over 60 inquiries. (RX3052 (RAPS) at 1–2; RX3867 (Deverka Expert Report) ¶ 56.) If a test receives a positive coverage determination via the Parallel Review process, private payors must cover the test for their Medicare Advantage population, but do not need to cover the test for their non-Medicare Advantage beneficiaries. (RX3138 (Podemska-Mikluch, 2018) at 1; RX3867 (Deverka Expert Report) ¶ 56.)

227.2 As a result of statutory restrictions preventing Medicare from covering preventive services, Parallel Review will not be an option for a MCED test like Galleri unless there is legislative action to add MCED tests as a Medicare benefit category, or alternatively, if the test first receives a grade of A or B following successful USPSTF review. (RX3646 (Social Security Act § 1833 [42 U.S.C. 1395I]); RX6001 (Deverka Trial Dep. at 53–54); RX3867 (Deverka Expert Report) ¶ 57.)

228. The MCIT Pathway. The Medicare Coverage of Innovative Technology (MCIT) Pathway is a new option that may become effective at the end of 2021, although it is unlikely that CMS will allow the rule to become finalized without additional revision given that CMS has delayed implementation of MCIT twice in 2021.

228.1 It was initially proposed in 42 CFR Part 405 in August 2020, but was later delayed as a result of a regulatory freeze implemented by the Biden administration on January 20, 2021. (RX3228 (CMS); RX6001 (Deverka Trial Dep. at 54–55); RX3867 (Deverka Expert Report) ¶ 58.)

228.2 While MCIT might offer an accelerated Medicare coverage pathway for certain innovative products, the pathway is limited to FDA-approved or cleared devices and offers only a temporary coverage window of four years, after which a qualifying device loses coverage if not granted coverage via LCD or NCD. (RX3228 (CMS); RX6001 (Deverka Trial Dep. at 54–55); RX3867 (Deverka Expert Report) ¶ 59.)

5. **Private Payors**

229. Private payors use a robust evidentiary framework when considering coverage for diagnostic tests, including screening tests. (RX6001 (Deverka Trial Dep. at 56); RX3867 (Deverka Expert Report) ¶ 60.) While private payors may consider Medicare coverage policies when determining the coverage provided to their commercial population, payors are only required to implement Medicare coverage policies for their Medicare Advantage populations. (RX3867 (Deverka Expert Report) ¶ 60.)

230. In addition to the components of evidence development previously discussed – *i.e.*, analytical validity, clinical validity, clinical utility and health economic evidence – payors consider a range of factors when determining medical necessity, such as regulatory approval, the product's clinical indication (intended test use based on the signs, symptoms and populations for which a product is used), and health economics. (RX3043 (Akhmetov, 2015) at 1; RX3005 (Deloitte) at 8; RX3584 (Chambers et al., 2015) at 1.)

231. Although all diagnostics do not require FDA-approval/clearance, private payors may factor regulatory status into coverage decisions. Separately, payors will consider the product's target population and intended indication, where products that are intended for use in broad populations, like oncology screening tests, will be subject to greater scrutiny due to increased budgetary impact. (RX3867 (Deverka Expert Report) ¶ 60.)

232. When considering the budgetary impact of new products and services, payors will often consider only the short-term benefit to health outcomes, which underemphasizes the potential for long-term cost savings that may be afforded by MCED tests. (RX6001 (Deverka Trial Dep. at 56);RX3084 (Dept. of Veterans Affairs) at 1–2; RX3867 (Deverka Expert Report) ¶ 60.)

F. Specific Barriers and Challenges for Commercialization of MCED Tests

233. As discussed above, manufacturers of new MCED tests face a number of unique challenges regarding test reimbursement and widespread adoption, including the requirement for significant time and financial investments. (RX6001 (Deverka Trial Dep. at 62–64); RX3867 (Deverka Expert Report) ¶ 85; Chahine (Helio) Tr. 1125–27; Getty (Guardant) Tr. 2646–50, 2661.)

233.1 Some of these challenges are due to the novel nature of MCED tests such as the detection of multiple cancers simultaneously, navigation of Medicare statutory coverage limitations that currently do not exist for MCED screening, code development and payment assignment processes for a novel product, FDA approval of a multi-cancer screening test, and campaigns for other education and adoption challenges. (RX3867 (Deverka Expert Report) ¶ 85.)

234. Illumina's planned acquisition of GRAIL would allow Illumina to provide critical support to address both the unique challenges for early cancer screening as well as the typical challenges that arise for widespread private and public payor coverage. (RX6001 (Deverka Trial Dep. at 62–64); RX3867 (Deverka Expert Report) ¶ 85.)

234.1 The particularly innovative aspects of a test that can screen for multiple cancers simultaneously and potentially lead to improvements in cancer outcomes are often the same features that make evaluation of these tests complicated for payors. (RX6001 (Deverka Trial Dep. at 61–62); RX3867 (Deverka Expert Report) ¶ 86.)

1. High Evidence Hurdles

235. The foremost challenge in bringing a MCED test to market will be the high evidence hurdles that a test developer must surmount before payors will consider providing coverage for the test. (RX6001 (Deverka Trial Dep. at 90–91); RX3867 (Deverka Expert Report) ¶ 87.)

236. MCED tests face particularly burdensome hurdles during evidence development stages given the broad nature of their clinical indication and large scale at which screening methods are implemented. (RX3867 (Deverka Expert Report) ¶ 87.)

236.1 Clinical trials for MCED tests must include many patients from a variety of backgrounds and medical histories. [redacted]; Aravanis (Illumina) Tr. 1909–10.) These large sample sizes are required to evaluate MCED tests due to the low prevalence of individual cancer types across the general, asymptomatic population and to account for natural patient attrition during these studies. (RX3867 (Deverka Expert Report) ¶ 87.)

236.2 Further, studies that look to assess the treatment pathway following cancer detection will require follow-up periods of several years. (RX6001 (Deverka Trial Dep. at 90–91); RX3867 (Deverka Expert Report) ¶ 87.)

237. High evidence hurdles are the norm for screening tests since the target population is individuals without any signs or symptoms of cancer. (RX3583 (Wilson et al., 1968) at 134; RX3608 (Andermann et al., 2008); RX3156 (Dobrow et al., 2018) at 5.)

238. It is difficult to be certain about predicting the intended use population for the early adoption of Galleri by payors. (RX6001 (Deverka Trial Dep. at 91–92, 94–95); RX3867 (Deverka Expert Report) ¶ 88.)

238.1 Payors may prefer to limit test coverage to higher cancer risk populations to increase the diagnostic yield, limit their financial exposure, and minimize the risk of false positive results, patient anxiety and unnecessary, costly, and potentially harmful follow-up diagnostic procedures. (RX3867 (Deverka Expert Report) ¶ 88.)

238.2 Payors may also want to understand the implications of false negatives to address concerns about the possibility of patients foregoing SOC screening, thereby delaying cancer diagnoses and potentially increasing patient morbidity. (RX3867 (Deverka Expert Report) ¶ 88.)

238.3 GRAIL will need to invest time and resources to develop this evidence, either based on additional clinical studies or real-world evidence. (RX6001 (Deverka Trial Dep. at 91–92, 94–95); RX3867 (Deverka Expert Report) ¶ 88.)

239. Some payors may want to see prospectively collected evidence of the impact of MCED screening on mortality, which will require large, long-term follow-up studies. (RX3867 (Deverka Expert Report) ¶ 89.) Valid assessment of patient safety data requires the return of results to participants in a prospective study. (RX3867 (Deverka Expert Report) ¶ 89.)

240. To date, GRAIL has only returned results to patients in one study. PATHFINDER is a prospective study that enrolled 6,662 participants from seven clinical institutions in the U.S. between December 2019 and December 2020. (RX3044 (NIH); RX6001 (Deverka Trial Dep. at 93–94); RX3867 (Deverka Expert Report) ¶ 89.)

241. Participants whose MCED test results indicated presence of cancer underwent diagnostic testing, as determined by their treating physician informed by standard practice guidelines, to reach a diagnostic resolution - either the diagnosis of an invasive cancer (a "true positive") or no cancer (a "false positive"). (RX3867 (Deverka Expert Report) ¶ 89.)

241.1 Out of 6,629 analyzable test results, 1.4% (or 92 individuals) had a cancer signal detected, and 65 individuals had achieved diagnostic resolution as of March 2021. (RX3053 (Beer et al., 2021).)

242. While the first prospective study of Galleri is an important initial step to developing the necessary clinical data, additional and larger studies will be required to begin generating the evidence that payors will require. (RX6001 (Deverka Trial Dep. at 93–94); RX3867 (Deverka Expert Report) ¶ 89.)

242.1 The novelty of a MCED screening approach is likely to slow payor evidence reviews given the unprecedented nature of a single test that screens for multiple cancers. [redacted]

2. **Lack of Precedent For Payor Evaluation**

243. There is no precedent that payors can rely on for evaluating the clinical validity and utility of MCED tests. (RX6001 (Deverka Trial Dep. at 116–17); RX3867 (Deverka Expert Report) ¶ 90.) MCED tests are a nascent technology and while some companies have announced plans to develop multi-cancer tests in the future, GRAIL's Galleri test is the only MCED test for asymptomatic individuals that is currently available. (PX7105 (Getty (Guardant) Dep. at 23); [redacted]

244. Given that GRAIL's test has only very recently been introduced, no company currently has, or is close to receiving payor reimbursement for a MCED test, meaning payors would be evaluating and making coverage decisions on MCED tests for the first time. (RX6001 (Deverka Trial Dep. at 116–17); RX3867 (Deverka Expert Report) ¶ 90.)

245. Typical payor questions regarding whether a new test is clinically meaningful (clinical validity) or useful (clinical utility) will need to be defined for MCED screening in the first instance, as there is currently no consensus interpretation of clinical validity or clinical utility for a MCED test. (RX3867 (Deverka Expert Report) ¶ 91.)

246. One of the major justifications for adopting MCED screening is the notion of "aggregate prevalence" which refers to where universal screening efficiencies are realized by summing the cancer prevalence rates of individual cancers, thereby increasing the cancer detection rate (CDR), the overall number of true positive cancers detected out of the total number of expected cancers in a monitored population. (RX3715 (Ahlquist, Universal Cancer Screening, 2018) at 4; RX3867 (Deverka Expert Report) ¶ 91.)

247. Even when adding across the five currently screened cancers, the CDR is only 16% for breast, colorectal, lung, cervical and prostate cancers combined—suggesting a relatively low percentage of cancers are identified by current screening methods. (RX3670 (Ong, 2021) at 1; RX3867 (Deverka Expert Report) ¶ 91.)

248. A MCED test could offer further benefits where the test can screen outside of the five currently screening cancers. (RX3867 (Deverka Expert Report) ¶ 91.) Whereas for many less prevalent cancers single-organ population-wide screening could not be recommended due to the rarity of individual cancer types in average risk adults, a single blood-based test that can detect many different cancer types simultaneously could be justified by aggregating tumor-specific prevalence rates and increasing the overall CDR. (RX3715 (Ahlquist, Universal Cancer Screening, 2018) at 4; RX3867 (Deverka Expert Report) ¶ 91.)

249. However, it is unclear whether payors will accept these presumed benefits of MCED screening or if they will continue to review the clinical validity of any new test for each cancer type individually. (RX3867 (Deverka Expert Report) ¶ 91.)

249.1 If payors were to review the clinical validity for individual cancer types, rather than accepting overall MCED test sensitivity and specificity, this would create an additional evidence challenge for test developers. (RX6001 (Deverka Trial Dep. at 61–62); RX3867 (Deverka Expert Report) ¶ 91.)

250. Regardless of how payors review MCED benefits and harms, any MCED test developer, including GRAIL, will need to develop extensive evidence to establish clinical utility of a MCED test. (RX3867 (Deverka Expert Report) ¶ 92.) GRAIL will need to go beyond demonstrating multi-cancer detection rates by cancer type and stage to link these intermediate outcomes to the net health outcomes, such as survival rates and quality of life.

251. Given the statistical infeasibility of observing significant survival outcome benefits in the near-term, screening outcomes will need to be modeled. (RX3867 (Deverka Expert Report) ¶ 92.) The requisite sample size, duration of follow-up and costs of data collection make these types of studies very expensive with definitive results not available for potentially decades. (RX3867 (Deverka Expert Report) ¶ 92.)

251.1 While some single cancer screening models have been used by groups such as CMS to make decisions about covering new tests (e.g., Cologuard for colorectal cancer), there has never been a multi-cancer screening model that has been both peer-reviewed and applied in payor decision-making. (RX3867 (Deverka Expert Report) ¶ 92.)

251.2 Further complicating these models is that each specific cancer included in the model will have different detection rates as well as diagnostic and treatment paths. (RX3727 (Berger et al., 2016) at 2–3; RX3867 (Deverka Expert Report) ¶ 92.)

252. More work will need to be done to account for modeling issues such as tumor sojourn times (the total time a cancer would exist in a particular stage if left undetected by screening), and estimating lifetime survival benefits given competing risks of death in a multi-cancer context. (RX3178 (Hubbell et al., 2020) at 4–7; RX3149 (van den Broek et al., 2017) at 12–13; RX3867 (Deverka Expert Report) ¶ 92.)

253. Models that can account for up to 50 cancer types while also following modeling best practices will be extremely complicated, difficult to communicate to payors, and difficult for payors to understand. (RX3178 (Hubbell et al., 2020) at 7; RX3149 (van den Broek et al., 2017)

at 12–13.) There will also need to be extensive provider and patient education regarding how to interpret and use Galleri test results in order to create the opportunity to meaningfully measure clinical utility. (RX6001 (Deverka Trial Dep. at 42–43); RX3867 (Deverka Expert Report) ¶ 92.)

3. Single Cancer vs. Multi-Cancer Screening

254. Currently, all covered screening paradigms involve testing for a single cancer. To obtain coverage for any new single-cancer screening test requires significant evidence, including studies comparing the benefits and risks of the new test to either *no screening* for cancers without current guideline-based testing options, or to the current *standard of care (SOC)* for that particular cancer. (RX3867 (Deverka Expert Report) ¶ 93.)

254.1 This presents a challenge for MCED tests both because a MCED test may screen for cancers for which there is no current standard of care (*e.g.*, pancreatic cancer) and because there is no current screening paradigm for screening for multiple cancers in a single test. (RX3867 (Deverka Expert Report) ¶ 93.)

255. For currently screened cancers, the harms of testing are typically well known. For example, screening for lung cancer using low-dose computed tomography carries known biopsy risks to evaluate suspicious nodules. (RX3567 (Wiener et al., 2011) at 8; RX3867 (Deverka Expert Report) ¶ 94.)

255.1 In contrast, while there are clear advantages to MCED screening tests (*e.g.*, ease of use given simple blood draw potentially leading to improved screening compliance) the benefits and harms of MCED tests are largely unknown at this time and will likely differ by tumor site depending on the different types of low-risk and high-risk follow-up diagnostic procedures and the unknown effects of MCED screening on compliance with SOC screening. (RX3428 (Underwood et al., 2019) at 3; RX3867 (Deverka Expert Report) ¶ 94.)

255.2 Achieving payor coverage for a MCED test based on robust evidence will be both difficult and time-consuming for any company working in the cancer screening space because of these challenges. (RX6001 (Deverka Trial Dep. at 112–13); RX3867 (Deverka Expert Report) ¶ 94.)

256. Studies designed to accurately characterize the benefits and harms of numerous cancers (up to 50 for Galleri) would need to be very large given the low prevalence of asymptomatic cancer in a screen-eligible population (and potential for patient attrition) and unknown harms of screening for cancers that currently do not have a SOC screening modality. (RX3867 (Deverka Expert Report) ¶ 95.)

257. The overall benefit/risk balance for MCED test screening tests as compared to single cancer screening tests will also likely be based on a much larger number of variables derived from multiple tumor types (up to 50 different cancer types in the case of Galleri). (RX3867 (Deverka Expert Report) ¶ 95.)

257.1 For example, MCED tests have shown varying test sensitivity and specificity that differs by cancer site and by cancer stage because these test performance characteristics depend on tumor size, location and cfDNA shedding rates. (RX3427 (Ignatiadis et al., 2021); RX3867 (Deverka Expert Report) ¶ 95.)

258. In addition, the ability to accurately localize the tissue of origin in a screened positive patient may also vary by cancer. (RX3867 (Deverka Expert Report) ¶ 95.) This complexity of benefit/risk assessment for MCED tests was the topic of discussion in a recent FDA public workshop held by Center for Devices and Radiological Health (CDRH) in 2020, and comparable difficulties will arise in payor decision-making as payors evaluate the clinical utility (net benefits) of new MCED tests. (RX3591 (FDA); RX6001 (Deverka Trial Dep. at 63–64); RX3867 (Deverka Expert Report) ¶ 95.)

4. **Evidence of a Clinical Benefit**

259. On average, patients diagnosed with earlier stage cancers have better rates of survival than patients diagnosed with later stage cancers. (RX3867 (Deverka Expert Report) ¶ 96.)

259.1 For example, the 5–year survival rate for patients diagnosed with Stage I breast cancer (cancer localized to the breast) is 99%, whereas it is only 26% for women diagnosed with Stage IV breast cancer (cancer has spread to other parts of the body). (RX3706 (Susan G. Komen) at 2.)

260. The major clinical advantage of MCED test is the presumed ability of the test to detect cancers at earlier stages where the prognosis is better and there is a greater likelihood of cure. (RX3588 (Clarke et al., 2020) at 1; RX3867 (Deverka Expert Report) ¶ 96.)

261. This benefit of a MCED test is referred to as "downstaging" and is the driver for claims about likely improvements in survival and quality of life. (RX6001 (Deverka Trial Dep. at 61–62); RX3867 (Deverka Expert Report) ¶ 96.)

261.1 This is particularly important for cancers without a current screening modality such as pancreatic or ovarian cancers where the assumption is that a cancer diagnosis obtained through screening is always better than waiting for symptoms to develop. (RX3867 (Deverka Expert Report) ¶ 96.)

262. However, payors may challenge this assumption as related to lead-time bias: the phenomenon where patients' time of death is unchanged, but when measuring survival from the time cancer was screened-detected leads to the erroneous conclusion that survival is improved. (RX3867 (Deverka Expert Report) ¶ 96.)

262.1 As a result, payors may require additional clinical utility evidence to establish increased survival due to earlier detection. (RX6001 (Deverka Trial Dep. at 61–62); RX3867 (Deverka Expert Report) ¶ 96.)

263. With respect to Galleri, specifically, the sensitivity of the assay varies by tumor type and stage. (RX3430 (Liu et al., 2020) at 1; RX3867 (Deverka Expert Report) ¶ 97.) In

addition to Galleri, Thrive has published results of a multi-cancer clinical study indicating different levels of sensitivity and specificity. (RX3867 (Deverka Expert Report) ¶ 97, n.193; RX3419 (Lennon et al., 2020).)

263.1 Given the reliance of the assay on detecting tumor DNA (ctDNA) fragments in the blood—which increase as cancer develops into later stages, it is unsurprising that Galleri has the highest sensitivity for later stage cancers as these represent tumors that have spread regionally or distantly and tend to shed a higher amount of ctDNA. (RX3773 (Klein et al., 2021); RX3867 (Deverka Expert Report) ¶ 97.)

5. Additive To Current Screening Tests

264. Because Galleri is intended to be additive to current standard-of-care screening tests, this approach raises additional questions for payors. (PX7130 (Deverka Dep. at 198); RX3867 (Deverka Expert Report) ¶ 98.)

264.1 For example, what are the additional clinical benefits of the MCED test for currently screened cancers versus the benefits of the MCED test for cancers that have no currently recommended screening modalities? (RX3867 (Deverka Expert Report) ¶ 98.)

264.2 And what evidence will be required by payors to mitigate the concern that patients who are tested with Galleri and found to have a "no cancer detected" result may have a false sense of reassurance and therefore decreased adherence to routine screening interventions? (RX3867 (Deverka Expert Report) ¶ 98.)

264.3 These issues stem from the unique features of MCED tests and are likely to complicate payor evidence reviews as part of coverage decision-making and will require significant educational outreach to payors on the part of MCED test developers. (PX7130 (Deverka Dep. at 198); RX3867 (Deverka Expert Report) ¶ 98.)

6. Economic Considerations

265. With a target population of individuals aged 50 or older with average cancer risk, the size of the eligible population for Galleri and other MCED tests is very large (i.e., most individuals ages 50–79). (RX3867 (Deverka Expert Report) ¶ 99.) [redacted] Qadan (Illumina) Tr. 4109.)

266. Affordability is heavily dependent on the price of Galleri and the testing interval (every 2 years, every year, or more frequently) with significant near-term impact on the per member per month (PMPM) costs of delivering care to an insured population. (RX3867 (Deverka Expert Report) ¶ 100.)

267. [redacted]

[redacted]

268. While GRAIL and other future MCED test manufacturers may be able to address these economic considerations by emphasizing the value (cost/outcome) of Galleri, in particular long-term value, that argument may not be persuasive to private insurers. (RX6001 (Deverka Trial Dep. at 34–35); RX3867 (Deverka Expert Report) ¶ 101.) In this context, value (synonymous with cost-effectiveness) is defined as patient cancer-related health outcomes achieved relative to the costs associated with cancer detection and appropriate clinical follow-up care. (RX3867 (Deverka Expert Report) ¶ 101.)

269. Costs are most commonly measured from the health care payor perspective. (RX3867 (Deverka Expert Report) ¶ 101.) Value assessment is inherently comparative, as the goal is to inform the question, "should we pay for this new test *compared to the standard of care?*" (RX3867 (Deverka Expert Report) ¶ 101.)

270. If the presumed benefits of MCED screening approaches are realized, this will result in improved survival and quality of life for individuals detected with cancer due to downstaging, which can be measured as cost-effectiveness. (RX6001 (Deverka Trial Dep. at 34–35); RX3867 (Deverka Expert Report) ¶ 101.)

270.1 For a stable insured population, downstaging is expected to translate into cancer-specific cost-effectiveness because of improved survival and reduced cancer treatment costs or even cures. (RX6001 (Deverka Trial Dep. at 34–35); RX3867 (Deverka Expert Report) ¶ 101.)

271. However, even if Galleri is likely to be cost-effective, it will likely not be cost saving. (RX3867 (Deverka Expert Report) ¶ 102.) Whereas a "cost-effective" new technology produces more health benefits at greater cost relative to the current standard of care, a "cost saving" new technology produces the same or more health benefits at a lower cost than the current standard of care. (RX3160 (Goodell et al., 2009) at 2; RX6001 (Deverka Trial Dep. at 115–16); RX3867 (Deverka Expert Report) ¶ 102.)

272. Most new technologies introduced into the healthcare marketplace are cost-effective, not cost-saving, with the health benefits accruing over a patient's lifetime. (RX3867 (Deverka Expert Report) ¶ 102.) In the U.S., private payors, however, often have a short time horizon for decision-making (1–3 years) because of high member turnover. (RX3671, (Graves et al., 2017) at 8.)

273. These private payors evaluating a new screening test may be less likely to cover a test that is not cost saving despite the potential cost-effectiveness over a longer time period because U.S. private payors are less likely to see the benefits of cost-effective devices during an individual patient's subscription to a particular insurer's plan. (RX3867 (Deverka Expert Report) ¶ 102.)

274. Test manufacturers will likely have to expend significant efforts to encourage private payors to incorporate cost-effectiveness data into their evaluation process for MCED tests. (RX3867 (Deverka Expert Report) ¶ 102.)

275. In contrast, net health outcome benefits may be more persuasive to Medicare given their lifetime insurance responsibilities to beneficiaries. (RX3867 (Deverka Expert Report) ¶ 102.) In addition, there is evidence that Medicare does consider cost-effectiveness data in their evaluation of preventive services. (RX3459 (Chambers et al., 2014) at 3–4.) Medicare is also prohibited from basing coverage decisions on cost effectiveness data. (RX3458 (Neumann et al., 2012); RX3867 (Deverka Expert Report) ¶ 102, n.199.)

276. Payors will also likely consider the economic costs incurred through the diagnostic follow up required for patients who receive a positive result from a MCED test. (RX3867 (Deverka Expert Report) ¶ 103). Similar to most current single cancer screening tests, while Galleri can presumptively localize the tumor, follow-up diagnostic testing will be required to definitively rule-in cancer. (RX3867 (Deverka Expert Report) ¶ 103.)

277. While data from case-control studies indicates Galleri has a very high specificity level (over 99%), until there are robust prospective data about the rates of false positive results with Galleri in average risk populations, payors are likely to be concerned about the potential for downstream clinical and economic harms with MCED screening approaches. (RX3430 (Liu et al., 2020) at 1; RX3867 (Deverka Expert Report) ¶ 103.)

277.1 For example, a false positive result with Galleri could lead to unnecessary diagnostic testing and costs, the risk of procedure-related complications, and diminished patient quality of life. (RX3867 (Deverka Expert Report) ¶ 103.)

278. The PATHFINDER study was GRAIL's first study that returned results of Galleri to patients at both average and increased risk of cancer. (RX3044 (NIH); RX3867 (Deverka Expert Report) ¶ 103.)

279. Payors will likely require further evidence to establish the clinical utility (net benefit) of Galleri and for payors to effectively evaluate the full economic costs of Galleri, including the costs of false positives. (RX6001 (Deverka Trial Dep. at 93–94); RX3867 (Deverka Expert Report) ¶ 103.); Aravanis (Illumina) Tr. 1947.)

7. **Equitable Access and the Size of the Eligible Patient Population**

280. The current lack of private and public payor coverage raises significant concerns about equality and access to potentially life-saving tests. (PX7130 (Deverka Dep. at 23–25); RX3867 (Deverka Expert Report) ¶ 104.) There are numerous disparities in cancer screening adherence and cancer outcomes for minorities and other underserved populations. (RX3662 (Patel et al., 2020) at 1).

280.1 Where a new technology could serve to expand access to cancer screening tests, all efforts should be made to avoid exacerbating these disparities and in fact to work towards reducing them in healthcare. (RX3180 (Virnig et al., 2009) at 6–8; RX3867 (Deverka Expert Report) ¶ 104.)

281. Factors that are being studied for their relationship to poorer cancer outcomes include insurance status, care-seeking behaviors, income, education, racial differences in healthcare providers, providers' role in delayed diagnosis and Medicaid enrollment. (RX3088 (Zavala et al., 2020) at 2–3; RX3867 (Deverka Expert Report) ¶ 104.)

282. The preferred approach is to take advantage of the potential for improved insured member uptake because of reliance on a simple blood draw so that the benefits of MCED screening can be equitably shared. (PX7130 (Deverka Dep. at 23–25); RX3867 (Deverka Expert Report) ¶ 104.)

283. Improved cancer outcomes for all persons will not be achieved if MCED screening is introduced under a strictly limited access framework that makes testing narrowly available to only those individuals that can afford these tests by paying out of pocket or who may be members of executive wellness programs or other employer-sponsored wellness initiatives—individuals that on average have lower cancer risk because of their younger age as compared to retirees. (RX3507 (NCI); RX3867 (Deverka Expert Report) ¶ 105.)

283.1 For example, Galleri is currently available without any insurance coverage at a list price of $949 per test. (RX3253 (GRAIL); RX3867 (Deverka Expert Report) ¶ 105.)

284. Paying out of pocket for an over $900 test that could be potentially life-saving may not be a significant burden for wealthy individuals but it is likely to be far outside the budget of most Americans. (RX3867 (Deverka Expert Report) ¶ 105.) The sooner that Galleri can be adopted and covered by a broad range of payors, the more likely the test could ameliorate long-standing disparities in access and outcomes. (PX7130 (Deverka Dep. at 23–25); RX3867 (Deverka Expert Report) ¶ 105.)

8. **Stakeholder Engagement**

285. Given that MCED is a new technology class, payors do not yet have relevant coverage policies. (RX3867 (Deverka Expert Report) ¶ 106). As such, MCED test manufacturers will have to engage with Medicare, Medicaid *and* private payors to adequately demonstrate medical appropriateness based on developed evidence prior to development of new policies. (RX6001 (Deverka Trial Dep. at 31–32); RX3867 (Deverka Expert Report) ¶ 106; Qadan (Illumina) Tr. 4152–53.)

286. Payors may be apprehensive to provide coverage due to the large indicated population, and therefore substantial budgetary impact, of screening applications without clear evidence of the benefits and harms (clinical utility) of MCED tests. (RX3867 (Deverka Expert Report) ¶ 106).

287. Given the challenges and the novelty of MCED screening, test manufacturers will be required to engage with multiple stakeholders to not only demonstrate the utility and effectiveness of their product but to generate interest and understanding about a new testing paradigm. (RX6001 (Deverka Trial Dep. at 31–32); RX3867 (Deverka Expert Report) ¶ 106).

288. After development of new codes, corresponding payment assignment, robust evidence development and securement of private and public payor coverage, MCED test manufacturers will still need to overcome a number of educational barriers prior to widespread test adoption, including at the prescribing physician, patient and payor level. (RX6001 (Deverka Trial Dep. at 42–43); [redacted]

288.1 The former Vice President of Clinical Business Development at Illumina, John Leite, summarized this particular challenge as: "[O]nce you have a test approved . . . you have to spend money to educate physicians, to educate payors, to educate hospital systems and employers as to why it's important to adopt your tests. And ultimately you're investing to change physician behavior to ultimately change the standard of care. All of these programs are very expensive and require capital." (PX7088 (Leite (Illumina/InterVenn) Dep. at 33).)

289. Physicians may be reluctant to adopt new technology, particularly as they may be uncertain how to interpret test results. (PX6097 (Abrams Expert Report) ¶ 32; RX3867 (Deverka Expert Report) ¶ 108.) Galleri offers a sensitivity of ~50% and a specificity of approximately 99%; the specificity rate of ~99% means that a positive test result is a reliable indication of cancer and has a very low risk that healthy individuals will be falsely diagnosed. (RX3279 (Precision Oncology); RX3867 (Deverka Expert Report) ¶ 108.)

290. However, the ~50% sensitivity rate (while higher than some current SOC screening tests) means that a negative test result does not guarantee that the patient does not have cancer. (RX3867 (Deverka Expert Report) ¶ 108.) While these rates may be appropriate for Galleri as a screening application, how to interpret and respond to aggregate cancer detection results may not be intuitive to all clinicians. (RX3867 (Deverka Expert Report) ¶ 108.)

291. The proper integration of positive MCED test results into the oncology clinical pathway may also differ across tumor types, which could require additional training for physicians depending on their specialty. (RX3534 (Putcha G., One Size Does Not Fit All); PX7130 (Deverka Dep. at 23–25); RX3867 (Deverka Expert Report) ¶ 108.)

292. In addition to educational campaigns, GRAIL will need to engage with specialty societies and patient advocacy organizations, and drive inclusion of MCED screening in standard treatment paradigms as outlined in key oncology treatment guidelines, such as those developed by NCCN. (RX6001 (Deverka Trial Dep. at 175–76); RX3867 (Deverka Expert Report) ¶ 109.)

293. The totality of these efforts will require substantial resources, time, and funding to ensure broad MCED screening access beyond initial commercial availability. (RX6001 (Deverka Trial Dep. at 175–76); RX3867 (Deverka Expert Report) ¶ 109.)

G. Developing a New Cancer Screening Test Capable of Screening for Multiple Cancers Simultaneously is Difficult and Takes Years

294. It is undisputed that developing a cancer screening test, particularly a cancer screening test that simultaneously identifies more than one type of cancer, is a challenging endeavor. [redacted]

295. Many years of research and development are needed to generate a blood-based assay that has the appropriate biomarkers needed to have the requisite sensitivity and specificity, not to mention ability to detect a molecular cancer signal of origin. (RX3869 (Cote Expert Report) ¶ 99.)

295.1 GRAIL was launched in 2016 within Illumina, and was only able to launch its multi-cancer screening test as an LDT in 2021. (Flatley (Illumina) Tr. 4090; Bishop (GRAIL) Tr. 1322–23.) GRAIL is still years away from seeking FDA approval for its multi-cancer screening test. (Bishop (GRAIL) Tr. 1343; PX7069 (Bishop (GRAIL) IHT at 94).)

296. Similarly, Thrive was originally founded based on the research from a company called PapGene as well as research from Johns Hopkins University. (PX7101 (Vogelstein (Johns Hopkins University) at 27–28;).) PapGene was started in 2014. (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 27–28).)

296.1 Thrive has still not launched a commercial version of its cancer screening test, CancerSEEK, seven years later.

296.2 In late 2020, Exact Sciences acquired Thrive. ; PX7101 (Vogelstein (Johns Hopkins University) Dep. at 48–49).)

296.3 PX7062 (Kollu (GRAIL) IHT at 162);

297. Other purported MCED test developers are much further behind. For example, Freenome was founded in 2014. (Nolan (Freenome) Tr. 2724; PX7121 (Otte (Freenome) Dep. at 13).)

298.

299.

300. [redacted]

301. Even if a company is seeking to add a new cancer type to a cancer screening test, it cannot skip new biomarker discovery, assay development, case-control study, and validation/clinical steps, even if it can reduce sample collection time by relying on previously collected samples for certain steps. [redacted]

302. [redacted]

1. **Sample Collection and Initial Research**

303. While test developers may pursue these steps in different orders, the initial steps typically involve sample collection, research and biomarker discovery. (Cote Tr. 3783–85; RX3869 (Cote Expert Report) ¶ 104.)

304. Specifically, a given company needs to collect samples for the new cancer type to perform the new biomarker discovery; even if this company had previously collected samples for

one cancer type, these existing samples would not have the new proposed cancer type.

304.1 It is critical that samples are collected uniformly according to a sample collection protocol to ensure high quality samples that are comparable. (Aravanis (Illumina) 1899–1900.) "If you were just to mix and match samples collected in different ways from different purposes, you would end up finding [cancer] signals that are just artifacts of those methods. And were you to develop a test in that way . . . likely it wouldn't perform well." (Aravanis (Illumina) 1899–1900.)

304.2

305. During the sample collection period, the test developer may also perform initial technology development and preliminary feasibility studies.

305.1 For example, as part of the preliminary feasibility assessment, the developer would assess what the development plan would look like, how much it would cost and its probability of success.

306. Biomarker discovery involves efforts by the test developer to identify which biomarkers are the best at predicting that an individual has cancer, and particularly, if that biomarker may be used to distinguish between an individual who has cancer and a healthy subject.

306.1 Biomarker discovery may involve research to understand what the biological drivers are, and depending on the drivers and the relevant mutations, a given biomarker may be selected.

306.2 While test developers may review the scientific literature, given the interest of test developers in developing a test that is unique and differentiated, developers are likely to attempt to identify new biomarkers and loci that are not present in the literature. (RX3869 (Cote Expert Report) ¶ 105.)

306.3 Once the test developer has discovered relevant biomarkers from the research step, which can take three to five years, the developer moves into assay development or optimization.

306.4 The research stage can often be a substantial investment, costing in the ballpark of $100 to $150 million when accounting for the samples analyzed and the

requisite processing. [redacted]

306.5 According to Dr. Cote, biomarker discovery can take anywhere from 18 months to three years, and in some cases much longer. (Cote Tr. 3785–86.)

307. Although it is possible that the R&D process may be shortened to add a new cancer type to an existing test because the company has already elected to pursue a mutation or methylation-based approach, the company would still need to pursue new biomarker discovery for the new cancer(s). (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 106.)

308. To date, scientists have not discovered any biomarkers that are "pan cancer", and this is not unexpected given what is understood about the biological drivers of cancer. (Aravanis (Illumina) Tr. 1883, 1896–98; RX3869 (Cote Expert Report) ¶ 106.)

309. Therefore, even though companies may chance upon one or a few relevant biomarkers for the new cancer type during development of their previous cancer screening test, full biomarker discovery would still be required to identify a panel of biomarkers for the new cancer type(s) to ensure the accuracy, specificity and sensitivity needed for an early cancer screening test. (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 106; *see also* Aravanis (Illumina) Tr. 1883, 1896–98.)

309.1 The challenge is multiplied many-fold as the number of cancers under consideration to be screened increases. (RX3869 (Cote Expert Report) ¶ 106; *see also* Aravanis (Illumina) Tr. 1883; 1896–98.)

309.2 As Gary Gao of Singlera explained, in ten years, Singlera has only had "enough sample type[s] for five given types of a cancer to validate . . . there are hundreds of different cancer types, and over a ten-year span, you can only collect enough sample for four or five different cancers for validation purpose. So for five different kinds that we can estimate, you know, it may take seven to eight years [to conduct a] prospective trial to have FDA approval. ***For 50 or 100 kinds of cancer, it would take maybe 50 years.*** You know, that's just the reality of it." (Gao (Singlera) Tr. 1883.)

310. After the test developer is satisfied with the biomarkers selected for the assay, the test developer enters the "development" stage and focuses on optimizing the assay across different metrics, including costs, quality control and other performance characteristics. [redacted]

310.1 For example, an assay that is interrogating multiple cancer types, or is analyzing multiple analytes may require more time than the assay development stage for a single cancer assay. [redacted]

310.2 The development stage can take multiple years and also impose a cost of about $50 to $100 million. (Cote Tr. 3786; [redacted]

2. Validation/Clinical Studies

311. After the test developer has completed the initial research and development steps, to support the marketing and reimbursement of a clinical oncology test as either an LDT or IVD test with FDA approval, oncology test developers must perform clinical studies to validate the efficacy of any clinical oncology test in detecting cancer and to identify the cancers that such tests are intended to detect at an early stage. (PX7086 (Cance (ACS) Dep. at 50); [redacted] 3783–3785, [redacted]

312. The studies that are required to validate a diagnostic test, and in particular a multi-cancer screening test, are well-established to be the biggest expense incurred by a clinical test developer in pursuing an early cancer screening test. (Cote Tr. 3793–3794, 3806; PX7118 (Fiedler (FMI) Dep. at 71); [redacted] *see also* PX7090 (Sood (Guardant) Dep. at 26–27); [redacted]

312.1 For example, FMI's COO states that clinical trials are "extremely expensive" and "in the tens of thousands per patient" (PX7118 (Fiedler (FMI) Dep. at 71); *see also* [redacted] *see also* PX7090 (Sood (Guardant) Dep. at 26–27).)

313. While the requirements for an LDT test are likely to be less stringent than would be required for FDA approval, for an LDT to gain traction with relevant stakeholders, it will have to undergo extensive and rigorous clinical validation. (RX3869 (Cote Expert Report) ¶ 108.)

313.1 [redacted]

313.2 The American Cancer Society "rel[ies] on published results of those clinical trials to help it establish screening guidelines for MCED tests" (PX7086 (Cance (ACS) Dep. at 36) and "multi-cancer detection tests need more data and validation in order to assist with cancer diagnosis determinations." (PX7086 (Cance (ACS) Dep. at 50); RX3869 (Cote Expert Report) ¶ 108, n.109.)

314. A test developer may conduct any one of several types of clinical trials in order to launch an LDT test conducted by a CLIA-certified laboratory,. (RX3869 (Cote Expert Report) ¶ 109; *see also* Cote Tr. 3783–85, 3806–07.)

314.1 The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA) passed by Congress in 1988, which

established quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. (RX3141 (CMS) at 1.)

314.2 Before a clinical laboratory can apply for state licensure to operate, it must first obtain CLIA certification from the CMS and become a CLIA-certified laboratory. (RX3869 (Cote Expert Report) ¶ 109, n.111; *see also* RX3141 (CMS) at 1; RX3912 (CMS).)

315. Retrospective, case-control study. The simplest of the types of clinical trials is known as a "case-control study." (Cote Tr. 3783–85; PX7086 (Cance (ACS) Dep. at 60–61); RX3869 (Cote Expert Report) ¶ 110.) In the case of the development of a cancer screening test, a study that analyzes specimens (*e.g.*, blood) collected from patients for whom the cancer status is already known (positive or negative) is "retrospective" because it is backward-looking. (RX3869 (Cote Expert Report) ¶ 110.)

315.1 A retrospective, case-controlled cohort study uses pre-collected samples from at least two cohorts of individuals: one with samples from patients diagnosed with the target cancer or cancers, and another with samples from healthy donors who have been "matched" by age or other parameters to the cohort of cancer patient. (PX7086 (Cance (ACS) Dep. at 60–61); RX3869 (Cote Expert Report) ¶ 110.)

315.2 A case-control study may also have a third cohort of samples from patients diagnosed with non-malignant diseases of the same organ or organs for the relevant cancer types. (RX3869 (Cote Expert Report) ¶ 110.)

315.3 There are no specific sample size requirements for such case-control studies. (RX3869 (Cote Expert Report) ¶ 111.) Such studies vary from fewer than 100 samples in each cohort to several thousands of samples in larger studies. (RX3869 (Cote Expert Report) ¶ 111.) Case-control studies range in cost and time from a few months at a cost of less than a million dollars up to a few years at a cost of tens of million dollars. (Cote Tr. 3786; RX3869 (Cote Expert Report) ¶ 111.)

315.4 [redacted]

315.5 A validation study is used to observe, document, and understand variation in the data generated under specific laboratory conditions. (Cote Tr. 3783–85; RX3869 (Cote Expert Report) ¶111, n.115.) Validation helps define the scope or range of conditions under which reliable results may be obtained. (Cote Tr. 3783–85; PX7086 (Cance (ACS) Dep. at 50); [redacted]; RX3869 (Cote Expert Report) ¶111, n.115.)

316. Prospective, observational study. In contrast to a retrospective study, a study which collects blood from patients who are asymptomatic, and thus have no signs of cancer, and

then follows these patients for a period of time to see who develops cancer, is "prospective" or forward-looking. (PX7086 (Cance (ACS) Dep.) at 61–62; Cote Tr. 3783–85.) Participants in a prospective study are enrolled into the study before they develop or are diagnosed with the disease or outcome in question—in the case of cancer screening tests, cancer. (RX3869 (Cote Expert Report) ¶ 112.)

316.1 A study is "observational," where the investigator will not act upon study participants, but instead will observe natural relationships between factors and outcomes. (Cote Tr. 3827–28, 3832; RX3869 (Cote Expert Report) ¶ 113.) In an observational study, the physician overseeing the patient will not be informed of any test results at least until after the study is over. (RX3869 (Cote Expert Report) ¶ 113.)

316.2 In contrast to a retrospective case-control study, [redacted] estimated that a prospective observational study of a potential cancer screening test would require samples from at least 5,000 patients over three years of sample acquisition, from both inside [redacted] and from blood banks, at a cost of about $100 million. [redacted]

316.3 However, many prospective observational studies for cancer screening tests have been even bigger. (RX3869 (Cote Expert Report) ¶ 114.) [redacted]

316.4 Prospective studies for tests that will analyze multiple cancer types simultaneously are likely to require more samples and more funding correspondingly. (Cote Tr. 3806; RX3869 (Cote Expert Report) ¶ 114.)

317. Prospective, interventional study. A study is "interventional" where the investigator intercedes as part of the study design. (RX3869 (Cote Expert Report) ¶ 115.) In other words, upon a positive finding in a cancer screening study, the physician overseeing the patient will be informed, and is likely to order follow-up tests to rule in or out cancer, and then corresponding treatments if the patient is diagnosed with cancer. (RX3869 (Cote Expert Report) ¶ 115.) The cost of prospective interventional studies is higher than the cost of a prospective observational study. ([redacted] 3783–85, 3793–94, [redacted]; RX3869 (Cote Expert Report) ¶ 115.)

317.1 A study may be called a "longitudinal" study where subjects are followed over time with continuous or repeated monitoring of risk factors or health outcomes, or both. (Gao (Singlera) Tr. 2877–78; RX3869 (Cote Expert Report) ¶ 119, n.123).

317.2 A "registrational" trial is where the study is intended (as of the time the first patient is enrolled) to obtain sufficient data and results to support the filing of an application for regulatory approval. (Lengauer (Exact/Thrive) Tr. 170; RX3869 (Cote Expert Report) ¶ 120, n.124.) Depending on the product being tested, a registrational

trial is often a randomized, controlled trial, or a prospective, interventional trial. (RX3869 (Cote Expert Report) ¶ 120, n.124.)

317.3 For any prospective study, the study size should be big enough to provide sufficient statistical power (with considerations of the associated variabilities) to answer the questions posed by the pre-specified endpoints under investigation, and not too big to avoid exposing participants of unnecessary procedures and treatments and to reduce unnecessary cost. (PX7086 (Cance (ACS) Dep. at 60); Cote Tr. 3806; RX3869 (Cote Expert Report) ¶ 116.)

318. FDA's requirements for obtaining premarket approval from the FDA may be more stringent than for a test developer to commercialize an LDT: an LDT can be launched by demonstrating results of a case-control study. (Cote Tr. 3824.) FDA is likely to only consider results from well-controlled clinical studies in "a significant portion of the target population" that will demonstrate that the test "will provide clinically significant results." (RX3220 (FDA) at 3; 21 CFR § 860.7.)

318.1 Specifically, for the FDA to approve a cancer screening test it is likely that the developer of a potential cancer screening test would need to conduct a large, prospective, interventional study in asymptomatic patients. (Cote Tr. 3783–85; [redacted] RX3869 (Cote Expert Report) ¶ 117.)

319. The FDA has said that "[t]here is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results. The valid scientific evidence used to determine the effectiveness of a device shall consist principally of well-controlled investigations." (RX3220 (FDA) at 3; 21 CFR § 860.7; RX3869 (Cote Expert Report) ¶ 117, n.120.)

320. In other words, for an early cancer screening test, whose target population comprises asymptomatic individuals who do not have a diagnosis of cancer, the clinical study cannot use samples from cancer patients, but will need to collect fresh samples prospectively from a large enough set of individuals to qualify as "a significant portion of the target population." (RX3220 (FDA) at 3; RX3869 (Cote Expert Report) ¶ 118.)

321. Because the incidence of cancer in an asymptomatic population is only 4 in 1000 individuals, this means that any proposed study will need to include many thousands of such individuals to provide the opportunity to find diverse cancer types and to have enough patients who will be diagnosed with cancer to be statistically valid. (RX3501 (National Cancer Institute) at 2; RX3869 (Cote Expert Report) ¶ 118.)

322. Further, the study must be interventional to evaluate whether the early cancer screening test can provide clinically significant results. (Cote Tr. 3783–85, 3793–94, 3804–05; RX3869 (Cote Expert Report) ¶ 118.)

323. In this case, "clinically significant results" will likely include a determination that a higher than expected proportion of the diagnosed cancers are detected at early, potentially curable stage, and may even require follow-up of these patients to determine if early diagnosis and intervention did indeed result in higher than expected cure rates. (RX3869 (Cote Expert Report) ¶ 119).

324. Such clinical studies will take months of planning, one or more years of recruiting participants at multiple sites, testing and analysis of samples, diagnostic follow-up to rule in or out cancer, further therapeutic intervention for those that are diagnosed with cancer, multiple years of follow-ups, and at least multiple hundreds of millions of dollars in cost over a minimum of 5-7 years. (Cote Tr. 3783–85, 3793–94, 3804–05; RX3869 (Cote Expert Report) ¶ 119.)

324.1 This would not include the years of work and expense that would be needed to develop a potential multi-cancer screening test in the first place. [redacted] RX3869 (Cote Expert Report) ¶ 119.)

325. As a result, completion of successful clinical studies in a population covering the intended use of a cancer screening product is one of the biggest hurdles for an early cancer screening test. (Cote Tr. 3783–85, 3793–94; RX3869 (Cote Expert Report) ¶ 120.)

325.1 [redacted]

325.2 [redacted]

326. Further, the results from a clinical study of a screening test for a single specific cancer cannot be used to support a screening test for a different cancer type or multiple cancer types. (RX3869 (Cote Expert Report) ¶ 121.)

326.1 For a retrospective, case-control study, only the healthy samples may be re-used to evaluate the efficacy of the new test, because samples from the cancer cohort would not have the new cancer or cancers under investigation. (RX3869 (Cote Expert Report) ¶ 121.)

326.2 As for a prospective, interventional study, the results of an earlier trial on a single cancer cannot be used because the intervention being analyzed for the new

cancer types covered by the new screening test will be different from the intervention in the original study. (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 121.)

327. [redacted]

327.1 [redacted]

3. **Addition of a New Cancer to An Existing Test**

328. Even once you have an existing cancer screening test, it does not become easier to add additional cancers. (Cote Tr. 3787; RX3869 (Cote Expert Report) ¶ 123.)

328.1 As Dr. Cote testified, going through the majority of the development steps for a single-cancer screening test does not put a cancer screening test developer in a position where they're ahead in developing a cancer screening test for a different cancer:

> The development of biomarkers for a particular cancer will not be adequate for other cancers. While there may be overlap, one still needs to go through all of the [development] steps. If . . . the test developer has made the decision that they've already undergone biomarker discovery with the assay that they have, they still need to go through the case-control verification to determine whether or not the assay has the performance characteristics needed . . . for the new target cancer, and then has to go through a prospective trial depending on which cancer is being targeted.
>
> (Cote Tr. 3787.)

328.2 Should the FDA adopt a relaxed approach to additional cancers, it would be a significant retreat from its longstanding practice to only consider studies of "a significant portion of the target population" that will demonstrate that the test "will provide clinically significant results." (RX3220 (FDA) at 3; 21 CFR § 860.7; RX3869 (Cote Expert Report) ¶ 123).

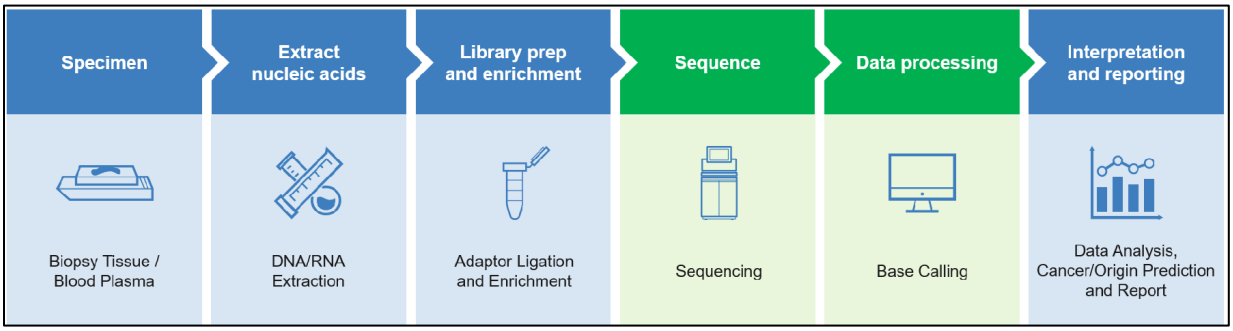
329. It would take much longer for a prospective, interventional clinical study to demonstrate the efficacy of the cancer screening test in asymptomatic population, and then for the FDA to approve the LDT test as an IVD test (whether as a single-site or as a distributable kit). (RX3869 (Cote Expert Report) ¶ 124.) The whole process will likely take seven to ten years, at minimum. (RX3869 (Cote Expert Report) ¶ 124).

H. Exemplary Clinical Oncology Testing Workflow

330. To the extent that a cancer screening test developer uses Illumina's NGS product, the sequencing step is only one part of a multi-step workflow. (Aravanis (Illumina) Tr. 1829–33; Berry (Illumina) Tr. 814–21; RX3869 (Cote Expert Report) ¶ 125.)

331. As shown in the below figure, sequencing comprises only one step in the overall testing workflow. (RX3860 (Cote Expert Report) ¶ 125, Figure 3.)

Figure 4: Testing Workflow



332. The steps are (i) specimen collection, (ii) sample preparation (nucleic acid extraction), (iii) library preparation, all of which are involved in preparing the sample, (iv) sequencing, (v) data processing and (vi) data interpretation/reporting. (Aravanis (Illumina) Tr. 1829–1833; Berry (Illumina) Tr. 814–21; RX3869 (Cote Expert Report) ¶ 126.)

333. For any test that uses NGS sequencing, only two of these six steps involve NGS instruments. (RX3869 (Cote Expert Report) ¶ 126; Aravanis (Illumina) Tr. 1829–33; Berry (Illumina) Tr. 814–21.)

334. *First*, an appropriate sample specimen is collected, such as a tissue biopsy sample, or blood sample for liquid biopsy. (Aravanis (Illumina) Tr. 1829–30; Berry (Illumina) Tr. 814; RX3869 (Cote Expert Report) ¶ 127.)

334.1 A blood sample is collected by a phlebotomist. (Aravanis (Illumina) Tr. 1829–30; Berry (Illumina) Tr. 814; RX3869 (Cote Expert Report) ¶ 127.) The samples are stored at low temperature and the relevant portion of the sample, such as the abnormal tissue or blood plasma, is separated for further use. (Aravanis (Illumina) Tr. 1829–30; Berry (Illumina) Tr. 814–20; [redacted]

335. [redacted] Aravanis (Illumina) Tr. 1829–30; Berry (Illumina) Tr. 814–20; RX3869 (Cote Expert Report) ¶ 128.)

335.1 [redacted] Aravanis (Illumina) Tr. 1829–30; Berry (Illumina) Tr. 814–15.)

335.2 This step is commonly referred to as sample preparation, or "sample prep," which is performed by a trained lab technician, and takes about 1 to 2 hours. [redacted]; Aravanis (Illumina) Tr. 1829–30; Berry (Illumina) Tr. 814.)

336. *Third*, the purified nucleic acids undergo library preparation. (Aravanis (Illumina) Tr. 1830–31; Berry (Illumina) Tr. 815–25; RX3869 (Cote Expert Report) ¶ 129.) Library preparation processes are proprietary to assay developers and are used to transform the purified nucleic acids into a library of DNA/RNA fragments that is capable of being sequenced using a sequencing instrument. (RX3869 (Cote Expert Report) ¶ 129; Aravanis (Illumina) Tr. 1830–31; Berry (Illumina) Tr. 815–25).

336.1 For short-read sequencers, the DNA/RNA is first fragmented into pieces comprising a length that is suitable for the read-length of the sequencer. (Aravanis (Illumina) Tr. 1830–31; RX3869 (Cote Expert Report) ¶ 129; Berry (Illumina) Tr. 815–25.)

336.2 Then adaptors suitable for the NGS sequencer, which are either included as part of the proprietary library preparation kit or purchased from one of many providers, are added (*i.e.*, ligated) to the end of the fragmented DNA. (Aravanis (Illumina) Tr. 1830–1831; RX3869 (Cote Expert Report) ¶ 129; Berry (Illumina) Tr. 815–25; PX0091 (Illumina) at 14.)

336.3 For short-read sequencers, the ligated DNA is typically amplified using PCR, using the adaptor sequence as primers. (RX3869 (Cote Expert Report) ¶ 129; Cote Tr. 3743–3756; Aravanis (Illumina) Tr. 1830–31; Berry (Illumina) Tr. 815–25.)

336.4 The adaptor-ligated (and amplified for short-read sequencers) samples are called sequence "libraries." (PX0091 (Illumina) at 14; RX3869 (Cote Expert Report) ¶ 129.)

336.5 This step is commonly referred to as library preparation, or "library prep," which is performed by a trained lab technician and takes about 2.5 hours for DNA library prep and about 5.5 hours for RNA library prep. (RX3869 (Cote Expert Report) ¶ 129; Aravanis (Illumina) Tr. 1830–31; Berry (Illumina) Tr. 815–25; PX0091 (Illumina) at 14.)

337. *Fourth*, the DNA libraries are sequenced using the NGS sequencers. (RX3869 (Cote Expert Report) ¶ 130; PX0091 (Illumina) at 14; Aravanis (Illumina) Tr. 1831.) This sequencing step is commonly automated by the sequencer and the sequencing time varies significantly between sequencers. (RX3869 (Cote Expert Report) ¶ 130; Aravanis (Illumina) Tr. 1831.)

337.1 For example, Thermo Fisher's Ion GeneStudioTM S5 sequencer with Ion 550TM Chip takes about 8.5–11.5 hours, whereas Illumina's NovaSeq 6000 with S4 flow cells takes about 45 hours. (RX3869 (Cote Expert Report) ¶ 130; RX3357 (Illumina) at 6–7; RX3587 (Thermo Fisher) at 1.)

338. *Fifth*, the data generated by the sequencer (which varies depending on the type of sequencer) is converted into DNA base sequences, *i.e.*, A, G, C, T, and U for bisulfite converted methylated C. (Berry (Illumina) Tr. 816–17; RX3869 (Cote Expert Report) ¶ 131; Aravanis (Illumina) Tr. 1831–33.) This step is called data processing, and is often conducted at the same time or soon after the sequencing step. (RX3869 (Cote Expert Report) ¶ 131; Aravanis (Illumina) Tr. 1831–33; Berry (Illumina) Tr. 816–17).

338.1 For example, the data may be image information generated by the fluorescent tags or electrical current information generated by the DNA strand passing through the nanopore. (RX3869 (Cote Expert Report) ¶ 131, n.137; Berry (Illumina) Tr. 819–22.)

338.2 Oxford Nanopore's long-read sequencers can directly detect methylated C and other base modifications because its base-detection sensor is sensitive to such modifications. (RX3869 (Cote Expert Report) ¶ 131, n.138; Cote Tr. 3753; RX3537 (Oxford Nanopore) at 2.)

339. *Last*, the sequence data is analyzed and interpreted by the software proprietary to the test developer, often driven by artificial intelligence, to classify the samples with genomic changes, epigenomic modifications, chromosomal changes, and RNA fusions, and a report is generated showing ultimate results of the test. (RX3869 (Cote Expert Report) ¶ 132; Aravanis (Illumina) Tr. 1831–33, 1837; Berry (Illumina) Tr. 817–18.)

339.1 This step is called data interpretation and reporting and can take anywhere from an hour to much longer, depending on the application. (RX3869 (Cote Expert Report) ¶ 132; Aravanis (Illumina) Tr. 1831–33, 1837; Berry (Illumina) Tr. 817–18.)

III. THE ONCOLOGY TESTING SPACE

A. GRAIL's Galleri Test

1. Overview of GRAIL's Galleri Test

340. GRAIL has developed a multi-cancer screening test, Galleri, that simultaneously screens for over 50 different types of cancers from a single blood sample. (Bishop (GRAIL) Tr. 1373–74; RX0744 (GRAIL) slide 22, 100; RX3869 (Cote Expert Report) ¶ 133.)

341. Galleri is the first blood-based multi-cancer early screening test to be offered to asymptomatic patients with no history of cancer and was launched in June 2021 as an LDT. (Bishop (GRAIL) Tr. 1322.)

342. Galleri is designed to detect cancer through epigenomic analysis of a single blood draw before a patient ever shows symptoms (*e.g.*, lesions, lumps, or other signs of cancer). (RX3869 (Cote Expert Report) ¶ 133; Bishop (GRAIL) Tr. 1319–21; RX3254 (GRAIL).)

343. In clinical studies, Galleri has detected over 50 types of cancers, of which 45 do not currently have a recommended screening procedure in the US. (Bishop (GRAIL) Tr. 1373, 1391; RX3285 (GRAIL) at 1; RX3286 (GRAIL) at 2; RX3287 (GRAIL) at 1)

344. Notably, Galleri has high sensitivity and specificity for forms of cancer that have no routine screening options, are usually detected at late stage and thus are often lethal. (Cote Tr. 3795–96; 3799–3801, RX3114 (Chen et al., 2021 at 1); RX0744 (GRAIL) at slide 60.)

345. Unlike certain other cancer screening test developers, who are taking a mutational approach to detecting cancer (including as one type of biomarker in a multiomics approach) (Cote Tr. 3810, 3844, 3852, 3870–71), the Galleri test detects cfDNA shed by cancer cells using a targeted methylation assay. (Bishop (GRAIL) Tr. 1319–21; (Ofman (GRAIL) Tr. 3286–87; [redacted] Specifically, GRAIL looks at regions of the genome for clusters of CpG sites that are methylated or unmethylated. (Bishop (GRAIL) Tr. 1320; RX0744 (GRAIL) at slides 30–40; [redacted]

345.1 Methylation is a form of epigenomic change: rather than change the code of a DNA molecule, methylation occurs when methyl groups attach to DNA and "affect which genes are turned on and off", which in turn "affects what the cell becomes and how it behaves". (Aravanis (Illumina) Tr. 1882.) Methylation is considered "a hallmark of cancer because they tend to turn tumor suppressor genes off and they tend to turn tumor promoter genes on." (Ofman (GRAIL) Tr. 3286.)

345.1.1 As Dr. Alex Aravanis explained, "if you think, for example, of a lung cell versus a liver cell, they have the same DNA in them. That's not different. What's different is the methylation patterns, so the places in the DNA that are methylated or unmethylated, which is this chemical change, is very different even though the underlying DNA is the same. And so this fingerprint really determines . . . what a cell is and what a tissue [is]. There [are] about 30

million methylation sites . . . in the human genome." (Aravanis (Illumina) Tr. 1882.)

346. GRAIL developed a machine learning algorithm that differentiates abnormal tumor cfDNA methylation patterns from normal cfDNA methylation patterns. (RX3083 (Bryce et al., 2021) at 1; [redacted]

346.1 As Dr. Josh 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.)

347. [redacted]

348. To date, GRAIL has developed three versions of Galleri. (Ofman (GRAIL) Tr. 3291–94.)

349. Version 1 ("v1") of Galleri was used in GRAIL's Circulating Cell-Free Genome Atlas substudy (CCGA2) and the PATHFINDER Study. (Ofman (GRAIL) Tr. 3291–94.)

350. [redacted] RX3869 (Cote Expert Report) ¶ 135.) GRAIL launched v2 of the Galleri test as an LDT in June 2021. (Bishop (GRAIL) Tr. 1322; RX3869 (Cote Expert Report) ¶ 135.)

351. GRAIL is currently developing a third version of Galleri, which GRAIL intends to submit for FDA approval. (PX7083 (Bishop (GRAIL) Dep. at 204–05); Ofman (GRAIL) Tr. 3301–02.)

351.1 The changes in the third version are geared toward reducing the amount of sequencing that needs to be done in order to lower costs; all of the same biomarkers are being interrogated as in v2, (Ofman (GRAIL) Tr. 3301–02.)

352. [redacted]; RX3869 (Cote Expert Report) ¶ 135.)

353. [redacted] RX3869 (Cote Expert Report) ¶ 135.)

354. Depending on the type of cancer, Galleri v1 can detect Stage I and Stage II cancers (i.e., its sensitivity) between 18–43% of the time overall, and a sensitivity of 43.9% for all cancer types, at 99.3% specificity. (RX3430 (Liu et al., 2020) at 1; RX0744 (GRAIL) at 54; [redacted]; RX3869 (Cote Expert Report) ¶ 136.)

355. Galleri's current sensitivity rate for v2 of its test (which is the version that is available as an LDT) is 51.5% for all cancer types across stages. (RX3408 (Klein et al., 2021) at 10; RX3869 (Cote Expert Report) ¶ 136.) This includes cancers that have no screening test today, are usually only found at an advanced stage and thus have a high mortality rate. (Cote Tr. 3795–96; 3799–3801; RX3869 (Cote Expert Report) ¶ 136.)

356. These results suggest that the Galleri test as currently constructed has the ability to save lives by detecting dangerous cancers at an earlier, potentially curable stage. (RX3869 (Cote Expert Report) ¶ 136.)

357. Galleri's specificity for v2 of its test is 99.5%. (RX3409 (Klein et al., 2021) at 5; RX3408 (Klein et al., 2021 AACR Presentation) at 10; RX0872 (GRAIL) at 9, 13; RX3869 (Cote Expert Report) ¶ 136.)

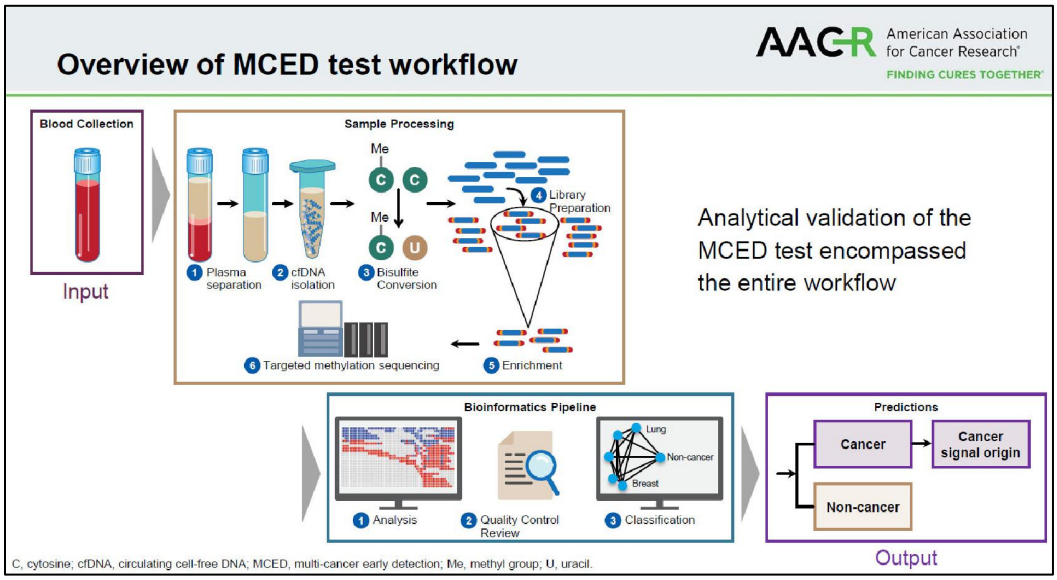
358. At this time, Galleri is not meant as an alternative or replacement to standard cancer screening procedures, but rather as a complement to recommended screenings, designed to detect more cancers earlier while minimizing the harms that may come from a false positive result. (RX0744 (GRAIL) at 76–90; [redacted] RX0867 (Clinical Overview Deck) at 15; PX7086 (Cance (ACS) Dep. at 50–53); [redacted]; RX3869 (Cote Expert Report) ¶ 136.)

359. Because the risk of cancer increases significantly after age 50, GRAIL expects the use of Galleri to be concentrated in an elevated risk population, for example, in individuals over the age of 50, when the risk of cancer increases significantly. (PX0043 (GRAIL) at 5, 110; *see also* PX7083 (Bishop (GRAIL) Dep. at 25); [redacted]

2. **Galleri Test Workflow**

360. To run the Galleri test, GRAIL's CLIA-certified laboratory follows a multi-step workflow that follows a standard procedure used for many NGS-based tests. (RX3025 (Alexander et al., 2021) at 4; [redacted]

Figure 5: Galleri Test Workflow



(RX3025 (Alexander et al., 2021) at 4; [redacted]

361. *First,* Galleri uses a blood biopsy specimen collected from participants. Blood plasma in the specimen is separated from blood cells. (RX3025 (Alexander et al., 2021) at 4; Bishop (GRAIL) Tr. 1375–76; [redacted]

362. *Second*, cfDNA (*i.e.*, the nucleic acids) are isolated through sample preparation by GRAIL. (Bishop (GRAIL) Tr. 1379–80; [redacted]

363. *Third*, the sample undergoes library preparation and enrichment by GRAIL. (Bishop (GRAIL) Tr. 1379–80; [redacted]

363.1 GRAIL fragments the DNA samples into smaller pieces of DNA and adds specialized adapters to both ends of the DNA fragments, which allow the fragments to bind to a flow cell, a surface designed for those DNA fragments to attach to for the purpose of sequencing. (PX7104 (Aravanis (Illumina) Dep. at 117); [redacted]

363.2 [redacted]

363.3 Like other tests that rely on NGS sequencing, the proprietary steps for GRAIL's test occur in the library prep stage, where GRAIL prepares the samples so that the analytes it seeks to analyze are detected, and at the last phase where GRAIL uses its proprietary algorithm to interpret the base calls that the NGS sequencer has provided.

[redacted] Aravanis (Illumina) Tr. 1832–33; [redacted]

364. *Fourth*, the prepared sample then is sequenced at GRAIL's laboratory. (Bishop (GRAIL) Tr. 1380; [redacted] GRAIL's laboratory currently uses the Illumina NovaSeq 6000 with an S4 flow cell to process the Galleri assay. (PX7103 (Jamshidi (GRAIL) Dep. at 31); PX7104 (Aravanis (Illumina) Dep. at 168–69); [redacted]

364.1 At this step, the library is loaded onto a flow cell and placed on the sequencer. (Aravanis (Illumina) Tr. 1831; [redacted] The sequencer amplifies the DNA fragments from the sample through "cluster generation," which copies the fragments into millions of copies of single-stranded DNA. (RX0461 (Illumina) at 22–23); [redacted]

365. *Fifth*, the sequencer then identifies the nucleotides in the fragments from the sample ("base calling") and gives the predicted accuracy of each base call. (Berry (Illumina) Tr. 819–22; [redacted]

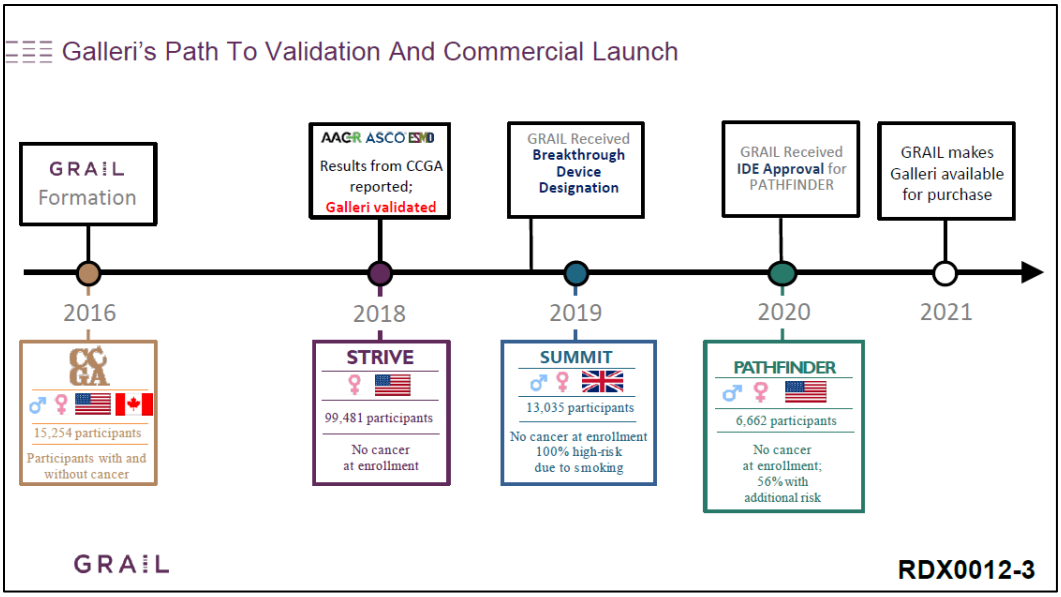
366. *Sixth*, GRAIL uses its proprietary algorithm (*i.e.*, the classifier) to analyze the raw data from the sequencer to identify the presence of cancer and the origin of the cancer signal. [redacted]; Bishop (GRAIL) Tr. 1380; [redacted] GRAIL also prepares a report for the physician to provide the results of the Galleri test. (Bishop (GRAIL) Tr. 1380–22; [redacted]

367. GRAIL uses a number of suppliers for inputs used in performing the Galleri test. [redacted]; RX3869 (Cote Expert Report), Appendix C.)

3. **Galleri's Clinical Studies**

368. Since 2016, GRAIL has undertaken four major clinical studies to validate its test, while another clinical study was enrolling participants at the time of trial. (Cote Tr. 3789–94; Ofman (GRAIL) Tr. 3291–94; RX0744 (GRAIL Core Slide Deck) at 46–47; RX3869 (Cote Expert Report) ¶ 138.)

368.1 These four clinical studies involved combined total of nearly 140,000 participants in North America and the United Kingdom. (RX3430 (Liu et al., 2020) at 3; Ofman (GRAIL) Tr. 3293; RX0744 (GRAIL) at 71; (RX3291 (GRAIL) at 1.)



a. Circulating Cell-Free Genome Atlas Study

369. The Circulating Cell-Free Genome Atlas Study ("CCGA"), started in August 2016, is GRAIL's foundational study. (Ofman (GRAIL) Tr. 3291–92; RX3287 (GRAIL) at 2; RX0867 (GRAIL) at 3; [redacted]; RX3869 (Cote Expert Report) ¶ 139.)

370. It is a prospective, multicenter (142 sites), case-control, observational study with longitudinal follow-up. (RX3430 (Liu et al., 2020) at 1; Ofman (GRAIL) Tr. 3291–95; [redacted] RX0744 (GRAIL) at 47–48.) It is believed to be the largest case-control study that's been for early detection.. (Ofman (GRAIL) Tr. 3291.)

371. It 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 a cost of about $30 million. (RX3430 (Liu et al., 2020) at 3; [redacted] RX3869 (Cote Expert Report) ¶ 139.) 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 3; RX3869 (Cote Expert Report) ¶ 139.)

371.1 "[F]or cancers where there is no existing screening methodology, those cancers tend to present very late stage in disease, so finding . . . patients with early-stage cancers is very hard and very rare." (Aravanis (Illumina) Tr. 1917–18.) In order to do so, GRAIL had to set up 142 trial sites to find rare examples of individuals with these unscreened cancers at early-stage disease. (Aravanis (Illumina) Tr. 1918.) It was "unprecedented in scale and complexity and cost to do that." (Aravanis (Illumina) Tr. 1918.) Because of this effort, Galleri is able to detect 45 cancer types which have no existing screening methodology. (Aravanis (Illumina) Tr. 1918.)

371.2 The study was also unique because the samples were prospectively collected. As Dr. Cote explained: "[The] case-control trial was actually prospectively collected, and it was done under a strict protocol for the collection of all of these samples. That makes it unique in terms of the case-control study, and . . . it was designed that way to provide sample collection under circumstances that would be similar to an actual clinical collection of samples. (Cote Tr. 3794–95.)

372. GRAIL collected up to 80 mL of blood from each participant, while also collecting tissue samples of the individuals with a known cancer diagnosis. (RX3430 (Liu et al., 2020) at 3; RX3869 (Cote Expert Report) ¶ 139.)

373. In the CCGA study, GRAIL followed up with its participants for a period of 5 years. (RX0744 (GRAIL) at 48; RX3869 (Cote Expert Report) ¶ 139.)

374. GRAIL designed the CCGA study to determine if cfDNA sequencing, in combination with machine learning, would be able to (1) detect a large number of cancers at a high enough specificity to be used as an early cancer screening test for the general population, and (2) determine the tissue of origin of detected cancers (an essential tool in determining next-steps once cancer has been detected in a patient). (RX3430 (Liu et al.,. 2020) at 3; Ofman (GRAIL) Tr. 3291–95; [redacted]; RX0744 (GRAIL) at 47–48; RX3869 (Cote Expert Report) ¶ 139.)

375. CCGA is expected to be completed in March 2024; in total, CCGA study will have spanned nearly eight years. (RX0744 (GRAIL) at 47; RX3869 (Cote Expert Report) ¶ 140.)

376. The design of CCGA involves three sub-studies. (Ofman (GRAIL) Tr. 3291–95; RX3869 (Cote Expert Report) ¶ 140.)

377. The first sub-study was designed to discover and differentiate cancer biomarkers, to determine the most effective way to identify multiple cancers and their signal of origin, and train GRAIL's machine learning algorithms to detect those biomarkers. (Ofman (GRAIL) Tr. 3291–94.); RX3410 (Liu et al., 2018) at 1; RX3869 (Cote Expert Report) ¶ 140.)

378. GRAIL then proceeded to "development" in CCGA2, which was designed to perform further analysis, training, and validation of v1 of the Galleri test: specifically, to discover methylation patterns of identified cancer biomarkers associated with known cancer types, and then train and validate a machine-learning classifier to differentiate methylation patterns associated with cancer vs. non-cancer as well as predict the origin of the cancer signal. (Ofman (GRAIL) Tr. 3292; RX3430 (Liu et al., 2020) at 3; RX3869 (Cote Expert Report) ¶ 141.)

378.1 This training and validation was to demonstrate the feasibility of detecting cancer and predicting signal of origin with minimal false positives. (RX3430 (Liu et al., 2020) at 3; RX0744 (GRAIL) at slide 46; RX3869 (Cote Expert Report) ¶ 141.)

379. The third sub-study was designed to further validate the assay for multi-cancer detection and the identification of the cancer signal of origin. (Ofman (GRAIL) Tr. 3292–93; RX3408 (Klein et al., 2021) at 6; RX3869 (Cote Expert Report) ¶ 141.)

(i) CCGA1

380. In CCGA1, 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; RX3869 (Cote Expert Report) ¶ 142.)

381. CCGA1 focused exclusively on a single analyte, blood, and investigated multiple types of biomarkers, including cancer-derived mutations (single nucleotide variants and small variants), chromosome alterations (copy number and fragment features such as length and endpoint analysis through whole-genome sequencing), and methylation patterns (through whole genome bisulfite sequencing). (Ofman (GRAIL) Tr. 3291–92; RX3430 (Liu et al., 2020) at 1–3; RX3869 (Cote Expert Report) ¶ 142.)

382. Through the CCGA1 sub-study, GRAIL concluded that interrogating genome-wide methylation patterns using bisulfite sequencing outperformed targeted sequencing and whole-genome sequencing approaches to detect cancer-derived mutations or chromosome alterations. (Ofman (GRAIL) Tr. 3291–92; RX3430 (Liu et al., 2020) at 3, 9; RX3410 (Liu et al., 2018) at 1.)

382.1 In other words, GRAIL concluded through the CCGA1 sub-study 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 regards to cancer signals. (Ofman (GRAIL) Tr. 3291–92; PX7103 (Jamshidi (GRAIL) Dep. at 60–67; RX3869 (Cote Expert Report) ¶ 142.)

383. Also, GRAIL found that methylation patterns are highly effective at identifying the origin of the cancer signals. (Ofman (GRAIL) Tr. 3291–92; RX3550 (Oxnard et al., 2019) at 1; RX3429 (Liu et al., 2019) at 2; RX3869 (Cote Expert Report) ¶ 142.)

384. GRAIL selected a targeted methylation-based assay (Galleri v1) for further development in CCGA2. (Ofman (GRAIL) Tr. 3291–92; RX3869 (Cote Expert Report) ¶ 142.)

385. In total, CCGA1 took two years (though GRAIL had already commenced research and biomarker discovery before commencing CCGA1). (Ofman (GRAIL) Tr. 3294; RX3869 (Cote Expert Report) ¶ 142.)

(ii) CCGA2

386. The second CCGA sub-study, CCGA2, was designed to perform analysis, training, and validation of the Galleri v1 test, using the Galleri v1 assay developed using the findings from CCGA1. (Ofman (GRAIL) Tr. 3291–92; RX3430 (Liu et al., 2020) at 3; RX3869 (Cote Expert Report) ¶ 143.)

387. CCGA2 included 6,689 participants, which were divided into a training set of 4,720 participants and an independent validation set of 1,969 participants, of which 4,316 participants (training: 3052; validation: 1264) were ultimately included in the final analysis population. (RX3430 (Liu et al., 2020) at 6–7; RX3869 (Cote Expert Report) ¶ 143.)

388. The results of the CCGA2 study, published in Annals of Oncology in March 2020, showed that Galleri was capable of detecting more than 50 cancer types at a specificity of 99.3% and a false-positive rate of less than 1% across the more than 50 cancer types. (RX3430 (Liu et al., 2020) at 1, 10.)

389. Galleri v1 achieved a sensitivity of 43.9% for all cancer types. (RX3430 (Liu et al., 2020) at 1,10; RX0744 (GRAIL) at 70; RX3869 (Cote Expert Report) ¶ 143.) Galleri v1 demonstrated a cancer signal of origin prediction accuracy of 93%. (RX3430 (Liu et al., 2020) at 1, 9; RX0744 (GRAIL) at 68; RX3869 (Cote Expert Report) ¶ 143.)

390. CCGA2 took another two years. (Ofman (GRAIL) Tr. 3294; RX3869 (Cote Expert Report) ¶ 143.)

(iii) CCGA3

391. CCGA3, the third CCGA sub-study, was designed to evaluate Galleri's performance by testing a large cohort of samples from participants with and without cancer and to validate Galleri v2 as a multi-cancer early detection test capable of population-wide testing. (Ofman (GRAIL) Tr. 3292; RX0744 (GRAIL) at 47–48; PX7069 Bishop (GRAIL), IHT at 80; RX3869 (Cote Expert Report) ¶ 144.)

392. CCGA3 ultimately reported that GRAIL's Galleri v2 test achieved a specificity of 99.5% across more than 50 cancer types, a false-positive rate of 0.5%, sensitivity of 51.5% for all cancers, and a signal of origin prediction accuracy of 88.7%. (RX3408 (Klein et al., 2021) at 10; RX3869 (Cote Expert Report) ¶ 144.)

393. Galleri v2 is the test currently being offered by GRAIL commercially as an LDT. (Ofman (GRAIL) Tr. 3317; RX3869 (Cote Expert Report) ¶ 144.)

b. PATHFINDER

394. Starting in December 2019, GRAIL began enrolling participants for its prospective, interventional multi-center study PATHFINDER. (RX3044 (GRAIL) at 1–2 RX3869 (Cote Expert Report) ¶ 145.)

395. PATHFINDER's primary goal 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.)

396. Another goal of PATHFINDER is to test the performance of Galleri's v1 assay and review patient experiences and satisfaction with the test. (Ofman (GRAIL) Tr. 3295–98, 3299–3300; RX0611 (GRAIL) at 9; RX3869 (Cote Expert Report) ¶ 145.)

397. It is the first study in which Galleri results were returned to participants and their clinicians to allow them to undertake the necessary diagnostic steps necessary for a proper cancer diagnosis after receiving the results of a Galleri test. (Ofman (GRAIL) Tr. 3296–97 [redacted] RX3869 (Cote Expert Report) ¶ 145.)

398. This study allowed GRAIL to evaluate the implementation of Galleri in clinical practice. (Ofman (GRAIL) Tr. 3296–97; RX3869 (Cote Expert Report) ¶ 145.)

398.1 "The purpose of PATHFINDER was very clear. We needed to show -- after the clinical validation of our test, we needed to better understand how positive results were going to get worked up, how the test was actually going to get implemented in clinical practice. And we also wanted to understand whether the positive predictive value, which again is the key clinical measure, that we saw in the CCGA study, how that would translate into the real world, and so that was going to be a core aspect of PATHFINDER. PATHFINDER was not designed or powered to replicate the sensitivity of Galleri or to try to find, you know, all the cancers that Galleri can find, because that would require hundreds of thousands of people. So it was really a feasibility study about implementing Galleri into actual clinical practice." (Ofman (GRAIL) Tr. 3296–97.)

398.2 The results of PATHFINDER so far have been promising:

> Q. And was GRAIL happy with the interim results of the PATHFINDER study?
>
> A. Yes. It was really remarkable that it performed pretty close to as we predicted it would, and the PPV that we've seen thus far on the interim seems to be very well-aligned with what we've seen in prior studies. And that's really important because in this field, you know, it's littered with companies that do these small, underpowered studies, case-control studies -- I have lots of examples -- where they put it into actual clinical care and the tests don't work. And so, you know, there's a lot of skepticism about that, and so it was really important for us to show that the robust CCGA study was able to replicate itself under real-world conditions. (Ofman (GRAIL) Tr. 3296–97.)

398.3 In PATHFINDER, Galleri has detected "13 different types of cancer, and some in their early stages. We found early pancreatic cancer. We found early liver cancer. We found early head and neck cancer. We found a lot of hematologic malignancies. So it was almost like you were standing on the street corner watching healthy 50-year-olds walk by that had no idea they had cancer and seeing the cancers just light up as they walked by. It was really remarkable." (Ofman (GRAIL) Tr. 3297–98.)

398.4 There was no concern that Galleri found 13 different types of cancer rather than 50 in PATHFINDER. To find "all 50 cancers, you know, in a real-world population is going to require hundreds of thousands of people, so PATHFINDER was not designed to do that. PATHFINDER was really designed to understand the specificity of the test and its positive predictive value. So no, we were -- we were thrilled that there was such a diversity of cancers that were found in PATHFINDER." (Ofman (GRAIL) Tr. 3298.)

399. PATHFINDER recruited 6, 662 participants over the age of 50 and divided them into two different cohorts, a cohort with additional risk of a positive cancer result (3695; ~55% of total enrollment), and another cohort containing participants without any heightened risk (2934). (Ofman (GRAIL) Tr. 3293; RX0744 (GRAIL) at 73; RX3869 (Cote Expert Report) ¶ 146.)

399.1 Heightened cancer risk was based on a history of smoking, genetic cancer predisposition, or a personal history of malignancy more than 5 years previously. (RX0611 (GRAIL) at 30–31.) [redacted]

400. In February 2021, GRAIL released interim PATHFINDER results that were positive and largely confirmed the previous studies. (Ofman (GRAIL) Tr. 3293; [redacted]

401. [redacted]

402. At the time of trial, GRAIL expected to complete the PATHFINDER study in January 2022. (RX3044 (GRAIL) at 2; RX3869 (Cote Expert Report) ¶ 147.)

c. STRIVE

403. STRIVE is a prospective, observational, longitudinal, cohort study of approximately 100,000 women undergoing mammography for screening indications and associated medical care, whose samples were taken around the time of a screening mammogram appointment. (Cote Tr. 3804; Ofman (GRAIL) Tr. 3293–95; RX0744 (GRAIL) at 71; RX3869 (Cote Expert Report) ¶ 148.)

404. The goals of the STRIVE study are to confirm the performance of Galleri in a population with no known active cancer diagnosis, validate Galleri's ability to detect breast cancer and to evaluate Galleri's test performance and sensitivity in the clinically meaningful subgroup of breast cancer patients. (Ofman (GRAIL) Tr. 3293–95; Cote Tr. 3804–05; RX0744 (GRAIL) at 71; RX3869 (Cote Expert Report) ¶ 148.)

405. The STRIVE study took its first sample in February 2017 and finished enrollment in November 2018. (RX0744 (GRAIL) at slide 71; RX3869 (Cote Expert Report) ¶ 148.)

406. The STRIVE study is actively following up on the participants from their first blood draw until the first documented invasive cancer diagnosis (assessed up to 30 months), collecting data on cancer diagnosis and treatment. (RX3134 (GRAIL) at 1–2; RX0744 (GRAIL) at 71; RX3869 (Cote Expert Report) ¶ 148.)

d. SUMMIT

407. SUMMIT is a prospective, observational, cohort study. (RX3291 (GRAIL) at 1; RX0744 (GRAIL) at 46–47, 72; RX3869 (Cote Expert Report) ¶ 149.)

408. The primary objective of SUMMIT is to evaluate Galleri's performance in a smoking population, meaning those with a high risk of lung cancer, with no known active cancer diagnosis. (RX3135 (GRAIL) at 1–2; RX0744 (GRAIL) at slide 72; RX3869 (Cote Expert Report) ¶ 149.)

409. SUMMIT enrolled approximately 13,000 participants between the ages of 50–77 with a substantial smoking history exclusively from the United Kingdom. (RX3291 (GRAIL) at 1; RX3135 (Clinicaltrials.gov) at 1–2; RX3869 (Cote Expert Report) ¶ 149.)

410. SUMMIT enrolled its first patient in April of 2019 and completed enrollment in May 2021. (RX3135 (GRAIL) at 2; RX3291 (GRAIL) at 1; RX0744 (GRAIL) at 72; RX3869 (Cote Expert Report) ¶ 149.)

411. Participants in SUMMIT will provide annual blood draws for three years, rather than a one-time blood draw. (RX3291 (GRAIL) at 1; RX0744 (GRAIL) at 72; RX3869 (Cote Expert Report) ¶ 149.)

412. The study intends to follow up with each participant through medical records and the National Cancer Registry for a period of 10 years. (RX0744 (GRAIL) at 72; RX3869 (Cote Expert Report) ¶ 149).

B. Other Test Developers Alleged by Complaint Counsel To Be in the Cancer Screening Space

413. Other companies, including Exact Sciences Corp. ('Exact'), Thrive Earlier Detection Corp. ('Thrive'), Guardant, Inc. ('Guardant'), Singlera Genomics, Inc. ('Singlera'), Freenome, Inc. ('Freenome'), Helio Health, Inc. ('Helio'), Natera, Inc. ('Natera'), and Foundation Medicine ('FMI'), are or purport to be developing cancer screening tests. These companies are all far behind GRAIL in the development of a multi-cancer screening test.

1. Exact Sciences / Thrive Earlier Detection

414. Exact Sciences Corp. ("Exact") is a molecular diagnostics company based in Madison, Wisconsin. (RX3197 (Exact/Thrive) at 1, 4.) Thrive Earlier Detection Corp.

("Thrive"), now a part of Exact, is a molecular diagnostics company based in Cambridge, Massachusetts and Baltimore, Maryland. (RX2650 (Morgan Stanley) at 4.)

415. Thrive was founded in 2019 by licensing technologies developed at the Johns Hopkins University by founding professors Bert Vogelstein, Kenneth W. Kinzler, and Nickolas Papadopoulos. (RX3398 (Johns Hopkins Technical Ventures) at 2; RX3869 (Cote Expert Report) ¶ 173.)

416. While Thrive was founded in 2019, it builds on research from the Vogelstein group and from Vogelstein's efforts in his prior company, PapGene, which was founded in 2014. (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 26–29); RX3869 (Cote Expert Report) at ¶ 173.)

417. Exact/Thrive is currently developing a cancer screening test known as "CancerSEEK". (Lengauer (Exact/Thrive) Tr. 158.)

418. Complaint Counsel has presented no evidence that the current version of CancerSEEK in development is capable of competing with the Galleri test unless significant changes are made to the assay. (Cote Tr. 3814–15, 3823; RX3869 (Cote Expert Report) ¶ 174.)

419. Specifically, the CancerSEEK assay is only designed to detect 10 cancer types, not the over 50 types of cancers by Galleri. (RX3869 (Cote Expert Report) ¶ 174.) Also, the CancerSEEK assay does not identify the cancer signal of origin, which is why it is combined with a whole-body PET-CT. (RX3869 (Cote Expert Report) ¶ 174.)

420. [redacted]

421. [redacted]

a. Exact/Thrive's CancerSEEK Test

422. CancerSEEK is a multiomics test. (RX3869 (Cote Expert Report) ¶ 174.) The reported version of CancerSEEK requires several steps. (RX3419 (Lennon et al., 2020); Lengauer (Exact/Thrive) Tr. 246–48, 260.)

[redacted]

423. The first iteration of the CancerSEEK blood test analyzed two types of biomarkers: 16 gene mutations and nine protein biomarkers (including 61 variant regions of interest within the genes, called "amplicons"). (Lengauer (Exact/Thrive) Tr. 210–11; RX3419 (Lennon et al., 2020) at 3.)

424. In the DETECT-A clinical trial, two blood tests were performed in the Thrive workflow. (Lengauer (Exact/Thrive) Tr. 247; RX3419 (Lennon et al., 2020) at 3.)

424.1 Initially, a baseline CancerSEEK test was performed and then an additional confirmatory blood test was performed on the individuals who tested positive for cancer to assess only the particular DNA or protein markers that were abnormal in the baseline, as well as to rule out the presence of clonal hematopiesis (CHiP), which is a blood mutation that might cause false positives in those DNA or protein markers. (Lengauer (Exact/Thrive) Tr. 247; [redacted]; RX3419 (Lennon et al., 2020) at 3).)

425. Individuals remaining positive after the two blood tests were then scanned using full-body PET-CT imaging. (Lengauer (Exact/Thrive) Tr. 248; Cote Tr. 3811–12; [redacted]; RX3419 (Lennon et al., 2020) at 3.)

425.1 The CancerSEEK assay as it exists today is not a liquid biopsy-only test, and does not solely rely on NGS. (RX3869 (Cote Expert Report) ¶ 175.)

426. [redacted]

426.1 In the earlier case-control study conducted by Thrive's founders, CancerSEEK was able to localize the cancer signal of origin to two anatomic sites in a median of 83% of patients. (RX3142 (Cohen 2018) at 3.)

426.2 However, this method was not used in the DETECT-A study, where Thrive opted for a full-body PET-CT instead. (Lengauer (Exact/Thrive) Tr. 248; RX3869 (Cote Expert Report) at n. 240.)

426.3 Of the 53 patients identified by PET-CT as having "imaging concerning for cancer," only 15 was determined to have cancer, with only a 28.3% detection rate. (RX3419 (Lennon et al., 2020) at 4, Fig. 2; Lengauer (Exact/Thrive) Tr. 255–56.)

426.4 Full-body PET-CT is a fairly poor tool for cancer signal of origin determination, compared with the 88.7% accuracy of cancer signal of origin prediction achieved by GRAIL's Galleri v1 in the CCGA3 study. (RX3869 (Cote Expert Report) at n. 240.)

427. To date, CancerSEEK has been studied in two trials: Cohen, a case-control study conducted by Thrive's founders at Johns Hopkins University involving 1817 participants (1005 cancer patients and 812 healthy individuals), and Lennon, the prospective, interventional DETECT-A (Detecting cancers Earlier Through Elective mutation-based blood Collection and Testing) study conducted by Thrive involving 10,006 female participants. (RX3142 (Cohen 2018) at 1; RX3419 (Lennon et al., 2020) at 2); [redacted]

428. Although all cancer types (with some exclusions) were purportedly included in the DETECT-A study, in fact the nature of the assay (focusing on 16 genes and 9 protein biomarkers) was such that it was clearly designed to focus on only a few cancers that might be detected in a liquid biopsy screening test using those limited markers. (RX3419 (Lennon et al., 2020) at 2–4.)

429. The study only detected cancers of 10 organs: lymphoma, colorectal, appendix, uterine, thyroid, kidney, lung, breast, ovary and cancer of unknown primary. (RX3419 (Lennon et al., 2020) at 4, 6–7, 9; Lengauer (Exact/Thrive) Tr. 243, 260–61.)

429.1 Based on these results and the assay design itself, the evidence does not support the proposition that CancerSEEK currently detects the same number of cancer types as GRAIL's Galleri test. (RX3869 (Cote Expert Report) ¶ 177.)

430. [redacted]

430.1 CancerSEEK is unable to detect several cancers that Galleri has detected. (*Compare* RX3419 (Lennon et al., 2020) at 1, 6–7, 9 *with* (RX3409 (Klein et al., 2021) at 1, 5; Cote Tr. 3818–19.)

[redacted]

431. In the DETECT-A study, CancerSEEK obtained specificities of 95.3% in its baseline blood test (that is, 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 8 & Table 2.)

432. Assessed using another test benchmark, 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 8 & Table 2; Lengauer (Exact/Thrive) Tr. 257–59; RX3869 (Cote Expert Report) ¶ 178.)

433. [redacted]

434. [redacted]

434.1 [redacted]

[redacted]

435. [redacted]

436. [redacted]

437. [redacted]

438. [redacted]

438.1 The inability of CancerSEEK to identify the cancer signal of origin through liquid biopsy alone is a key differentiator and means that if CancerSEEK were to launch today in its current form, it is unlikely to be a close substitute for GRAIL's Galleri test. (Cote Tr. 3814; PX6097 (Abrams Expert Report) ¶ 38.)

438.2 [redacted]

439. [redacted]

[redacted]

439.1 [redacted]

[redacted]

440. [redacted]

441. [redacted] (Conroy (Exact/Thrive) Tr. 1709, 1717; [redacted]

442. [redacted]

[redacted]

443. [redacted]

2. **FMI / Roche**

444. Foundation Medicine, Inc. ("FMI") is a subsidiary of the Roche Group based in Cambridge, Massachusetts. (RX3869 (Cote Expert Report) ¶ 184.) [redacted]

445. [redacted]

a. [redacted]

446. [redacted]; PX7068 (Perettie (FMI) IHT at 68); RX3869 (Cote Expert Report) ¶ 185.)

[redacted]

447. [redacted]

448. [redacted]

448.1 [redacted]

448.2 [redacted]

449. [redacted]

[redacted]

450. [redacted]

451. [redacted]

[redacted]

[redacted]

452. [redacted]

453. FMI and Roche currently do not have any clinical trials relating to screening for multiple cancers listed on clinicaltrials.gov. (RX3869 (Cote Expert Report) ¶ 189.)

b. FMI/Roche's Other Oncology Test Development Efforts

454. FMI/Roche currently markets the following types of oncology tests: FoundationOne® CDx, an FDA-approved solid tumor therapy selection test; FoundationOne® Liquid CDx, an FDA-approved liquid biopsy therapy selection test; FoundationOne® Heme, a solid tumor therapy selection test; and Roche's AVENIO line of comprehensive genomic profiling solid tumor kits for therapy selection. (RX3232 (Roche/FMI); RX3234 (Roche/FMI);

RX3233 (Roche/FMI); RX3615 (Roche/FMI); RX2565 (Roche/FMI); RX3869 (Cote Expert Report) ¶ 190.)

455. [redacted]

3. **Freenome**

456. Freenome is a biotechnology company based in South San Francisco, California. [redacted] Freenome was started in 2014 and has been working on its colorectal cancer early detection test since that time. (Nolan (Freenome) Tr. 2724, **{2792.)}**

457. Freenome commenced development of its multiomics platform (which it intends to use for cancer screening) in 2016. [redacted] at 13, [redacted].) Freenome has published data only relating to a single cancer, colorectal, and has commenced additional clinical trials only relating to colorectal cancer screening. (RX3869 (Cote Expert Report) ¶ 192; [redacted]

458. There is no indication based on Freenome's work to date that Freenome will be a competitor to GRAIL in the foreseeable future, and depending on the test that Freenome develops in the future, it is unclear if it will be a competitor to GRAIL or will develop a complementary test. [redacted]; RX3869 (Cote Expert Report) ¶ 193.)

a. [redacted]

459. [redacted] However, Dr. Scott Morton has not presented evidence supporting this contention, and there is none. [redacted]

[redacted]

460. The former CEO of Freenome, Gabriel Otte, testified that Freenome is developing a "multiomics cancer screening assay" and is currently "in the process of assessing the clinical performance of the CRC [*i.e.*, colorectal] portion of that test." (PX7121 (Otte (Freenome) Dep. at 16).) [redacted]

461. [redacted] RX3869 (Cote Expert Report) ¶ 194.)

462. [redacted]

463. [redacted]

464. [redacted]

464.1 [redacted]

465. [redacted]

466. [redacted]

467. [redacted]

468. [redacted]

469. [redacted]

470. [redacted]

b. Freenome's Colorectal Cancer Screening Test

471. Freenome is currently developing a blood biopsy colorectal cancer screening test by combines data from whole-genome sequencing, DNA methylation, and protein quantification using a multiomics approach. (RX3426 (Lin et al., 2021); RX3592 (Putcha et al., 2020).) Freenome is able to achieve single cancer specificity of 94% with sensitivity of 91% using this multiomics approach. (RX3869 (Cote Expert Report) ¶ 199.)

472. Freenome is currently conducting a 14,000–participant, prospective, observational cohort study to validate its blood-based multiomics test for the early detection of colorectal cancer. (RX3132 (Freenome).) [redacted]

4. Guardant Health

473. Guardant Health ("Guardant") is a molecular diagnostics company based in Redwood City, California. (RX3472 (Guardant) at 4.) Guardant was founded in 2011, and launched its first product, a therapy selection test around the same time. (RX3472 (Guardant) at 4; PX7045 (Chudova (Guardant) IHT at 17).) [redacted]

474. [redacted]

475. [redacted]

a. [redacted]

476. There is no evidence that that Guardant will launch in the foreseeable future a cancer screening test that is a close substitute to the Galleri test. (RX3869 (Cote Expert Report) ¶ 203.)

477. [redacted]; PX7045 (Chudova (Guardant) IHT at 19); RX3869 (Cote Expert Report) ¶ 203).

[redacted]

478. [redacted]

478.1 [redacted]

479. [redacted]

479.1 [redacted]

479.1.1 [redacted]

479.2 [redacted]

479.2.1 [redacted]

479.2.2 [redacted]

479.3 [redacted]

479.4 [redacted]

479.4.1 [redacted]

479.4.2 [redacted]

479.5 [redacted]

479.5.1 [redacted]

480. Guardant has also testified that its "platform in its foundation doesn't have anything specific for [] individual cancer types other than selection of the regions of the genomes that are most representative for that specific cancer." (PX7100 (Chudova (Guardant) Dep. at 24).)

481. Guardant also acknowledged that "[t]here's also [the] possibility that we would need to bring other biomarkers to support the sensitivity and specificity requirements in those other cancers, but that's an area of development at this point." (PX7100 (Chudova (Guardant) Dep. at 23–24, 26); RX3869 (Cote Expert Report) ¶ 205).

482. [redacted]

482.1 [redacted]
Chudova (Guardant) Tr. 1179.)

482.2 [redacted]

483. [redacted]

483.1 [redacted]

484. [redacted] Dr. Scott Morton provided no basis for this, and Guardant testified that this determination is based on "internal development data" that has not been validated or published. ([redacted] 26–27); [redacted]

485. In addition, Guardant currently does not have any clinical trials relating to screening for multiple cancers simultaneously listed on clinicaltrials.gov. (RX3869 (Cote Expert Report) ¶ 208.) [redacted]

b. Guardant's LUNAR-2 Colorectal Cancer Screening Tests

486. Guardant is currently developing an NGS-based blood biopsy early cancer screening test using genomic and methylation signatures called LUNAR-2, to detect and screening for early-stage colorectal cancer. (RX3296 (Guardant) at 7.)

486.1 In 2019, Guardant reported a 107–participant study with 72 patients with Stage I–IV colorectal cancer and 35 age-matched cancer-free individuals. (RX3405 (Kim et al., 2019) at 1–2.) The LUNAR-2 test was 94% sensitive at 94% specificity, with sensitivity at 97% in Stage I/II, 90% in Stage III, and 100% in stage IV. (RX3405 (Kim et al., 2019) at 2).) The authors also found that DNA methylation analysis significantly enhanced ctDNA detection relative to somatic mutational analysis alone (94% vs. 56%; $p<0.0001$). (RX3405 (Kim et al., 2019) at 2).)

486.2 In 2020, Guardant reported a 205–participant study with 113 patients with stage I-III colorectal cancer and 88 age-matched colonoscopy screen-negative individuals. (RX3740 (Westesson et al., 2020) at 2); (RX3869 (Cote Expert Report) ¶ 209). The LUNAR-2 test was 90.3% sensitive at 96.6% specificity, with sensitivity at

90% in Stage I; 88% in Stage II; 96% in Stage III. (RX3740 (Westesson et al., 2020) at 2); (RX3869 (Cote Expert Report) ¶ 209.)

487. In 2019, Guardant initiated the approximately 10,000–participant ECLIPSE prospective observational trial to evaluate the performance of the LUNAR-2 colorectal cancer screening test and support its submission to the FDA. (RX3128 (Guardant) at 1–2; Chudova (Guardant) Tr. 1155, [redacted] ECLIPSE is expected to complete enrollment in 2021. (RX3296 (Guardant Health, Solutions) at 7; Chudova (Guardant) Tr. 1155, [redacted]

487.1 The ECLIPSE trial's population consists of patients undergoing regular screening procedures for colorectal cancer using colonoscopy, and the aim of the study is to be able to assess performance of Guardant's CRC screening device in comparison to standard of care, which is colonoscopy. (Chudova (Guardant) Tr. 1189; PX7100 (Chudova (Guardant) Dep. at 32–33); (RX3869 (Cote Expert Report) ¶ 210.)

488. Guardant has completed a 40–participant, prospective observational pilot study in lung cancer, and is conducting a 590–participant, prospective observational study in the U.S. and a 700 participant, prospective observational study in South Korea to evaluate the LUNAR-2 test in lung cancer. (RX3125 (Guardant) at 1–2); RX3122 (Guardant); RX3124 (Guardant); (RX3869 (Cote Expert Report) ¶ 211.)

489. [redacted]

490. [redacted]

c. Guardant's Other Oncology Test Development Efforts

491. Guardant currently markets the following types of oncology tests: Guardant360® CDx, a 61–gene panel, FDA-approved therapy selection test; Guardant360® LDT, an 80–gene panel therapy selection test; GuardantOMNI, a 500–gene panel therapy selection test; and Guardant Reveal, an MRD monitoring test. (RX3219 (Guardant)*;* RX3295 (Guardant); (RX3869 (Cote Expert Report) ¶ 214.)

492. Guardant's Guardant360® CDx, Guardant360® LDT and GuardantOMNI tests are therapy selection tests based on NGS sequencing of genomic materials, and would not be sensitive enough for multi-cancer screening tests. (RX3869 (Cote Expert Report) ¶ 215.)

5. **Helio Health**

493. Helio Health (formerly known as Laboratory for Advanced Medicine ("LAM")) is a molecular diagnostics company based in Irvine, California. (RX3310 (Helio) at 1, 5; Chahine (Helio) Tr. 1001.) It also has an office in Beijing, China. (RX3310 (Helio) at 1,5.) LAM was founded in 2014. [redacted]

494. [redacted]

495. [redacted]

496. [redacted]

497. [redacted]

498. There is no indication based on Helio Health's work to date that Helio Health will be a competitor to GRAIL in the foreseeable future, and depending on the test that Helio Health develops in the future, it is unclear if it will be a competitor to GRAIL or will develop a complementary test. (RX3869 (Cote Expert Report) ¶ 217; **{Cote Tr. 3872.).}**

499. [redacted] Helio discloses that its pipeline of cancer testing and screening products, includes tests for colon, breast, lung and "multi-cancer" indications. (RX3308 (Helio) at 1.) Both Helio's recent announcements, as well as its prior work on IvyGene, shows that it has only ever studied four cancers: breast, colon, liver, nasopharyngeal and lung. (RX3302 (Hao et al., 2017); RX3308 (Helio) at 2); RX3616 (Roy et al., 2019).)

500. [redacted]

501. [redacted]

[redacted]

501.1 Helio was previously developing a multi-cancer screening test called IvyGene but has since abandoned those efforts. (PX7077 (Chahine (Helio) Dep. at 218); RX3417 (Helio); RX3263 (GenomeWeb) at 1; RX3869 (Cote Expert Report) n. 334.)

502. Dr. Scott Morton has not presented any evidence showing that the Helio two cancer-type test (or even a test screening for five cancer types), including many cancers with an existing cancer screening test, is a close substitute of the Galleri test, which simultaneously screens for more than 50 cancer types, 45 of which have no current screening test. (RX3869 (Cote Expert Report) ¶ 219; [redacted]

503. In 2020, Helio Health renamed the IvyGene liver cancer panel to the "Helio Liver Test," and aims to market it in early 2021 as an LDT, followed by an FDA-approved test in 2022. (RX3263 (GenomeWeb) at 1.)

504. In addition to NGS-based cfDNA methylation biomarkers, Helio is also using ELISA to identify protein biomarkers linked to liver cancer, including the alpha-fetoprotein (AFP). (RX3263 (GenomeWeb) at 1.)

505. Helio is taking a multiomics approach, by combining methylation data, protein biomarkers and patients' demographic information using an AI algorithm to determine whether the patient has early-stage liver cancer. (RX3869 (Cote Expert Report) ¶ 220.)

505.1 Helio is pursuing a path of using very limited numbers of biomarkers, (9, 8, 5 and even one), and has done some of their clinical studies not with NGS but with ddPCR. (*See* RX3747 (Xu et al 2017); RX3436 (Luo et al 2020).).

506. Helio (and LAM) have conducted a few different trials relating to its liver cancer test, including certain trials relying on Bio-Rad's droplet digital platform (ddPCR) rather than NGS. (RX3265 (GenomeWeb) at 1.)

506.1 In March 2019, LAM presented results of a blinded validation study to evaluate individual panels of DNA methylation markers developed for the detection of liver cancer. (RX3617 (Roy et al., 2019).) In the 154 participant liver cancer panel study with 60 Stage I–IV liver cancer patients, 30 patients of another cancer type, 10 patients with benign liver disease and 30 healthy individuals, the IvyGene liver cancer panel showed an overall sensitivity of 95% and specificity of 97.5%. (RX3617 (Roy et al., 2019); (RX3869 (Cote Expert Report) ¶ 221.)

506.2 In November 2020, Helio presented results of a prospective validation study to evaluate the Helio Liver Test, together with protein markers and demographics, for the detection of liver, breast or colorectal cancers. (RX3618 (Roy et al., 2020).) In the 631–participant study with 291 liver cancer patients and 340 age-matched healthy controls, the multiomics test achieved an overall sensitivity of 93.0% and a specificity of

95.6%, with sensitivities for Stages I, II, III and IV at 77.8%, 99.8%, 96.8%, and 98.6%, respectively, at a 95% specificity. (RX3618 (Roy et al., 2020).)

506.3 Helio further disclosed that the Helio Liver Test alone only achieved sensitivity of 88.7% in Stage I–II liver cancer patients, while sensitivity for AFP alone was 57.5% and for ultrasound was approximately 47%. (RX3308 (Helio) at 1; RX3869 (Cote Expert Report) ¶ 222).

506.4 In February 2019, LAM started a 1,600–participant, prospective observational CLiMB trial to compare the performance of the IvyGene Dx Liver Cancer Test with ultrasound, CT or MRI for the detection of liver cancer within a population that is at high risk for liver cancer due to liver cirrhosis. (RX3127 (Clinicaltrials.gov) at 2.) The CLiMB trial is expected to complete in 2023. (RX3127 (Clinicaltrials.gov) at 2.) The Helio-led team has enrolled at least 500 of 800 high-risk patients and anticipates releasing the results of the trial by early next year. (RX3263 (GenomeWeb) at 3.)

506.5 Helio also partnered with Chinese collaborators to validate the Helio Liver Test in a blinded case-control study, called "Evaluate Methylation Markers for Detection of Liver Cancer Study" (VICTORY). (RX3308 (Helio) at 1.)

506.6 The study evaluated 1,093 individuals in China with liver cancer and benign liver diseases as well as healthy controls, and Helio "plan[s] to share the encouraging details of the VICTORY trial at a later date." (RX3308 (Helio) at 1.)

506.7 The results of the VICTORY study, which has not been published yet, was used as the basis of Helio's registration submission for the Helio Liver Test in China. (RX3308 (Helio) at 1; (RX3869 (Cote Expert Report) ¶ 224).

6. **Natera**

507. Natera, Inc. ("Natera") is a molecular diagnostics company based in San Carlos, California and Austin, Texas. (*See* PX0155 (Natera).) Natera was founded in 2004 with an initial focus on genetic testing in women's health, including non-invasive prenatal testing ("NIPT"). (RX3488 (Natera) at 5.)

508. [redacted]; RX3492 (May 2019 Earnings Call) at 6; [redacted]

509. [redacted]

510. While data from a different context may be helpful preliminarily for biomarker discovery purposes, it is unlikely to accelerate the development of a cancer screening test for multiple cancer types or to add a new cancer type to an existing screening test.

510.1

511. There is no evidence based on Natera's work to date that Natera will be a competitor to GRAIL in the foreseeable future, and depending on the test that Natera develops in the future, it is unclear if it will be a competitor to GRAIL or will develop a complementary test. (RX3869 (Cote Expert Report) ¶ 227;

512. To date, Natera has not published any studies relating to cancer screening. (RX3869 (Cote Expert Report) ¶ 228.)

513.

514.

515.

516. [redacted]

516.1 [redacted]

516.2 Further, Natera contends that it will be able to use the biomarkers that it has identified for its Signatera MRD test. (RX3869 (Cote Expert Report) ¶ 230.) However, Natera's CEO as recently as November 2020 stated to its investors that "Signatera technology is not something that can be used for early detection." (RX3496 (Nov. 5, 2020 Earnings Call) at 18.) [redacted]

517. The MRD test that Natera has developed actually depends on the pre-diagnosis of cancer. (RX3869 (Cote Expert Report) ¶ 230.) The Natera MRD test is based on identifying DNA point mutations that are specific to an individual patient's cancer, and each patient requires assessment of their cancer cells to identify the mutations that cancer might have. (*See* RX3601 (Reinert et al., 2019); RX3157 (Coombes et al., 2019); RX3118 (Christensen et al., 2019).) This type of assay is inapplicable to a cancer screening test, which is performed in asymptomatic individuals who do not have a cancer diagnosis or tumor tissue to analyze. (RX3869 (Cote Expert Report) ¶ 231.)

518. Even if there was a way for Natera to adopt the tumor profiling results it has collected for a cancer screening test, there are several issues that would structurally impede any rapid adaptation of its findings to such an test: (RX3869 (Cote Expert Report) ¶ 232.)

518.1 [redacted]

518.2 [redacted]

519. [redacted].) Thus, any early cancer screening test Natera may develop is likely to be further delayed after the development of the non-tumor-informed MRD panel is complete. (RX3869 (Cote Expert Report) ¶ 233.)

520. [redacted]

521. [redacted]

522. [redacted]

523. [redacted]

524. [redacted]

525. [redacted]

526. [redacted] The significance of this prior work is undermined by Natera's own subsequent strategic decisions regarding the development of its putative cancer screening tests. (PFF ¶¶ 526.1–526.3.)

526.1 [redacted]

526.2 Natera's own public statements show that while Natera may have been focused on early detection around the time of its IPO, it clearly shifted its focus to MRD and has only recently turned its focus back to early detection: until its recent shift, Natera appears to have last mentioned its efforts in early detection in 2016 and 2017. (RX3495 (Natera) at 7 (discussing exploring breast and ovarian cancer screening); RX3491 (Natera) at 18.

526.3 By early 2019, CEO Steve Chapman said, "I want to level set on the market opportunity and where we are positioned. ***We're not focused on asymptomatic cancers strain or early detection.***" (RX3492 (Natera) at 6.)

7. **Singlera**

527. Singlera Genomics ("Singlera") is a molecular diagnostics company based in La Jolla, California. (PX2780 (Singlera) at 1.) Singlera was founded in 2014 to focus on early cancer detection. (PX7102 (Gao (Singlera) Dep. at 16, 17; 97–98).)

528. Though Singlera has been focusing on early cancer screening for seven years, it still views itself as "early in the run." (PX7102 (Gao (Singlera) Dep. at 17).)

529. It appears that Singlera is in the research and development stage for a cancer screening test for five cancer types, and in the clinical stage for its ColonES colorectal cancer screening test. (RX3869 (Cote Expert Report) at ¶ 237.)

530. [redacted]

[redacted]

a. Singlera's PanSeer Test

531. Singlera's PanSeer test is a pipeline NGS-based cfDNA methylation RUO cancer screening test that uses Singlera's cell-free methylated DNA immunoprecipitation sequencing ("cfMeDIP-seq") method that is capable of methylome analysis of small quantities (1–10 ng) of cfDNA to provide broad insight into genome-wide DNA methylation patterns of cfDNA without the increased costs associated with whole-genome sequencing. (*See* RX3628 (Shen et al., 2019).)

532. PanSeer examines about 10,613 to over 20,000 methylation markers in cfDNA for the detection of five (5) cancer types – colorectal, esophageal, liver, lung, and stomach. (RX3115 (Chen et al., 2020) at 3; RX3637 (Singlera) at 1–8; Gao (Singlera) Tr. 2874–75.)

533. The PanSeer test only requires approximately 2 million sequencing reads per sample, and is compatible with both Illumina's MiSeq or NextSeq systems and Thermo Fisher's Ion Torrent S5 systems, though it appears to primarily use the NextSeq 550Dx system from Illumina. (RX3115 (Chen et al., 2020) at 7; RX3637 (Singlera) at 1–6; Gao (Singlera) Tr. 2875, 2894, 2928–29; PX7102 (Gao (Singlera) Dep. at 78); RX3869 (Cote Expert Report) ¶ 239.)

534. In a retrospective, observational study of 418 participants from part of the Taizhou Longitudinal Study with samples from 113 post-diagnosis cancer patients, 98 pre-diagnostic cancer patients, and 207 healthy individuals, PanSeer achieved a 96.1% specificity, 87.6% sensitivity in post-diagnostic cancer patients, and 94.9% sensitivity in 98 pre-diagnostic cancer patients. (RX3637 (Singlera) at 1–6; Gao (Singlera) Tr. 2877–79.) Singlera envisions, however, that any patient testing positive on PanSeer would then undergo additional blood test and/or follow-up imaging to allow tissue of origin mapping. (RX3869 (Cote Expert Report) ¶ 239; RX3115 (Chen et al., 2020) at 6.)

534.1 [redacted] In fact, only a very small portion of the samples from 100,000 participants of the Taizhou Longitudinal Study were used. (RX3115 (Chen et al., 2020) at 3; RX3869 (Cote Expert Report) n. 38.)

535. [redacted] No analytical or clinical data that Singlera has collected provides support for the proposition that PanSeer can detect more than 5 cancer types, let alone 50 or 150 cancer types. (Gao (Singlera) Tr. 2917–18; RX3869 (Cote Expert Report) ¶ 241; [redacted]

536. [redacted]

However, Singlera's subsequent deposition testimony suggests that such a timeline does not appear to be feasible. (Gao (Singlera) Tr. 2925–27, 2942–43, 2949; PX7102 (Gao (Singlera) Dep. at 81–85).)

536.1 In particular, Singlera testified that it is "far away" from starting clinical trials for PanSeer in the United States, and that it is "still not in the really starting clinical trial state." (Gao (Singlera) Tr. 2926; PX7102 (Gao (Singlera) Dep. at 113–14, 81–82.) For a pan-cancer trial, Singlera estimates that a clinical trial would need to be for 100,000 or 200,000 people, somewhere around eight or 10 years. (Gao (Singlera) Tr. 2925–26; PX7102 (Gao (Singlera) Dep. at 122–23).).

536.2 Therefore, by Dr. Gao's own calculation, PanSeer is at least eight to ten years away from potential launch in the United States. (Gao (Singlera) Tr. 2925–26; RX3869 (Cote Expert Report) ¶ 242.)

536.3 Singlera does not currently have any clinical trials relating to screening for multiple cancers listed on clinicaltrials.gov. (RX3869 (Cote Expert Report) ¶ 242.); Gao (Singlera) Tr. 2926; Cote Tr. 3869.)

b. Singlera's ColonES® Tests

537. In addition to the PanSeer cancer screening test in development, Singlera is also developing single cancer screening tests for colorectal cancer and likely lung cancer. (Gao (Singlera) Tr. 2872–73; RX3869 (Cote Expert Report) ¶ 243.)

538. The ColonES® rapid colon cancer assay is a targeted bisulfite NGS sequencing test of ctDNA methylation signatures from blood plasma. (Gao (Singlera) Tr. 2873–74; RX3869 (Cote Expert Report) ¶ 244.)

539. Singlera reported that it had an initial Pre-Submission Meeting with the FDA regarding its ColonES® test in the fall of 2019, and a second Pre-Submission Meeting on April 21, 2020, and that Singlera planned to start the ColonES® pivotal study in the United States in the second half of 2020. (RX3635 (Singlera) at 1–2.)

540. In 2018, Singlera reported the results of its ColonES retrospective study to screen for early stage colorectal cancer and precancerous advanced adenomas. (RX3869 (Cote Expert Report) ¶ 244.)

540.1 In this 1,243 participant study with 291 Stage I colorectal cancer patients, 133 Stage II patients, 124 Stage III patients, and 102 Stage IV patients, 204 advanced adenomas patients and 429 healthy individuals, the ColonES® test achieved sensitivities of 93% for colorectal cancer and 88% for advanced adenoma with a specificity of 99%. (RX3636 (Singlera) at 1–2; RX3273 (Gole et al., 2018); RX3869 (Cote Expert Report) ¶ 244.)

541. Singlera has also conducted a prospective, observational study in China of 300 participants for the detection of early-stage lung cancer. (RX3130 (Clinicaltrials.gov) at 1–5.) Singlera has not reported results of this study yet. (RX3869 (Cote Expert Report) ¶ 245.)

542. Despite these efforts with clinical trials in China, Singlera believes that it is "far from" starting FDA clinical trials for ColonES in the United States. (PX7102 (Gao (Singlera) Dep. at 113).) Singlera testified that it will need a three to four year study for at least 10,000 people for the trial. (PX7102 (Gao (Singlera) Dep. at 120–21); Gao (Singlera) Tr. 2923.) In addition, Singlera is considering a qPCR version—not NGS—of the ColonES test to be launched in China first. (PX7042 (Gao (Singlera) IHT at 90–91); Gao (Singlera) Tr. 2911–12.) Therefore, by its own admission, Singlera appears to anywhere from three to seven years away from completing clinical trials for ColonES, and likely even longer. (RX3869 (Cote Expert Report) ¶ 246; Gao (Singlera) Tr. 2923.)

C. Non-NGS Cancer Screening Developers

1. StageZero

543. StageZero Life Sciences ("StageZero"), formerly known as Genenews, is a molecular diagnostics company based in Richmond Hill, Canada and Richmond, Virginia. (PX8542 (StageZero) at 1.)

544. [redacted]

545. StageZero was founded in 2000, and began working on its colorectal cancer screening test (called ColonSentry) in 2003. (PX7114 (Stamatiou (StageZero) Dep. at 10–11, 25).) [redacted]

546. StageZero intends to provide, on a limited basis to a network of oncologists, a microarray-based cancer screening LDT test, together with partners Health Clinics and Care Oncology, called Aristotle. (RX3659 (StageZero) at 1.)

547. Aristotle is a microarray-based blood biopsy test that interrogates mRNA from whole blood (blood transcriptome) to detect gene expression profiles indicative of 10 discrete cancers. (RX3171 (Dempsey et al., 2020) at 1–2.)

548. Aristotle will detect 9 cancers relevant for women (the "female" test): ovarian, breast, cervical, endometrial, colorectal, bladder, stomach, liver and nasopharyngeal, and 6 cancers for men (the "male" test): prostate, colorectal, bladder, stomach, liver and nasopharyngeal. (RX3653 (StageZero) at 4; [redacted] RX3869 (Cote Expert Report) ¶ 248.)

549. In contrast to the DNA methylation or genomic mutation based approaches used by GRAIL, Thrive, and other companies, StageZero uses an approach called immunoediting, under the theory that when normal cells transform into clinically-detectable cancer, the human immune system protects the human body from cancer and forces the developing tumors to undergo immunogenic "sculpting" through three phases: elimination, equilibrium and escape. (RX3643 (Smyth et al., 2006) at 1–50.)

549.1 As a result of this immunoediting, gene expressions in the transforming cancer cells, *i.e.*, the mRNA from the transcriptome, display signature profiles, and cause a corresponding change in the mRNA profiles in the peripheral blood plasma. (RX3869 (Cote Expert Report) ¶ 249.)

549.2 StageZero's Aristotle detects this change using Thermo Fisher/Affymetrix's GeneChipTM Gene Expression Profile microarray—not NGS—which tests more than 36,000 gene transcripts and variants. (RX3171 (Dempsey et al., 2020) at 1–2.)

550. In a 2,845 unique blood samples validation study with 1,013 samples from patients diagnosed with 10 cancers and 1,832 control samples including 1,042 samples from healthy subjects and the remaining from patients diagnosed with non-cancer diseases, Aristotle achieves sensitivity from 55.6% to 100% for various cancers at 99.0% specificity, with PPVs from 5.6–77.7% and mean false positive rate ranging from 0.3% to 6.8%. (RX3171 (Dempsey et al., 2020) at 1–2.)

551. StageZero states that the Aristotle test can fully discriminate each cancer, but has not fully disclosed how the tissue of the origin of the cancers are determined. (RX3653 (StageZero) at 1–4.) [redacted]

552. [redacted] StageZero currently does not have any multi-cancer clinical trial listed on clinicaltrials.gov. (RX3869 (Cote Expert Report) ¶ 251.)

2. **Genesys Biolabs**

553. Genesys Biolabs, a business unit of 20/20 GeneSystems, Inc., is a molecular diagnostics company based in Rockville, Maryland. (RX3869 (Cote Expert Report) ¶ 252.) Genesys Biolabs currently provides a cancer screening test for lung, liver, pancreas, ovaries, kidneys, prostate and colon cancers. (RX3869 (Cote Expert Report) ¶ 252.)

554. Genesys Biolabs currently provides a proteomics-based LDT blood test, called OneTestTM. (RX3259 (Genesys Biolabs) at 1.) OneTest measures a panel of seven widely used cancer protein biomarkers (AFP, CEA, PSA, CA 19–9, CA 125, CA 15–3, and CYFRA 21–1)—not NGS—from a single blood biopsy sample, to simultaneously screens for cancers from the lung, liver, pancreas, ovaries, kidneys, prostate and colon using immunoassay on the Roche Cobas e411 immunoassay analyzer. (RX3259 (Genesys Biolabs) at 1.)

555. In a prospective observational study of 41,516 participants taking health check-up examination at the Chang Gung Memorial Hospital in Taoyuan, Taiwan between May 2001 and April 2013, the OneTest panel of protein biomarkers, together with squamous cell-specific antigen, a biomarker associated with head and neck cancer not common in the U.S., achieved 57% sensitivity at 88.7% specificity, with PPV of 3.7%, and NPV of 99.6%. (RX3739 (Wen et al., 2015) at 2.)

555.1 The panel's sensitivity for liver, lung, prostate, and colorectal cancers was 90.9%, 75.0%, 100%, and 76.9%, respectively, but the panel had a poor sensitivity for identifying head and neck cancer (17.6%), breast cancer (37.5%), and cervical cancer (44.4%). (RX3739 (Wen et al., 2015) at 2.)

556. Genesys Biolabs currently does not have any clinical trials relating to screening for multiple cancers listed on clinicaltrials.gov. (RX3869 (Cote Expert Report) ¶ 254.)

3. InterVenn Biosciences

557. InterVenn Biosciences ("InterVenn") is a biotechnology company based in South San Francisco, California. (RX3388 (InterVenn) at 1.) InterVenn is known to be developing early cancer detection tests for advanced adenoma, colorectal cancer and nasopharyngeal carcinoma. (Leite (Illumina/InterVenn) Tr. 2171–74.) InterVenn is also developing a population diagnostic test for ovarian cancer; a therapy selection test for pancreatic cancer, lung cancer and melanoma, called Dawn; and a renal cell carcinoma test. (Leite (Illumina/InterVenn) Tr. 2170, 2172, 2180; *see also* RX3869 (Cote Expert Report) ¶ 255.)

a. InterVenn's VISTA™ proteomics platform

558. InterVenn currently provides an AI-enabled, mass spectrometry glycoproteomics based proteomics platform—not NGS—called VISTA. (RX3389 (InterVenn) at 1.) VISTA is a scalable platform to assess glycoprotein post-translational modifications in a site-specific manner across thousands of peptides and glycopeptides. (RX3869 (Cote Expert Report) ¶ 256.) It can quantify thousands of glycoproteoforms in a single measurement using only 10 microliters of serum/plasma. (RX3389 (InterVenn) at 1.)

559. The VISTA platform can be used to identify new cancer biomarkers. (RX3869 (Cote Expert Report) ¶ 256.) For example, using multienzyme digestion and glycopeptide enrichment, InterVenn simultaneously monitored the abundances of over 600 glycopeptides, showing its potential for clinical deployment in the fields of cancer. (RX3424 (Li et al., 2019) at 1.)

560. InterVenn has used VISTA to conduct oncology research in over a dozen different cancers, including ovarian, renal, lung, liver, prostate, pancreas, nasopharyngeal, and colorectal cancer and several others. (RX3388 (InterVenn) at 2.)

561. In November 2020, InterVenn announced that its VISTA panel has demonstrated multi-indication performance in early cancer detection for different cancers with sensitivities and specificities consistently above 90 and as high as 98%. (RX3087 (BusinessWire) at 1; RX3869 (Cote Expert Report) ¶ 56.)

b. InterVenn's Dawn™ Immuno-Oncology test

562. InterVenn currently provides a glycoproteomics-based clinical diagnostic test called Dawn™ to help physicians make the best possible choice for patient outcomes when deploying immuno-oncology therapies. (RX3387 (InterVenn) at 1.)

563. InterVenn currently has data to support Dawn™ in pancreatic cancer, lung cancer, melanoma, and are working on other cancers. (RX3387 (InterVenn) at 2.)

563.1 In a 181–sample case control study with 45 samples from patients with pancreatic ductal adenocarcinoma and 136 control samples, the Dawn pancreatic cancer screening test achieved sensitivity of 91% and specificity of 86%. (RX3403 (Kasi et al., 2020) at 1–2.)

4. **Seer**

564. Seer, Inc. ("Seer") is a biotechnology company based in Redwood City, California. (RX3774 (Seer) at 1.) Seer has a proteomics platform—not NGS—that may be used to develop multi-cancer screening tests. (RX3869 (Cote Expert Report) ¶ 258.) Seer's subsidiary, PrognomIQ, is known to be developing early cancer detection tests. (RX3869 (Cote Expert Report) ¶ 258.)

a. Seer's ProteographTM proteomics platform

565. Seer is developing a ProteographTM automated workflow proteomics platform that combines its proprietary magnetic nanoparticles for highly parallel protein separation with commonly used liquid chromatography-mass spectrometry (LC-MS) technology for efficient proteomic profiling. (RX1605 (Blume et al., 2020) at 1–14.)

565.1 The Proteograph platform allows for multiplexing of the protein markers using tandem mass tags (TMTs), thus increasing the throughput of proteomic detections. (RX1605 (Blume et al., 2020) at 1–14; RX3869 (Cote Expert Report) ¶ 259.)

566. Seer has used its Proteograph platform to detect over 2,000 proteins from blood plasma samples of healthy and non-small cell lung cancer patients in a cancer classification study, demonstrating the applicability of the Proteograph platform to early cancer screening. (RX1605 (Blume et al., 2020) at 1–14.)

566.1 In a 288 participant study with 125 lung cancer patients, 81 patients with comorbidity, and 82 health individuals, Seer's Proteograph platform was used to analyze 1779 plasma proteins and Seer identified clusters of proteins with at least 10 members that should differential behavior in lung cancer patients compared with healthy and comorbid individuals. (RX3632 (Siddiqui et al., 2020) at 1; RX3869 (Cote Expert Report) ¶ 260.)

567. Seer currently does not have any clinical trials listed on clinicaltrials.gov. (RX3869 (Cote Expert Report) ¶ 261.)

b. PrognomiQ

568. PrognomiQ is a subsidiary and a recent spin-off of Seer. (RX3869 (Cote Expert Report) ¶ 262.) It is also developing early cancer screening tests by combining rich proteomic information, obtainable using Seer's Proteograph platform, with genomic, metabolomic, and

other health data. (RX3587 (PrognomiQ) at 2.) There are no details available publicly about PrognomiQ's technologies or plans. (RX3869 (Cote Expert Report) ¶ 262.)

569. PrognomiQ currently does not have any clinical trials listed on clinicaltrials.gov. (RX3869 (Cote Expert Report) ¶ 263.)

5. **Somalogic**

570. Somalogic is a biotechnology company based in Boulder, Colorado. (RX3869 (Cote Expert Report) ¶ 264.) Somalogic has a proteomics platform—not NGS—that may be used to develop screening tests for multiple cancers. (RX3869 (Cote Expert Report) ¶ 264.) Somalogic is known to be developing an early cancer detection test for lung cancer. (RX3869 (Cote Expert Report) ¶ 264.)

571. Somalogic developed an aptamer-microarray based proteomics platform called SomaScan that can measure approximately 7,000 unique human protein analytes in small volumes of biological samples. (RX3651 (Somalogic) at 1–7.)

571.1 The SomaScan Platform uses a proprietary protein-capture reagents called SOMAmer® (Slow Off-rate Modified Aptamer) reagents, which consist of short single-stranded DNA sequences with hydrophobic modifications. (RX3869 (Cote Expert Report) ¶ 265.)

571.2 These chemical modifications facilitate the aptamer binding to proteins and enhance the specificity and affinity of protein-nucleic acid interactions. (RX3869 (Cote Expert Report) ¶ 265.) As a result, these modified aptamers can bind target proteins with specificity, and also be recognizable as nucleotide sequences by specific DNA hybridization probes. (RX3869 (Cote Expert Report) ¶ 265.)

571.3 The SomaScan Platform measures the levels of target proteins by capturing them using these unique target-binding, fluorescent labeled aptamers, and then measures the corresponding aptamer concentrations using microarrays of complementary DNA probes. (RX3651 (Somalogic) at 1–7; (RX3869 (Cote Expert Report) ¶ 265.).)

572. As a highly multiplexed, sensitive, quantitative, and reproducible proteomic tool, the SomaScan platform is not only used for identification of relevant protein biomarkers relating to cancers, but also for biomarker detection and analysis. (RX3869 (Cote Expert Report) ¶ 266.)

572.1 For example, researchers at the Indiana University School of Medicine recently used the SomaScan platform to identify potential serum protein biomarkers and pathways for pancreatic cancer cachexia. (RX3471 (Narasimhan et al., 2020) at 1–23.)

572.2 Researchers at MIT used the SomaScan platform, in part, to identify a panel of prostate cancer proteases biomarkers. (RX3177 (Dudani et al., 2018) at 1–6.)

572.3 Researchers in Germany also used the SomaScan platform to identify links between the recurrence of ovarian carcinoma and proteins released into the tumor microenvironment. (RX3229 (Finkernagel et al., 2019) at 1–2.)

572.4 Researchers in the U.K. and Spain collaborated with Somalogic to use the SomaScan platform to analyze protein biomarkers isolated from exosomes in plasma and urine of prostate cancer patients. (RX3738 (Welton et al., 2016) at 1–2; RX3736 (Webber et al., 2014) at 1.)

573. Somalogic currently does not have any clinical trials relating to screening for multiple cancers listed on clinicaltrials.gov. (RX3869 (Cote Expert Report) ¶ 267.)

IV. NGS COMPETITION

A. Current Players

1. Illumina

574. Illumina entered the sequencing market following its acquisition of Solexa in 2006 and its subsequent debut of its first instrument, the Genome Analyzer, in 2007. (PX0091 (Illumina) at 4; RX3407 (Kircher et al., 2010) at 5.) The Genome Analyzer was capable of simultaneously sequencing several million very short sequences (up to 26 nucleotides) in a single sequencing run. (RX3407 (Kircher et al., 2010).)

574.1 Since the introduction of the Genome Analyzer, Illumina has significantly improved its NGS sequencers' capabilities. Initially, the length of the sequence reads were limited to 26 nucleotides because of steeply increasing sequencing errors as the reads became longer. (RX3407 (Kircher et al., 2010).)

574.2 Within three years of its introduction, the Genome Analyzer was able to simultaneously sequence more than 200 million fragments per run and generate sequence reads of up to 100 nucleotides from each strand, generating more than 50 Gb of sequence output. (RX3407 (Kircher et al., 2010).)

574.3 The Genome Analyzer was replaced in 2010 by the HiSeq sequencers, which were subsequently replaced by the NovaSeq sequencers. (RX3869 (Cote Expert Report) ¶ 276.)

575. Illumina currently provides five classes of NGS sequencers based on the same sequencing-by-synthesis mechanism of action. The below chart shows each of the Illumina instruments and their current throughput:

Table 3

Instrument(s)	Throughput	Read Length	Run Time
iSeq	Simultaneous sequencing of 4 million DNA fragments	2x150 nucleotides to generate outputs of -1.2 Gb per run	8–19 hours
MiniSeq	Simultaneous sequencing of 8–25 million DNA fragments	2x150 nucleotides to generate outputs of -1.9 to -7.5 Gb per run.	4–24 hours
MiSeq	Simultaneous sequencing of 1–25 million DNA fragments	2x150 to 3x300 nucleotides to generate outputs of -300 Mbp to -15 Gb per run	10–56 hours
NextSeq 500	Simultaneous sequencing of 130– 400 million DNA fragments	2x150 nucleotides to generate outputs of - 40 to 120 Gb per run	15–29 hours
NextSeq 550/550 Dx	Simultaneous sequencing of 130– 400 million DNA fragments	2x150 nucleotides to generate outputs of -16.25 to 120 Gb per run	12–30 hours
NextSeq 2000	Simultaneous sequencing of 400 million to 1.2 billion DNA fragments	2x150 nucleotides to generate outputs of - 40 to 360 Gb per run	11–48 hours
HiSeq X (discontinued)	Simultaneous sequencing of 6 billion DNA fragments	2x150 nucleotides to generate outputs of -1600 to -1800 Gb per run	
NovaSeq 6000	Simultaneous sequencing of 800 million to 20 billion DNA fragments	2x150 to 2x250 nucleotides to generate outputs of -80 Gb to -6 Tb per run	13–45 hours
[redacted]	[redacted]	[redacted]	[redacted]

(RX3357 (Illumina) at 6–7; RX3354 (Illumina) RX3353 (Illumina,); RX3364 (Illumina); (RX3371 (Illumina); RX1600 (Illumina) at 19, 25); PX0091 (Illumina) at 11.)

576. Illumina NGS sequencers are about 99.9% accurate (>87% of bases >Q30) in calling the correct base from the DNA sequence. (RX3368 (Illumina).)

577. Illumina's improvements to its sequencing technology have driven down the cost of sequencing dramatically. Twenty years ago, the human genome project took the joint effort of more than 200 scientists 13 years and about $3 billion to read a single human genome of about 3 Gbs. (RX3113 (Hayden) at 1–2.)

577.1 When Illumina introduced the Genome Analyzer, the cost to sequence a full human genome was about $10 million, which dropped to about $200,000 in 2009. (RX3113 (Hayden) at 1; RX3370 (Illumina).)

577.2 In January 2014, Illumina announced the achievement of $1000 genome with its introduction of the HiSeq X system at 30x coverage (about 100 Gbs). (RX3370 (Illumina).)

577.3 In August 2020, Illumina announced the introduction of the $600 genome with the NovaSeqTM 6000 v1.5 Reagent Kit. (RX3355 (Illumina).)

577.4 [redacted]

2. **Thermo Fisher**

578. Thermo Fisher Scientific, based in Waltham, Massachusetts, offers the Ion Torrent line of NGS platforms. (RX2577 (Thermo Fisher) at 1.) Thermo Fisher inherited the Ion Torrent brand via its merger with Life Technologies and Life's prior acquisition of Ion Torrent Systems Inc. (PX7070 (Felton (Thermo Fisher) IHT at 11.) Ion Torrent Systems Inc. developed and released the Ion Torrent NGS sequencers in 2010. (PX2482 (Thermo Fisher) at 50.)

578.1 As with the Illumina sequencers, the nucleic acids to be sequenced must undergo sample preparation before sequencing. (RX3869 (Cote Expert Report) ¶ 281.) The DNA fragments are attached to microscopic beads and the fragments undergo amplification using PCR so that each bead is covered with many copies of the fragment to be sequenced. (RX3869 (Cote Expert Report) ¶ 281.) Each time a nucleotide is incorporated into the sequence (e.g., for the sequencing by synthesis), a hydrogen ion is released. (RX3690 (Thermo Fisher) at 2–3.)

578.2 The Ion Torrent sequencers use semiconductors to measure the pH change resulting from the release of hydrogen ions during the incorporation reaction to identify the nucleotides in the sample being sequenced. (RX3690 (Thermo Fisher) at 3.)

579. Thermo Fisher currently markets four Ion Torrent NGS systems: the Ion PGM Dx System, the Ion Proton System, the Ion GeneStudio S5 Systems, and the Ion Torrent Genexus System. The below chart shows each of the Thermo Fisher instruments and their current throughput:

Table 4

Instrument(s)	Throughput	Read Length	Run Time
Ion PGM Dx	Simultaneous sequencing of 4 to 5.5 million DNA fragments	200 nucleotides to generate outputs of ~ 0.6 to ~1 Gb per run	4.4 hours
Ion Proton	Simultaneous sequencing of ~ 60 to 80 million DNA fragments	200 nucleotides to generate outputs of up to 15 Gb per run	~2.5 hours
Ion GeneStudio S5	Simultaneous sequencing of ~ 2 to 130 million DNA fragments	200 to 600 nucleotides to generate outputs of ~ 0.3 to 50 Gb per run	~3 to 12 hours
Ion Torrent Genexus	Simultaneous sequencing of ~ 48 to 60 million DNA fragments	200 to 400 nucleotides to generate outputs of 10 to 12 Gb per run	12 hours

(RX3688 (Thermo Fisher); RX3689 (Thermo Fisher); RX3687 (Thermo Fisher); RX3685 (Thermo Fisher).)

580. The Ion Torrent NGS sequencers are about 98.4–99.2% accurate (>Q20) in calling the correct base from the DNA sequence. (RX3693 (Thermo Fisher).) Thermo Fisher's Ion Torrent sequencers' run time is typically less than 12 hours, comparable to Illumina's 11–45 hours run time for the NextSeq and NovaSeq NGS sequencers. (RX3869 (Cote Expert Report) ¶ 282.)

581. Thermo Fisher's Ion GeneStudio S5 Systems are also equipped to perform three types of genome-wide methylation profiling strategies: (i) bisulfite conversion; (ii) enzymatic genomic partition to separate the genome into methylated and unmethylated compartments with methylation-sensitive restriction enzymes, thus allowing more sensitive detection of DNA methylation through NGS sequencing; and (iii) enrichment of methylated DNA using affinity purification of methylated genomic DNA fragments, thus similarly allowing more sensitive detection of DNA methylation through NGS sequencing. (RX3691 (Thermo Fisher).)

581.1 Thermo Fisher also offers chromatin immunoprecipitation sequencing ("ChIP-Seq") for its Ion Torrent sequencers. (RX3680 (Thermo Fisher).)

581.2 Researchers have also developed protocols to perform methylated DNA immunoprecipitation sequencing ("MeDIP-Seq") using Thermo Fisher's Ion Torrent sequencers; MeDIP Seq may be used to study DNA methylation genome-wide. (RX3158 (Corley et al., 2015).)

582. Thermo Fisher's share of the clinical oncology segment has increased over the last five years. (PX7097 (Felton (Thermo Fisher) Dep. at 91).) [redacted]

583. [redacted]

584. Thermo Fisher will offer its solutions to MCED test developers and agrees that its sequencers are capable of being used for multi-cancer screening tests, and researchers are successfully developing new ways to use Thermo Fisher products for early cancer screening applications. (Felton (Thermo Fisher) Tr. 2021–23; PX7097 (Felton (Thermo Fisher) Dep. at 65–68).)

585. Even though the technical parameters of Thermo Fisher's Ion Torrent platform may be inferior to Illumina's high-end sequencers, the Ion Torrent sequencers are nonetheless suitable for certain multi-cancer screening tests. (RX3869 (Cote Expert Report) ¶ 285.)

586. If a test developer came to Thermo Fisher and wanted to reconfigure its assay to run on Thermo Fisher's platforms, Thermo Fisher would assist in putting the test onto its platform. (Felton (Thermo Fisher) Tr. 2021–23; PX7097 (Felton (Thermo Fisher) Dep. at 143–44).)

586.1 [redacted]

586.2 [redacted]

3. **BGI**

587. BGI Genomics, formerly known as the Beijing Genomics Institute, is a Chinese genome sequencing company. (RX3060 (BGI) at 1.) It acquired California-based sequencing company Complete Genomics in 2013 and launched its BGISEQ-500 NGS sequencer in 2015 based on Complete Genomics' core technology. (RX3063 (BGI).)

588. BGI's NGS sequencers use an SBS technology that is similar to Illumina's NGS sequencing technology. (RX3869 (Cote Expert Report) ¶ 286.)

588.1 BGI is currently enjoined from launching its sequencing instruments and related reagents in the United States due to its infringement of a certain Illumina patents that expire in 2022 and 2023. (RX3356 (Businesswire).)

588.2 BGI may enter the U.S. market by August 2022. *Illumina, Inc. v. BGI Genomics, Co.*, 20-cv-01465-WHO (N.D. Cal. Mar. 27, 2022), ECF No. 665 at 48 ("If [BGI] make[s] offers to sell Accused Products in the U.S. before the expiration of the patents-in-suit—as they are permitted—they must include the following conspicuous

written disclaimer: 'No sales will occur, and no purchase orders will be accepted, until after August 23, 2022.'").

589. BGI's technology also measures the light emission when a fluorescent labeled base is incorporated into the DNA strand. (RX3065 (BGI).) BGI recently introduced a CoolMPSTM (Massively Parallel Sequencing) technology that measures the light emission when a fluorescently-labeled antibody specifically binds to the base that has been incorporated into the DNA strand. (RX3175 (Drmanac et al., 2020).)

590. BGI currently markets five sequencers. The below chart shows each of the BGI instruments and their current throughput:

Table 5

Instrument(s)	Throughput	Read Length	Run Time
DNBSEQ-G50	Simultaneous sequencing of ~ 100 to 500 million DNA fragments	50 to 2x150 nucleotides to generate outputs of up to ~ 150 Gb per run	10–66 hours
DNBSEQ-G400 FAST	Simultaneous sequencing of ~ 550 million DNA fragments	100 to 2x150 nucleotides to generate outputs of up to 330 Gb per run	13–37 hours
DNBSEQ-G400	Simultaneous sequencing of ~ 1,500 to 1,800 million DNA fragments	50 to 2x200 nucleotides to generate outputs of up to 1,440 Gb (1.44 Tb) per run	13–37 hours
DNBSEQ-T7	Simultaneous sequencing of ~ 20 billion DNA fragments	100 to 2x150 nucleotides to generate outputs of up to 6,000 Gb (6 Tb) per run	<24 hours
DNBSEQ-T10×4RS / DNBSEQ-Tx	Simultaneous sequencing of ~ 80 billion DNA fragments	100 to 2x150 nucleotides to generate outputs of up to 20 Tb per day	<24 hours

(RX3465 (MGI Tech); RX4004 (MGI Tech).)

591. BGI's DNBSEQ sequencer's reported accuracy is comparable to Illumina's sequencers, and guarantees more than 80% of bases with a quality score greater than Q30—which is over 99.9% accurate. (RX3465 (MGI Tech); RX3067 (BGI).)

592. BGI's highest throughput instrument has a higher reported throughput than the highest performance instrument and flow cell currently offered by Illumina, the NovaSeq 6000 with the S4 flow cell (up to 6 Tb/run), [redacted] (*Compare* RX4004 (MGI Tech) at 1–2 *with* RX3357 (Illumina) at 7; [redacted]

593. BGI/MGI offers the MGIEasy Whole Genome Bisulfite Sequencing Library Prep Kit for DNA methylation analysis using bisulfite conversion. (RX3465 (MGI Tech).) BGI also provide whole-genome bisulfite sequencing and target region bisulfite sequencing for either genome-wide DNA methylations profiling or DNA methylations profiling in specific regions of interest. (RX3070 (BGI).)

593.1 BGI also offers ChIP-Seq services to analyze protein interaction with DNA using its DNBSEQ sequencers. (RX3066 (BGI).) Sequencers capable of sequencing DNA that has been prepared using chromatin immunoprecipitation (ChIP) are also capable of sequencing DNA that has been prepared using methylated-DNA immunoprecipitation (MeDIP).

594. BGI's reported sequencing costs for its DNBSEQ sequencers are lower than those for Illumina's NovaSeq instrument.

594.1 For example, BGI advertises Whole Genome Sequencing service for $400 in the U.S. and worldwide on the DNBSEQ platforms, at about $4 per Gb. (RX3068 (BGI); RX3071 (BGI).)

594.2 BGI also announced that its DNBSEQ-T10×4RS sequencers can generate $100 genomes, making it per Gb cost only $1.00. (RX4004 (MGI); *see also* deSouza (Illumina) Tr. 2331 ("Last year, BGI announced its hundred-dollar genome and has talked about its T-10 being ready to be deployed around the world").

595. [redacted]

595.1 [redacted]

595.1.1 [redacted]

4. **GenapSys**

596. GenapSys, Inc., based in Redwood City, California, launched its GenapSys Sequencer in 2019. (RX3402 (GenomeWeb).) This new NGS sequencing platform uses semiconductors to measure the minute impedance change, i.e., the change in the effective resistance of the reaction solution, resulting from the incorporation reaction. (RX3257 (GenapSys).) GenapSys's technology also relies on a sequencing-by-synthesis approach. (RX3869 (Cote Expert Report) ¶ 290.)

597. GenapSys' NGS sequencer has comparably low costs for both the equipment and per run cost. Reports suggest that the list price of the GenapSys Sequencer is only $9,900 and a sequencing kit for a 16 MM chip single run costs $299. (RX3262 (GenomeWeb).) GenapSys announced in January 2021 that the cost on its 144 MM chip to be shipped this year would be about $27 per Gb. (RX3732 (Vilella).)

5. Oxford Nanopore

598. Oxford Nanopore Technology ("ONT") is a spin-out from the University of Oxford that launched in 2005. (RX3538 (ONT) at 1–3.) ONT's nanopore sequencing technology measures the minute change in electrical conductance across biological nanopores when DNA molecules thread through those nanopores under the control of enzyme motors, using nanopore sensors with the ability to differentiate nucleotides. (RX3538 (ONT); RX3166 (Deamer et al., 2016).)

599. ONT currently makes four NGS sequencers, with one more in development. The below chart shows each of the ONT instruments and their current throughput:

Table 6

Instrument(s)	Throughput	Read Length	Run Time
Flongle	Simultaneous sequencing of up to 126 DNA strands	No limit to read length; highest to date is 4 million. Total throughput per run is up to ~ 2 Gb per run	1 min–16 hours
MinION	Simultaneous sequencing of up to 512 DNA strands	No limit to read length; highest to date is 4 million. Total throughput per run is ~ 10 to 20 Gb, up to 42 Gb	1 min–72 hours
GridION	Simultaneous sequencing of up to 2,560 DNA strands	No limit to read length; highest to date is 4 million. Total throughput per run is up to 210 Gb	1 min–72 hours
PromethION	Simultaneous sequencing of up to 128,400 DNA strands	No limit to read length; highest to date is 4 million. Total throughput per run is up to 10,000 Gb (10 Tb)	1 min–72 hours
Plongle (in development)	Parallel sequencing with 96 flow cells	No limit to read length; highest to date is 4 million	1 min–72 hours

(RX3913 (ONT,) at 1–5; RX3543 (ONT) at 1; RX3536 (ONT); RX3542 (ONT); RX3869 (Cote Expert Report) ¶ 293.)

600. Core components of ONT's long-read sequencing technology as well as other recent innovations have made its platform more suitable for multi-cancer screening. (*See* RX3869 (Cote Expert Report) ¶¶ 293, 295–98.)

600.1 Because it does not require PCR amplification, ONT's long-read sequencing eliminates amplification bias while preserving base modifications, making it ideal for epigenomic analysis such as methylation profiling. (RX3439 (Mantere et al., 2019) at 2; *see also* RX3236 (Folkard et al., Methylation with Oxford Nanopore Technologies Video Seminar).) ONT recently released a Cas9 targeted nanopore

sequencing kit, which enables high depth sequencing and retains methylation patterns and other base modifications. (RX3537 (ONT).)

600.2 ONT's nanopore sequencing technology is capable of directly detecting methylation and other epigenomic markers on DNA or RNA, without the bisulfite conversion step used by other sequencing technologies (*e.g.*, for Illumina's sequencing technology) that can cause sample degradation, and that can complicate data analysis. (RX3869 (Cote Expert Report) ¶ 295.)

600.3 Using ONT's nanopore sequencing, researchers have directly identified epigenomic modifications at nucleotide resolution, including DNA methylation, with detection of other epigenomic modifications possible through training base-calling algorithms. (RX3539 (ONT).)

600.4 The use of ONT's nanopore direct sequencing also means that DNA methylation and other base modifications data is captured together with sequence data and is available for analysis at any future timepoint. (RX3539 (ONT).)

600.5 ONT's MinION nanopore sequencer has also been used by researchers for ChIP-Seq to study protein-DNA binding activity and strength. (*See* RX3077 (Borlin et al., 2020).) Researchers are also improving the Rapid Analysis of ChIP-Seq data (RACS) software for the analysis of ONT's nanopore sequencing data. (*See* RX3620 (Saettone et al., 2019).)

601. While ONT has historically focused on long-read sequencing, recently published research has demonstrated ONT's capability to perform short-read sequencing. (PFF ¶¶ 601.1–601.4.) Such research suggests that ONT's nanopore sequencers are "a reliable alternative to Illumina sequencing, with the advantages of minute instrumentation costs and extremely short analysis time". (RX3446 (Martignano et al., 2021) at 1.)

601.1 For example, in 2016, researchers from the Albert Einstein College of Medicine developed a method that enabled rapid real-time sequencing of short DNA fragments using the MinION nanopore sequencer in a test for aneuploidy. (RX3737 (Wei & Williams 2016).)

601.2 In 2019, researchers from the Stanford University developed a rolling-circle amplification method to produce long stretches of concatemeric repeats of short DNA sequences <100 bp from cfDNA that is sensitive enough to achieve SNV (single-nucleotide variants) discrimination in mixtures of sequences and enables quantitative detection of specific variants present at ratios of <10% using ONT's MinION nanopore sequencer. (RX3744 (Wilson et al., 2019).)

601.3 In 2020, researchers from Utrecht University of the Netherlands developed a CyclomicsSeq method that uses similar rolling-circle amplification to accurately detect lowly abundant (0.02%) circulating tumor DNA (ctDNA) from liquid biopsies of patients with head-and-neck squamous cell carcinoma (HNSCC) using MinION nanopore sequencer. (RX3441 (Marcozzi A et al., 2020).)

601.4 In February 2021, researchers from Italy also showed successful use of low-coverage MinION nanopore sequencing for profiling of copy number variation from plasma cfDNA from liquid biopsies of lung cancer patients as a reliable alternative to Illumina sequencing. (RX3446 (Martignano et al., 2021).)

602. ONT has also announced its intent to support the liquid biopsy market. (RX3470 (Nanopore); RX3521 (NCM) at 50–52; RX3167 (Nanopore); RX3520 (NCM) at 6, 9–10).)

603. The per gigabase sequencing costs for ONT's NGS sequencers are comparable to those for the highest throughout Illumina NGS sequencers. (PFF ¶¶ 603.1–603.3.)

603.1 For example, the University of Wisconsin-Madison Biotechnology Center offers ONT nanopore sequencing at $730 for a single cell, $1250 for GridION and $2100 for a PromethION run. (RX3717, University of Wisconsin-Madison Biotechnology Center.)

603.2 A PromethION customer reported repeatedly achieving 220 Gb of sequencing data output per single $625 flow cell, making per Gb cost for the PromethION only $3/Gb. (RX3698 (Amadeus Capital).)

603.3 ONT states that its PromethION can achieve best in field yield per flow cell of 254 Gb at $625 flow cell, making best per Gb cost for the PromethION only $2.55. (RX3543 (ONT) (showing $625 per flow cell at 245 Gb).)

604. With regard to accuracy, ONT has announced that its single-molecule modal accuracy is now >99.3% (Q20) using its "Q20+" chemistry, and also developed a new approach termed "Duplex" sequencing, which enables the sequencing of both template and complementary strands and accuracy "trending towards 99.9% (Q30)". (RX3541 (ONT) at 1; RX3535 (ONT) at 1.)

604.1 In addition, methods have been developed to obtain consensus sequences from homogenous DNA samples by genome assembly, resulting in accuracies of more than 99.999% (Q50). (RX3541 (ONT) at 1; RX3535 (ONT); RX3536 (ONT).)

B. New and Future Entrants

1. Singular Genomics

605. Singular Genomics was founded in 2016 and is headquartered in La Jolla, California. (PX8561 (Singular) at 15.) Singular has developed a sequencing-by-synthesis NGS platform comprising their NGS instrument, called the G4 Instrument, and associated consumable kits, which they refer to collectively as the G4 Integrated Solution or the G4 System. (PX8561 (Singular) at 1–2.)

606. Singular has also developed multiomics platform that incorporates NGS called the PX System. (PX8561 (Singular) at 1–2; PX7117 (Velarde (Singular) Dep. at 17).) Singular has completed pilot testing of its G4 System, involving their first external third-party evaluation, and is about to launch its early-access program. (PX7117 (Velarde (Singular) Dep. at 22–23).)

607. Singular commercially launched the G4 NGS sequencer at the end of 2021 and will begin shipping the G4 NGS systems in the first half of 2022. (Velarde (Singular) Tr. 4515–16, 4522; *see also* PX8561 (Singular) at 1–2; PX7117 (Velarde (Singular) Dep. at 30–31).)

608. Singular's mission is to develop fast, powerful, efficient, flexible sequencing platforms to solve challenges, such as long analysis times, labor intensive protocols, sample batching requirements and high cost, that sequencing technologies face in oncology, including for early cancer detection. (PX8561 (Singular) at 92.)

609. The G4 System's performance characteristics claim to be comparable or better to Illumina's NextSeq and NovaSeq systems:

609.1 Throughput of greater than 100 million paired-end reads per flow cell for four flow cells; targeted 330 million reads per flow cell at commercial launch for a total of 1,320 million reads. (Velarde (Singular) Tr. 4528–30; PX8561 (Singular) at 4–5; [redacted]

609.2 Read lengths of 50 bases to 150 bases. (PX8561 (Singular) at 4–5; [redacted]

609.3 Targeted 400 Gbs per sequencing run. (PX8561 (Singular) at 4–5; [redacted]

609.4 High speed sequencing at 4.0 minute cycle time, with a targeted 2.5 minute cycle time that will generate a sequencing time of approximately 16 hours to complete a 2x150 base run. (PX8561 (Singular) at 4–5; [redacted]

609.5 High accuracy of 99.7% on 150 base reads (>70% Q30 on base calls, with targeted >80% Q30 on base calls at launch); 99.99% (Q40) accuracy with the "HD-Seq" methodology. (PX8561 (Singular) at 4–5; PX7117 [redacted]

609.6 Independent, flexible throughput that uses flow cells with independent lanes, enabling libraries to be kept separate in each lane while still retaining high throughput capacity. (PX8561 (Singular) at 4–5; [redacted]

610. Singular expects that the G4 System will compete with Illumina for sales of sequencers and integrated systems to multicancer early detection test developers. [redacted] Tr. 4522, [redacted] *see also* PX8561 (Singular) at 8.)

611. Singular is targeting clinical oncology applications for the G4 system; Singular is developing HD-Seq as one of the potential applications for MCED tests; Singular believes that in addition to faster turnaround time in clinical settings, Singular's HD sequencing process also

gives it an advantage; Singular expect to compete with Illumina for sales of sequencers and consumables to MCED test developers. (Velarde (Singular) Tr. 4522, [redacted]

612. [redacted]

613. Singular does not believe that Illumina's reacquisition of GRAIL will have an effect on Singular's ability to innovate in the NGS space and Singular does not project that Illumina's reacquisition of GRAIL will slow down Singular's commercialization plans. (Velarde (Singular) Tr. 4534.)

2. **Ultima Genomics**

614. Ultima Genomics, a biotechnology company based in Newark, California, is developing a low-cost alternative sequencing-by-synthesis platform to Illumina's highest throughput instrument and flow cell (NovaSeq 6000 with S4 flow cells) aimed at high-volume users. (PX7119 (Lauer (Ultima) Dep. at 34–36, 146–48).)

615. [redacted]

616. [redacted]

617. [redacted]

617.1 [redacted]

617.2 [redacted]

618. [redacted]

619. [redacted]

620. [redacted]

621. [redacted]

622. [redacted]

622.1 [redacted]

622.2 [redacted]

623. [redacted]

3. **Roche**

624. Roche Diagnostics, parent of the company that previously brought to the market the first NGS sequencer—the 454 GS FLX Titanium sequencer—in 2005, acquired two NGS sequencer developers: Stratos Genomics that is developing a nanopore DNA sequencing technology utilizing Sequencing by Expansion (SBX), and Genia Technologies that is

developing a single-molecule, nanopore technology. (RX3407 (Kircher et al., 2010); RX3615 (Roche); RX3614 (Roche).)

625. Roche expects to bring to market an NGS nanopore sequencer by the 2024 time frame. (RX3614 (Roche).)

626. [redacted]

627. [redacted]

628. [redacted]

628.1 [redacted]

629. [redacted]

630. [redacted]

631. [redacted]

4. **Element**

632. Element Biosciences is a biotechnology company headquartered in San Diego, California that was founded in 2017. [redacted] Element is developing a currently unnamed NGS platform through its sequencing-by-trapping technology. (RX3186 (Element Biosciences, International Patent Application No. WO2020242901).) [redacted]

633. Element's focus for its platform is to provide high-quality, low cost, easy-to-use DNA sequencing tools in order to increase accessibility of sequencing to individual labs. [redacted]

634. [redacted]

635. [redacted]

636. [redacted]

637. [redacted]

638. [redacted]

5. **Omniome**

639. Omniome is a biotechnology company headquartered in San Diego, California that was founded in 2013. (PX7071 (Song, IHT at 13).) In July 2021, Pacific Biosciences of California ("PacBio") announced it had acquired Omniome for $800M. (RX3947 (Clinical OMICs).)

639.1 Many of PacBio/Omniome's senior executives came from Illumina: PacBio CEO Christian Henry held several positions at Illumina, including former Chief Commercial Officer; Omniome President Richard Shen is a former Illumina Vice President of Oncology R&D. (RX3947 (Clinical OMICs) at 2.)

640. The combined PacBio and Omniome have said they would specifically target the cancer screening market, as well as other oncology applications. (RX3947 (Clinical OMICs) at 3.)

640.1 PacBio stated that it believes Omniome's data accuracy should help the combined company target oncology applications like cancer screening. RX3947 (Clinical OMICs) at 3.)

641. Omniome is developing an NGS sequencer using its sequencing-by-binding technology. (RX3533 (Omniome).) [redacted]

642. Omniome's sequencer will reportedly have comparable throughput and run times to Illumina's NexSeq sequencers, but with better accuracy—98%> Q50 to 99% Q70—10 to 100x better than the accuracy of Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 82, 100–01); [redacted]

642.1 Omniome expects that, at l[redacted] its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 43, 58, 68–72)**;** [redacted]

642.2 In a recent earnings call, PacBio CEO Christian Henry claimed that PacBio/Omniome's "error rates are so low, we're more than 15-fold better than what other SBS players can do today". (RX4050 (PacBio) at 7.)

643. [redacted] RX3189 (Encodia).) Omniome currently plans to launch its sequencer in early 2023. (PX7096 (Song (Omniome) Dep. at 28–29, 56).)

644. Omniome expects its NGS platform will be used for "applications like cancer," and has general interest in oncology, including companies that are developing blood-based early cancer screening tests. (PX7096 (Song (Omniome) Dep. at 59–63, 66); [redacted]

C. Switching Platforms

645. Switching between Illumina's platform and alternative platforms is feasible. (RX3869 (Cote Expert Report) ¶ 336.) To the extent a test developer believes this sort of switching is costly, there are alternative methods of switching between platforms, including concurrent development on multiple platforms. (RX3869 (Cote Expert Report) ¶ 336.)

646. In fact, cancer screening developers will inevitably need to switch between different Illumina instruments in the course of developing their respective screening tests. (RX3869 (Cote Expert Report) ¶ 336.)

646.1 Illumina's own model contemplates that a portion of test developers will switch to an alternative sequencing platform developer in the process of upgrading Illumina instruments. (PX7087 (Goswami (Illumina) Dep. at 16).)

1. Feasibility

647. Test developers routinely re-validate their tests to account for new developments in their tests, new and improved technology relating to consumables or sequencers, or for any number of other reasons. (RX3869 (Cote Expert Report) ¶ 338.) These revalidations are part of a good test developer's business plan. (RX3869 (Cote Expert Report) ¶ 338.) It is routine to switch or to upgrade platforms (which from a re-validation point of view is equivalent). (Cote Tr. 3739; Aravanis (Illumina) Tr. 1865; (RX3869 (Cote Expert Report) ¶ 338.) This is built into all clinical labs' workflow and plan for long-term functioning for the lab. (Cote Tr. 3771.)

648. Given that test developers will need to undergo such redevelopment simply to maintain their use of Illumina's instruments, there are multiple opportunities for test developers to switch to alternative sequencing platforms, or validate an alternative sequencing platforms for the purposes of managing their supply chain. (RX3869 (Cote Expert Report) ¶ 338.)

649. For companies developing early cancer screening tests, these requirements for such switching to a different NGS platform or another cancer screening modality are no different from the requirements to modify their tests to use different biomarkers, different reagents, or different testing equipment, for versioning, costs, or whatever the reason, either during or after the initial development of the tests, which happens rather frequently. (RX3869 (Cote Expert Report) ¶ 339; Cote Tr. 3786–87.)

650. [redacted] RX3419 (Lennon et al., 2020) at 18; RX3772 (Cohen 2018 Supplementary Material) at 2–3.) [redacted]

650.1 [redacted]

[redacted]

651. Similarly, FMI is using Illumina's HiSeq 2500 and 4000 as its NGS platforms for the FoundationOne CDx test for tissue biopsy sample based therapy selection, but switched to Illumina's NovaSeq 6000 for its FoundationOne® Liquid CDx test for liquid biopsy sample based therapy selection. (RX3231 (FMI) at 4; RX3234 (FMI) at 7.) There is no indication that switching from HiSeq to NovaSeq meaningfully delayed FMI's development of the FoundationOne® Liquid CDx test, or its FDA approval, and neither Roche nor FMI have stated publicly that FMI faced delays from such switching. (RX3869 (Cote Expert Report) ¶ 341.)

652. Natera and BGI Genomics formed a partnership to commercialize Natera's Signatera NGS-based cancer monitoring test on BGI's DNBSEQ platform in China, and has now launched a version of the Signatera test in China "that incorporates MGI sequencing platforms." (PX7111 (Fesko (Natera) Dep. at 251–52); RX3062 (BGI) at 1.) Natera's Signatera test was initially validated on Illumina's HiSeq 2500 NGS platform. (RX3499 (Natera) at 6.)

653. Ariosa (at the time part of Roche) switched its Harmony non-invasive prenatal test from an NGS-based approach to a microarray-based approach, and claimed to have achieved lower cost and decreased turnaround time for the test. (PX7096 (Song (Omniome) Dep. at 124–28); RX3400 (Juneau et al., 2014).) Ariosa completed this platform switching without interrupting the commercial availability of the Harmony test. (PX7096 (Song (Omniome) Dep. at 125–26).)

654. [redacted]

654.1 [redacted]

654.2 [redacted]

655. In addition, a test developer may develop its test on one platform, but choose to commercialize on another. (RX3869 (Cote Expert Report) ¶ 345.) [redacted]

656. Even if switching requires a more substantial change, for example in capture technology or a different/unfamiliar sequencing chemistry, in light of the long way multi-cancer screening tests have to go before commercialization, the time to switch is unlikely to meaningfully affect the test developer's timeline. (Cote Tr. 3776.)

656.1 For example, it took approximately nine months for Dr. Cote's lab to revalidate the AML clinical trial exome assay to use a different library prep and exome capture reagent, while transitioning from HiSeq to NovaSeq, with substantially different sequencing chemistry. (RX3869 (Cote Expert Report) ¶ 346; Cote Tr. 3774–75.)

2. **Expectations**

657. Although it cannot be estimated precisely how long it would take for a multi-cancer screening test to switch between an Illumina platform and a third party sequencing platform, for example, the length of time required would likely depend on a number of factors including whether clinical trials are required, the laboratory process, and access to validation scientists and clinical samples. (RX3869 (Cote Expert Report) ¶ 347.)

658. Assuming no clinical trials are required, a test developer may need to conduct a revalidation study (which is estimated to take 6–12 months) potentially followed by a bridging or comparison study (which can take up to one month). (Aravanis (Illumina) Tr. 1865.) In the re-validation stage, a test developer needs to repeat the analytical studies on a new NGS platform. (RX3869 (Cote Expert Report) ¶ 348.)

659. Dr. Cote estimates that re-validating a test on a new NGS platform, if successful, would take approximately 6–12 months. (Cote Tr. 3774–75.) For a test developer to re-validate its test on a new NGS instrument, it would need to show that the performance of the test on the new machine was appropriate and similar to the performance using Illumina's machine. (RX3869 (Cote Expert Report) ¶ 348; Cote Tr. 3773.)

660. For an LDT test not approved by the FDA, switching NGS platforms or technical modalities is fairly straightforward. (RX3869 (Cote Expert Report) ¶ 349.) The test developer merely needs to complete the technical development, and then conduct a validational, case-control study using previously collected samples or freshly collected sample. (RX3869 (Cote Expert Report) ¶ 349.)

661. Dr. Cote expects that most test developers who are already working on or have validated a test will have access to banks of clinical samples (used for that validation), which can be revalidated retrospectively for these purposes in relatively short order. (RX3869 (Cote Expert Report) ¶ 349.)

662. For an IVD test approved by the FDA, if the clinical testing portion of the IVD test has changed since the clinical trial demonstrating its efficacy, the FDA requires the IVD

sponsor to provide data from a bridging or comparison study to demonstrate that the new clinical test using the third party NGS platform "has performance characteristics that are very similar to those of the test that was used in the trial," *i.e*, using the Illumina platform. (Cote Tr. 3776; RX3218 (FDA) at 30).)

663. The performance similarity is often demonstrated in a bridging or comparison study by performing the new test using original clinical trial samples and a pre-specified statistical analysis plan, thereby showing both concordance and discordance between the two tests using the same specimens. (RX3218 (FDA) at 30.)

663.1 Such a requirement also means that a costly new clinical trial need not be conducted: the IVD sponsor just need to run the new test on the already collected sample to show consistent results. (RX3869 (Cote Expert Report) ¶ 350.) If the results of the bridging or comparison study demonstrate that the two platforms lead to equivalent performance, no additional clinical trials may be required. (RX3869 (Cote Expert Report) ¶ 350.)

664. Dr. Cote estimates that conducting the bridging or comparison study—including a repeatability study—would take approximately one month to complete. (Cote Tr. 3773.) It would cost approximately $1 million to $2 million if samples need to be purchased. (Cote Tr. 3775.) [redacted] The time and cost of these bridging or comparison studies are both relatively low compared to overall development time and cost for clinical tests. (PX7065 (Aravanis (Illumina) IHT at 164–66); [redacted]

665. If the results generated by the two systems were not substantially equivalent, the clinical studies might have to be repeated on the alternative platform. (RX3869 (Cote Expert Report) at 174.) If new clinical trials are required, or if the bridging or comparison study does not show that the Illumina platform and the third-party platform are equivalent, new large-scale clinical trials may be required, which would require a lengthier process and would be in addition to the revalidation process discussed in above. (RX3869 (Cote Expert Report) ¶ 352.)

665.1 The chance for a bridging or comparison study failing to show the Illumina platform and the third-party platform to be equivalent is very low, because given the comparable accuracy of the third-party platforms, they should be able to accurately reproduce the sequence obtained using the Illumina platform. (Cote Tr. 3775–76; RX3869 (Cote Expert Report) ¶ 352.)

666. Another factor which will likely determine the length of time a company would need to adapt its test to a new supplier is the way the test was developed. (RX3869 (Cote Expert Report) ¶ 353.) Tests may be developed based on more than one platform. (RX3869 (Cote Expert Report) ¶ 353.)

667. Singlera has publicly stated that its test is compatible with both Illumina and Thermo Fisher NGS systems. RX3637 (Singlera) at 6.)

668. Singlera notes that its PanSeer assay is "compatible with the two leading next-generation sequencing platforms on the market (systems from Illumina such as the MiSeq or NextSeq as well as from Thermo Fisher Scientific including the Ion Torrent S5) any laboratory familiar with NGS library construction can quickly implement this method". (RX3637 (Singlera) at 6.) Therefore, switching between these two NGS suppliers would not be likely to require any significant time to adapt the technology for that developer. (RX3869 (Cote Expert Report) ¶ 353.)

669. Natera and BGI Genomics formed a partnership and has now launched the Signatera in China "that incorporates MGI sequencing platforms." (RX3062 (BGI) at 1.) Neither Natera nor BGI has complained about any difficulty switching from Illumina's HiSeq to BGI's NGS platform. (RX3499 (Natera) at 6); (RX3869 (Cote Expert Report) ¶ 354.)

670. Ariosa switched its Harmony NIPT test from an NGS-based approach to a microarray-based approach, and claimed to have achieved lower cost and decreased turnaround time for the test. (PX7096 (Song (Omniome) Dep. at 124–28); RX3400 (Juneau et al., 2014).) Switching for the Harmony test, which is an LDT, required only a bridging study; no additional clinical trials were needed. (RX3869 (Cote Expert Report) ¶ 355.)

670.1 For the bridging study, Ariosa conducted a case-control study with 878 maternal venous blood samples, 486 samples had been originally tested using Harmony, and 392 samples were freshly collected for the study. (RX3400 (Juneau et al., 2014) at 2.) [redacted]

671. Companies routinely conduct bridging or comparison studies for modifications of their clinical oncology tests. (RX3869 (Cote Expert Report) ¶ 356.) [redacted]

672. When Roche initiated its EURTAC study for the correlation between EGFR activating mutations and Non–Small-Cell Lung Cancer (NSCLC), the test utilized Sanger sequencing, then confirmed by fragment length analysis and Taqman assay for two mutations. (RX3057 (Benlloch et al., 2014) at 3.)

672.1 Roche developed a multiplex PCR-based cobas® EGFR Mutation Test of 41 *EGFR* mutations after patients had been screened and enrolled in EURTAC study using the previous LDT. (RX3221 (FDA) at 28.)

672.2 A retrospective bridging study was conducted to test tissue specimens already collected from the EURTAC study patients using the cobas® EGFR Mutation Test, and the EURTAC study results with the previous LDT data using Sanger sequencing and the bridging study results showing the concordance of the multiplex PCR-based cobas® EGFR Mutation Test results with the LDT supported the FDA approval of the cobas® EGFR Mutation Test. (RX3221 (FDA) at 28.)

672.3 The bridging study concluded that the "PCR test showed superior sensitivity and specificity compared with conventional Sanger sequencing." (RX3057 (Benlloch et al., 2014) at 2.)

673. When Guardant expanded its Guardant360® CDx cancer therapy selection assay to also include testing of *EGFR* exon 19 deletions and two specific mutations, *EGFR* L858R, *EGFR* T790M for treatment of NSCLC using Tagrisso® (osimertinib), it conducted two bridging studies – one for adding the test for *EGFR* exon 19 deletions and the *EGFR* L858R mutation, and one for adding the test for the *EGFR* T790M mutation – using existing samples from the original clinical trials. (RX3223 (FDA) at 49.)

674. FMI conducted a similar bridging study when it added testing of *NTRK* gene fusions for treatment of cancer patients with Vitrakvi® (larotrectinib) to its FoundationOne® CDx cancer therapy selection assay. (RX3240 (Roche/FMI) at 1–2.)

D. Distributable IVDs

675. Several features of sequencing instruments and pipeline multi-cancer screening tests suggest that distributable IVDs would not be an appropriate option for MCED tests. (RX3869 (Cote Expert Report) ¶ 359.)

676. [redacted] PX0064 (Illumina) at 7.)

677. [redacted]

677.1 For customers who are performing cancer screening using a centralized model (as is the case with an LDT or a single-site PMA), the evidence suggests that customers will be likely to be able to achieve full capacity. (Goswami (Illumina) Tr. 3194–95.)

677.2 In a distributed model, a small hospital or laboratory—precisely the types of customers who purportedly benefit from distributed kitted tests—are unlikely to be able to achieve the throughput necessary to make a NovaSeq Dx platform cost-effective. (Goswami (Illumina) Tr. 3194–95.) [redacted]

678. In addition, with respect to distributable IVD test kits, there are several reasons why Illumina's position as a platform provider is relatively weaker with respect to distributable IVDs than in other areas. (RX3869 (Cote Expert Report) ¶ 361.)

678.1 Illumina has not yet received clearance for NovaSeq Dx system. (Goswami (Illumina) Tr. 3194.) Illumina currently has regulatory clearance in the United States for the NextSeq Dx and MiSeq Dx systems. (Goswami (Illumina) Tr. 3191–92.) [redacted] Nolan (Freenome) Tr. 2715; PX7112 (Bailey (PGDx) Dep. at 107).)

678.2 If such developers were to pursue a distributable IVD kitted test for cancer screening, their test would need to be adapted to match the parameters of the NextSeq 550Dx, a system with different specifications from the RUO NovaSeq system. (RX3869 (Cote Expert Report) at 178.) [redacted]

678.3 Because the evidence suggests that many sequencing platforms suitable for multi-cancer screening will become available in the next 1–2 years, test developers could validate their tests on an alternative NGS platform with regulatory clearance on a similar timeframe as validation on the (future) NovaSeq Dx platform. (RX3869 (Cote Expert Report) at 178.)

678.4 [redacted] The NovaSeq instrument is a substantial investment. (Goswami (Illumina) Tr. 3189–91.)

678.5 Most hospitals and independent laboratories would continue using the NextSeq Dx and may elect not to invest in a NovaSeq Dx for around $1 million, especially given the issues in meeting the requisite throughput by pooling samples. (Goswami (Illumina) Tr. 3194–95.) As of 2021, there are nearly 30,000 diagnostic and medical laboratory businesses in the U.S. (RX3174 (IBISWorld).) [redacted]

V. COMPLAINT COUNSEL FAILED TO PROVE THE REQUISITE ANTITRUST MARKETS

A. The Alleged Relevant Market

1. Speculative and Simultaneously Over- and Under-Inclusive

a. The Alleged Relevant Market is Speculative

679. Complaint Counsel alleges an MCED market consisting of the Galleri test and any other test in development, so long as its developers contend that it will detect more than one cancer type and use NGS, no matter its anticipated features, functions, or launch timeline. (*See* FTC Pretrial Br. at 43–44; Compl. ¶ 3; PX6090 (Scott Morton Expert Report) ¶¶ 141–46.)

680. This definition is impermissibly speculative. (PFF ¶¶ 680.1–680.5.)

680.1 [redacted] Gao (Singlera) Tr. 2925–26.)

680.2 [redacted] Gao (Singlera) Tr. 2925–26.)

680.3 [redacted]

680.4 [redacted]

680.5 These "products" cannot be considered substitutes for Galleri. ([redacted] 3727, 3777, 3782–83, 3814–15, [redacted]

681. Numerous fact witnesses testified that the future contours of the MCED field were largely speculative or unknown:

681.1 [redacted]

681.2 [redacted]

681.3 Dr. William Cance, Chief Medical Officer of the American Cancer Society, said it "would be very hard to even speculate" on how long it will be before there is a blood-based test that's sensitive and specific enough to replace the standard of care cancer screens available today. (PX7086 (Cance (ACS) Dep. at 51).)

681.4 Quest's Kristie Dolan testified that "the field is too nascent to say with any level of specificity" whether MCED tests would compete with each other in the absence of identical capabilities. (PX7116 (Dolan (Quest) Dep. at 106).)

682. Because the proposed market does not exist, Complaint Counsel's economic expert admitted that she did not and could not consider any real world evidence regarding the pricing of MCED tests:

682.1 [redacted]

682.2 [redacted]

682.3 [redacted]

682.4 [redacted]

682.5 "Q. In forming your opinions, is it accurate to say that you did not consider data describing the past purchase patterns of consumers in their responses to price changes for MCED tests? A. As I have said, the MCED test was only launched a couple of months ago. We don't really have a setting in which consumers can do anything except [buy] Galleri in an uninsured fashion." (RX3852 (Scott Morton Dep. at 19).)

683. [redacted]

683.1 She also did not attempt to fill the information gaps using surveys or other means, including information about the likely preferences and potential switching behavior of clinicians, patients, and payors related to the products she includes and excludes from her proposed MCED market. (RX6004 (Katz Trial Dep. at 17–22).)

683.2 Nor did she attempt to analyze likely substitution from the perspective of payors, despite acknowledging that payor choices will drive adoption of different screening tests. (RX6004 (Katz Trial Dep. at 17–22).)

684. The evidence in the record demonstrates is that it is unlikely customers (*i.e.*, patients, doctors and payors) will view the products in development as substitutes with Galleri. (PFF ¶¶ 684.1–684.3.)

684.1 None of the tests in development has demonstrated the capability to detect 50 cancers. (*See* Lengauer (Exact/Thrive) Tr. 243, 260–61; [redacted] Gao (Singlera) Tr. 2874–75.)

684.2 Nor has any test in development demonstrated the ability to identify cancer signal of origin without the aid of a PET-CT scan. (Lengauer (Exact/Thrive) Tr. 246–48; [redacted]); RX3115 (Chen et al 2020) at 6.)

684.3 Determining the boundaries of Complaint Counsel's alleged market depends on a comparison to, or of, one or more non-existent tests. [redacted] Gao (Singlera) Tr. 2925–26.)

685. As Dr. Katz testified, "[t]he timing of when [putative MCED developers are] going to actually have commercial products and when they're going to launch them and ultimately when [they are] going to get insurance coverage so that they have a chance of significant competitive success, . . . is highly uncertain and it's in the future." (RX6004 (Katz Trial Dep. at 34–35).)

b. Simultaneously Over- and Under-Inclusive

686. [redacted]

[redacted] (Bishop (GRAIL) Tr. 1373–74; RX0744 (GRAIL) slide 22, 100.)

687. [redacted] RX6004 (Katz, Trial Dep. at 30 ("[I] t's counterintuitive that a test, say, for testicular cancer should be out of the market because it's not a close enough substitute to a test that [detects] testicular cancer *and* prostate cancer" but that two hypothetical tests that detect "two completely nonoverlapping" cancer types are included "because they each do two").)

688. In addition to clearly not being substitutes for *Galleri*, many of the tests in Complaint Counsel's proposed market are also not even substitutes with *each other*. (*See* RX6004 (Katz Trial Dep. at 29).)

689. Complaint Counsel's proposed market would include any test that screens for two or more cancer types, even though that would necessarily group together screening tests that detect distinct cancer types in different populations. (*E.g.*, PX6090 (Scott Morton Expert Report) ¶¶ 141–42.)

690. As Dr. Katz testified: "suppose we have two tests, one of which covers testicular cancer and prostate cancer . . . and then we have another one that does uterine cancer and ovarian cancer. It's really difficult for me to see how those could be substitutes for one another. I believe they're not. And I think that shows a fundamental defect in [Complaint Counsel's proposed] market." (RX6004 (Katz Trial Dep. at 29).)

690.1 Dr. Katz also testified that by defining the market to include tests that cannot be shown to be substitutes for Galleri or each other, Complaint Counsel's proposed market violates the narrowest market rule: "[Dr. Scott Morton] did not attempt to define the narrowest relevant market . . . that would pass the hypothetical [monopolist] test, and I believe this is a fact, that she did not explain or offer a justification for why that would be appropriate. And that's not something that's relying on testimony by other people. It's a failure of the logic and the form of analysis that she's applied." (RX6004 (Katz Trial Dep at 165–66).)

691. At the same time, Complaint Counsel's proposed market is also under-inclusive, because it excludes MCED tests that are not based on NGS technology.

692. It is undisputed that there are at least two MCED tests on the market that are not based on NGS technology. (PFF ¶¶ 692.1–692.2.)

692.1 StageZero's Aristotle test is a microarray-based liquid biopsy test that interrogates mRNA to detect 10 cancers. (Cote Tr. 3875–76; RX3171 (Dempsey et al., 2020); RX3869 (Cote Expert Report) ¶ 248.)

692.2 Genesys Biolabs' OneTest is a proteomics-based test that measures seven cancer protein biomarkers to screen for lung, liver, pancreatic, ovarian, prostate and colon cancers. (RX3259 (Genesys Biolabs); RX3869 (Cote Expert Report) ¶ 253.)

693. Moreover, a number of companies are developing cancer screening tests that are not based on NGS technology, including tests in development from InterVenn Biosciences, PrognomiQ and Somalogic. (Leite (Illumina/InterVenn) Tr. 2171–74; RX3587 (PrognomiQ) at 2; RX3651 (Somalogic) at 1–7; RX3869 (Cote Expert Report) ¶¶ 247–67.)

693.1 These tests are too undeveloped to be included in a relevant market with Galleri. (Leite (Illumina/InterVenn) Tr. 2171–74; RX3587 (PrognomiQ) at 2; RX3651 (Somalogic) at 1–7.)

694. There is no evidence, or reason to believe, that an MCED test must use NGS technology to compete with GRAIL. (*See* Cance (ACS) Tr. 606; Cote Tr. 3729–30, 3736–37, 3872; RX3869 (Cote Expert Report) ¶ 75.)

695. Nor is there any evidence, or reason to believe, that patients or doctors have any preference for an MCED test based on the platform used to run it. (*See, e.g.*, RX3852 (Scott Morton Dep. at 51).)

696. What patients and doctors care about is whether a test works and for which indications, not how exactly it works. (*See, e.g.*, RX3852 (Scott Morton Dep. at 51) ("[U]ltimately the patient and the doctor are going to care about the ability of the test to prevent the disease and save lives.").)

2. **No Reasonable Interchangeability**

697. Not on the Market. At present, there is no product in existence that is reasonably interchangeable with GRAIL's Galleri test. (Bishop (GRAIL) Tr. 1401.)

698. Galleri is the only multi-cancer early detection test testing for anywhere near 50 cancer types on the market. (Bishop (GRAIL) Tr. 1401, **{1459}**); Ofman (GRAIL) Tr. 3308; RX3852 (Scott Morton Dep. at 53); (Cance (ACS) Tr. 632–33).)

699. Indeed, the prices and qualities of these yet-to-exist products are not even specified. (*See* PFF ¶¶ 750.1–750.4.)

700. Years Away. Most of the putative MCED developers identified by Complaint Counsel do not expect (and none can reasonably be expected) to launch a screening test for more than one cancer for many years. (PFF ¶¶ 701–706.)

701. Guardant. Guardant's LUNAR-2 product is being developed initially with an indication only for colorectal cancer. (Chudova (Guardant) Tr. 1154, 1179; [redacted] Thereafter, Guardant is prioritizing adding cancers with existing screening guidelines such as lung and breast cancer. (Chudova (Guardant) Tr. 1154.)

701.1 [redacted] Chudova (Guardant) Tr. 1154, [redacted].)

701.2 [redacted]

701.3 [redacted]

701.4 [redacted]

[redacted]

701.5 [redacted]

701.6 [redacted]

701.7 [redacted]

702. [redacted]

702.1 [redacted]

702.2 [redacted]

702.3 [redacted]

702.4 [redacted]

702.5 [redacted]

702.6 [redacted]

702.7 [redacted]

702.8 [redacted]

702.9 [redacted]

702.10 [redacted]

[redacted]

703. [redacted]

703.1 [redacted]

703.2 [redacted]

703.3 [redacted]

703.4 [redacted]

703.5 [redacted]

703.6 [redacted]

703.7 [redacted]

703.8 [redacted]

[redacted]

703.9 [redacted]

[redacted]

703.10 [redacted]

703.11 [redacted]

703.12 [redacted]

703.13 [redacted]

[redacted]

704. [redacted]

704.1 [redacted]

704.2 [redacted]

705. [redacted]

705.1 [redacted]

705.2 [redacted]

706. Singlera. Singlera is "far, far away" from launching its PanSeer test. (PX7102 (Gao (Singlera) Dep. at 118–19).)

706.1 Singlera does not plan on marketing its PanSeer test in the US until it has received FDA approval. (Gao (Singlera) Tr. 2873.)

706.2 Singlera is not currently in talks with the FDA. (Gao (Singlera) Tr. 2926–27).

706.3 It will "take at least seven to ten years of time for [the current PanSeer] test to be able to go to FDA". (Gao (Singlera) Tr. 2891).

707. These far-off projections are consistent with other record evidence regarding the product development timeline to launch an MCED test, and show that many years of development are required before launching an MCED test like Galleri. (PFF ¶¶ 707.1–707.3.)

707.1 For each cancer included in an MCED test, you "have to go through a somewhat similar process to what GRAIL did", meaning '"a research phase", '"a test development phase", and '"a clinical phase", and that must be done "for each cancer", which, if done "serially" would take a "very long time" and is "not practical". (Aravanis (Illumina) Tr. 1895–96.)

707.2 As Dr. Chahine of Helio Health confirmed, compared to the R&D process for a single-cancer screening test, "[i]t probably gets exponentially harder if you're adding . . . five and ten cancers, and so just from a practical standpoint, a small company trying to go after multiple cancers at the same time I think is just really just not feasible." (Chahine (Helio) Tr. 1032.)

707.3 Accounting for all of these steps in the development process, Dr. Cote opined that most of the putative MCED developers identified by Complaint Counsel were at least five to seven years away from launching any kind of MCED test. ([redacted] 3727, [redacted]

708. No proof of interchangeability. Even if the tests in development were on the market, or could be expected to launch in the near term, Complaint Counsel failed to prove that any of these tests will be reasonably interchangeable with Galleri if and when they are launched. (PFF ¶¶ 708.1–708.3.)

708.1 The purchasers of any MCED test will be patients, health care providers and/or insurers. (*See* RX3871 (Willig Expert Report) ¶ 12.)

708.2 Complaint Counsel did not call any medical expert, nor a single patient, health care provider or insurer to testify that he/she would substitute one of the tests in development (were it ever to be sold) for Galleri. (RX6004 (Katz Trial Dep. at 18.)

708.3 Nor did Complaint Counsel conduct any surveys of such groups. (RX6004 (Katz Dep. at 19–20) (Complaint Counsel's expert "didn't attempt to fill those information gaps in by, say, doing some sort of survey of, you know, clinicians or payers to understand what they would think about, you know, various alternatives and how close they would view those to be substitutes and then try to infer from that what that would mean for their switching behavior.").)

709. Ample proof of no interchangeability. Numerous witnesses testified that Galleri is not reasonably interchangeable with the MCED tests in development. (PFF ¶¶ 709.1–709.6.)

709.1 Francis deSouza, Illumina's CEO, testified, based on his conversations with doctors during due diligence for the Transaction, that Galleri would not compete

with tests that screen for fewer than ten cancers or with tests that do not identify cancer signal of origin. (deSouza (Illumina) Tr. 2336–37 ("[D]octors who are looking for 50 cancers and doing a screen would not want a test that did not tell the patient where that cancer was. They felt that that [it] would [not work] to raise so much anxiety in a person without telling them what they actually have. And so for that use case, for doing screening of a healthy person to identify if they have 50 cancers, they felt it was essential that as part of the conversation with the patient you're immediately able to say what to do next, you know, look at this organ, image your pancreas or something . . . and so they would not substitute Galleri with another test that identified 50 cancers but didn't tell you what cancer it was and where it was, and so they are not substitutes."))

709.2 Illumina's Chief Technology Officer (and GRAIL's former Chief Science Officer and Head of R&D), Dr. Alex Aravanis, testified 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.)

709.3 GRAIL's then-CEO, Hans Bishop, testified that he did not foresee Galleri competing with other MCED developers, such as Guardant, Freenome, Exact/Thrive and Singlera, given the substantial differences between the tests those companies may be developing and Galleri. (Bishop (GRAIL) Tr. 1390–91; 1393–94 (Freenome); 1397 (Exact/Thrive); 1399 (Singlera).)

709.4 Dr. Josh Ofman, GRAIL's Chief Medical Officer, testified that Galleri will not compete with MCED tests that are first pursuing colon cancer tests: "[w]e 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.) Dr. Ofman also testified that Galleri would not compete with a test that detected 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.)

709.5 Dr. Cote testified that [redacted]

709.6 [redacted]

710. The intuition as to complementarity between a 50 cancer test and a test that screens for fewer cancers was also supported by some of Complaint Counsel's third party witnesses. (PFF ¶¶ 710.1–710.3.)

710.1 [redacted]

710.2 [redacted]

710.3 In response to questioning about what customers will view PanSeer and Galleri as substitutable options, Singlera's Chairman Gary Gao testified that "I don't think there is a product yet. And I could not say how we are interchangeable right now . . .." (PX7042 (Gao (Singlera) IHT at 101).)

711. Complaint Counsel has no testimony from potential consumers of MCED tests. (*See* RX6004 (Katz Trial Dep. at 18.)

712. The only testimony that Complaint Counsel elicited regarding this point is self-serving testimony from certain MCED test developers that they view GRAIL as a rival and expect the tests they are working on to compete with Galleri (if ever they were launched). (*E.g.*, [redacted]; PX7100 (Chudova (Guardant) Dep. at 22–23); PX7042 (Gao (Singlera) IHT at 96, 98–100); [redacted] PX7068 (Perettie, IHT at 76).)

3. ***Brown Shoe*** **Factors**

a. No industry or public recognition of the alleged market as a separate economic entity

713. Neither the industry nor the public recognizes an MCED market as defined by Complaint Counsel. (PFF ¶¶ 717–721.)

714. There is an NGS-based multi-cancer early detection test available for sale in the U.S. (Galleri) and a number of companies are working to develop cancer screening tests, some of which have been loosely described as MCED tests. (PFF ¶¶ 698, 701–706.)

715. But there is no industry or public recognition of a separate "economic entity" comprised of any NGS-based screening test that detects more than one cancer type. (PFF ¶¶ 717–721.)

715.1 Galleri is the only test on the market, and it has been shown (with published data) to detect more than 50 cancers and tissue of origin. (Bishop (GRAIL) Tr. 1373–74; RX0744 (GRAIL) slide 22, 100.)

715.2 None of the MCED tests in development has had a single sale. (*See* Bishop (GRAIL) Tr. 1401.)

715.3 None has been shown to detect more than 10 cancers (and most far fewer) and none has the ability to detect cancer signal of origin. (PFF ¶¶ 684.1–684.2.)

715.4 Indeed, most of the in-development tests are focused at present solely on detecting a single cancer with the aspiration of one day detecting more cancers by adding additional bio markers and conducting additional clinical trials. (*See* Chudova (Guardant) Tr. 1154, 1179; [redacted] (Helio) Tr. 1082.)

716. The available industry or public information about the putative MCED tests in development does not suggest that these tests belong in the same product market as Galleri. Instead, they make clear that they are all very different from Galleri. (PFF ¶¶ 717–721.)

717. Analyst reports from investment banks that cover the broader biotechnology space recognize that Galleri is very different. (PFF ¶¶ 717.1–717.2.)

717.1 For instance, a report on the liquid biopsy market from Cowen notes that GRAIL has "conducted systematic clinical studies" and that Galleri "has been shown to be capable of identifying >50 types of cancers by scanning methylation patterns". (PX2022 (Cowen) at 27).)

717.1.1 The only other entity it recognizes as pursuing a multicancer screening test is Thrive, but notes that it had only been shown to detect 10 cancers and required the use of a confirmatory PET-CT scan. (PX2022 (Cowen) at 27, 29.)

717.1.2 The report notes that Freenome and Guardant are among the companies in a separate market segment pursuing single-cancer screening tests to detect colorectal cancer (PX2022 (Cowen) at 30–31), lists Singlera in passing under the heading "[s]ome [o]thers" following its summary of the colorectal cancer screening market (PX2022 (Cowen) at 33), and considers Helio in a separate segment for "High Risk Cancer Detection" for its liver cancer screening test. (PX2022 (Cowen) at 29, 35, 37, 38.)

717.1.3 Cowen does not recognize [redacted] as pursuing early cancer detection at all: it notes [redacted] as a participant in the recurrence monitoring/MRD and "liquid biopsy for biopharma" (*i.e.* companion diagnostic)

segments (PX2022 (Cowen) at 46–53), and [redacted] in the therapy selection and "liquid biopsy for biopharma" market segments (PX2022 (Cowen) at 39, 54).

717.2 An analyst note from SVBLeerink comes to a similar conclusion, only mentioning GRAIL and Thrive as pursuing "multi-cancer detection" and noting that Guardant and Freenome are among those in the colorectal cancer screening space. (PX4180 (SVBLeerink) at 32.)

717.2.1 SVBLeerink also notes a number of "must have" features for an multi-cancer screening assay, including cancer signal of origin capability (which it notes as "essential"); "99%+ specificity"; detection of "higher mortality cancers with no current screening methodologies"; "and [l]arge-scale, prospective trials that reflect prevalence of cancer in the real world". (PX4180 (SVBLeerink) at 32.) Only Galleri can claim to have these features. (PFF ¶¶ 61–62, 355, 400–01.)

718. [redacted]

718.1 [redacted]

[redacted]

719. The features and functions of Galleri are described in detail in several peer-reviewed publications, including Annals of Oncology, (RX3409 (Klein et al 2021); RX3430 (Liu

et al 2020)), and GRAIL has multiple clinical trials listed at clinicialtrials.gov. (*See* RX3133 (Clinicaltrials.gov); RX3134 (Clinicaltrials.gov); RX3135 (Clinicaltrials.gov).)

719.1 The available peer-reviewed publications show, with only two exceptions, that Complaint Counsel's so-called "MCED" developers have only published peer reviewed articles or initiated clinical trials, if any, for single-cancer screening tests. (RX3132 (Clinicaltrials.gov); RX3426 (Lin et al., 2021), RX3592 (Putcha et al., 2020); RX3740 (Westesson et al., 2020); RX3128 (Clinicaltrials.gov), RX3405 (Kim et al., 2019) (Guardant); RX3616 (Roy et al., 2019); RX3617 (Roy et al., 2019) (Helio).)

720. Some have not even published articles or initiated clinical trials relating to cancer screening at all. (RX3869 (Cote Expert Report) at 301 (FMI/Roche); RX3869 (Cote Expert Report) ¶ 228, at 303 (Natera).)

721. Other than Galleri, only Exact/Thrive and Singlera have conducted clinical trials and/or published one or more peer reviewed articles about MCED tests in development. (RX3419 (Lennon et al., 2020); RX3115 (Chen et al., 2020).) But that data shows that these tests are very different from Galleri. (PFF ¶¶ 721.1–721.4.)

721.1 The Exact/Thrive data shows only that its CancerSEEK assay can detect, at most, 10 types of cancer—with no identification of tissue of origin (a whole body PET-CT scan is required to identify the tissue of origin for every positive case). (RX3419 (Lennon et al 2020); Cote Tr. 3811–14.)

721.2 [redacted]

721.3 Similarly, the published Singlera data is from a 418–sample case control study and shows only that Singlera's PanSeer assay could detect five types of cancer. (RX3115 (Chen et al 2020) at 3.)

721.4 Moreover, the data show that PanSeer achieved only 96.1% specificity, (RX3115 (Chen et al 2020) at 1), [redacted]

b. The products' peculiar characteristics and uses

722. Unique characteristics. Galleri sequences a patient's blood sample to detect methylation and then takes the data and analyzes it using a machine learning algorithm, which will classify the methylation pattern as a cancer signal or noncancer signal. (Ofman (GRAIL) Tr. 3285–88; Aravanis (Illumina) Tr. 1886–87; RX3025 (Alexander et al 2021) at 4.)

723. If a cancer signal is detected, the sample is analyzed again using the machine learning algorithm to predict the cancer's signal of origin. (Ofman (GRAIL) Tr. 3285–88; Aravanis (Illumina) Tr. 1886–87; RX3025 (Alexander et al 2021) at 4.)

724. Galleri has been shown to detect more than 50 cancers with high specificity, and cancer signal of origin with high accuracy. (Bishop (GRAIL) Tr. 1373–74; RX0744 (GRAIL) slide 22, 100.) No other test has been shown to detect more than 10 cancers or been able to detect the cancer signal of origin. (*See* PFF ¶¶ 684.1–684.2.)

725. 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 (not MCED tests), but the three for which there are data are readily distinguishable, as illustrated in the below table:

Table 7

Test	Galleri	CancerSEEK			PanSeer
		1 Blood Test	2 Blood Tests	2 Blood + PET-CT	
Study	CCGA3	DETECT-A			Taizhou L.S.
Types of Cancer	50	10			5
Cancer Signal of Origin	Yes	No	No	Yes	No
Specificity	99.5%	95.3%	98.9%	99.6%	96.1%
Sensitivity	51.5%	30.2%	27.1%	15.6%	94.9%
PPV	44.4%	5.9%	19.4%	28.3%	

(RX3409 (Klein et al., 2021) at 5; RX3419 (Lennon et al., 2020) at 7; RX3115 (Chen et al., 2020) at 4.)

726. In addition to obvious differences in the number of cancers detected, the nature of the testing and the ability to detect cancer signal of origin, there are significant differences between the specificity and sensitivity of the tests. (PFF ¶¶ 726.1–726.8.)

726.1 For example, the specificity of Galleri is 99.5% compared to 95.3% for the single blood draw in CancerSEEK (the apples-to-apples comparison). While those numbers may seem close, the difference between them is huge in the context of a screening test. (*See* RX3869 (Cote Expert Report) ¶ 93.)

726.2 The 4.2% difference means that for every 100,000 patients screened, an additional 4,200 people using CancerSEEK will receive a false positive result that they have cancer. (*See also* Cote Tr. 3779–81.)

726.3 The specificity of CancerSEEK comes closer to Galleri only when an additional blood draw and full body PET-CT scan are added.

726.4 The sensitivity of the tests is not at all comparable (51.5% as compared to 30.2%). (*See* RX3409 (Klein 2021) at 5; RX3419 (Lennon et al., 2020) at 7.) This means that when both tests are used in a random population, CancerSEEK will miss 20% more instances of cancer in patients than Galleri would. (*See* Cote Tr. 3778-79.)

726.5 These metrics enable a calculation of positive predictive value ("PPV"): the percentage of participants with a positive test result who truly have the disease. (PX0043 (GRAIL) at 93; *see also* PX7103 (Jamshidi (GRAIL) Dep. at 136-37).)

726.6 Any analysis of CancerSEEK's characteristics is premature, as Exact is going back to the drawing board with the test and "combining the Exact Sciences and Thrive approaches in one test." (RX4007 (Exact/Thrive) at 7.)

726.7 [redacted]

726.8 [redacted]

727. Different uses. The Galleri test is recommended for use in asymptomatic adults aged 50 and older. (PX0043 (GRAIL) at 5.) It is intended to be used in addition to, and not to replace, other cancer screening tests. (Ofman (GRAIL) Tr. 3309–10.)

728. While we do not know exactly what the MCED tests in development will look like, if ever they launch, there is no question that the tests Complaint Counsel points to will be used very differently than Galleri. (PFF ¶¶ 728.1–**Error! Reference source not found.**.)

728.1 Most of the tests are single cancer tests to which the developer may use as a starting point for a test that includes an additional cancer or two in the future. (PFF ¶¶ 701–706.) [redacted]

728.2 [redacted]

729. The overwhelming evidence showed that the purported MCED tests cited by Complaint Counsel are likely to be used very differently from Galleri in the event of launch. (PFF ¶¶ 730–736.)

730. [redacted]

730.1 As Bill Getty explained, "Galleri is going after something very different, which is just a larger population, test for more things. We are saying use us for colorectal cancer screening ostensibly when we are commercialized." (PX7040 (Getty (Guardant) IHT at 155–56).)

730.2 [redacted]

730.3 [redacted]

730.4 [redacted]

730.5 [redacted]

731. [redacted]

731.1 [redacted]

731.2 [redacted]

731.3 [redacted]

732. Helio. [redacted]

732.1 Helio had previously developed a multi-cancer screening test called IvyGene but has since abandoned those efforts. (PFF ¶ 501.1.)

732.2 Helio has only ever studied five cancers: breast, colon, liver, nasopharyngeal and lung. (RX3302 (Hao et al., 2017) at 1; RX3616 (Roy et al., 2019).)

732.3 [redacted]

732.4 [redacted]

733. Natera**.** [redacted]

733.1 [redacted]

733.2 [redacted]

733.3 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 the test's sensitivity, so it can serve as a "rule-out" test that does not require follow-up to confirm a negative result. As a corollary, in such tests, a lower level of specificity (and increase in the false-positive rate) can be tolerated, especially where there is a standard of care screening available that a doctor can reflex to, such as colonoscopy. (Cote Tr. 3829; RX3869 (Cote Expert Report) ¶ 95.)

734. FMI. FMI admittedly has no test. [redacted] (PX7074 (Perettie (FMI) Dep. at 79–80).) [redacted]

[redacted]

735. Exact/Thrive. Exact/Thrive's CancerSEEK requires three separate tests to conclude a positive sample: first, a patient takes a baseline blood test, and if that returned a positive result, they then had a confirmation blood test. (Lengauer (Exact/Thrive) Tr. 246–48.) If both the baseline and the confirmatory blood tests were positive, then a patient would have to undergo a diagnostic full-body PET-CT scan to confirm the results of the blood testing and also to localize the potential cancer. (Lengauer (Exact/Thrive) Tr. 246–48.) [redacted]

736. Singlera. Singlera's PanSeer assay has been shown to detect five types of cancer at 96.1% specificity in a retrospective, observational study of 418 participants. (RX3115 (Chen et al., 2020) at 1, 3.) On that measure alone, it is likely that Singlera would not be used in the same target population as Galleri. [redacted]

737. This is further confirmed by the fact that any patient testing positive on PanSeer would then undergo an additional blood test and/or follow-up imaging to allow tissue of origin mapping. (RX3115 (Chen et al 2020) at 6).)

738. [redacted] But the patient experience with the only version of the CancerSEEK test for which Exact/Thrive has published any data is very different from that same patient's experience with Galleri [redacted]

739. The version of CancerSEEK used in the DETECT-A study consisted of three separate tests—two blood draws and a PET-CT scan that must each be collected at a different time (Lengauer (Exact/Thrive) Tr. 246–48)—makes it very different from Galleri, which consists of one blood draw that can be conducted as part of an annual physical exam. (PX0043 (GRAIL) at 112, 114.)

740. Moreover, a comparison between Galleri and the first blood draw in CancerSEEK further shows the significant differences between them. As shown in the table below, the performance of Galleri is superior to CancerSEEK's single blood draw:

Table 8

Test	Galleri	CancerSEEK 1 Blood Test
Study	CCGA3	DETECT-A
Types of Cancer	50	10
Cancer Signal of Origin	Yes	No
Specificity	99.5%	95.3%
Sensitivity	51.5%	30.2%
PPV	44.4%	5.9%

(*See* RX3409 (Klein 2021) at 5; RX3419 (Lennon et al., 2020) at 7).)

740.1 [redacted]

c. Unique production facilities

741. [redacted]

741.1 As Nicole Berry explained, "[t]he mechanism by which a test provider translates the variant calls or the presence of absence of a combination of biomarkers into a clinically relevant conclusion is typically part of the proprietary piece of the workflow." (Berry (Illumina) Tr. 822.)

741.2 According to Ken Chahine, "[t]he magic occurs in basically deciphering the information you get back from that sequencing machine and determining what algorithm may or may not predict whether someone has cancer." (Chahine (Helio) Tr. 1015.)

741.3 As part of the CCGA study, GRAIL determined that the most appropriate biomarker to identify early cancer through blood tests were methylation sites, in which plasma cfDNA is subjected to bisulfite conversion, prepared as a dual indexed sequencing library and enriched using standard hybridization capture conditions, followed by paired-end sequencing. (*See* RX3430 (Liu et al 2020) at 5.)

741.4 GRAIL developed a proprietary method for library preparation to efficiently prepare methylated DNA fragments for sequencing, and then developed proprietary machine learning algorithms to take those methylation signals and make a

prediction about whether or not a patient has cancer, and if they do, what type of cancer. (Aravanis (Illumina) Tr. 1887.)

741.5 This approach is unique to GRAIL, [redacted] Aravanis (Illumina) Tr. 1883 ("So the methylation patterns between different cancers can be quite different. Methylation patterns actually within a cancer, even of the same type that looks the same, can also be quite different. And this is actually why you need so many markers, which is that you need many markers to be able to understand which type of cancer, to distinguish it from someone who doesn't have cancer.").)

741.5.1 There are about 30 million methylation sites in the human genome, and Galleri uses about one million of those. (Aravanis (Illumina) Tr. 1882–83; [redacted]

742. The library preparation and back-end algorithms used by the other putative MCED test developers are different from GRAIL's. (PFF ¶¶ 742.1–742.4.)

742.1 Exact/Thrive is focusing only on 16 gene mutations and nine protein sites to screen for ten cancers. (*See* RX3419 (Lennon et al., 2020) at 4.)

742.2 [redacted]

742.3 Freenome's approach combines data from whole-genome sequencing, DNA methylation, and protein quantification using a multiomics approach. (RX3426 (Lin et al., 2021); RX3592 (Putcha et al., 2020).) [redacted]

742.4 [redacted]

d. Distinct customers

743. But what is clear already (and Complaint Counsel has not demonstrated otherwise) is that these tests will have different indications, and therefore distinct customers, from Galleri.

744. The Galleri test can detect the presence of more than 50 cancers as well as the cancer signal of origin in positive cases. GRAIL expects Galleri will be ordered annually as part of a patient's annual physical exam. (PX0043 (GRAIL) at 112, 114.) The test is likely to be of interest to anyone above 50 who wishes to know whether they have cancer, regardless of location in the body, at an early stage through a single blood draw, without any need for a PET-CT scan

and the risks such scans entail. (*See* Aravanis (Illumina) Tr. 1921–22; Ofman (GRAIL) Tr. 3315; Cote Tr. 3812.)

745. In contrast an MCED test capable of detecting only two or three cancer types would be used only by customers with reason to suspect susceptibility to the few cancers the test could detect, [redacted]

746. [redacted]

e. Distinct prices

747. At present, Galleri is the only MCED test with a price, currently selling for $949, (Bishop (GRAIL) Tr. 1322) [redacted]

748. It is virtually impossible to compare Galleri to tests not yet in existence: as Bill Getty of Guardant testified, "[i]n the context of the blood-based screening market, which is yet to evolve to its maturity, it would be very difficult to speculate about the relevancy of price." (PX7105 (Getty (Guardant) Dep. at 106–07).)

749. Complaint Counsel failed to show that any will have a similar price point to Galleri. (PFF ¶¶ 750.1–750.4.)

750. None of the putative MCED tests has a published price and no test developer has determined what the price of a putative MCED test might be. (PFF ¶¶ 750.1–750.4.)

750.1 Singlera has said that it "couldn't know right now" at what price Singlera plans to market PanSeer. (PX7042 (Gao (Singlera) IHT at 99).)

750.2 [redacted]

750.3 [redacted]

750.4 There is no evidence to suggest any other putative MCED developer has made any determination on the price of any putative test that detects multiple cancer types. [redacted]

751. While none of the putative MCED tests in development has an established price point, if they do not launch with comparable characteristics as Galleri, such as the number of cancers detected or the ability to detect cancer signal of origin, the evidence suggests they will not share the same price as Galleri. [redacted]

f. Sensitivity to price changes

752. Just as it is impossible to compare the price of Galleri to the prices of tests not yet in the market, it is impossible today to say whether the price of Galleri will be sensitive to the availability and pricing of the putative tests in development. (*See* Getty (Guardant) Tr. 2678 ("Q. Based on what you know about healthcare markets and your determinations about competition between LUNAR-2 and Galleri, once LUNAR-2 is on the market at a given price, if that price were to increase by, let's say, $10, you could not say one way or another that that increase would cause doctors to prefer Galleri over LUNAR-2; right? A. No. Q. In other words, what I've just asked you is correct; you agree with my statement. A. Yes, I do.").)

753. [redacted]

754. On top of that, there is no record evidence that an increase in price to the 50-cancer test is likely to cause consumers to switch to a two- or three-cancer test. (RX6004 (Katz Trial Dep. at 18).)

755. In any case, Complaint Counsel did not undertake any study concerning the price sensitivity of Galleri or any of the purported MCED tests in development. (RX6004 (Katz Trial Dep. at 20-23).)

755.1 Indeed, they did not offer any evidence at all that the prices of Galleri will be sensitive to the changes in the prices of the MCED tests in development. (RX6004 (Katz Trial Dep. at 20-23).)

756. It is undisputed that an MCED test's price will in part depend on the level of payor adoption, and that payor adoption will in large part depend on the development of extensive evidence to establish clinical utility of a MCED test. (*See* RX3867 (Deverka Expert Report) ¶ 92.)

756.1 [redacted]

g. Specialized vendors

757. While all purported MCED tests except for Galleri are still in early stages of development, all available evidence indicates that Galleri and the purported MCED tests in development have unique attributes which involve specialized vendors.

758. Different vendors provide different medical services to patients. For example, a blood test may be performed in a physician's office by a phlebotomist, (RX3869 (Cote Expert Report) ¶ 127), while imaging or other scanning must be performed in a specialist offices and through other means, (Aravanis (Illumina) Tr. 1829–30; Berry (Illumina) Tr. 814–16.)

759. Because the Galleri test is exclusively a blood test, it can be performed in a single physician's office alone. (*See* Bishop (GRAIL) Tr. 1402–03.)

760. By contrast, Thrive's CancerSEEK assay entails at least two separate tests: one blood draw and the use of a PET-CT scan to confirm positive results and determine cancer signal of origin. (Lengauer (Exact/Thrive) Tr. 248–49.)

761. Similarly, based on the current published data, a patient with a positive result from Singlera's PanSeer test could potentially undergo follow-up imaging to allow tissue of origin mapping. (RX3115 (Chen et al 2020) at 6.)

762. [redacted]

763. Should additional imaging be required to do so, those putative tests would likely require specialized vendors, that are not utilized in the routine workflow of the Galleri test, to provide a result to the patient. (*See* Aravanis (Illumina) Tr. 1829–30; Berry (Illumina) Tr. 814–16.)

4. **Hypothetical Monopolist Test**

764. To show the hypothetical monopolist test is met here, Complaint Counsel relies exclusively on the testimony of Dr. Scott Morton. (CC Pretrial Br. at 47.)

764.1 [redacted]

[redacted]

764.2 [redacted]

765. Dr. Scott Morton did not conduct a SSNIP analysis based on quantitative purchase data. [redacted]

766. [redacted]

767. In addition, Dr. Scott Morton did not attempt to fill the information gaps in her assessment using surveys or other means, including information about the preferences and likely switching behavior of clinicians, patients and payors related to the products she includes and excludes from her proposed MCED market. (RX3871 (Willig Expert Report) ¶ 21; RX6004 (Katz, Trial Dep. at 21).) She did not attempt to analyze substitution from the perspective of payors, despite acknowledging that payor choices will drive adoption of different screening tests. (RX3871 (Willig Expert Report) ¶ 20.)

767.1 For instance, the need to obtain payor coverage of NGS-based screening tests will exert pressure on test developers to keep prices low when they commercialize their products. (*See* RX6004 (Katz, Trial Dep. at 19–20) ("[T]here's an information gap there then because we don't have the actual experience and she didn't, as far as I can tell certainly from her reports and her testimony, that she didn't attempt to fill those information gaps in by, say, doing some sort of survey of, you know, clinicians or payers to understand what they would think about, you know, various alternatives and how close they would view those to be substitutes and then try to infer from that what that would mean for their switching behavior."); [redacted]

768. Dr. Scott Morton's failure to account for payor adoption in this way is compounded by her failure to assess how the possible characteristics of the MCED tests in

development might impact the likelihood of switching within her defined market.

768.1

768.2

768.2.1

768.2.2

768.3

768.4

768.5 [redacted]

769. [redacted]

769.1 [redacted]

770. [redacted]

5. **Subjective and Changing Policy Assessments**

771. Complaint Counsel seeks to dismiss the shortcomings in its proof by asserting that the relevant market is nascent and that there is limited evidence available to it. (*See* CC Pretrial Br. at 31.) It suggests that the law is specially written to protect nascent markets and that such markets are not inoculated from application of the antitrust laws. (*See* CC Pretrial Br. at 31.)

772. Dr. Scott Morton has not performed the analysis necessary to define an innovation market. (RX6004 (Katz Trial Dep. at 26) ("If she had been doing an innovation market, she should have been asking a different question about the hypothetical monopolist. You would ask the question did a hypothetical monopolist that controlled some set of assets to innovation -- you know, you already think of those as easier just think of controlled a bunch of firms that were innovators -- could it find it profitable to cut back on innovation. And thinking about the boundaries of the market, you'd be focusing on capabilities to do innovation. You'd be

looking at different factors. I think it's clear that Professor Scott Morton when she applies her hypothetical monopolist test is applying it to defining a product market, not an innovation market.").)

B. The Alleged Related Product Market

1. No Proof to Support Alleged Related Product Market

773. Complaint Counsel defines the related product market as "Illumina's NGS instruments and consumables". (CC Pretrial Br. at 49; Complaint ¶ 50 ("Illumina's NGS platform is the related product".) The narrowness of this alleged market, in which Illumina would obviously be a monopolist (as it would necessarily be the only supplier), stands in stark contrast to the very broad manner in which Complaint Counsel seeks to define the relevant product market. (*See* PFF V.A.)

774. In discussing the relevant product market, Complaint Counsel acknowledges that an appropriate antitrust market is dependent on reasonable interchangeability, the *Brown Shoe* practical indicia and the hypothetical monopolist test. (*See* CC Pretrial Br. at 30–48.)

775. Neither Complaint Counsel nor its expert (Dr. Scott Morton) does the requisite analysis, despite the availability of quantitative data. Complaint Counsel says simply that MCED test developers prefer Illumina's NGS instruments and consumables to the alternatives. (FTC Pretrial Br. at 53–57; [redacted]

2. Current NGS Platform Alternatives to Illumina

776. Contrary to Complaint Counsel's unproven contention, there are other viable NGS platforms on the market that can support MCED tests in development.

777. BGI. BGI already has a commercially available NGS platform, markets its NGS technology in many other countries and is expected to enter the U.S. market in the near future. [redacted]

777.1 BGI is currently enjoined from launching its sequencing instruments and related reagents in the United States due to its infringement of a certain Illumina patents that expire in 2022 and 2023. (RX3356 (Businesswire); RX3869 (Cote Expert Report) ¶ 287.)

777.2 BGI may enter the U.S. market by August 2022. *Illumina, Inc. v. BGI Genomics, Co.*, 20-cv-01465-WHO (N.D. Cal. Mar. 27, 2022), ECF No. 665 at 48 ("If [BGI] make[s] offers to sell Accused Products in the U.S. before the expiration of the patents-in-suit—as they are permitted—they must include the following conspicuous written disclaimer: 'No sales will occur, and no purchase orders will be accepted, until after August 23, 2022.'")

777.3 [redacted]

[redacted] RX3869 (Cote Expert Report) ¶ 287; *see also* [redacted]

777.4 BGI's DNBSEQ sequencer's reported accuracy is comparable to Illumina's sequencers, and guarantees >80% of bases with quality score of >Q30 (over 99.9% accurate). (RX3465 (MGI Tech); RX3067 (BGI) at 1.)

777.5 [redacted] Cote Tr. 3743–44; RX3869 (Cote Expert Report) ¶ 287.)

778. Thermo Fisher. [redacted]

778.1 [redacted]

778.2 [redacted]

779. Oxford Nanopore. In addition to BGI and Thermo Fisher, Oxford Nanopore is also a viable alternative for MCED developers. (RX3521 (NCM) at 50–51; RX3167 (ONT); RX3520 (NCM) at 6, 9–10; RX3869 (Cote Expert Report) ¶ 268.)

779.1 ONT's recent improvements, such as adaptations to its sequencers and library preparation, has made its platform more suitable for multi-cancer screening. (*See* RX3441 (Marcozzi et al., 2020); RX3446 (Martignano et al., 2021); RX3869 (Cote Expert Report) ¶¶ 293, 295–98.)

779.2 ONT's instruments reportedly will compete with Illumina's on throughput, accuracy and cost. ONT's highest throughput instrument, the PromethION, has a higher throughput than the highest performance instrument and flow cell currently offered by Illumina, the NovaSeq 6000 with the S4 flow cell. (RX3543 (ONT); RX1205 (Illumina); RX3869 (Cote Expert Report) ¶ 294.)

779.3 ONT's claims its instruments have similar accuracy to Illumina. (*Compare* RX3541 (ONT) at 1; RX3535 (ONT) at 1 *with* RX3368 (Illumina).) And, as

shown in the table below, ONT may offer per Gb sequencing costs that are lower than what Illumina offers.

780. Liquid biopsy test makers view these platforms as viable substitutes for Illumina's platform:

780.1 [redacted] *see also* RX3062 (Natera).)

780.2 [redacted]

780.3 [redacted]

780.4 Dr. Gao of Singlera testified that the PanSeer test can be run using Thermo Fisher equipment. (Gao (Singlera) Tr. 2928.)

780.5 [redacted]

780.6 [redacted]

781. [redacted] RX3543 (ONT) at 2; RX3258 (Genengnews).)

3. Promising NGS Sequencers in Development and Likely Entrants

782. In addition to the viable platforms on the market, there are also many NGS platforms in development and likely to enter the market in the near future that will be viable platforms for MCED tests. (Cote Tr. 3923; *see* PFF ¶¶ 782.1–787.)

782.1 [redacted]

783. Singular Genomics. Singular Genomics has developed an NGS platform, the G4 System, which launched at the end of 2021 and expects to begin shipping units in the second quarter of 2022. (RX4048 (Singular); Velarde (Singular) Tr. 4515–16; (PX8561 (Singular) at 1; PX7117 (Velarde (Singular) Dep. at 30); RX3869 (Cote Expert Report) ¶ 301).)

783.1 The G4 Systems's performance characteristics claim to be comparable to that of Illumina's NextSeq and NovaSeq systems, with read lengths of 50 to 150 bases, targeted 400 Gbs per sequencing run, high speed sequencing at 4–minute cycle times and high accuracy of 99.7% on 150 base reads. (PX8561 (Singular) at 4–5; [redacted]

783.2 [redacted]

783.3 [redacted]

784. Ultima Genomics. [redacted]

784.1 [redacted]

784.2 [redacted]

[redacted]

784.3 [redacted]

784.4 [redacted]

784.5 [redacted]

784.6 [redacted]

785. Roche. [redacted]

785.1 [redacted]

785.2 [redacted]

785.3 [redacted]

786. Element. [redacted]

786.1 [redacted]

786.2 [redacted]

786.3 [redacted]

787. Omniome. Omniome, recently acquired by PacBio (RX3552 (GenomeWeb) at 1), is developing an NGS sequencer using its sequencing-by-binding technology. (RX3533 (Omniome) at 1.)

787.1 [redacted] —"10 to 100x better than" the accuracy of Illumina's sequencers. (PX7096 (Song (Omniome) Dep. at 82).)

787.2 Omniome expects that, at launch, its NGS sequencer will have higher accuracy, longer sequence read and lower reagent costs than Illumina's sequencers. PX7096 (Song (Omniome) Dep. at 43, 58); [redacted] RX3869 (Cote Expert Report) ¶ 319.)

787.3 [redacted]

788. [redacted]

[redacted]

789. Complaint Counsel bases its alleged market definition on speculation about future entry by early-stage developmental MCED tests (*see* Section I.A above), while simultaneously discarding evidence of actual competition and future entry by NGS developers in defining the alleged related product market. (*See* RX6000 (Carlton Trial Dep. at 37–38) ("[A]ll I can do is point out the asymmetry in [Complaint Counsel's] analysis . . . in which [it] assumes that the MCED products are going to come into existence, but the NGS alternatives to Illumina are not.")

4. Adapting Assays Developed on Illumina's Platforms to Another Platform

790. [redacted]

791. It is likely that a test developer will need to switch between different sequencing platforms (such as between different Illumina NGS platforms) during the course of developing a screening test, even absent the acquisition. (Cote Tr. 3739, 3771; Aravanis (Illumina) Tr. 1865.)

791.1 Test developers routinely re-validate their tests to account for new developments in their tests, new and improved technology relating to consumables or sequencers, or for any number of other reasons. (RX3869 (Cote Expert Report) ¶ 338.) These revalidations are integral to a sound business plan for any test developer. (RX3869 (Cote Expert Report) ¶ 338.)

792. [redacted]

793. Other screening test developers have, in fact, switched platforms for their MCED tests in development. (PFF ¶¶ 793.1–793.4.)

793.1 For example, during Thrive's initial development of the CancerSEEK test, including for the DETECT-A study, Thrive used Illumina's HiSeq 4000 and MiSeq instruments as its NGS platforms. [redacted]; RX3419 (Lennon et al 2020) at 18; [redacted]

793.2 [redacted]

793.3 [redacted]

793.4 [redacted]

794. Given the increased availability of competing NGS platforms in the next few years, screening test developers have many opportunities to switch from Illumina's platform to another platform, with a process no more burdensome than that they would use to switch to the next generation of Illumina sequencers. (RX3869 (Cote Expert Report) ¶ 271.)

795. [redacted]

796. [redacted]

VI. COMPLAINT COUNSEL FAILED TO PROVE THE TRANSACTION IS LIKELY TO SUBSTANTIALLY LESSEN COMPETITION

A. Vertical Mergers

797. Vertical mergers do not raise the same concerns as horizontal mergers because they do not involve the combination of substitutable products and the reduction of competition between those products. (RX6000 (Carlton Trial Dep. at 16).)

798. Vertical mergers can harm competition only in narrow circumstances. (RX3864 (Carlton Expert Report) ¶ 43; RX6000 (Carlton Trial Dep. at 15–24.)

799. A vertical merger involves combining firms that have complementary assets. (RX3864 (Carlton Expert Report) ¶¶ 42, 54; RX6000 (Carlton Trial Dep. at 16:7–24; 17:7–24.)

800. Most vertical mergers are likely to generate significant efficiencies for reasons that are well understood in the literature. (RX3864 (Carlton Expert Report) ¶¶ 42, 52; RX6000 (Carlton Trial Dep. at 15–18.)

800.1 It is well known that when two firms with complementary assets combine, it can eliminate transaction costs that enable procompetitive collaboration that would not be achieved by the firms in an arm's-length relationship. (RX6000 (Carlton Trial Dep. at 16.)

800.2 The efficiency benefits from vertical integration can provide a powerful motivation for a vertical merger and can eliminate any concerns about potential adverse competitive impacts since efficient mergers lead to lower prices and/or improvements in the quality or availability of products, all of which benefit consumers. (RX3864 (Carlton Expert Report) ¶ 42; RX6000 (Carlton Trial Dep. at 16.)

800.3 As Commissioner Wilson as noted, "[e]conomists have conducted a number of retrospective studies of vertical mergers. Most suggest that consumers benefit. For example, LaFontaine and Slade found in a 2007 survey that 'efficiency considerations overwhelm anticompetitive motives in most contexts.' A 2005 survey by four FTC economists found similar results. So did a 2018 survey by economists at the Global Antitrust Institute." (RX4008 (Wilson).)

800.4 A single firm able to coordinate how these assets are used may be able to streamline production, inventory management or distribution. (RX3701 (FTC) at 13; RX3864 (Carlton Expert Report) ¶ 54; RX6000 (Carlton Trial Dep. at 17–18, 57.)

800.5 It may also be able to create innovative products in ways that would not likely be achieved through arm's-length contracts. (RX3701 (FTC) at 13; RX3864 (Carlton Expert Report) ¶ 54; RX6000 (Carlton Trial Dep. at 17–18, 57.)

800.6 Such efficiencies are particularly important in industries that are characterized by high levels of R&D expenditures and where firms are unwilling to share

their valuable, proprietary knowledge with others, absent a merger. (RX3864 (Carlton Expert Report) ¶ 54; RX6000 (Carlton Trial Dep. at 57.)

800.7 Efficiencies that bring products to market more quickly and facilitate more productive R&D efforts benefit consumers directly. (RX3864 (Carlton Expert Report) ¶ 54; RX6000 (Carlton Trial Dep. at 17–18, 57.)

801. An analysis of a vertical merger that ignores evidence of merger-specific efficiencies is incomplete and likely to arrive at an unsupportable conclusion. (RX3864 (Carlton Expert Report) ¶ 54.)

801.1 [redacted]

B. Importance of a Full Economic Model

802. A complete analysis of a vertical merger requires an economic model that accurately reflects the upstream and downstream markets in which the merging firms operate. (RX3864 (Carlton Expert Report) ¶¶ 51–55; RX6000 (Carlton Trial Dep. at 24:6–25:10.)

803. A full economic model must simultaneously accounts for the change in incentives to price to downstream rivals (bearing in mind the impact of post-merger contractual and reputational constraints) as well as any efficiencies, while taking into consideration any constraints on the firms' behavior. (RX3864 (Carlton Expert Report) ¶¶ 51–55; RX6000 (Carlton Trial Dep. at 24–25.)

803.1 As Dr. Carlton testified "[i]f you don't take account of the efficiencies or, more broadly, the incentive to lower price, you risk preventing a merger that would bring large benefits to society because you've failed to balance the benefits against the possible harms." (RX6000 (Carlton Trial Dep. at 26).)

804. The outcome of a vertical model is influenced by a number of factors, including (i) the efficiencies arising from the merger, (ii) the incentives on the merged firm that can exert downward pricing pressure, (iii) the merged firms' profit margins, (iv) the demand curves of each of the merging firms, (v) the diversion ratios of the downstream product (that is, the share of downstream rivals' sales that would divert to the merged firm in response to an upstream price increase), (vi) the competitive forces facing the upstream firm, (vii) the cost of the upstream inputs relative to downstream revenues and margins, (viii) downstream product differentiation, and (ix) any reputational and contractual constraints on the merged firm. (RX3864 (Carlton Expert Report) ¶¶ 44–50; RX6000 (Carlton Trial Dep. at 24.)

804.1 [redacted]

805. The economic model must also take account of the "timing and magnitude of potential harm versus likely benefit" because "if the harms are far off in the future, but the

benefits are closer in", that critical balance of potential harms versus benefits would be skewed and a procompetitive vertical merger could, as a result, be disallowed, depriving consumers of enormous benefits. (RX6000 (Carlton Trial Dep. at 25–26).)

806. Only with such a model could one make a judgment as to whether the merger would likely result in net harm to consumers. (RX3864 (Carlton Expert Report) ¶ 55; RX6000 (Carlton Trial Dep. at 24–25).)

807. If an economic model fails to reflect the efficiency benefits of a vertical merger and balance those effects against the possible harms, it creates the risk of preventing a merger that would bring large benefits to society. (RX6000 (Carlton Trial Dep. at 25 –26).)

C. Complaint Counsel Failed to Present a Full Economic Model Supporting the Alleged Harms

808. [redacted]

809. [redacted]

810. [redacted]

811. Complaint Counsel and Dr. Scott Morton offer no model that properly accounts for the costs and benefits associated with the transaction, including massive merger-specific efficiencies; properly credits the impact of contractual and reputational constraints on Illumina's post-merger behavior; and properly accounts for the ability of MCED test providers to take steps to reduce their reliance on Illumina. (RX3864 (Carlton Expert Report) ¶ 55.)

812. [redacted]

813. Complaint Counsel and Dr. Scott Morton have posited a future downstream market, but it fails to specify what that market will look like, what firms will compete in that market, and what will be the characteristics of the rivals' products. (RX3864 (Carlton Expert Report) ¶ 87.)

814. Such facts are necessary in order to model the effect of any incentive to raise rivals' costs, but they are absent from Dr. Scott' Morton's analysis. (RX3864 (Carlton Expert Report) ¶ 87.)

D. 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

815. 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).)

816. Absent the Transaction, Illumina would have a 12% stake in GRAIL's profits and would receive 7% of GRAIL's net revenues on every sale. (PFF ¶ 50.)

817. The royalty is a unique feature of GRAIL's contract with Illumina, reflecting Illumina's contributions to the formation of GRAIL—Illumina has no comparable arrangement with any other test developer purportedly developing an MCED test. (deSouza (Illumina) Tr. 2463–64; PX7107 (deSouza (Illumina) Dep. at 191); Strom (Morgan Stanley) Tr. 3543–44; RX6000 (Carlton Trial Dep. at 92–94).)

818. In light of the pre-merger royalty and equity stake, under Complaint Counsel's own theory of Illumina's incentives, Illumina "makes much more money if a customer uses the GRAIL test than if it uses that of" a GRAIL rival, which means "there already is an incentive to favor GRAIL" and "therefore, the merger" has no effect on Illumina's dealings with GRAIL rivals. (RX6000 (Carlton Trial Dep. at 93–94).)

819. [redacted]

820. Dr. Scott Morton purports to quantify Illumina's incentives before and after the transaction, but her only attempt at quantifying those incentives makes unwarranted assumptions and carries no weight:

820.1 [redacted]

820.2 [redacted]

820.3 [redacted]

820.4 [redacted]

820.5 [redacted]

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

822. Correcting for the erroneous assumption that any rival MCED test developer would pay a royalty similar to GRAIL, the result of her analysis shows that there is an incentive to favor GRAIL in the world without the merger because Illumina makes much more money if a customer uses the GRAIL test than if it uses that of the hypothetical rivals in Professor Scott Morton's quantification analysis. That means, if Professor Scott Morton were right about Illumina having a post-merger incentive to favor GRAIL, it would have that incentive even without the merger. (RX6000 (Carlton Trial Dep. at 92–94); RX3864 (Carlton Expert Report) at ¶ 148, Table 4.)

822.1 The table below shows the results of Dr. Scott Morton's quantification after correcting for her erroneous assumption:

Table 10

[redacted]

(RX3864 (Carlton Expert Report) ¶ 148, Table 4.)

822.2 The first row of Table 4 replicates the conclusions from Scott Morton Table 2. According to this hypothetical, pre-merger, Illumina makes similar profits from selling to GRAIL and selling to GRAIL's hypothetical rivals. The second row corrects the error on royalty rates; and the third row additionally corrects the error of relying on 2023 data. The third row demonstrates that, even pre-merger, Illumina makes approximately five times as much from selling a unit through GRAIL rather than through

GRAIL's rivals. Therefore, any incentive to foreclose, by Dr. Scott Morton's reasoning, currently exists. (RX3864 (Carlton Expert Report) ¶ 149.)

822.3 As Dr. Carlton put it: "if you believed those assumptions -- which I do not -- but if you correct for the fact that she has improperly excluded royalties from rival one and rival two, you find that in her -- with her assumptions, there already is an incentive to deal with GRAIL and not deal with the rivals, and, therefore, the merger would do nothing." (RX6000 (Carlton Trial Dep. at 92–94).)

E. There is No Basis to Predict That Foreclosure Would Cause Material Diversion From Future MCED Tests to GRAIL

1. Diversion is a Necessary Condition for Foreclosure

823. Significant diversion is a necessary condition for a vertical merger to give rise to foreclosure incentives because, as a matter of basic economics, "if there's no diversion, then there's no incentive to engage in [a foreclosure] strategy because the vertically integrated firm would just lose sales" and therefore "you need significant diversion for the strategy to make sense." (RX6000 (Carlton Trial Dep. at 21–22).)

824. [redacted]

2. Relevance of Product Differentiation

825. Downstream harm from a raising-rivals-costs strategy can only occur if the downstream rivals' products are not too differentiated and, even then, only under specific circumstances. (RX3864 (Carlton Expert Report) ¶ 50.)

826. 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).)

827. 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 its rivals, the less diversion would be expected to GRAIL if Illumina attempted to raise rivals' costs. (RX3697 (Carlton 2019) at 7–9; RX3864 (Carlton Expert Report) ¶ 87.)

828. [redacted]

829. [redacted]

3. **No Possibility of Current Diversion**

830. Galleri is the only NGS-based MCED test on the market. (*Supra* PFF ¶ 698.)

831. Because Galleri is the only NGS-based MCED test on the market, there could be no sales from Galleri rivals to divert today – current diversion is impossible. (RX6000 (Carlton Trial Dep. at 46).)

4. **No Basis To Predict Future Diversion Given Differentiation Of Galleri And Other Tests In Development**

832. There also is substantial uncertainty around the MCED tests in development. (*Supra* PFF ¶¶ 701–706).)

833. There is no way to exactly know what the MCED tests-in-development will look like, if and when they are launched. (*Supra* PFF ¶¶ 680.1–680.5.)

834. It is unfounded speculation to say that any MCED tests-in-development would include, at any point in the foreseeable future, features that could make them reasonably close substitutes for GRAIL's Galleri test. (*Supra* PFF ¶¶ 680.1–680.5.)

835. Most of the MCED test developers cited by Complaint Counsel are planning to launch tests as single-cancer tests, with additional plans to incrementally add additional cancers to their tests at some point in the future. (*Supra* PFF ¶¶ 701–705.)

836. None of the MCED test developers cited by Complaint Counsel have ascertained the specific features of any MCED test that they may launch in the future, although it is clear that none are on a path to launching a test, like Galleri, that can detect 50 cancer types and cancer of origin in a single blood draw:

836.1 [redacted]

836.1.1 [redacted]

836.1.2 [redacted]

836.1.3 [redacted]

836.2 [redacted]

836.2.1 [redacted]

}

836.2.2 [redacted]

836.2.3 [redacted]

836.3 [redacted]

836.3.1 [redacted]

836.3.2 [redacted]

836.3.3 [redacted]

836.4 [redacted]

836.4.1 [redacted]

[redacted]

836.5 [redacted]

836.5.1 [redacted]

836.5.2 [redacted]

836.5.3 [redacted]

836.5.4 [redacted]

837. Given the vast differences between those tests and Galleri, it is clear that they will be too dissimilar to permit a foreclosure strategy to divert material sales to Illumina from GRAIL rivals at any point in the foreseeable future. (*Supra* PFF ¶¶ 825–829.)

838. A test that detects only colon cancer, or only lung and liver cancer, is not substitutable for a test that screens for more than 50 cancer types. (*Supra* PFF ¶ 687.)

839. Number of cancers detected. Galleri differs from the MCED tests-in-development based on the numbers of cancers that can be detected.

839.1 [redacted]

839.2 [redacted]

839.2.1 [redacted]

839.3 [redacted]

839.4 [redacted]

839.5 [redacted]

839.6 [redacted]

839.6.1 [redacted]

839.7 Exact/Thrive's data shows only that its CancerSEEK assay can detect whether a patient has one of 10 types of cancer (and is unable to identify which one without further invasive testing in the form of a PET-CT scan). [redacted] RX3419 (Lennon et al., 2020); Cote Tr. 3811–14.)

839.8 The published Singlera data is from a small, 418–sample case control study and shows only that Singlera's PanSeer assay potentially could detect five types of cancer. (RX3115 (Chen 2020) at 3.)

840. Number of tests performed. Galleri differs from the MCED tests-in-development based on the number of tests of which it is comprised, in that Galleri consists of a single blood draw, whereas some of the tests in development actually comprise a series of tests.

840.1 For example, Exact's CancerSEEK test is actually three separate tests in the form of its latest published trial: two blood draws and a PET-CT scan. (Lengauer (Exact/Thrive) Tr. 246–48.)

840.2

840.3

840.4

841. Cancer Signal of Origin. Galleri also differs from the MCED tests in development based on its ability to determine cancer signal of origin.

841.1 Galleri is able to detect tissue of origin; that is, for positive cases, the test reveals where (lung, stomach, etc.) the detected cancer is likely located based on the same blood draw used to detect the cancer's presence. (*Supra* PFF ¶ 61.)

841.2 No other MCED test-in-development has demonstrated this capability. (*Supra* PFF ¶ 684.2.)

841.3 For example, Thrive's CancerSEEK cannot detect tissue of origin and instead requires a diagnostic full-body PET-CT scan both to confirm the results of the blood testing—*i.e.*, that cancer has in fact been detected— and also to localize the potential cancer. (Lengauer (Exact/Thrive) Tr. 246–48.)

841.4 Similarly, Singlera has said that any patient testing positive would then undergo additional blood testing and/or follow-up imaging to detect cancer signal of origin. (RX3115 (Chen 2020) at 6.)

841.5

841.6 [redacted]

841.7 [redacted]

841.8 [redacted]

841.9 [redacted]

841.10 However, Dr. Abrams, the only expert primary care physician to testify in this case, explained that the ability to detect tissue of origin is a key differentiating feature that will influence physician and patient choice. (Abrams Tr. 3624.)

841.11 [redacted]

841.12 [redacted]

842. Sensitivity. Galleri differs from the MCED tests-in-development based on its degree of sensitivity, meaning how often a test correctly returns a positive result for an individual who has the cancer for which they are being screened. (*Supra* PFF ¶ 172.)

842.1 [redacted]

842.2 [redacted]

843. Specificity. Galleri also differs from the MCED tests in development based on its degree of specificity, meaning how often a test correctly returns a negative result for an individual who does not have the cancers for which they are being screened; the higher the specificity, the lower the false positive rate. (*Supra* PFF ¶ 173.)

843.1 [redacted]

843.2 Further, most of the tests-in-development are focused on cancers with existing standard-of-care screening protocols (*supra* PFF ¶¶ 482, 701–705), for which a high sensitivity is necessary but a lower specificity is acceptable given the ability to turn to standard-of-care screening to assess whether a positive case is a true positive. (Cote Tr. 3829.) As Dr. Cote explained:

> "[T]he requirements for a single cancer screening test, particularly one that has a standard of care screen that can be reflexed to . . . are very different from a multicancer screening test. What is really required . . . in the colorectal assay would be a high level of sensitivity, hopefully superior to that of the standard of care screening, which is a colonoscopy, and the lower level of specificity and the increase in the false-positive rate can be tolerated because the reflex here would be colonoscopy, which would be the direct visualization of the colon." (Cote Tr. 3829.)

843.3 [redacted]

843.4 As the table below also shows (*see supra* PFF Table 7), the specificity of the MCED tests-in-development to which Complaint Counsel points, for which there is any specificity information in the record, differ from specificities for the cancers detected by Galleri.

Table 7

Test	Galleri (GRAIL) 1 Blood Test	CancerSEEK (Exact/Thrive)			PanSeer (Singlera) 1 Blood Test
		1 Blood Test	2 Blood Tests	2 Blood + PET-CT	
Study	CCGA3	DETECT-A			Taizhou L.S.
Types of Cancer	50	10			5
Cancer Signal of Origin	Yes	No	No	Yes	No
Specificity	99.5%	95.3%	98.9%	99.6%	96.1%
Sensitivity	51.5%	30.2%	27.1%	15.6%	94.9%
PPV	44.4%	5.9%	19.4%	28.3%	

(RX3409 (Klein 2021); RX3419 (Lennon et al., 2020); RX3115 (Chen 2020).)

843.5 [redacted]

[redacted]

843.6 [redacted]

844. The only medical experts called to testify agree that Galleri is very different from the MCED tests in development. (PX6097 (Abrams Expert Report) ¶ 42; Cote Tr. 3727, 3777–78, 3782–83.)

844.1 [redacted]

844.2 Dr. Cote opined that other MCED tests in development would not be substitutes for Galleri, both because of their inability to detect cancer signal of origin, as well as other performance metrics such as sensitivity and specificity. (Cote Tr. 3727, 3777–78, 3782–83.)

844.3 Dr. Cote testified:

[redacted]

845. [redacted]

5. **No basis to predict limited-cancer tests will develop to close rivals to Galleri in foreseeable future.**

846. Expanding a single cancer test to a 50–cancer test is not a viable approach to developing a test like Galleri in the foreseeable future:

846.1 As Dr. Aravanis explained, for each cancer included in an MCED like Galleri, the developer has "to go through a somewhat similar process to what GRAIL did", meaning "a research phase", "a test development phase", and "a clinical phase", and that must be done "for each cancer", which, if done "serially" would take a "very long time" and is "not practical". (Aravanis (Illumina) Tr. 1895–96.)

846.2 Dr. Aravanis further explained that it is not "straightforward to expand [a single cancer test] to all other cancers" because **"**to develop a test for a new indication, like a new cancer, you have to go get samples related to that different cancer. You have to find the signals. Then you have to develop a technology for that. Then you have to do a -- the relevant clinical trial. There's no shortcut. . . . [T]here's hundreds of diagnostics developed" and "I've never heard of an example where because you developed a test for one thing, you can now – it's a shortcut to develop a test for something different." (Aravanis (Illumina) Tr. 1901–02).

846.3 Similarly, Dr. Cote testified that developing a single-cancer test does not put a test developer "in a position where they're ahead in developing a cancer screening test for a different cancer" because the "development of biomarkers for a particular cancer will not be adequate for other cancers" and, for each cancer, the developer must "go through the case-control verification to determine whether or not the assay has the performance characteristics needed for . . . the new target cancer, and then has to go through a prospective trial depending on which cancer is being targeted" – a process that can take years and with no certainty of a successful outcome. (Cote Tr. 3787.)

F. Complaint Counsel Failed to Account for the Impact Any Attempted Foreclosure would have on Illumina's NGS Sales and Reputation.

1. Illumina's Core Business Consists Of Selling NGS Instruments And Consumables.

847. Illumina's core business consists of selling NGS instruments and consumables. (*Supra* PFF ¶ 22.)

848. Illumina's NGS products comprise the vast majority (more than 90%) of its revenues and profits. (*Supra* PFF ¶ 22.)

849. Illumina's NGS business is expected to be the dominant driver of Illumina's profits well into the future:

849.1 As Mr. deSouza explained, "[t]he vast majority of Illumina's revenue in the next ten years will come from our sequencing business, our sequencers and consumables." (deSouza (Illumina) Tr. 2291.) Because Illumina's "core business is to sell sequencers and consumables", its "strong incentive is to continue to be successful selling sequencers and consumables into the market segments that we serve." (deSouza (Illumina) Tr. 2378.)

849.2 Dr. Aravanis similarly testified that "Illumina's business is based on growing sequencing markets" by "lowering the cost, allowing people to do more

sequencing" and "has also been driven by new applications that are developed", and "Illumina is hoping for more of those applications to be developed" on its platforms, which creates "a strong incentive for us to continue to decrease cost, and that's our plan." (Aravanis (Illumina) Tr. 1922.)

849.3 Dr. Goswami testified that the majority of Illumina's revenues come from NGS tools, and the Transaction "keeps our commitment to delivering NGS solutions to the broad sector of customers we serve." (PX7087 (Goswami (Illumina) Dep. at 145–46).)

850. Any attempt by Illumina to foreclose GRAIL's alleged rivals would harm Illumina's core NGS business, because it would result in the loss of highly profitable NGS sales in MCED and non-MCED applications. (deSouza (Illumina) Tr. 2378; [redacted], 86).)

850.1 Those sales either would divert to rival sequencing platforms, such as those in active development described above, or they would dissipate because customers would respond to foreclosure by choosing to no longer invest in NGS applications on Illumina systems. (RX6000 (Carlton Trial Dep. at 33–37); deSouza (Illumina) Tr. 2380–81; Febbo (Illumina) Tr. 4331–32; [redacted], 86.)

850.2 In either case, the loss to Illumina would be enormous – unless, contrary to fact, Illumina was assured of recouping a substantial volume of the resulting loss in profits through diversion to GRAIL. (RX3864 (Carlton Expert Report) ¶ 86.)

850.3 As Mr. deSouza explained, "if we [raised prices] we would lose [our customers'] business. They would move on to . . . a BGI or a Thermo", that is, Illumina would lose upstream revenues it earns today and expects in the future both from MCED developers and other customers. (deSouza (Illumina) Tr. 2379–80.)

850.4 Dr. Febbo similarly confirmed that attempted foreclosure would "really disincentivize an R&D lab or clinical labs from using our platforms, which would have a major impact on our business" through lost NGS sales. (Febbo (Illumina) Tr. 4331–32.)

851. [redacted]

852. Dr. Scott Morton admitted that she did not 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, as a result of attempted foreclosure of an MCED test developer, the test developer moves all of its tests, including non-MCED tests, to a different platform. (RX3852 (Scott Morton Dep. at 242–44).)

2. Any Attempted Foreclosure Would Inflict Significant Reputational Harm on Illumina.

853. Illumina has cultivated a reputation as a trusted supplier of NGS technology. (*See* PX7101 (Vogelstein (Johns Hopkins) Dep. at 57–58) ("Illumina makes fantastic instruments. I mean, they are unbelievably good . . . it's amazing what they've done.").)

854. Illumina has developed its reputation by investing substantial amounts into innovation and dramatically lowering sequencing costs over time. (Aravanis (Illumina) Tr. 1922; (RX1100 (George (Invitae) Decl. ¶ 8).)

855. Today, Illumina's brand is synonymous with innovative, low-cost sequencing systems. (*See* Berry (Illumina) Tr. 811–12.)

855.1 Since the release of its first Genome Analyzer instrument in 2007, Illumina has driven down sequencing costs from roughly $300,000 per gigabase to less than $8 per gigabase today. (RX3515 (National Human Genome Research Institute Sequencing Costs Data) at 1; RX3864 (Carlton Expert Report) ¶ 77.)

855.2 The phenomenon of dramatically declining sequencing costs is known in the industry as "Flatley's law", referring to Jay Flatley, Illumina's former CEO and Chairman. (*See* Berry (Illumina) Tr. 811–12 ("'Flatley's law' was a term coined by . . . a writer in Forbes magazine when he wrote an article comparing the reduction in the price of sequencing to Moore's law, which describes the reduction in the price of like silicon wafers or something in the computer industry, and [under Jay Flatley's] leadership where we really drove significant, significant reductions in the price of sequencing . . . down towards the level that they are today.").)

855.3 Reductions in sequencing costs have encouraged the development of entire industries that would not otherwise exist and for which Illumina is the primary supplier of sequencing inputs. (RX3864 (Carlton Expert Report) ¶ 77.)

856. Both Illumina witnesses and third parties attested to Illumina's long-standing reputation for innovation and driving down sequencing costs.

856.1 In a sworn declaration to the FTC, an Illumina oncology customer (Invitae) stated that "Illumina's role as an innovator in NGS has moved the field forward tremendously, as they have constantly and steadily reduced sequencing costs over time." (RX1100 (George (Invitae) Decl. ¶ 8).)

856.2 Gary Gao of Singlera testified that Singlera is "very happy Illumina has paved the way for NGS" and that he credited "the Illumina team for leading a genome revolution". (PX7102 (Gao (Singlera) Dep. at 70).)

856.3 Ms. Berry explained that Illumina routinely measures its reputation using "net promoter score" customer surveys, a widely-used survey methodology, and frequently receives "very high Net Promoter Scores relative to industry benchmarks." (Berry (Illumina) Tr. 837–38.)

857. Illumina's reputation for NGS innovation and lowering sequencing costs is critical to the continued success of its NGS business and overall profitability:

857.1 Illumina's profits from clinical applications are largely in the future. (S*ee* deSouza (Illumina) Tr. 2326–27 ("even with all the progress we've made in the last . . . almost two decades since the first human genome, today we still understand very little of how your genome translates into health and disease states. . . . There is a lot of research going on in that area, and once the researchers uncover the connections between your genome and those conditions, we'll start to see clinical applications emerge to do the testing based on that finding. . . . [W]e have so much undiscovered in front of us. As we discover that, I have no doubt we will see a lot more clinical applications emerge in the future."); Aravanis (Illumina) Tr. 1842–43 (NGS is still in the "early days" as a "tool for clinical diagnostics", and there are "many new applications emerging, and some of those could be even bigger than the ones we have today"—it is "still early in seeing how [NGS] can benefit medicine.").)

857.2 Illumina relies on its customers to invest in costly R&D to generate demand for Illumina's products, including in applications that have not yet been developed or possibly even conceived, creating a future stream of sequencing sales and profits. (*See, e.g.*, Berry (Illumina) Tr. 811 ("Our mission remains to . . . enable all attributes of our technology to drive accessibility and utilization across as many use cases as possible, and certainly pricing is a key element of that, a key enabler of that, and so continuing to drive down the price of sequencing is something that we are absolutely relentlessly continuing to pursue."); [redacted]

857.3 To realize those future profits, Illumina must incentivize customers to invest, which requires that Illumina maintain its reputation as a supporter of innovation by its customers in products that use Illumina's NGS technology. (RX6000 (Carlton Trial Dep. at 33–35, 186, 188).)

857.4 [redacted]

857.5 Illumina cannot predict which of its customers will create the next breakthrough product that will greatly expand the adoption of NGS. (RX6000 (Carlton Trial Dep. at 33–35, 186, 188).)

857.6 The future uses for Illumina's sequencing inputs are unknown and future demand for Illumina's sequencing inputs depends on downstream firms' willingness to invest in costly and uncertain R&D efforts using the Illumina sequencing platforms. [redacted]; PX7065 (Aravanis (Illumina) IHT at 143–44); [redacted]

857.7 Illumina thus has the incentive to support all of its customers even where foreclosure could theoretically result in short term gain. (RX6000 (Carlton Trial Dep. at 33–35, 186, 188).)

857.8 [redacted]

858. If Illumina attempted to foreclose cancer screening test developers, its reputation would change from a supporter of clinical development on its platforms to a supplier willing to engage in opportunistic hold-up when the applications it encourages customers to develop reach scale and profitability. (Aravanis (Illumina) Tr. 1922–23, 1931–32; Febbo (Illumina) Tr. 4331–32; [redacted]

859. Such a reputation would damage Illumina's NGS business and its expectation of future profits from the expansion of NGS-based clinical testing. (Aravanis (Illumina) Tr. 1922–23, 1931–32; Febbo (Illumina) Tr. 4331–32; deSouza (Illumina) Tr. 2379–80.)

860. Many innovators would choose not to invest in developing emerging and future applications using Illumina's platforms—not just limited to cancer screening—opting instead to pursue such applications on rival upstream platforms, or not at all. (Aravanis (Illumina) Tr. 1922–23, 1931–32; Febbo (Illumina) Tr. 4331–32; deSouza (Illumina) Tr. 2379–80; [redacted]

861. This in turn would stunt the growth and expansion of Illumina's NGS products to new applications and diminish Illumina's future sales in markets in which GRAIL is not active, making recoupment of those lost sales impossible. (Aravanis (Illumina) Tr. 1922–23, 1931–32; Febbo (Illumina) Tr. 4331–32; deSouza (Illumina) Tr. 2379–80; [redacted]

862. Raising price to disadvantage clinical oncology test developers would thus substantially harm the growth of Illumina's core business. (RX3864 (Carlton Expert Report) ¶ 86).

863. The reputational damage from an attempted foreclosure strategy would also harm Illumina by making it difficult to attract and retain the best scientists and innovators. (Aravanis (Illumina) Tr. 1922–23, 1931–32 (explaining that "many employees come to Illumina because of our culture and our values" and "impeding innovation would be counter to that" and make it difficult to "retain[] the talent we have and attract[] new people who want to work on developing new sequencing technology applications.").)

864. Illumina's witnesses offered uncontested evidence an attempted foreclosure strategy would harm Illumina's reputation and, in turn, Illumina's future NGS growth and profitability:

> 864.1 As Dr. Aravanis explained, attempting to foreclose a GRAIL rival "would be very detrimental" because "our business is based on customers using our platforms for their applications, developing new applications" and "[w]ere we to do something like foreclose on a customer's business . . . we would jeopardize the existing customer relationships", and "at a kind of reputational level, to do something like that . . . is not consistent with our mission and values." (Aravanis (Illumina) Tr. 1922–23; 1931–32.)
>
> 864.2 Dr. Febbo explained: "[I]f we were to behave in a way that precluded competition or in a way that disincentivized groups to use our sequencing [in] screening, that would disincentivize other companies, laboratories from early research and development through the development of clinical tests from using our platform and, thus, it is in our best interest to make sure that we continue to create an environment where laboratories are excited to use our platform to develop screening tests for cancer, as well as all the other applications we see happening." (Febbo (Illumina) Tr. 4331–32.)
>
> 864.3 Mr. deSouza explained: "[I]f people heard that we were raising costs in a market, I mean, that would cause us to have a ripple effect of losses in our sequencer business, not just in the cancer screening market, not just in the oncology market, but across our customer base as a whole." (deSouza (Illumina) Tr. 2386–87) Mr. deSouza further noted that the reason it is "very important for us that our customers . . . recognize that we are the company that drives the cost of sequencing down at high quality and makes sequencing more accessible" is because we would lose their business. They would move on to, you know, a BGI or a Thermo", and for Illumina it is important to remain known as the company "that drives prices down" and "encourages an ecosystem even in markets where we have a test." (deSouza (Illumina) Tr. 2379–80.)

865. Complaint Counsel suggested that Illumina's reputation is not valuable to Illumina because, in its SEC disclosures, Illumina noted that its decision to close the Transaction could have potentially adverse consequences to Illumina's reputation; however, Mr. deSouza explained that, although there was *a risk* of reputational harm that had to be disclosed, Illumina believed that "once people hear what we did . . . there won't be damage to our reputation" given the reasons for closing and the impact of the Transaction on cancer care and saving lives. (deSouza (Illumina) Tr. 2236–37, 2340.)

> 865.1 In other words, Mr. deSouza, and Illumina, believe that closing the Transaction will *in fact* have a positive impact on Illumina's reputation. (deSouza (Illumina) Tr. 2236–37, 2340.)
>
> 865.2 There is nothing in the SEC disclosure that suggests that closing the Transaction would harm Illumina's reputation for lowering costs and innovating to encourage development on its platforms. (deSouza (Illumina) Tr. 2236–37, 2340.)

866. From an economic perspective, it is critical to consider a firm's reputation in analyzing that firm's incentives and ability to foreclose its customers following vertical integration. (RX6000 (Carlton Trial Dep. at 25).)

866.1 [redacted]

866.2 Illumina's reputation constrains its incentive and ability to foreclose any GRAIL rival, because Illumina's customers are "investing large amounts of money right now in the hopes of having profitable products in the future", but "[i]f Illumina got a reputation for either jacking up price when someone's successful or harming them in some other way, that would have implications for the willingness of customers to continue to do business with Illumina as they're doing now." (RX6000 (Carlton Trial Dep. at 33–34).)

866.3 If Illumina "did start raising rivals' costs, its reputation for doing that would become known, and Illumina's customers now, as well as future customers, would be reluctant to do business with Illumina because they wouldn't want to make these huge investments if they think that Illumina is going to take advantage of them in the future". (RX6000 (Carlton Trial Dep. at 33–34).)

866.4 "Illumina's strategy of having customers who are inventing new uses for Illumina's NGS technology would be upended, and that would have negative consequences for Illumina and its profits." (RX6000 (Carlton Trial Dep. at 33–34).)

867. Illumina thus has an incentive to continue to innovate and reduce sequencing costs for customers who will discover clinical applications for Illumina's sequencers, not just in clinical oncology but in other areas as well. (RX3864 (Carlton Expert Report) ¶ 79).)

3. **No Offsetting Advantage to Foreclosure.**

868. [redacted]

869. As Mr. deSouza explained, "the testing business for many, many years will not have a profit, will lose business, and that's very typical in clinical testing businesses". (deSouza (Illumina) Tr. at 2386.)

870. [redacted]

871. It is only "after 2026" that Illumina gets "its first dollar of profit" from GRAIL, but "it's not until 2030 where we've recouped the losses we've made in GRAIL", and therefore, "about the next decade even, we really need and are really fueled by the profit pools associated with our sequencers." (deSouza (Illumina) Tr. 2383.)

872. Thus, the uncontested evidence shows that Illumina's NGS business will remain its core business and will account for most of its profits for "many, many years". (deSouza (Illumina) Tr. at 2386.)

4. No Evidence Illumina Can Target a Foreclosure Strategy to Avoid Upstream Losses.

873. Although Illumina may have an understanding of the types of applications a customer is developing or marketing, in many cases it does not know what specific tests are in its customers' development pipeline. (Berry (Illumina) Tr. 849–53.)

873.1 For example, many of the MCED tests Complaint Counsel claims are in development are unknown to Illumina even today—much less their specific attributes that would allow Illumina to predict with confidence whether any test will be a close substitute to Galleri, or, instead, a market-expanding complement, foreclosure of which would cause no material diversion to Galleri but would result in substantial lost upstream sales. (RX6000 (Carlton Trial Dep. at 24, 26–27).)

874. [redacted]

875. Moreover, Illumina's instruments and consumables are multi-use products that can be and often are used by Illumina customers for a variety of sequencing applications. (*Supra* PFF ¶¶ 6–11.)

875.1 For example, Illumina markets its NovaSeq instrument and consumables, which are used by GRAIL for developing its early-detection tests, as "[f]lexibl[e] for virtually any genome, sequencing method, and scale of project". (RX2557 (Illumina) at 1.)

876. If, hypothetically, Illumina were to cut off service to an instrument as Complaint Counsel speculates, that action could impact a range of tests (commercialized and in development), resulting in upstream losses without offsetting downstream gains from diversion. (RX6000 (Carlton Trial Dep. at 26–27).)

877. Moreover, even if Illumina hypothetically could target a particular MCED test in development, news of Illumina's opportunistic conduct would reduce future sales to a range of applications, not just the targeted MCED test. (RX3864 (Carlton Rep.) ¶ 49); RX6000 (Carlton Trial Dep.) at 33–34).)

877.1 As Mr. deSouza observed:

> "[I]f we were to raise prices on GRAIL, we would lose a lot more in sequencing business from the other markets. . . . The rest of our customers, whether they are in cancer detection or cancer at all, would look at what we did here and would be concerned about us doing that in the other markets that they're in. And so there would be a knock-on effect where we would lose sequencing business across our 7000 other customers who would be concerned about that kind of behavior. And so we wouldn't do that because, again, the much bigger part of our business is the sequencer business. So losses there really are much more impactful."
>
> (deSouza (Illumina) Tr. 2381–82.)

878. Complaint Counsel's foreclosure theory does not take these real-world constraints into account. (*Supra* PFF ¶¶ 847–877.)

G. NGS Costs Will be a Very Small Part of Future MCED Test Revenues and Profits.

1. Relevance of Upstream Input Costs Relative to Downstream Margins and Revenues.

879. One factor influencing the ability to successfully carry out a RRC strategy—and thus the incentive to engage in it—is the importance of an upstream firm's input costs to downstream rivals. (RX3864 (Carlton Expert Report) ¶ 62).

880. There is "a very close relationship" between the prices a vertically integrated firm charges a rival for an input and the firm's incentive and ability to foreclose because "that ability is going to depend on the importance of cost in the downstream firm's reliance on" the upstream firm. (RX6000 (Carlton Trial Dep.) at 28.)

881. If input costs are a small number today, or expected to be a small number in during the relevant time frame for the vertical analysis, it means the upstream firm will not have the ability to impose a large cost increase on a downstream rival because the cost increase would have to be substantial. (RX6000 (Carlton Trial Dep.) at 28–29.)

882. If downstream margins are big enough, an input price increase could be absorbed by reducing downstream rivals' profits, rather than raising downstream price. This would result in no harm to consumers and, also, no diversion to GRAIL. (RX3864 (Carlton Expert Report) ¶ 62, n.181.)

883. In a case where input costs are, or are projected to be, a small share of downstream revenues, that alone shows that "there are real constraints on the ability" of the upstream firm to foreclose downstream rivals. (RX6000 (Carlton Trial Dep. at 28–30).)

2. Evidence of projected Illumina NGS costs relative to projected downstream MCED revenues and margins.

884. The only evidence in the record on NGS costs as a percentage of future downstream MCED revenues and margins shows that NGS costs will be a very small percentage of MCED test revenues and margins in the future. (RX6000 (Carlton Trial Dep.) at 30–31.)

885. The only evidence of projected future NGS costs in the record is from Illumina's [redacted]

a. Illumina.

886. [redacted]

887. [redacted]

888. [redacted]

888.1 [redacted]

888.2 [redacted]

888.3 Illumina's technological improvements are expected to drive significant reductions in Illumina input costs for GRAIL and any rival, and, even in the absence of those improvements, GRAIL and any rival, can improve the sequencing efficiency of

their tests, reducing their reliance on Illumina inputs. (RX3864 (Carlton Expert Report) ¶ 70.)

888.4 The projected improvements in the number of reads per flow cell reduce the cost per test of Illumina's inputs for test developers and underpin Illumina's commitment to reduce sequencing costs per gigabase made available to customers by at least 43 percent by 2025. (PX7104 (Aravanis (Illumina) Dep. at 218–19);

888.5

888.6

888.7

888.8 As Dr. Aravanis explained: "it became clear to the leadership at GRAIL and the R&D team that we were quickly approaching a point where sequencing cost would be immaterial. In fact, things like the blood tube would end up being more expensive . . . ." (PX7104 (Aravanis (Illumina) Dep. at 205–06);

889.

890.

891. At the time of the Illumina deal model, GRAIL paid Illumina approximately $135 per test, which the deal model projects will fall by ~80% in 2023 when V3 of Galleri is released, which will allow GRAIL to run five times as many samples per flow cell. (PX4091 (GRAIL) at -016).

892. Illumina's supply contracts commit to reducing the price of Illumina's instruments and consumables by 43% by 2025. (PX0064 (Illumina) §5.d.)

893. [redacted]

894. [redacted]

895. [redacted]

896. [redacted]

896.1 [redacted]

897. [redacted]

898. [redacted]

899. To the extent that any GRAIL rival emerges and has similar costs and test prices to GRAIL and [redacted], Illumina would need to raise price to GRAIL's rivals by a large amount for a RRC strategy to have significant impact. (RX3864 (Carlton Expert Report) ¶ 65.)

900. To the extent that any GRAIL rival has comparable sequencing efficiency to GRAIL, Illumina input costs are not likely to be an important determinant of downstream profits. (RX3864 (Carlton Expert Report) ¶ 70.)

901. [redacted]

902. Consistent with the documentary evidence from the internal business documents, Dr. Aravanis explained that sequencing costs will continue to "decrease over time" as a percentage of Galleri's costs due to GRAIL "innovations that will lead to a decreased usage of sequencing over time," which by itself, would reduce the amount of cost associated with sequencing per test," and in addition, "Illumina is also going to lower the cost of sequencing over time," as will "other sequencing providers", which will "compound the overall reduction in sequencing costs as a fraction of the test." (Aravanis (Illumina) Tr. 1924–25.)

903. Mr. deSouza similarly explained that, "today sequencing costs represent about 10 percent of the price of Galleri" and "[b]y 2025, we project that sequencing costs will be less than 4 percent of the price of GRAIL's Galleri test." (deSouza (Illumina) Tr. 2388.)

b. [redacted]

904. [redacted]

904.1 [redacted]

904.2 [redacted]

904.3 [redacted]

904.4 [redacted]

904.5 [redacted]

904.6 [redacted]

904.7 [redacted]

904.8 [redacted]

904.9 [redacted]

904.10 [redacted]

904.11 [redacted]

905. [redacted]

906. [redacted]

907. [redacted]

908. [redacted]

3. **Significance Of Illumina's Declining NGS Costs And NGS Innovation.**

909. [redacted]

910. [redacted]

910.1 For example, Mr. deSouza explained that Illumina "will continue to see profit pool[s] in the sequencer business, but we believe that because of the competition in this business, the profit pools will -- the operating margin will decline over the years. And so . . . because of the competition, we expect a decline in the profit pools associated with sequencers, although it will continue to be a profitable business." (deSouza (Illumina) Tr. 2385.)

910.2 Mr. deSouza further noted, that NGS competition is "reflected in Illumina's pricing plans and strategy" in that it "shows up in our expectation of the price of sequencing in the market, and it's continuing to decline" and "in our expectations of sort of the margin evolution in the industry". (deSouza (Illumina) Tr. 2331–32.)

910.3 Similarly, Dr. Febbo explained, "[w]e have dropped the cost of sequencing through our investment in R&D, through our kind of dogged focus on making sequencing more affordable, because in research what we saw is a term we called elasticity, where the less expensive the sequencing was, the more sequencing was performed, so that it made sense to continue to drop the cost." (Febbo (Illumina) Tr. 4329–30.)

911. Even if a large increase in input prices were permitted and Illumina had no reputational concerns, a downstream rival could completely absorb an increase of even, say, 100 percent, without materially affecting their margins. (RX3864 (Carlton Expert Report) ¶ 75, n.208.)

911.1 For example, even in the absence of the contractual prohibition on raising costs, if Illumina doubled the prices it charges for its instruments, consumables, and services, and the GRAIL rival left its test price unchanged, the rival would see only a nominal decline in profits. (RX3864 (Carlton Expert Report) ¶ 75, n.208.)

911.2 [redacted]

911.3 It is inconceivable that even this very large increase in Illumina's input price would have a large effect on the competitiveness of downstream firms. (RX3864 (Carlton Expert Report) ¶ 75, n.208.)

912. [redacted]

4. **Dr. Scott Morton failed to analyze Illumina NGS input costs relative to downstream prices and margins.**

913. [redacted]

914. [redacted]

915. Dr. Scott Morton fails to address whether she believes the large price increases that would be required to raise rivals' costs meaningfully are likely or indicate the magnitude of such increases or assess the negative impacts that such increases could have on Illumina's business. (RX3864 (Carlton Expert Report) ¶ 65.)

H. Complaint Counsel's Theory Ignores Intensifying Upstream Competition.

1. Relevance Of Current And Future Upstream Competition.

916. A necessary condition for a vertical merger to harm competition in the relevant market is a limited ability by the merged firm's rivals to switch their purchases of the related product to sufficiently close substitutes. (RX3871 (Willig Expert Report) ¶ 41, n.59; RX3701 (Vertical Merger Guidelines) at 4-5).)

916.1 Complaint Counsel was required to establish that Illumina has a monopoly over platforms viable for MCED development, and that there will be no viable substitutes (from the standpoint of MCED test developers that could potentially compete with Galleri) for Illumina's NGS platforms during the relevant time period. (RX3871 (Willig Expert Report) ¶ 41.)

917. The presence of current and future NGS competitors is significant "in two ways. First, if you could substitute to another company, then that constrains what Illumina can do. . . [Second], [e]ven if you can't switch immediately, the fact that these technologies might be available . . . in the future, you really want to be focusing on not what is possible today, but you . . . really want to be talking about what are the alternatives in the future when the MCED market, to . . . when the MCED industry develops more fully." (RX6000 (Carlton Trial Dep. at 36).)

918. The presence of upstream NGS alternatives on the market and in development, and the constraints they impose on Illumina, must be taken into account in any economic

analysis of Illumina's post-merger incentives and ability to substantially foreclose MCED competition. (*Supra* at [●].)

2. **The Evidence Shows Current And Future Upstream Competition.**

919. There are today alternatives to Illumina as a provider of NGS sequencing products and services. (*Supra* PFF ¶¶ 777–779.)

919.1 Suppliers such as Thermo Fisher ONT and Singular are available on the market today and can be used for MCED test development. (*Supra* PFF ¶¶ 778–779.)

920. A number of other companies are poised to offer NGS sequencing products and services in the near term. (*Supra* PFF ¶¶ 782–787.)

921. There is substantial evidence that MCED test developers will have many commercially viable NGS options within the next few years, before most, if not all, MCED tests in development are ready for commercial launch. (*Supra* PFF ¶¶ 782–787.)

922. For example, BGI will enter the U.S. market not long after Illumina's patents that underlie the injunction against BGI's entry expire in 2023, and it is undisputed that BGI's technology is comparable to Illumina's NGS systems in terms of throughput, accuracy, turnaround time and cost. (*Supra* PFF ¶¶ 777.)

923. There are hundreds of millions of dollars being invested to fund these NGS innovators, many of which are specifically targeting the screening (and other oncology) segments and have disclosed roadmaps that project commercial launch within the next few years—and in the case of Singular, late last year. (*Supra* PFF ¶¶ 782–787; Velarde (Singular) Tr. 4515–16 ("we're going to be commercially launching at the end of [2021] and shipping systems in the first half of next year").)

923.1 A number of these innovators are led by former Illumina executives, who are extremely knowledgeable about the industry and what it takes to succeed. Moreover, in speculating that all of these well-funded, serious players will simply fail, Complaint Counsel adopts an entirely inconsistent position on the evidence. (*Supra* PFF ¶¶ 782–787, 789.)

924. Numerous Illumina executives testified about their expectations for NGS competition, including with the expiration of key patents in 2023, and how that dynamic impacts Illumina's strategies. (PFF ¶¶ 924.1–924.3.)

924.1 [redacted]

924.2 Ms. Berry testified that "there are numerous competitors already participating in the genomics space with instruments and consumables similar to ours", and "we anticipate that that competitive environment will . . . only become more intensive over time." (Berry (Illumina) Tr. 813).

924.3 Dr. Aravanis similarly testified that there will be "many new sequencing platforms, so a tremendous intensification of competition" and "there will be even more platforms in the coming years." (Aravanis (Illumina) Tr. 1866).

924.4 Dr. Aravanis identified a number of sequencing platforms on the market today and in development that would be viable platforms for an MCED test such as Galleri. (Aravanis (Illumina) Tr. 1848–63.)

925. Furthermore, it is well accepted that sequencing technology is becoming substantially cheaper every year – it is thus substantially likely that all existing and future sequencing options will improve and become cheaper over time. (PFF ¶ 22.)

926. Complaint Counsel infers from the mere fact of "excitement" and "investment" in downstream test development that it is "highly likely that there are going to be several successful cancer tests" in the alleged MCED market. (RX3852 (Scott Morton Dep. at 112).) There is no basis to accept that MCED test developers will be successful and compete with Galleri, yet the upstream alternatives to Illumina in development are too uncertain to predict their likely success. (RX6000 (Carlton Trial Dep. at 37–38).)

926.1 As Dr. Carlton put it:

> "[A]ll I can do is point out the asymmetry in [the government's expert's] analysis. None of the MCED products that [Dr. Scott Morton is] talking about exist. . . . All of them are in the future and some, as I read the evidence, far in the future. In contrast, when she's evaluating NGS alternatives to Illumina, even though those seem from the evidence to be more readily available and likely, she dismisses them. So I agree it's hard to make predictions, very hard, as to who will be an actual competitor in the future. That's true both for MCED and NGS, and she takes a very asymmetric stance in which she assumes that the MCED products are going to come into existence, but the NGS alternatives to Illumina are not."

(RX6000 (Carlton Trial Dep. at 37–38).)

3. The FTC's Theory Is Belied by Investment Activity Before and Since the Announcement of the GRAIL Merger Agreement

927. Numerous companies have been investing in the liquid biopsy early cancer detection space, since both before and after Illumina announced its agreement to acquire GRAIL. (RX3871 (Willig Expert Report) ¶¶ 50–51.)

928. Shortly after the merger was announced, analysts predicted that the deal would accelerate investment and innovation in the space, with one observing that "the recent acquisition of GRAIL by ILMN has catalyzed the excitement in the market to new highs – even ahead of our

prior expectations", and "there is an expectation that more companies will increasingly pursue liquid biopsy screening as ILMN's acquisition of pre-revenue GRAIL has 'validated' the liquid biopsy early detection theses." (RX1096 (SVBLeerink) at 3.)

929. Investment has in fact poured into cancer test development since the time Illumina announced its agreement to acquired GRAIL. (RX3871 (Willig Expert Report) ¶ 50.)

929.1 For example, approximately one month after Illumina announced its agreement to acquire GRAIL, Exact entered into an agreement acquire Thrive for over $2 billion, and completed the acquisition approximately four months after Illumina announced its agreement to acquire GRAIL. (RX3196 (Exact) at 1.)

929.2 [redacted]

929.3 As another example, in December 2020, Singlera obtained $150 million in financing, which it planned to utilize "mainly to expand the company's early cancer screening product research and development pipeline and focus on promoting product registration and commercialization, as well as expanding prospective studies into pan-cancer early screening." (RX3633 (PR Newswire) at 1); {([redacted]

930. As Mr. deSouza observed, in addition to Thrive's acquisition of Exact, other liquid biopsy companies experienced large rounds of investments after Illumina announced its agreement to acquire GRAIL, including a significant increase in investment in the early cancer detection space. (deSouza (Illumina) Tr. 2392–93.)

930.1 This "was very consistent with what we saw in the noninvasive prenatal testing space [another downstream testing space, discussed below, that Illumina entered through a vertical merger and that is now thriving competitively] when we entered in 2013 – investment increased there too." (deSouza (Illumina) Tr. 2392–93.)

931. Firms raised capital at least partly directed towards the development of NGS-based cancer screening tests after Illumina announced in September 2020 that it would be acquiring GRAIL, signaling an expectation that Illumina's alleged ability and incentive to increase prices or diminish its service to firms that are developing NGS-based cancer screening tests will be constrained. (RX3871 (Willig Expert Report) ¶ 51, n.104) (citing (RX3015 (GlobeNewswire) at 1); (RX3075 (BusinessWire) at 1); (RX3170 (PR Newswire) at 1).)

932. The timing and amount of investment activity in cancer test development is directly contrary to Complaint Counsel's speculation that the merger will disincentivize investment in NGS cancer screening.

933. The timing and amount of investment activity in cancer test development is directly contrary is also inconsistent with Complaint Counsel's claim that test developers are "captive" to Illumina and locked in to Illumina platforms with no options even if Illumina disadvantaged their tests. According to Complaint Counsel, customers are and will remain locked into Illumina's NGS platform, they would have no choice but to pay the higher price demanded by Illumina. This concept is commonly referred to by economists as the "hold-up problem." (RX3871 (Willig Expert Report) ¶ 52.)

934. However, the substantial investment in liquid biopsy cancer test development on Illumina's platform, by itself, refutes the notion that MCED test developers are indefinitely locked into Illumina's platform or that they fear Illumina can impede their test development efforts. (RX6004 (Katz Trial Dep. at 43–44).)

935. That is because it would be economically irrational for firms to make such large investments if they truly anticipated that they would have no options or opportunities to switch by the time their tests are commercialized and earning profits. (RX6004 (Katz Trial Dep. at 43–44).)

936. Otherwise, these firms would be knowingly subjecting themselves to opportunistic hold-up, since (if Complaint Counsel's long-term monopoly theory had merit) Illumina would have both an incentive and ability to extract all their returns, even *without* the GRAIL merger. (RX6004 (Katz Trial Dep. at 43–44); RX3871 (Willig Expert Report) ¶¶ 52–54.)

936.1 [redacted]

936.1.1 [redacted]

936.2 [redacted]

936.3 [redacted]

936.4 [redacted]

937. The investment activity by these Illumina customers are a compelling market signal—one backed by large sums of money, not just words—that NGS-based test developers expect that competition will powerfully constrain Illumina's ability and incentive to increase prices or diminish its service to firms that are developing NGS-based cancer screening tests. (RX3871 (Willig Expert Report) ¶ 57.)

938. Even after Illumina announced in September 2020 that it would be acquiring GRAIL, the marketplace continued to show strong signals that Illumina's alleged ability and incentive to increase prices or diminish its service to firms that are developing NGS-based cancer screening tests will be constrained, as evidenced by the investment activity occurring after the announcement. (RX3871 (Willig Expert Report) ¶ 58.)

938.1 [redacted]

938.2 In other words, even without the merger, economic logic states that, if (contrary to fact) Illumina were a long-term monopolist of NGS platforms for MCED development, it would extract all the profits by raising prices of NGS inputs once the downstream developers have "invented the relevant technology." (RX6004 (Katz Trial Dep. at 43–44); RX3852 (Scott Morton Dep. at 171).)

939. The substantial investment in NGS-based tests indicates that Complaint Counsel's long-term monopoly theory is unfounded. (RX6004 (Katz Trial Dep. at 43–44); (RX3871 (Willig Expert Report) ¶ 50.))

940. Dr. Scott Morton has attempted to explain away this economic evidence by claiming that, absent the merger, the market would develop into a "bilateral monopoly" where there would be only one or a few winning MCED test developers, who would then have sufficient bargaining leverage to "divid[e] the rent" with Illumina, but this claim is without support. (RX3852 (Scott Morton Dep. at 172 ("So while Illumina would like to expand the

market and have more sales and the tests can't [be] delivered without Illumina's product, likewise, tests can't be delivered without the MCED developers' product. So it's a case of a bilateral monopoly. If you think just the MCED developer and Illumina, and that means that they will be dividing the rent. . . . [The] [p]rospect of those rents is what is inducing investment in entry is what I'm trying to say.").)

940.1 Dr. Scott Morton can cite no evidence to support her speculation that the market is likely to develop that way, or that the purported MCED developers she identifies have such expectations and justify their investments on this basis.

940.2 Further, she separately contended that a bilateral monopoly is unlikely, arguing that, in the but-for world without the merger, Illumina would ensure that there are multiple MCED makers in the market to "lower the profits of the MCED makers and deliver more of it to Illumina." (RX3852 (Scott Morton Dep. at 290).)

940.3 [redacted]

941. The only economically logical explanation for the sunk investments is that test developers—just as Illumina does—anticipate intensifying upstream competition and being able to switch to alternative platforms if Illumina attempted any opportunistic hold up. (Katz Trial Dep. at 42:17–46:14.)

941.1 As Dr. Katz explained, "if Complaint Counsel's view of the world and Dr. Scott Morton's view of the world is correct, it would be a risk of really substantial holdup, and these firms just shouldn't be making these investments. But in fact they have made these investments in the past, and . . . those investments are ongoing, and that indicates that in fact they don't believe that they're going to be held up like this. And so . . . their conduct then is inconsistent with Complaint Counsel and Dr. Scott Morton's theory of harm and . . . view of how the economic world operates." (Katz Trial Dep. at 42:17–46:14.)

941.2 Dr. Katz further explained, that inference holds true both for investment activity before Illumina announced its agreement to acquire GRAIL and afterward – it is "really the same economic logic in either case." (RX6004 (Katz Trial Dep. at 46:15–47:3).)

942. Professor Scott Morton also claims that investment could have been even greater but for the Transaction, but she offers no evidence of that but-for world, and as Dr. Katz explained, in all events, "the point still remains that there's substantial investment . . . both before and after the merger, and the existence of that investment is inconsistent with . . . these companies fearing the holdup that would be implied by Dr. Scott Morton's view of the world." (Katz Trial Dep. at 47:21–48:14.)

4. **The FTC's Theory Is Belied by the Purchase Price Illumina Paid For GRAIL**

943. [redacted]

944. [redacted]

945. [redacted]

5. **No Evidence That Switching Costs Would Prevent Switching in Response to sn Attempted Foreclosure Strategy.**

946. Complaint Counsel's contention that switching an MCED test to any alternative NGS platform would be too costly and time-consuming for a test developer to profitably undertake is without empirical support. (*Supra* PFF ¶¶ 790–796.)

947. Complaint Counsel also did no analysis of the size of one-time switching costs relative to the benefits of switching in a hypothetical scenario where Illumina has attempted to foreclose an MCED rival. (RX3871 (Willig Expert Report) ¶¶ 46, 48.)

947.1 As Dr. Carlton explained, given the magnitude of the potential downstream market—which, if it reaches its full potential, could be in the tens of billions of dollars—it cannot be assumed that even high switching costs would deter test developers from migrating to a rival platform in response to a hypothetical foreclosure strategy, since whether switching costs impede customer defections depends on not only the magnitude of switching costs but also the benefits from switching. (RX6000 (Carlton Trial Dep. at 38–39).)

948. [redacted] (*Supra* PFF ¶ 791.)

948.1 [redacted]

948.2 Yet neither Complaint Counsel nor Dr. Scott Morton offered any empirical assessment of the *incremental* cost of switching from an Illumina platform to a third-party platform as compared to the switching cost that would be incurred by a test

developer that seeks to upgrade to Illumina's next generation system. (RX3871 (Willig Expert Report) ¶¶ 46, 48.)

949. Numerous fact witnesses, as well as Dr. Cote, the only technical expert to opine on the matter, testified as to the feasibility of switching, and some Illumina customers have done so for their oncology tests. [redacted]; Febbo (Illumina) Tr. 4325–26; Aravanis (Illumina) Tr. 1865.)

I. Illumina's Prior Vertical Integrations Belie Complaint Counsel's Theory

1. NIPT

950. Illumina's most analogous past vertical acquisition—that of Verinata Health, Inc. ("Verinata")—shows that when Illumina vertically integrates, it continues to support downstream rivals, Illumina helps grow the space, and innovation and competition flourish to the benefit of patients. (RX3864 (Carlton Expert Report) ¶ 162.)

951. In February 2013, Illumina acquired Verinata which had developed an NIPT test for fetal chromosomal abnormalities using a blood sample. (RX3337 (Illumina).)

952. At the time it was acquired, Verinata used Illumina sequencers to develop and perform its test, so the acquisition was vertical, just as Illumina's acquisition of GRAIL is vertical. [redacted] RX3864 (Carlton Expert Report) ¶ 164.)

953. Verinata was one of four companies offering an NIPT test in the U.S.: Sequenom was first to market in 2011, followed by Verinata, Ariosa, and Natera. (PX7089 (Naclerio (Illumina) Dep. at 42); RX3864 (Carlton Expert Report) ¶ 164.)

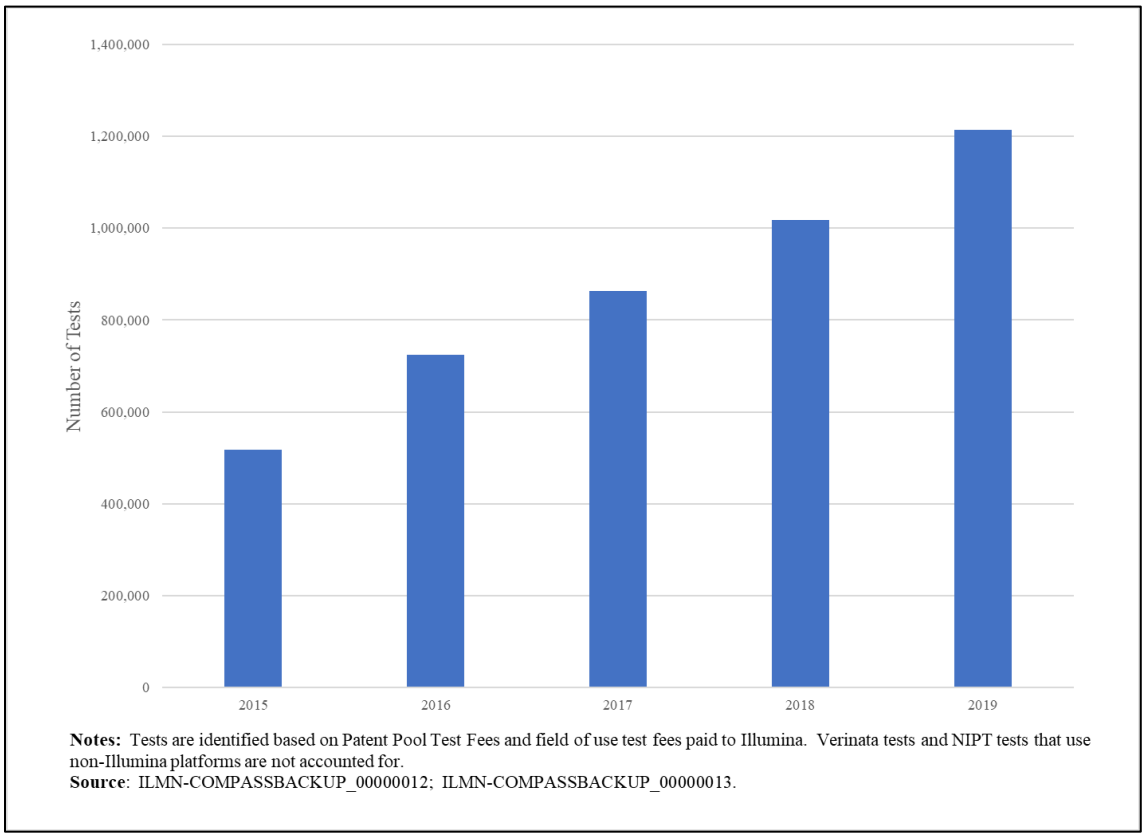
954. As in this case, Illumina was the upstream supplier of sequencing inputs to each of these companies. (RX3864 (Carlton Expert Report) ¶ 164.)

955. Illumina was the upstream supplier of sequencing inputs to each of these companies, and, under Dr. Scott Morton's theory in the present case, would have had incentives to raise the costs of rivals to Verinata in order to restrict NIPT competition downstream and divert sales to Verifi. However, a simple examination of the data contradicts such a theory. In contrast to what would be expected had Illumina attempted to raise rivals' costs following its acquisition of Verinata, NIPT output has expanded, Verinata's share has decreased, and Natera's share has increased. (RX3864 (Carlton Expert Report) ¶ 164.)

956. Since the acquisition, the number of NIPT tests conducted by Verinata's rivals on Illumina's platforms in the U.S. has increased in each year for which there is available data. (RX3864 (Carlton Expert Report) ¶ 165.)

956.1 Figure 7 below shows that total NIPT tests conducted by Verinata's rivals on Illumina's sequencing platform have more than doubled between 2015 and 2019.

Figure 7: NIPT Tests Conducted in the U.S. by Verinata Rivals on Illumina's NGS Platform



Notes: Tests are identified based on Patent Pool Test Fees and field of use test fees paid to Illumina. Verinata tests and NIPT tests that use non-Illumina platforms are not accounted for.
Source: ILMN-COMPASSBACKUP_00000012; ILMN-COMPASSBACKUP_00000013.

(RX3864 (Carlton Expert Report), ¶ 165, Figure 3).

957. In addition to the fact that total output has expanded, Verinata's share of U.S. NIPT sales has decreased. (RX3864 (Carlton Expert Report) ¶ 164.)

958. Natera, in contrast, became the market leader after Illumina acquired Verinata, with a consistently high share. (RX3864 (Carlton Expert Report) ¶ 166.)

959. Figure 8 below shows the respective shares of U.S. NIPT providers who use the Illumina NGS platform:

Figure 8: Shares of NIPT Tests Conducted in the U.S. on Illumina's NGS Platform

(RX3864 (Carlton Expert Report) Figure 4).

960. Natera has remained the market leader throughout with a consistently high share, while Verinata's share has fallen more than 50%. (RX3864 (Carlton Expert Report) ¶ 162.)

961.

962. Furthermore, there has been a steady stream of new entry and substantial investment into NIPT testing in the U.S. since the Verinata acquisition, indicating that downstream competitors to Verinata are not concerned that Illumina will act anticompetitively, and that Illumina has not in fact acted anticompetitively, in the NIPT space. (RX3589 (Illumina); RX3864 (Carlton Expert Report) ¶ 162.)

962.1 Figure 9 below shows the NIPT providers in the U.S. that use Illumina's platform and which providers entered or exited each year (other providers, using other sequencing platforms, may exist). (RX3864 (Carlton Expert Report) ¶ 167.)

Figure 9: Number of NIPT Providers Using Illumina's Sequencing Platform

(RX3864 (Carlton Expert Report) at Figure 5.)

962.2 Since Illumina acquired Verinata, seven new NIPT providers have launched using the Illumina platform and two have exited (with one customer switching to a non-Illumina platform and one customer being acquired). (RX3864 (Carlton Expert Report) ¶ 167.)

962.3 Overall, the number of NIPT providers on Illumina's platform has more than doubled. Such entry (and the significant investment required to pull it off) is inconsistent with the claim that Illumina has disadvantaged downstream rivals, or that the fear that it would do so has impeded innovation in the NIPT space. (RX3864 (Carlton Expert Report) ¶ 167.)

963. A number of fact witnesses confirmed what the economic evidence alone starkly demonstrates: that Illumina's entry into NIPT via a vertical transaction was decidedly procompetitive:

963.1 Dr. Aravanis testified that since the Verinata acquisition, "the cost of noninvasive prenatal testing has decreased by over 90 percent"; "[t]he number of tests performed has gone up by a factor of a hundred"; "[t]he number of companies offering noninvasive prenatal tests has . . . increased significantly"; and "[t]he coverage of patients for noninvasive prenatal testing has increased by at least 100 million women." (Aravanis (Illumina) Tr. 1933–34.)

963.2 Mr. deSouza testified that in NIPT, Illumina makes "eight times as much revenue selling sequencers and consumables to companies that compete with our test than we do from our own test", which is one of multiple factors driving Illumina's incentives to support all NIPT customers, including its downstream rivals, as the economic evidence demonstrates Illumina has done. (deSouza (Illumina) Tr. 2393–94, 2378–79.)

963.3 Mr. deSouza further noted that investment in NIPT increased substantially after Illumina entered that market through the Verinata acquisition. (deSouza (Illumina) Tr. 2392–93.)

963.4 Invitae, an Illumina NIPT (and oncology) customer, has attested through a sworn declaration from its CEO that Illumina has been a "partner[]" and a "leader[]" in achieving payor coverage for NIPT tests for a broader set of patients, which has benefitted all market participants in that space. (RX1100 (George (Invitae) Decl.¶ 10).)

2. **Therapy Selection**

964. Illumina has also vertically integrated into therapy selection through organic development of its therapy selection test, TSO500. (Leite (Illumina/InterVenn) Tr. 2075–76; Aravanis (Illumina) Tr. 1952.)

964.1 [redacted] As a result, therapy selection test developers compete with each other to convince pharmaceutical companies—who market the therapies—to partner with them for a particular therapy. (Goswami (Illumina) Tr. 3184.)

965. Although Complaint Counsel claims Illumina's vertical integration into therapy selection resulted in Illumina raising rivals' costs and harming competition, the evidence is to the contrary. (PFF ¶¶ 966–973.)

966. Today, Illumina has collaboration agreements in place with Roche, PGDx and numerous other test developers in therapy selection pursuant to which these formidable competitors to Illumina are developing in-vitro diagnostic ("IVD") tests that will compete with Illumina's own TSO500 therapy selection test. (Goswami (Illumina) Tr. 3202–03.)

967. Illumina provides customer support to its therapy selection rivals and there is increasing investment and innovation in this space in recent years. (Goswami (Illumina) Tr. 3202–03.)

967.1 As Dr. Joydeep Goswami, who oversees Illumina's IVD agreements, testified, "test developers are investing in developing IVD kits under the terms of [Illumina's] IVD agreements", and far from diminishing innovation in kitted oncology tests, Illumina's IVD program "spurs innovation" because test developers can "just tap into a network of instruments that is available globally that can run the assay that they're providing, so it's a huge saving of investment on their side and time on their side and resources on their side." (Goswami (Illumina) Tr. 3217–18.)

968. From a strategic perspective, Illumina views more test developers using its IVD platform (which it refers to as "IVD partners") as a positive regardless of whether those partners compete with Illumina's TSO500 test. (Goswami (Illumina) Tr. 3201–02, 3217–18.)

968.1 As Mr. deSouza testified, "[e]ven in markets where we have our own test, so noninvasive prenatal testing, for example, or cancer therapy selection, . . . or genetic disease diagnosis – even in those markets, we make significantly more money by selling sequencers and consumables to companies that compete with our test than we do from our own test." (deSouza (Illumina) Tr. 2378–79).

968.2 As Mr. deSouza testified, "[i]n cancer therapy selection, we make 14 times as much money selling sequencers and consumables to companies that compete with our test than we do from our own test", and that dynamic drives Illumina's strategy which "has been consistently to open up a market and then enable lots of players to serve that market, each with their own different approach, because we believe that maximizes the opportunity in the market." (deSouza (Illumina) Tr. 2379–80).

969. [redacted]

969.1 [redacted]

969.2 [redacted]

969.3 However, Illumina has in fact signed IVD agreements in therapy selection—including with TMB rights—with anyone that has pursued such rights, and test developers are investing in developing and seeking regulatory approvals for tests under those agreements. (Leite (Illumina/InterVenn) Tr. 2141–3219; Goswami (Illumina) Tr. 3218.)

970. Complaint Counsel places particular weight on Illumina's interactions with PGDx; however, the evidence refutes Complaint Counsel's claims concerning these interactions:

970.1 [redacted]

970.2 [redacted]

970.3 [redacted]

970.4 [redacted]

970.5 [redacted]

971. Complaint Counsel also places particular weight on Illumina's interactions with Roche; however, the evidence refutes Complaint Counsel's claims concerning these interactions as well:

971.1 [redacted]

971.2 [redacted]

971.3 [redacted]

971.3.1 [redacted]

971.4 [redacted]

971.5 [redacted]

971.6 [redacted]

972. Dr. Scott Morton concluded that the events in the therapy selection space show that Illumina has engaged in foreclosure where it is vertically integrated, yet she does no actual analysis of the therapy selection space and the competitive impact of Illumina's vertical integration into therapy selection. RX6000 (Carlton Trial Dep. at 201).)

972.1 As Dr. Carlton explained, if one were to do an actual economic analysis of the impact of Illumina's vertical integration into therapy selection, "the relevant question" would have to be "what's the but-for world", meaning, "was there a benefit from Illumina being vertically integrated into therapy selection and selling to Roche compared to not having Illumina in therapy selection". (RX6000 (Carlton Trial Dep. at 201).)

972.2 Yet that is not what Dr. Scott Morton did by a long shot—"she pays no attention to the benefit of vertical integration of Illumina into therapy selection." (RX6000 (Carlton Trial Dep. at 201).)

972.3 [redacted]

972.4 [redacted]

972.5 [redacted]

972.6 [redacted]

972.7 [redacted]

972.8 [redacted]

973. In licensing IVD rights in a field of use and charging fees for those rights, Illumina has simply followed market practice in the industry.

973.1 [redacted]

973.2 [redacted]

3. **Population Genomics and Helix**

974. Several of the exhibits offered by Complaint Counsel relate to Illumina's spinout of Helix, a population genomics company that competes with providers such as Ancestry.com. (*See, e.g.,* PX7077 (Chahine (Helio) Dep.); [redacted]; PX 2420–2421 (Illumina); [redacted]

975. Yet, Illumina's conduct in connection with the formation and spinout of Helix was recognized, even by Helix's competitors, as "fantastic". (PX7077 (Chahine (Helio) Dep. at 57) ("Illumina was -- you know, was and continues to be a fantastic partner to -- to Ancestry.").)

976. [redacted]

977. [redacted]

977.1 [redacted]

977.2 [redacted]

977.3 [redacted]

977.4 [redacted]

978. [redacted]

J. GRAIL Formation and Spinout

979. Any special pricing and other benefits Illumina may have provided to GRAIL in its original supply agreement when GRAIL was formed and controlled by Illumina are irrelevant to evaluating the effects of the Transaction on competition.

980. At the time of GRAIL's formation, the objective of creating a cancer screening test was a moonshot concept, and Illumina believed that without deep discounting, it would be impossible for GRAIL to develop a cancer screening test:

> 980.1 As Dr. Aravanis, who helped form GRAIL, testified, the industry reaction to the formation of GRAIL was "very, very skeptical" because the conventional wisdom was that, while GRAIL's mission was "noble", "it will be very hard, may not work at a scientific level and, even if it did, will take a very long time and be very challenging from a cost and clinical development" perspective. (Aravanis (Illumina) Tr. 1873–74.)
>
> > 980.1.1 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 276).)

980.2 As Illumina's contemporaneous internal documents noted, at the time, Illumina believed that "no customer has the ability to implement a pan-cancer screening test responsibly and economically anytime in the next 5 years"; therefore, to accelerate the growth of the segment, Illumina "felt an imperative to organize an entity" focused on that moon-shot mission. (RX1088 (Illumina) at 7; (Flatley (Illumina) Dep. at 111–12).)

980.3 In other words, there was no one else pursuing the goal that Illumina set GRAIL on a path to pursue, and any special pricing at that time was not designed to put rivals at a disadvantage—there were no rivals, and the goal was in fact to *accelerate* the development of the cancer screening space by years, which would benefit others who might seek to invest in the space. (Aravanis (Illumina) Tr. 1873–74; RX1088 (Illumina) at 7.))

980.4 As Dr. Naclerio put it: "Illumina really went out of its way 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 . . . we designed it specifically so that they wouldn't be competing with any other near-term products of any of the other companies we've talked about. It was really meant to be bringing in something that might someday 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 275–76).)

981. These considerations from the time of GRAIL's formation no longer exist for many reasons, including because (i) the cost of sequencing has come down since 2016 (*supra* PFF ¶ 22); and (ii) Illumina's assumptions about the volume of sequencing required to develop a cancer screening test were significantly higher than what is actually required (Flatley (Illumina) Dep. at 118–20).)

VII. COMPLAINT COUNSEL ERRS IN DISMISSING THE OPEN OFFER

A. Background on Supply Agreements and Illumina's Commercial Operations Organization

982. 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 5.)

982.1 Illumina's customers include genomic research centers, academic institutions, government laboratories and hospitals. (PX0061 (Illumina) at 5.) They also include pharmaceutical companies, biotechnology companies, commercial molecular diagnostic laboratories and consumer genomics companies. (PX0061 (Illumina) at 5.)

983. Illumina's commercial operations organization for the Americas region is responsible for customer-facing activities to drive both revenue and customer success for all of Illumina's current and potential customers in the region. (Berry (Illumina) Tr. 833–34.) The team consists of about 700 people and is led by Nicole Berry, Illumina's Senior Vice President and General Manager of the Americas Commercial Team. (Berry (Illumina) Tr. 833.)

983.1 The sales organization is responsible for ongoing customer interactions in the normal course of business, including prospecting and acquiring new customers, managing existing customers and providing post-sale support. (Berry (Illumina) Tr. 834.)

983.2 The commercial team is highly focused on driving customer success because a key part of Illumina's value proposition and ability to drive growth is customer satisfaction. (Berry (Illumina) Tr. 835.)

983.3 Illumina validates customer satisfaction through surveys and other methods for collecting feedback. (Berry (Illumina) Tr. 837–38.)

983.4 Since acquiring GRAIL, Illumina has not changed the way its commercial team (or Illumina as a whole) will interact with customers because Illumina's goal of unlocking the power of the genome can be accomplished only by making it easy for customers to access Illumina's technology. (Berry (Illumina) Tr. 838–39.)

983.5 After the transaction, Illumina's core commercial sales team will not have any role in selling GRAIL's products. (Berry (Illumina) Tr. 839.)

984. Existing Illumina customers that do not have a pricing agreement begin the process of purchasing a sequencing instrument or core consumable by initiating a conversation with their Illumina sales representative. (Berry (Illumina) Tr. 840.)

984.1 The representative ensures that the customer purchases the Illumina products best fit for their needs and then provides a price quote. (Berry (Illumina) Tr. 840–41.) The customer then executes a purchase order consistent with the price quote. (Berry (Illumina) Tr. 841.)

985. Sometimes, Illumina's customers desire terms and conditions that are sufficiently different from Illumina's standard terms and conditions to warrant negotiating a customer-specific supply agreement. (Berry (Illumina) Tr. 841–42.)

985.1 In these circumstances, Illumina is very open to negotiating terms and conditions. (Berry (Illumina) Tr. 842.) These negotiations often culminate in a separate supply agreement that captures all of the terms and conditions for that customer that differ from the standard terms and conditions. (Berry (Illumina) Tr. 842.)

985.2 Illumina enters all of its supply agreements with the intent to follow them and has never entered a supply agreement planning to not follow it. (Berry (Illumina) Tr. 843.)

986. Customer testimony supports the view that Illumina abides by the terms of its supply agreements. (*See* Fiedler (FMI) Tr. 4471.) For example, Dr. Fiedler, COO of FMI, testified that since entering into a supply agreement with Illumina in 2013:

986.1 Illumina has acted in good faith with respect to its obligations under the supply agreement. (Fiedler (FMI) Tr. 4471.)

986.2 FMI is a satisfied customer. (Fiedler (FMI) Tr. 4471.)

986.3 Illumina has never monkeyed with supply. (Fiedler (FMI) Tr. 4471.)

986.4 Illumina has never interrupted supply because it claimed FMI had infringed on Illumina's intellectual property. (Fiedler (FMI) Tr. 4471.)

986.5 Illumina has never reneged on a commitment it made to FMI. (Fiedler (FMI) Tr. 4471.)

986.6 Dr. Fiedler trusts Illumina to abide by its commitments. (Fiedler (FMI) Tr. 4471.)

B. The Development of the Open Offer

987. [redacted]

987.1 [redacted]

987.2 [redacted]

[redacted]

988. [redacted]

988.1 [redacted]

988.2 [redacted]

988.3 [redacted]

988.4 [redacted]

988.5 [redacted]

989. [redacted]

989.1 [redacted]

989.2 [redacted]

989.3 [redacted]

989.4 [redacted]

989.5 [redacted]

989.6 [redacted]

989.7 [redacted]

989.8 [redacted]

989.9 [redacted]

989.10 [redacted]

989.11 [redacted]

989.12 [redacted]

989.13 [redacted]

989.14 [redacted]

989.15 [redacted]

989.16 [redacted]

989.17 [redacted]

989.18 [redacted]

989.19 [redacted]

989.20 [redacted]

989.21 [redacted]

989.22 [redacted]

989.23 [redacted]

990. Based on the customer outreach discussions and on what was learned in negotiations with customers [redacted], Illumina developed a standardized supply contract to offer to all of its U.S. oncology customers (the Open Offer.) (Berry (Illumina) Tr. 857, [redacted]

991. On March 30, 2021, Illumina made the Open Offer available on its website for all for-profit U.S. oncology customers who purchase NGS products for developing and/or commercializing oncology tests. (deSouza (Illumina) Tr. 2338–39, 2401–02; Berry (Illumina) Tr. 688–89, 709–10; RX4003 (Illumina) at 1; PX0064 (Illumina); PX0087 (Illumina); PX0088 (Illumina); PX0089 (Illumina).)

992. While Illumina does not believe that the transaction will have any anticompetitive effect, it made the Open Offer available to address concerns raised by both Complaint Counsel and certain customers that the Illumina-GRAIL transaction would allow Illumina to foreclose GRAIL rivals. (*See* Berry (Illumina) Tr. 688–89, 709–10; deSouza (Illumina) Tr. 2338–39, 2401; Goswami (Illumina) Tr. 3207; PX0064 (Illumina) at 1; PX7122 (Eisenberg (LabCorp) Dep. at 107–08).)

993. Illumina has made the terms of the Open Offer available to any existing or new customer of Illumina that is a For-Profit Entity and purchases NGS products for developing and/or commercializing oncology tests. (PX0064 (Illumina) at 3.)

> 993.1 A For-Profit Entity means 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 3.) A For-Profit Entity excludes governments, government agencies, hospitals, research institutes,

academic institutions, nonprofits and Illumina Affiliates (including GRAIL.) (PX0064 (Illumina) at 3.)

993.2 The Supplied Products are "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 4–5.)

993.3 Sequencing Consumables are "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 4.)

993.4 The fact that the Open Offer is available to more than just MCED test developers makes the Open Offer more effective in protecting competition and limiting Illumina's ability to foreclose GRAIL rivals. (RX6002 (Guerin-Calvert Trial Dep. at 26–27).) It also makes the Open Offer easier to implement because it applies to a class of customers who are readily identifiable. (RX6002 (Guerin-Calvert Trial Dep. at 27).)

994. For customers who signed the Open Offer before the close of the acquisition, the terms took effect on August 18, 2021, when the Illumina-GRAIL transaction closed; for others, the terms will take effect immediately upon signing. (PX0064 (Illumina) at 1.)

994.1 The Open Offer is irrevocable, binding and governed by New York law. (PX0064 (Illumina) at 1, 11) ("[t]his irrevocable offer is binding on Illumina.")

994.2 Illumina executives have made several public commitments to the Open Offer, including under oath at this trial, thus giving reasons even beyond New York contract law for Illumina to adhere to the Open Offer. (*See, e.g.*, Berry (Illumina) Tr. 688–89, 709–10; deSouza (Illumina) Tr. 2338–39, 2401; Goswami (Illumina) Tr. 3207.)

995. Existing or new customers of Illumina may sign the Open Offer at any time until 6 years after the close of Illumina's acquisition of GRAIL, which is August 18, 2027. (Berry (Illumina) Tr. 861–62.) Customers thus do not need to make a rapid decision whether to sign the Open Offer. (Nolan (Freenome) Tr. 2785.)

996. On September 8, 2021, Illumina amended the Open Offer to offer additional benefits and protections to customers. (RX3935 (Illumina) at 1; deSouza (Illumina) Tr. at 2405–06.) This addendum provided customers with greater protections in terms of pricing, access to products and services, and enforcement, as outlined below. (RX3935 (Illumina) at 2–3; deSouza (Illumina) Tr. at 2407–09.)

997. The Open Offer effectively addresses the concerns that FTC has raised that Illumina will have the incentive and ability to anticompetitively disadvantage GRAIL's rivals now that Illumina has re-acquired the remainder of GRAIL that it did not already own. (RX6002 (Guerin-Calvert Trial Dep. at 20–21).)

997.1 The Open Offer provides the economically necessary terms to prevent the alleged anticompetitive harms from the transaction in both the short term and the long term. (RX6002 (Guerin-Calvert Trial Dep. at 21–22).)

997.2 The Open Offer addresses the specific concerns about market power and related conduct raised by Complaint Counsel, its expert, Dr. Fiona Scott Morton, and certain Illumina customers. (RX6002 (Guerin-Calvert Trial Dep. at 22).)

997.3 The Open Offer provides a comprehensive set of protections for its customers for all aspects of conduct and competition including access, pricing and quality of products and services, and rights to develop distributable IVD kits on Illumina's FDA-regulated systems. (RX6002 (Guerin-Calvert Trial Dep. at 22, 94–95).)

997.4 The Open Offer provides for effective monitoring and enforceability mechanisms. (RX6002 (Guerin-Calvert Trial Dep. at 22).)

998. Additionally, extrinsic aspects of the Open Offer will increase its enforceability. (RX6002 (Guerin-Calvert Trial Dep. at 22–23).)

998.1 All of the provisions of the Open Offer are publicly known and publicly available because the Open Offer is posted on Illumina's website. (deSouza (Illumina) Tr. 2338–39, 2401; RX4003 (Illumina) at 1; PX0064 (Illumina); PX0087 (Illumina); PX0088 (Illumina); PX0089 (Illumina); PX7076 (Berry (Illumina) Dep. at 275–76.)

998.2 The letter accompanying the publicly available Open Offer indicates that the Open Offer's purpose is to allay concerns and constraining conduct that could competitively disadvantage rivals. (PX0064 (Illumina) at 1.)

998.3 The Open Offer was made available to a large number of customers—all of Illumina's for-profit clinical oncology customers in the United States. (RX4003 (Illumina's Oncology Contract Terms Website) at 1.)

998.4 All of these extrinsic aspects of the Open Offer—its publicness, its strong preamble and its availability to a large number of customers—exert external pressure to make the Open Offer more effective. (RX6002 (Guerin-Calvert Trial Dep. at 22–23).)

998.5 [redacted]

999. The Open Offer also represents an improvement for customers over the premerger status quo. (RX6002 (Guerin-Calvert Trial Dep. at 37, 52–53, 57); *see also* RX6000 (Carlton Trial Dep. at 48).)

C. Illumina's Binding Commitments in the Open Offer

1. Term, Unilateral Termination, and Purchase Orders

1000. The Open Offer provides for a 12–year supply contract for the Supplied Products. (Berry (Illumina) Tr. 690–91, 861, 874–75; Conroy (Exact/Thrive) Tr. 1725; deSouza (Illumina) Tr. 2402; PX0064 (Illumina) at 5.)

1000.1 The Open Offer "shall be effective for twelve (12) years from the closing of the Transaction, regardless of the date either party signs this Supply Agreement." (PX0064 (Illumina) at 5.) Therefore, the Open Offer and Addendum are in effect until August 18, 2033 for any customer that signs these agreements. (PX0064 (Illumina) at 5; PX0378 (Illumina) at 3.)

1000.2 The Open Offer's 12–year term is longer than the typical agreements between Illumina and its customers in the pre-merger world, though some customers entered into long-term agreements with Illumina in the past. (Berry (Illumina) Tr. 690–91.) The 12–year term was chosen to assure customers that Illumina was absolutely invested in maintaining longstanding relationships with these customers as a technology provider. (Berry (Illumina) Tr. 862.)

1000.3 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); *see, e.g.*, RX3082 (*In re Broadcom Ltd.* Decision and Order) at 11; RX3664 (*In re Sycamore Partners II* Analysis of Agreement Containing Consent Order) at 4).)

1000.4 The 12–year term is an improvement on the status quo, in which many customers do not have supply agreements and those that do have supply agreements have shorter term agreements. (RX6002 (Guerin-Calvert Trial Dep. at 29); PX7085 (Harada (Exact/Thrive) Dep. at 94).)

1000.5 The 12–year term provides customers with long-term protections and gives customers certainty about price, quality, access and conduct for the next 12 years. (RX6002 (Guerin-Calvert Trial Dep. at 28–29).)

1000.6 The 12–year term allows customers to plan for the long term more effectively. (Fiedler (FMI) Tr. 4485; RX6002 (Guerin-Calvert Trial Dep. at 28–29).)

1000.7 The 12–year term is long enough to address the foreclosure concerns and alleged competitive harms from the merger. (RX6002 (Guerin-Calvert Trial Dep. at 29–30).)

1001. Under the Open Offer, Customers can terminate the supply relationship with Illumina at any time and without specifying any reason. (Berry (Illumina) Tr. 862–63; deSouza (Illumina) Tr. 2402; PX0064 (Illumina) at 10.)

1001.1 The Open Offer requires that "Customer has a unilateral right to terminate its supply relationship with Illumina at any time and for any reason without termination liability upon ninety (90) days' prior written notice to Illumina, provided, however, that Customer shall honor all invoices, which invoices shall be issued upon shipment, for Supplied Products ordered under a Purchase Order that was accepted by Illumina prior to the termination date." (PX0064 (Illumina) at 10.)

1001.2 The 90–day notice period provision is intended to be as "customer friendly as possible". (Berry (Illumina) Tr. 863.)

1002. The Open Offer requires that "Illumina cannot terminate this Supply Agreement for convenience during the Term." (PX0064 (Illumina) at 10; *see also* (Berry (Illumina) Tr. 863; deSouza (Illumina) Tr. 2402.)

1002.1 This asymmetry in the termination provisions addresses the alleged anticompetitive effects and foreclosure concerns related to the merger: Because Illumina cannot exit the agreement, its conduct will be restrained over the entire 12–year term, but the customer enjoys the benefit of being able to switch to alternative suppliers for sequencing instruments or consumables at any time. (RX6002 (Guerin-Calvert Trial Dep. at 30–31).)

1003. 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 9; *see also* Berry (Illumina) Tr. 864–65.)

1003.1 The Offer also requires that "[w]ritten purchase orders ("Purchase Orders") submitted in accordance with this Supply Agreement, Illumina's Terms and Conditions, or an operative supply agreement may be rejected by Illumina only if Illumina does not have sufficient supply of the applicable Supplied Product to fulfill the order or if the Purchase Order is not in accordance with standard lead times for the applicable Supplied Product." (PX0064 (Illumina) at 9.)

2. **Uninterrupted and Timely Access to Services**

1004. Under the Open Offer, Illumina must provide customers with the same access to services that GRAIL or any other For-Profit Entity has access to, at the same prices. [redacted]; Berry (Illumina) Tr. 865–66; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.)

1004.1 The Open Offer requires that "Customer shall have access to the same product services and support services for purchase relating to the Supplied Products to which GRAIL or any For-Profit Entity has access, or which Customer had access before the Transaction." (PX0064 (Illumina) at 6.)

1004.2 The Open Offer also requires 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 transaction, at the Customer's option." (RX3935 (Illumina) at 2.)

1004.3 Illumina customers can purchase 3 different levels of service contracts—gold, silver or bronze. (Berry (Illumina) Tr. 681–82.) The different levels of service contracts vary based on considerations like response times and the number of instances that Illumina technicians will proactively service the customer's instruments. (Berry (Illumina) Tr. 682.)

1004.4 To comply with the access-to-services provision and ensure consistency in treatment, Illumina keeps track of services that customers order using service contract SKUs. (Berry (Illumina) Tr. 866–68.) When a customer purchases a service SKU, there is an agreement that describes aspects of the service relationship such as turnaround time and the number of preventative maintenances to which a customer is entitled. (Berry (Illumina) Tr. 867.) As with products, there is a standard list of orderable service SKUs, each associated with a standard U.S. list price. (Berry (Illumina) Tr. 868–69.)

1004.5 Illumina has a long and sophisticated onboarding process when it hires new service technicians, which helps ensure that service quality among technicians is consistent. (Berry (Illumina) Tr. 869–70.) It also ensures consistent service among technicians by tracking individual cases to determine whether there is any gap in performance between service engineers. (Berry (Illumina) Tr. 870–71.)

1004.6 In order to ensure that it satisfies its obligations when a customer orders a service SKU, Illumina measures its customer support using key performance indicators (KPIs). (Berry (Illumina) Tr. 867–68.) These KPIs include metrics like instrument downtime or the length of time between when a case is opened to when it is closed. (Berry (Illumina) Tr. 867–68.) These KPIs enable Illumina to compare how it performs in terms of service and support across individual customers or groups of customers. (Berry (Illumina) Tr. 868.)

1004.7 If Illumina delayed or refused to service an instrument that belonged to a customer who had signed the Open Offer, Illumina would be in breach of the agreement. (Berry (Illumina) Tr. 871.) Illumina would also be in breach if it provided worse services to a customer laboratory who did not also purchase Galleri. (Berry (Illumina) Tr. 879.) Moreover, refusing to service instruments would hurt Illumina's overall business because customers would stop buying kits from Illumina. (Berry (Illumina) Tr. 871–72.)

1004.8 The Open Offer's equal services commitment places customers who have never had a supply agreement and who purchase subject to a purchase order in a superior position to the pre-merger status quo by removing the uncertainty of accessing Illumina's servicing resources. (RX6002 (Guerin-Calvert Trial Dep. at 57).)

1004.9 The equal services commitment ensures that customers will receive at least the same level of service that they did before the merger. (RX6002 (Guerin-Calvert Trial Dep. at 58).)

1004.10 The commitment also addresses the concern that customers could suffer a delay in support services because the commitment requires that customers receive the same quality and type of services. (RX6002 (Guerin-Calvert Trial Dep. at 58–59).)

3. Uninterrupted and Timely Access to the Latest Sequencing Instruments and Core Consumables

1005. The Open Offer provides customers the same access to purchase sequencing instruments and core consumables to which GRAIL has access. (Rabinowitz (Natera) Tr. 421; Berry (Illumina) Tr. 878–79; deSouza (Illumina) Tr. 2434–35, 2437–38; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.)

1005.1 The Open Offer requires that "Customer shall have access to the Supplied Products for purchase that GRAIL . . . has access, within 5 days of when GRAIL . . . is offered such access (if not earlier) for purchase." (RX3935 (Illumina) at 2.)

1005.2 For example, if Illumina created a "NovaSeq-3", there is no way that it could provide it to GRAIL (meaningfully) ahead of potential competitors because everyone would receive access to it within 5 days of GRAIL receiving access. (deSouza (Illumina) Tr. 2448.)

1005.3 Illumina will ensure that GRAIL does not get access to a sequencing instrument or core consumable before other customers get access because Illumina is designing its organization to prevent leaks between Illumina and GRAIL. (Berry (Illumina) Tr. 878.)

1005.4 Further, customers can ensure that Illumina adheres to this provision because 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. (RX3935 (Illumina) at 2.)

1005.5 The Open Offer specifically requires that "Illumina shall publish, on the "Oncology Contract Terms" website, (i) the Supplied Products, by SKU, that GRAIL is purchasing; (ii) the service plans, by SKU, that GRAIL is purchasing; and (iii) the pricing grid for both products and services under which GRAIL is purchasing Supplied Products and services. To the extent necessary, Illumina shall update this website within 5 days of entry of any purchase order for Supplied Products or any service contract relating to the Supplied Products by GRAIL." (RX3935 (Illumina) at 2; RX4003 (Illumina) at 1; RX3960 (Illumina).)

1006. In addition to requiring equivalent access to products for purchase, the Open Offer requires Illumina to provide customers, within 5 days, with the same information that GRAIL receives about final product specifications of any sequencing instruments or core consumables. (RX3935 (Illumina) at 2.)

1006.1 Specifically, the Open Offer requires that "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." (RX3935 (Illumina) at 2.)

1007. The Open Offer also provides customers the same access to purchase sequencing instruments and core consumables to which any For-Profit Entity has access. (Rabinowitz (Natera) Tr. 421; Berry (Illumina) Tr. 878–79; deSouza (Illumina) Tr. 2434–35, 2437–38; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.)

1007.1 The Open Offer requires that "Customer shall have access to the Supplied Products for purchase that . . . any For-Profit Entity has access, within 5 days of when . . . such For-Profit Entity . . . is offered such access (if not earlier) for purchase." (RX3935 (Illumina) at 2.)

1007.2 For example, if Illumina made improvements to a sequencing instrument (such as to its speed, throughput, or cost), there is no way for Illumina to limit these improvements to one particular user or customer. (deSouza (Illumina) Tr. 2446–47.)

1007.3 Illumina can ensure that it complies with this provision because when Illumina launches a product, the product is made available to all customers at once. (Berry (Illumina) Tr. 877.) In other words, there is no selective restriction that Illumina can apply to a product in a full commercial launch. (Berry (Illumina) Tr. 877.)

1007.4 Also, the Open Offer contains a table showing the specific orderable SKUs that comprise the Supplied Products under the Open Offer. (Berry (Illumina) Tr. 878; PX0064 (Illumina) at 15–27.) If Illumina launched a new product, it would update this table accordingly. (Berry (Illumina) Tr. 878.)

1008. Customers who sign the Open Offer must also receive equitable access to purchase any Pre-Release Sequencing Products. (Rabinowitz (Natera) Tr. 421; Berry (Illumina) Tr. 702; PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.)

1008.1 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, as applicable, is offered such access (if not earlier), and for the same categories of uses . . . ." (PX0064 (Illumina) at 6; RX3935 (Illumina) at 2.)

1008.2 Pre-Release Sequencing Product "means Illumina sequencing hardware or Sequencing Consumables 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 4.)

1008.3 The pre-release access provision was intended to assure customers that there would be no advantage conferred on GRAIL or another commercial player in the oncology testing space. (Berry (Illumina) Tr. 880.)

1008.4 Because providing Pre-Release Sequencing Products to customers is quite unusual, it will be very manageable for Illumina to ensure that it complies with this provision. (Berry (Illumina) Tr. 880.)

1008.5 Illumina will provide access to Pre-Release Sequencing Products as quickly as practically possible. (Berry (Illumina) Tr. 703–06.)

1008.6 Considering the length of time that it takes to develop a test on a sequencing platform, 5 days is "a very inconsequential amount of time" for a developer making a test. (*see* Aravanis (Illumina) Tr. 1930; *see also* Berry (Illumina) Tr. 702–03; [redacted]; PX7100 (Chudova (Guardant) Dep. at 75–79); [redacted]

1009. These provisions requiring equitable access to Supplied Products and Pre-Release Sequencing Products very directly address the foreclosure concerns that have been raised. (RX6002 (Guerin-Calvert Trial Dep. at 59–60).)

1009.1 The provisions directly address the concern that products could be withheld so as to disadvantage GRAIL rivals because they require providing equivalent access within a very short time frame. (RX6002 (Guerin-Calvert Trial Dep. at 60).)

1009.2 The provisions directly guarantee that MCED test developers will have notice of technical enhancements and technical upgrades because they require upgraded technologies to be made available to customers on a timely basis. (RX6002 (Guerin-Calvert Trial Dep. at 60–61).)

1009.3 The provisions guarantee that MCED test developers will have a consistent quality of supply because, as newer products of higher quality are released, they must be made available to customers. (RX6002 (Guerin-Calvert Trial Dep. at 61).)

1009.4 The provisions specifically address the concern that Illumina could disadvantage GRAIL rivals by delaying access to products because they level the playing field for customers and prevent individual customers from lagging behind in terms of what products are available to them. (RX6002 (Guerin-Calvert Trial Dep. at 61–62).)

1010. In addition to the provisions requiring equivalent access to products, the Open Offer requires Illumina to enter into development agreements, on customers' requests, to design or modify Illumina's products to optimize interoperability with customers' tests. (Berry (Illumina) Tr. 881; PX0064 (Illumina) at 6.)

1010.1 The Open Offer requires that "Illumina shall enter into, upon Customer request, a separate development agreement with Customer on commercially reasonable terms, relating to the design or modification of any Supplied Product, in a manner that optimizes interoperability with Customer's tests, including, without limitation, capabilities, performance, speed, efficiency, cost, convenience, accuracy, specificity, precision, ease of use and user experience." (PX0064 (Illumina) at 6.)

1010.2 The development agreement term was added based on a specific request from FMI to incorporate this type of clause into an agreement. (Berry (Illumina) Tr. 881.)

1010.3 Illumina typically has not entered into such separate development agreements with any customers. (Berry (Illumina) Tr. 844, 882.) [redacted]

1010.4 Customers typically develop their tests without Illumina's developmental assistance or any optimization support with respect to their sequencing instruments or consumables. (Berry (Illumina) Tr. 844–47; *see, e.g.*, [redacted]

1010.5 Customers do not typically come to Illumina for advice on the development of their assays. (Berry (Illumina) Tr. 844.)

1010.6 Illumina typically does not provide support in the development or commercialization of its customers' products. (Berry (Illumina) Tr. 846–47.)

1010.7 Customers typically purchase Illumina equipment and reagents "off the shelf" and do not commission Illumina to make custom sequencing equipment. (Berry (Illumina) Tr. 845; [redacted]

1010.7.1 Customers *prefer* to develop their tests on their own because they do not want to share key algorithms or analyses used to analyze the genetic data—*i.e.*, the "secret sauce"—with Illumina. (*See* Berry, Tr. 679.)

1010.7.2 [redacted]

1010.8 Although Illumina does not typically enter into separate development agreements, the development agreement provision was added to the Open Offer to accommodate, in a customer-friendly way, the possible categories of requests that Illumina might be likely to receive over a 12–year period. (Berry (Illumina) Tr. 882.)

1010.9 The development agreement term works with the term on access to Pre-Release Sequencing Products to prevent Illumina from materially advantaging GRAIL or materially disadvantaging GRAIL's rivals because customers will be notified of any Pre-

Release Sequencing Products and can pursue a development agreement to optimize interoperability of their tests with those products. (RX6002 (Guerin-Calvert Trial Dep. at 70–71).)

1010.10 The development agreement term not only prevents Illumina from disadvantaging GRAIL rivals, but also requires Illumina to act in a particular way to support rivals developing their own competitive products. (RX6002 (Guerin-Calvert Trial Dep. at 68).)

1011. The Open Offer forbids Illumina (under the "no-obsolescence term") from discontinuing products that any oncology customer has purchased in the prior year. (Rabinowitz (Natera) Tr. 421–22; Berry (Illumina) Tr. 883; PX0064 (Illumina) at 6; [redacted]

1011.1 The Open Offer requires that "Illumina shall not discontinue any Supplied Product so long as Customer continues to purchase that Supplied Product. Illumina may discontinue a Supplied Product that Customer has not purchased in more than one year." (PX0064 (Illumina) at 6.)

1011.2 Illumina will ensure compliance with this provision through comprehensive recordkeeping, which makes it easy for Illumina to know which products customers are buying. (Berry (Illumina) Tr. 885.)

1011.3 Before the Open Offer, there were no prohibitions on Illumina discontinuing any of its sequencing products. (Berry (Illumina) Tr. 883–84.)

1011.4 The no-obsolescence term was introduced into the Open Offer to ensure that customers did not feel they were being forced to transition to a new product, even if that new product was better and cheaper. (Berry (Illumina) Tr. 884–85.) The term commits Illumina to supporting older platforms even if Illumina develops newer platforms. [redacted]

1011.5 The addition of the no-obsolescence term represents a significant change and improvement from the premerger status quo. (RX6002 (Guerin-Calvert Trial Dep. at 71–73).)

1011.6 Dr. Sean George, the Chief Executive Officer of Invitae, testified that Illumina's commitment to provide long-term continued access to Illumina products is reassuring for customers. (PX7081 (George (Invitae) Dep. at 59).) [redacted]

1011.7 The no-obsolescence provision of the Open Offer adequately addresses the concern often raised by economists in vertical transactions that an upstream firm could advantage its affiliate by simply no longer providing a product. (RX6002 (Guerin-Calvert Trial Dep. at 71–72).)

1011.8 The no-obsolescence term interacts with the pricing terms of the Open Offer by ensuring that customers are "certainly no worse off than in the current world" and are actually better off because they are assured continued availability of products and no price increases. (RX6002 (Guerin-Calvert Trial Dep. at 72–73).)

1012. Under the Open Offer, if Illumina experiences a supply shortage, it must allocate the existing supply in an equitable manner among its customers, including GRAIL and other affiliates. (Berry (Illumina) Tr. 885–86; PX0064 (Illumina) at 9.)

1012.1 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) based on expiring lots, and which shall not favor Affiliates over other customers." (PX0064 (Illumina) at 9.)

1012.2 Illumina can ensure compliance with this provision because it tracks its supply when there is a supply shortage. (Berry (Illumina) Tr. 886–87.)

1012.3 Under the Open Offer, Illumina cannot disadvantage a customer in the event of a short supply relative to GRAIL. (Berry (Illumina) Tr. 886.)

1012.4 Under the premerger status quo, Illumina would be able to allocate short supply to GRAIL or to customers who were willing to pay the highest price. (RX6002 (Guerin-Calvert Trial Dep. at 76–77).) The short supply provision of the Open Offer addresses this concern by providing for an equitable manner of allocation. (RX6002 (Guerin-Calvert Trial Dep. at 77).) It also ensures that customers with the greatest need—those whose lots are expiring the earliest—will receive allocations of short supply first. (RX6002 (Guerin-Calvert Trial Dep. at 77).)

4. **Pricing**

1013. The Open Offer requires Illumina to treat customers equitably relative to GRAIL and any other For-Profit Entity in terms of pricing. (deSouza (Illumina) Tr. 2402–03; PX0064 (Illumina) at 7–8.)

1014. Customers may select one of two options for each product purchased under the Open Offer: 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 7.)

1014.1 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 4.)

1014.2 Universal Pricing under the Open Offer refers to "the Volume-Based Net Price for [any given] Supplied Product in accordance with Appendix 1" of the Open Offer. (PX0064 (Illumina) at 7.) "The universal pricing grid in Appendix 1 contains all currently available universal pricing, including list prices and volume-based discount tiers, for currently available Supplied Products, and [the Open Offer requires that] such Appendix 1 will be updated as additional pricing tiers or new Supplied Products (including new versions of existing Supplied Products) become available." (PX0064 (Illumina) at 7.) "Volume-Based Net Price" 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." (PX0064 (Illumina) at 5.)

1014.3 The Open Offer requires that "Customer will be able to select one of two options for each Supplied Product that they purchase under this Supply Agreement. 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." (PX0064 (Illumina) at 7.)

1014.4 Customers can pick Grandfathered Pricing for some products and Universal Pricing for others. (Berry (Illumina) Tr. at 892.)

1014.5 The ability to choose on a product-by-product basis presents benefits over the premerger status quo because it gives customers added flexibility on pricing. (RX6002 (Guerin-Calvert Trial Dep. at 37).)

1015. If a customer chooses Grandfathered Pricing, it will have the option of maintaining the pricing it had prior to the Illumina-GRAIL transaction for the duration of the 12–year term of the Open Offer. (Berry (Illumina) Tr. 889–90, 902–03; PX0064 (Illumina) at 7.)

1015.1 The Open Offer requires that Illumina allow any "Customer" to "continue to receive the benefit of any Grandfathered Pricing for the Term." (PX0064 (Illumina) at 7.)

1015.2 The Grandfathered Pricing option was included because some customers may have the view that their current (pre-merger) pricing was more favorable for a particular product than the price offered in the Open Offer. (Berry (Illumina) Tr. 889–90.) Grandfathered Pricing was included to give customers the option to keep their legacy price. (Berry (Illumina) Tr. 889–90.)

1015.3 If an existing customer uses Grandfathered Pricing, their prices would not increase during the 12–year term, and, provided that they continue to purchase those products, the products themselves would not be discontinued. (Berry (Illumina) Tr. 902–03.) The Open Offer requires this because of the interaction between the Grandfathered Pricing provision and the no-obsolescence provision: 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 6–7.)

1016. If a customer chooses Universal Pricing, that customer will receive the standard pricing in Illumina's Universal Pricing grid. (PX0064 (Illumina) at 7.)

1016.1 The Open Offer requires that "[i]f Customer is not receiving Grandfathered Pricing for a Supplied Product, Customer shall receive the Volume-Based Net Price for that Supplied Product in accordance with Appendix 1." (PX0064 (Illumina) at 7.) Appendix 1 provides the Universal Pricing grid. (PX0064 (Illumina) at 12–27.)

1016.2 [redacted]

1016.3 The purpose of providing the Universal Pricing grid was to be transparent around the prices that GRAIL and other For-Profit Entities pay for the products and services it buys from Illumina. (deSouza (Illumina) Tr. 2403.)

1016.4 The Universal Pricing grid will be helpful to customers as they create multiyear business plans because they will know what prices they can access. (deSouza (Illumina) Tr. 2403, 2439.)

1016.5 GRAIL receives pricing under the Universal Pricing grid. (Berry (Illumina) Tr. 894.)

1016.6 Under Universal Pricing, customers will know with certainty that they are not disadvantaged relative to GRAIL or anyone else in the market. (deSouza (Illumina) Tr. 2403–04.)

1016.7 The Universal Pricing grid directly addresses the concern that Illumina could treat GRAIL more favorably in terms of pricing. (RX6002 (Guerin-Calvert Trial Dep. at 37–38).)

1017. If a customer chooses Universal Pricing, it will receive "most favored nation" (MFN) pricing protections relative to Equivalent customers. (Berry (Illumina) Tr. 893; PX0064 (Illumina) at 7–8.)

1017.1 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 after the date the Transaction closes, for that Supplied Product." (PX0064 (Illumina) at 8.)

1017.2 "'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 3; *see also* Berry (Illumina) Tr. 895.)

1017.3 Illumina has a contract with Deloitte Consulting to operationalize the terms of the Open Offer, including the MFN terms. (*See* Berry (Illumina) Tr. 800, 894–96.) Deloitte will help guarantee Illumina's compliance with the Open Offer provisions and ensure that Illumina is prompt in upholding its obligations under the agreement. (Berry (Illumina) Tr. 896–97; PX7135 (Rock Dep. at 90).) As part of its work with Illumina, Deloitte will help translate the definition of Equivalent customer to processes that allow Illumina to operationalize the Equivalent customer MFN term. (Berry (Illumina) Tr. 896–97.)

1017.4 If an Equivalent customer received a discretionary discount higher than the discounts in Appendix 1 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. (Berry (Illumina) Tr. 893–94; RX6002 (Guerin-Calvert Trial Dep. at 38–39).)

1018. If a customer chooses Universal Pricing, it will also receive MFN pricing protections relative to GRAIL. (Berry (Illumina) Tr. 893; PX0064 (Illumina) at 7–8.)

1018.1 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), after the date the Transaction closes, for that Supplied Product." (PX0064 (Illumina) at 8.)

1018.2 Now that GRAIL is part of Illumina, it receives pricing under the Universal Pricing grid. (Berry (Illumina) Tr. 894.)

1018.3 If GRAIL receives a discretionary discount higher than the discounts in Appendix 1 for equivalent volume or a price that is lower than the prices in Appendix 1 for an equivalent volume, then Illumina would be obliged to reduce the price for other customers at the same volume levels to match the prices under such discretionary discount. (Berry (Illumina) Tr. 893–94; RX6002 (Guerin-Calvert Trial Dep. at 38–39).)

1018.4 Customers testified that the MFN pricing protections would help mitigate their concerns with the merger if properly executed. (*See* PX7077 (Chahine (Helio) Dep. at 114–15); PX7081 (George (Invitae) Dep. at 60–61).) [redacted]

[redacted]

1019. 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 8.)

1019.1 Specifically, the Open Offer requires 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 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." (PX0064 (Illumina) at 8.)

1020. The Grandfathered Pricing, Universal Pricing and MFN provisions represent an improvement over the status quo for customers. (RX6002 (Guerin-Calvert Trial Dep. at 42–44); *see also* [redacted]

1020.1 For nearly all MCED test customers, the Open Offer Universal Pricing is superior than their current agreement prices. (RX6002 (Guerin-Calvert Trial Dep. at 43–44).) Additionally, for any current pricing that is superior under a current agreement, customers may opt for Grandfathered Pricing. (Berry (Illumina) Tr. 889–90; PX0064 (Illumina) at 7.) [redacted]

1020.2 An MCED test developer that currently pays list price would also receive benefits under these provisions. (RX6002 (Guerin-Calvert Trial Dep. at 44).) They have the benefit of being able to opt into a supply agreement subject to the Universal Pricing grid, should they so choose. (RX6002 (Guerin-Calvert Trial Dep. at 44).) They also have the benefit of receiving improved discounts as their volume grows. (RX6002 (Guerin-Calvert Trial Dep. at 44).)

1020.3 [redacted]

1021. In addition to the Grandfathered Pricing, Universal Pricing and MFN terms, the Open Offer commits Illumina not to increase prices beyond inflation for the 12–year term of the agreement (*i.e.*, the "no-price-increase provision".) (Rabinowitz (Natera) Tr. 433; Berry

(Illumina) Tr. 899; Conroy (Exact/Thrive) Tr. 1731; PX0064 (Illumina) at 7; [redacted]

1021.1 The Open Offer requires 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 7.)

1021.2 This commitment not to raise prices applies to all potential GRAIL rivals, including any companies that may develop products similar to the Galleri test. (Aravanis (Illumina) Tr. 1926.)

1021.3 The no-price-increase provision applies whether a customer is using Grandfathered Pricing or Universal Pricing. (Berry (Illumina) Tr. 902; PX0064 (Illumina) at 7.)

1021.4 The no-price-increase provision was not available to customers prior to the Open Offer. (Berry (Illumina) Tr. 900–01.)

1021.5 [redacted]

1021.6 [redacted]

1022. 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.)

1022.1 The Open Offer requires 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 (based on the PPI) Volume-Based Net Price per gigabase of sequencing shall not be higher as compared to the Volume-Based Net Price of the prior version of the Supplied Product, provided that the new version of the Supplied Product does not result in any material improvements in performance or capability." (PX0064 (Illumina) at 7.)

1022.2 The Open Offer also requires that "[t]he price for a new Supplied Product or a new version of a materially improved Supplied Product must be commercially reasonable. For any materially improved Supplied Product, the price of the new version

must take into account the value of the improvement. For avoidance of doubt, in any arbitration in which the price of a new version of a Supplied Product or a new Supplied Product is disputed, the arbitrator is empowered to determine the reasonableness of the price, including the value of the any improvement in performance or capability, and to require that Illumina charge a price that is commensurate with the improvement, as well as require any associated refunds to Customer." (RX3935 (Illumina) at 2; *see also* deSouza (Illumina) Tr. 2408.)

1022.3 The new-product-pricing provision does not obligate customers to switch to a new product. (RX6002 (Guerin-Calvert Trial Dep. at 47).) If a customer did not agree that there was a material improvement in performance or capability of a new version of a Supplied Product, they could stay with their existing product. (RX6002 (Guerin-Calvert Trial Dep. at 48).) Alternatively, if a customer felt that there was a material improvement in performance or capability, but that this improvement did not justify a new price, the customer could take this issue directly to Illumina or to arbitration. (RX6002 (Guerin-Calvert Trial Dep. at 48).)

1023. Under the Open Offer, Illumina also agrees that by 2025, it will continue its pre-merger approach to reducing sequencing pricing and reduce the pricing of sequencing by at least 43%, regardless of whether a customer is receiving Grandfathered Pricing or Universal Pricing. [redacted]; Berry (Illumina) Tr. 712–13, 897, 903–04; Conroy (Exact/Thrive) Tr. at 1731–32; deSouza (Illumina) Tr. 2403; PX0064 (Illumina) at 7; [redacted]

1023.1 Specifically, the Open Offer provides 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." (PX0064 (Illumina) at 7.)

1023.2 Sequencing involves analyzing the nucleotides, or bases, of DNA or RNA in a sample. (*See* Berry (Illumina) Tr. 818–20; PX8399 (Henry (PacBio) Decl.) at 1.) A gigabase is one million DNA or RNA bases. (PX7076 (Berry (Illumina) Dep. at 265).) Sequencing flow cells are described in terms of the number of gigabases of DNA or RNA that can be sequenced. (Berry (Illumina) Tr. 904–05.) Thus, describing the price reduction using a price per gigabase nomenclature allows for normalizing different capacity flow cells and comparing different kits' pricing on an "apples-to-apples basis". (Berry (Illumina) Tr. 905; *see also* RX6002 (Guerin-Calvert Trial Dep. at 43).)

1023.3 While the number of gigabases refers to a number of DNA or RNA bases, a "read" refers to the processing of a fragment of DNA or RNA. (*See* Berry (Illumina) Tr. 818–20; PX8399 (Henry (PacBio) Decl.) at 1–2.) Thus, if Illumina reduced price per gigabase of the S4 300 flow cell by 43%, it would also reduce the price per read by 43%

because the given number of reads in that S4 300 flow cell kit is constant. (Berry (Illumina) Tr. 923.)

1023.4 By reducing price per gigabase, Illumina will also reduce a customer's price per sample on an absolute linear basis, presuming that the customer's assay does not change in terms of the amount of sequencing required for that sample. (Berry (Illumina) Tr. 905–06.)

1023.5 The price-reduction provision is intended to commit Illumina to a significant price reduction by January 1, 2025. (Berry (Illumina) Tr. 711–12.)

1023.6 Illumina selected the 43% number because that is the price Illumina assumed in its deal model that GRAIL would pay in 2025. (deSouza (Illumina) Tr. 2338; [redacted] Illumina also chose this number by considering both what customers wanted and what Illumina could achieve. (Berry (Illumina) Tr. 907–08; Aravanis (Illumina) Tr. 1868.)

1023.7 Although the Offer requires "at least" a 43% price reduction by January 1, 2025, Illumina intends to try to achieve that goal faster. (Aravanis (Illumina) Tr. 1868.)

1023.8 The 43% discount still applies even if, in 2025, the highest throughput flow cell has a material improvement in performance or capability. (Berry (Illumina) Tr. 908.)

1023.9 Illumina cannot avoid its obligation under the 43% reduction provision by changing what it defines as a new product because Illumina's minimum obligation is to reduce the price of the NovaSeq S4 300 flow cell. (Berry (Illumina) Tr. 908–09.)

1023.10 Illumina's track record shows that it has consistently sought to drive down pricing through innovation. (Berry (Illumina) Tr. 714–15; [redacted] Indeed, since Illumina entered the sequencing market in the mid-2000s, it has dramatically driven down the price of sequencing. (Berry (Illumina) Tr. 810–11.) Illumina lowered genomics pricing so dramatically that a writer in Forbes coined the term "Flatley's Law" to describe the price reduction achieved during the tenure of Illumina's former Chief Executive Officer, Jay Flatley. (Berry (Illumina) Tr. 810–11.)

1023.11 The price-reduction term directly addresses the foreclosure concerns that have been raised by providing a specific pricing commitment for the price of the highest throughput, best performance product on a specific future date. (RX6002 (Guerin-Calvert Trial Dep. at 49).)

1023.12 The price-reduction term represents an improvement over the status quo because the price reduction is contractually guaranteed. (RX6002 (Guerin-Calvert Trial Dep. at 52); *see* [redacted]

1023.13 [redacted]

1024. 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 8.) Illumina is also required to notify customers of short-term pricing granted to GRAIL. (PX0064 (Illumina) at 8.)

1024.1 The Open Offer requires that "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." (PX0064 (Illumina) at 8.)

1024.2 "'Short Term Project' means a project or circumstance giving rise to a discrete purchase of Sequencing Consumables outside of ongoing ordinary course of purchases made by a For-Profit Entity. The duration of a Short Term Project is no more than two years." (PX0064 (Illumina) at 4.)

1024.3 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 8.) The Open Offer specifically provides that "[n]o customer, including GRAIL, may receive Short Term Project pricing for more than two consecutive years. No customer, including GRAIL, may use Short Term Project pricing for ongoing ordinary course purchases, including for its standard commercial testing." (PX0064 (Illumina) at 8.)

1024.4 The Short Term Project pricing provision was added because certain discrete situations arise where there is a good reason for a customer to pay less than the pricing in the universal grid or grandfathered pricing agreements. (Berry (Illumina) Tr. 909–10.) Short Term Project pricing was offered, for example, to support COVID-19 studies and in situations where Illumina offered to replace perished inventory, for example, from a freezer malfunctioning. (Berry (Illumina) Tr. 910–13.)

1024.5 The Short Term Project pricing provision addresses the potential foreclosure concerns that have been raised because it allows for MFN pricing relative to GRAIL and Equivalent customers for Short Term Project needs. (RX6002 (Guerin-Calvert Trial Dep. at 44–45).)

1025. The Open Offer's pricing provisions, in their totality, address the foreclosure concerns that have been raised. (RX6002 (Guerin-Calvert Trial Dep. at 34–36).)

1025.1 The pricing provisions, in their totality, provide guarantees to potential MCED test developers that they will receive fair pricing from Illumina in the short term, medium term and long term. (RX6002 (Guerin-Calvert Trial Dep. at 53).) The provisions also treat customers fairly in terms of advance knowledge and information about pricing. (RX6002 (Guerin-Calvert Trial Dep. at 53).)

1025.2 [redacted]

1025.3 [redacted]

5. **IVD Agreements and FDA Documentation**

1026. The Open Offer provides that, for 6 years after the closing of the Illumina-GRAIL transaction (*i.e.*, until August 18, 2027), customers may enter into one or more separate agreements with Illumina to develop IVD test kits for use on Illumina's platforms. (Rabinowitz (Natera) Tr. 423–24; deSouza (Illumina) Tr. 2404; PX0064 (Illumina) at 8; [redacted]

1026.1 The Open Offer requires that "Customer may enter into, at any time from today, effective as of the closing of the Transaction, until the sixth anniversary of the closing of the Transaction, an agreement with Illumina under which Customer may develop and commercialize in-vitro diagnostic ("IVD") test kits for use on Illumina's diagnostic ("Dx") sequencing platforms." (PX0064 (Illumina) at 8.)

1026.2 To ensure transparency with potential partners, the types of IVD agreements available are posted on Illumina's website. (Goswami (Illumina) Tr. 3204–07.)

1026.3 IVD agreements under the Open Offer allow for developers to create test kits for all oncology applications, including cancer screening generally and multicancer screening specifically. (Goswami (Illumina) Tr. at 3233–35; PX0064 (Illumina) at 34.)

1026.4 Customers are investing in developing IVD test kits under the terms of these IVD agreements. (Goswami (Illumina) Tr. 3218–19.)

1026.5 Test developers do not need to enter into IVD agreements to pursue either LDTs or single-site PMAs. (Goswami (Illumina) Tr. 3273.)

1027. The Open Offer requires Illumina to provide customers with standard terms for IVD agreements and to provide documentation to assist the customer with FDA approval or marketing authorization. (PX0064 (Illumina) at 8; PX7093 (Young Dep. at 68).)

1027.1 The Open Offer requires that "Illumina will provide standard terms for Customer to enter into a stand-alone agreement to enable Customer to develop and commercialize IVD test kits on one or all of Illumina's Dx sequencing platforms. Illumina shall provide any documentation or information reasonably required for Customer to seek FDA approval or FDA marketing authorization to sell a for-profit, clinical test using the Supplied Products." (PX0064 (Illumina) at 8.)

1027.2 The Open Offer includes a right of reference to any relevant Illumina regulatory documentation for Illumina's IVD partners. (Leite (Illumina/InterVenn) Tr. 2156; PX0064 (Illumina) at 39; [redacted] Under this right, a partner developing on Illumina systems may reference Illumina's files in their regulatory submission. (PX0064 (Illumina) at 39; [redacted]

1027.3 Illumina may not withhold support of documentation and information for FDA approval even from a customer who is a cancer screening competitor. (Berry (Illumina) Tr. 914–16.)

1027.4 [redacted]

1028. The Open Offer provides 3 template agreement options for customers interested in IVD test kit agreements: an All-Platforms Agreement, a NextSeq Agreement, and a NovaSeq Agreement. (Goswami (Illumina) Tr. 3208; PX0064 (Illumina) at 28–40.)

1028.1 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.)

1028.2 The Open Offer lays out the summary terms for the different types of IVD agreements. (Goswami (Illumina) Tr. 3208; PX0064 (Illumina) at 28–40.) More detailed templates of the different agreements are also available to interested customers. (Goswami (Illumina) Tr. 3208.)

1028.3 The terms in the Open Offer's template IVD agreements are standard in the industry and are generally accepted by companies like Thermo Fisher that serve multiple clients in the same industry. (Goswami (Illumina) Tr. 3210, 3212, 3215, 3228–29; *see* [redacted] 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. 3181.) Dr. Goswami confirmed that the Open Offer's IVD agreement terms reflect industry standards. (Goswami (Illumina) Tr. 3210, 3212, 3215, 3228–29.)

1029. A customer can develop an unlimited number of IVD test kits under the All-Platforms Agreement. (Goswami (Illumina) Tr. 3208–09; PX0064 (Illumina) at 28.) For the

NextSeq Agreement and the NovaSeq Agreement, customers can develop up to 3 tests. (Goswami (Illumina) Tr. 3209; PX0064 (Illumina) at 28.)

1029.1 Illumina determined the number of tests that customers could develop on each platform based on what Illumina had agreed to with previous partners. (Goswami (Illumina) Tr. 3209.)

1030. All IVD agreements under the Open Offer extend to all jurisdictions worldwide where Illumina has obtained regulatory clearance for the instruments. (Goswami (Illumina) Tr. 3209; PX0064 (Illumina) at 28.)

1031. The All-Platforms Agreement has a 15–year term. (Goswami (Illumina) Tr. 3210; PX0064 (Illumina) at 29.) The NextSeq Agreement and the NovaSeq Agreement have 10–year terms. (Goswami (Illumina) Tr. 3210; PX0064 (Illumina) at 29.) Developers may also commercialize their tests beyond the stated term lengths. (Goswami (Illumina) Tr. 3210; PX0064 (Illumina) at 29.)

1031.1 Specifically, the Open Offer requires that, for the All-Platforms Agreement, the "Term of Agreement (during which time Customer could sell IVD Test Kits) would be 15 years from the date the Transaction closes. Customer could enter into new IVD Plans for IVD Test Kit development during the first 10 years (the 'Development Term')". (PX0064 (Illumina) at 29.) For the NextSeq Agreement, the Open Offer requires that the term is "10 years from the date the Transaction closes". (PX0064 (Illumina) at 29.) And for the NovaSeq Agreement, the Open Offer requires that the term is "10 years from the later of (i) the date the Transaction closes or (ii) the date NovaSeqDx is listed with FDA in the U.S. pursuant to applicable law". (PX0064 (Illumina) at 29.)

1031.2 The Open Offer also requires that "[a]fter 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. (PX0064 (Illumina) at 29.)

1031.3 Illumina selected the 10 and 15–year terms based on industry standards and the goal of giving customers enough time to develop kits on the relevant platforms. (Goswami (Illumina) Tr. 3210.)

1032. The Open Offer's IVD agreement templates include 3 types of financial considerations: (1) a technology access fee, paid upfront; (2) milestones 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 29–30.)

1032.1 The financial terms of the agreements are standard in the industry. (Goswami (Illumina) Tr. 3212; [redacted]; PX7097 (Felton (Thermo Fisher) Dep. at 127–29).)

1032.2 The financial terms are split into 3 components to ensure fairness and to distribute the fees over a period of time based on the success and commercial milestones of the developer. (Goswami (Illumina) Tr. 3213.)

1032.3 For the All-Platforms Agreement, the technology access fee is $25 million. (PX0064 (Illumina) at 29.) 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 29.) The technology access fees were selected based on recovering Illumina's upfront investment in the platforms and staying consistent with standard market. (Leite (Illumina/InterVenn) Tr. 2162–63; Goswami (Illumina) Tr. 3213–14.)

1032.4 The 6% revenue share was chosen based on a midpoint of what is common in the life sciences and diagnostics industry. (Goswami (Illumina) Tr. 3215.)

1032.5 The milestone payments were determined based on securing a return on Illumina's initial investment, as well as on previous successful negotiations with partners. (Goswami (Illumina) Tr. 3215–16.)

1032.6 Developers who develop competing tests to those being developed by Illumina are not charged more than noncompetitors under the Open Offer. (Goswami (Illumina) Tr. 3216.)

1033. The Open Offer provides for interested customers to submit proposed IVD plans to Illumina, which Illumina may not unreasonably reject. (PX0064 (Illumina) at 34–35.)

1033.1 The Open Offer requires that "[e]ach IVD Test Kit, and the parties' specific development obligations and timelines with respect to each IVD Test Kit, would be described in a development plan to be negotiated in good faith (each, an 'IVD Plan'.) Customer would propose potential IVD Plans. Illumina may not unreasonably reject any proposed IVD Plan." (PX0064 (Illumina) at 34–35.)

1033.2 Illumina provides two categories of information to customers during the IVD agreement process: (1) an overview of countries where Illumina has regulatory approval and the number of instruments in each region or country and (2) authorization to access the device master file when the customer requires it for FDA approval. (Goswami (Illumina) Tr. 3223–24.)

1033.3 In the IVD agreement process, Illumina receives from developers only basic information about the kind of test the developer is creating and the developer's development plans. (Goswami (Illumina) Tr. 3226–27.) This information is to help Illumina plan for certain commitments and obligations that it has to the developer. (Goswami (Illumina) Tr. 3227.)

1033.4 Illumina does not receive access to proprietary information from developers through the IVD agreement process. (Goswami (Illumina) Tr. 3227.)

1034. [redacted]

1034.1 [redacted]

1034.2 [redacted]

1034.3 The terms of IVD agreements that Illumina has entered into were not intended to raise the prices of kitted oncology assays, nor to diminish innovation in the area of kitted oncology assays. (Goswami (Illumina) Tr. 3217–18.) Providing an infrastructure on which developers can create tests allows them to develop more quickly and to lower costs for development. (Goswami (Illumina) Tr. 3217.) These IVD agreements spur innovation because many customers would not have been able to consider IVD tests without access to an infrastructure like Illumina's. (Goswami (Illumina) Tr. 3217–18; *see also* Leite (Illumina/InterVenn) Tr. at 2181–82.)

1034.4 Illumina is holding GRAIL separate and would be happy to enter into an IVD agreement with GRAIL, but GRAIL has not indicated any intention to do so yet. [redacted], 3273.)

1034.5 [redacted]

1035. The Open Offer provision on IVD agreements and FDA documentation addresses the potential foreclosure concerns that have been raised because they prevent Illumina from withholding support as MCED test developers seek FDA approval. (RX6002 (Guerin-Calvert Trial Dep. at 74).)

1035.1 By using standardized agreements, the provision ensures that customers know in advance what the terms of such an agreement will be. (RX6002 (Guerin-Calvert Trial Dep. at 74–75).)

1035.2 [redacted]

1035.3 The IVD agreement and FDA documentation provision specifically guarantees that Illumina will provide equal or greater assistance to MCED test developers with respect to FDA approval than it did premerger. (RX6002 (Guerin-Calvert Trial Dep. at 75).)

6. **Intellectual Property**

1036. Customers who sign the Open Offer receive a right under Illumina's core intellectual property to use the relevant products. (deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.)

1036.1 "'Intellectual Property Right(s)' 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 4.)

1036.2 "'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 4.)

1036.3 "'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 3.)

1036.4 The Open Offer requires that "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." (PX0064 (Illumina) at 9.)

1036.5 The Open Offer's provision on the right to use the Supplied Products under Illumina's Core IP addresses the potential foreclosure concerns that have been raised by ensuring that there will be no concern or confusion about whether these Core IP rights will be provided to customers in the future. (RX6002 (Guerin-Calvert Trial Dep. at 77–79).)

1037. Under the Open Offer, Illumina commits that it will not have the right to cease shipments of the products solely on the basis of a claim of infringement of Illumina's intellectual property rights. (Berry (Illumina) Tr. 864; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 9.)

1037.1 The Open Offer requires that "[i]n no event will Illumina have the right to cease shipping of the Supplied Product solely on the basis of any alleged claim of infringement of any intellectual property rights of Illumina." (PX0064 (Illumina) at 9.)

1037.2 This provision applies even if Illumina has a legitimate claim of infringement. (RX6002 (Guerin-Calvert Trial Dep. at 78).) [redacted]

1037.3 This provision effectively addresses the foreclosure concern that Illumina could disrupt supply to GRAIL rivals. (*See* RX6002 (Guerin-Calvert Trial Dep. at 77–79).)

7. **Firewalls and Protection of Confidential Information**

1038. The Open Offer requires Illumina not to share any customer confidential information with GRAIL or its subsidiaries or employees, or with Illumina employees who work with GRAIL. (Rabinowitz (Natera) Tr. 425; Berry (Illumina) Tr. 916–17; PX0064 (Illumina) at 9.)

1038.1 The Open Offer requires that "[t]o 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." (PX0064 (Illumina) at 9.)

1039. Under the Open Offer, Illumina must establish a firewall to protect customers' confidential information by prohibiting the flow of information between Illumina and GRAIL. (Rabinowitz (Natera) Tr. 425; deSouza (Illumina) Tr. 2404–05; PX0064 (Illumina) at 9–10; PX7085 (Harada (Exact/Thrive) Dep. at 113–14).)

1039.1 The Open Offer requires that "Illumina shall establish a firewall designed to prevent any GRAIL personnel (and any Illumina personnel carrying out activities with respect to the GRAIL business or products) from accessing any Confidential Information obtained by or made available to Illumina relating to Customer or its business or products, whether pursuant to this Supply Agreement or otherwise." (PX0064 (Illumina) at 9–10.)

1039.2 The firewall provision was added to assure customers that Illumina will not allow GRAIL personnel or Illumina personnel who have interactions with GRAIL to access customer confidential information. (Goswami (Illumina) Tr. 3231.)

1039.3 The firewall would still be able to protect information if employees moved from Illumina to GRAIL or from GRAIL to Illumina because Illumina clearly outlines what counts as confidential information and what the employees' obligations are under their confidentiality agreements. (Goswami (Illumina) Tr. 3232.)

1039.4 If someone at Illumina shares confidential information of a test developer with someone at GRAIL, there are codified disciplinary procedures in place, up to termination of the employee. (Goswami (Illumina) Tr. 3232–33.)

1039.5 If Illumina becomes aware of a breach of confidentiality of any kind, it is obligated to notify the other party of the breach. (Goswami (Illumina) Tr. 3233; RX3935 (Illumina) at 3.) Illumina will also conduct a biannual audit to identify any breaches it could have missed. (Goswami (Illumina) Tr. 3233; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.)

1039.6 The firewall provision in the Open Offer will not impede Illumina from realizing efficiencies from the merger. (Aravanis (Illumina) Tr. 1946, 1948, 1959.)

1039.7 Implementing the firewall envisioned by the Open Offer would mitigate customer concerns about the potential for sharing sensitive information between Illumina and GRAIL. (PX7077 (Chahine (Helio) Dep. at 123–24.)

1040. Illumina protects the confidentiality of information it receives from developers in the IVD agreement process in multiple ways. (Goswami (Illumina) Tr. 3227–28.)

1040.1 First, Illumina sets up a confidentiality agreement with all of its partners early on in the process. (Goswami (Illumina) Tr. 3228.)

1040.2 Second, Illumina trains its staff and requires them to sign confidentiality agreements when they are hired. (Goswami (Illumina) Tr. 3228.)

1040.3 Third, Illumina separates teams that work with customers who might have similar products. (Goswami (Illumina) Tr. 3228.)

1040.4 Fourth, Illumina uses document control processes to keep confidential documents from certain individuals within Illumina. (Goswami (Illumina) Tr. 3229–30.) These processes include software access controls, as well as storing confidential physical documents in a separate and controlled location. (Goswami (Illumina) Tr. 3230–31.)

1040.5 Fifth, if someone requests access to a protected document, the person responsible for the document receives legal guidance before granting access to someone else. (Goswami (Illumina) Tr. 3230.)

1040.6 In addition, Illumina often requires a separate internal confidentiality agreement for particular projects that require confidentiality. (Goswami (Illumina) Tr. 3232.)

1040.7 High-level executives at Illumina generally do not have access to customer databases. (Berry (Illumina) Tr. 918–19; Goswami (Illumina) Tr. 3232.)

1040.8 These practices are standard in the industry and they are generally accepted by companies like Thermo Fisher that serve multiple clients in the same industry. (Goswami (Illumina) Tr. 3228–29.)

1041. [redacted]

1041.1 Firewalls are not novel or unusual. [redacted]; *see also* RX3082 (*In re Broadcom Ltd.* Decision and Order) at 5–7; RX3192 (*In re Evanston Northwestern Healthcare Corp.* Final Order) at 6; RX3319 (Highmark Health Competitively Sensitive Information Policy) at 2–9; RX3527 (*In re Northrop Grumman* Decision and Order) at 9–13; RX 3557 (*In re PepsiCo, Inc.* Decision and Order) at 6–9; RX3664 (*In re Sycamore Partners II* Analysis of Agreement Containing Consent Order) at 3–4; Fielder, Tr. 4488 (noting that FMI has firewalls and complies with them)) These types of firewalls have been implemented with success by the FTC (and other antitrust agencies or regulatory agencies) in vertical transactions, and these provisions can be effectively implemented. (RX6002 (Guerin-Calvert Trial Dep. at 81–82); PX7138 (Scott Morton Trial Dep. at 294); *see also* RX3082 (*In re Broadcom Ltd.* Decision and Order) at 5–7; RX3192 (*In re Evanston Northwestern Healthcare Corp.* Final Order) at 6; RX3527 (*In re Northrop Grumman* Decision and Order) at 9–13; RX 3557 (*In re PepsiCo, Inc.* Decision and Order) at 6–9; RX3664 (*In re Sycamore Partners II* Analysis of Agreement Containing Consent Order) at 3–4.)

1041.2 [redacted]

1041.3 Illumina is very familiar with how to set up and operate these types of confidentiality procedures because it already shields confidential information between customers in similar fields. (Goswami (Illumina) Tr. 3231.)

1041.4 Illumina is currently implementing the confidentiality provisions of the Open Offer by operating GRAIL as a completely separate and distinct organization and by thoroughly reviewing any interface points with GRAIL. (Berry (Illumina) Tr. 917–18.)

1041.5 The firewall between Illumina and GRAIL will have the characteristics of an effective firewall because it will provide at least the essential features common to past successful firewalls. (RX6002 (Guerin-Calvert Trial Dep. at 85).) Specifically, the firewall provides for monitoring and auditing, methods to report violations and consequences for violations. (RX6002 (Guerin-Calvert Trial Dep. at 85).)

1042. The confidentiality and firewall provisions directly address the foreclosure 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).)

8. **Enforcement**

1043. 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. at 2405, 2438; PX0064 (Illumina) at 10–11; RX3935 (Illumina) at 3.)

1044. The enforcement terms of the Open Offer provide Illumina's clinical oncology customers with effective monitoring and enforcement mechanisms to ensure compliance with the Open Offer terms and to effectuate its purpose of ensuring that Illumina cannot materially disadvantage GRAIL rivals post-merger. (RX6002 (Guerin-Calvert Trial Dep. at 22–23).) The very public aspect of the Open Offer can also bolster compliance. (*See* RX6002 (Guerin-Calvert Trial Dep. at 22–23).)

1045. The audit and arbitration provisions of the Open Offer play complementary roles to address the potential foreclosure concerns that have been raised. (RX6002 (Guerin-Calvert Trial Dep. at 89–90).) The audit provision assures customers that they will have access to the necessary information to ensure that Illumina abides by its obligations, and the arbitration provision allows for a mechanism to resolve any disputes that could arise. (RX6002 (Guerin-Calvert Trial Dep. at 89–90).)

1046. [redacted]

a. Audits

1047. The Open Offer requires Illumina to engage in a biannual audit to ensure compliance with the Open Offer. (deSouza (Illumina) Tr. 2405, 2438; PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.) Further, if a customer has a good-faith basis for alleging that Illumina is in breach of the Open Offer, Illumina will engage an auditor to assess the customer's allegation separate from the biannual audits. (PX0064 (Illumina) at 10.)

1047.1 The Open Offer requires Illumina to conduct a bi-annual audit "by an independent third-party auditor selected by Illumina from among the 'Big 4' accounting firms to audit Illumina's compliance with the commitments set forth herein." (PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.)

1047.2 The Open Offer requires that "[t]o the extent Customer has a good faith basis for alleging that Illumina is in breach of a commitment contained herein, Illumina shall engage an auditor to assess Customer's allegation separate from and in addition to Illumina's [biannual] audit." (PX0064 (Illumina) at 10; RX3935 (Illumina) at 3.)

1047.3 Mr. deSouza testified that, as Illumina's CEO, he does not have a problem with "raising the hood, and inspecting what's going on under there". (deSouza (Illumina) Tr. 2452.)

1047.4 [redacted] Nonetheless, to provide customers with even greater security, the Open Offer provides for regular audits *twice* a year (as well as additional audits when customers have a good-faith basis for alleging breach). (RX3935 (Illumina) at 3.)

1048. Illumina is obligated to provide customers with a written report confirming compliance with the Open Offer's commitments. (PX0064 (Illumina) at 10; PX7076 (Berry (Illumina) Dep. at 287).) Additionally, customers must be promptly notified, within 10 days, of any potential noncompliance. (deSouza (Illumina) Tr. 2478; RX3935 (Illumina) at 3.)

1048.1 The Open Offer requires that "Illumina will provide Customers with a written report (with reasonable redactions) confirming compliance with the commitments set forth herein." (PX0064 (Illumina) at 10.)

1048.2 The Open Offer requires that "[i]n addition to providing the written report, in the event of any finding of potential noncompliance with Illumina's performance under the Supply Agreement, Customer shall be notified within 10 days of identifying such a finding of potential noncompliance." (RX3935 (Illumina) at 3.)

1049. Illumina is committed to cooperating with any audits. (PX7076 (Berry (Illumina) Dep. at 287–88); PX0064 (Illumina) at 10.)

1049.1 The Open Offer requires that "Illumina shall provide cooperation, including access to necessary books and records, in support of any audit conducted." (PX0064 (Illumina) at 10.)

1049.2 Illumina will also pay for any audits. (Berry (Illumina) Tr. 921; PX7076 (Berry (Illumina) Dep. at 284, 285).)

1050. Audit provisions in general are common and can be effectively implemented. (RX6003 (Rock Trial Dep. at 29–32, 35–36, 45–46).)

1050.1 Audits like those provided for in the Open Offer can effectively address allegations of breach. (RX6003 (Rock Trial Dep. at 31–32).)

1050.2 Independent auditors are fully capable of assisting Illumina in developing the appropriate procedures, 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).)

1050.3 Independent auditors can be effective in (1) examining an entity's compliance with 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).)

1050.4 The role of an independent auditor is similar to that of a monitor and can perform the same essential oversight role in many respects. (RX6003 (Rock Trial Dep. at 32).)

1050.5 Audit provisions are common in commercial contracts, supply agreements, credit agreements, service contracts and regulatory compliance matters. (RX6003 (Rock Trial Dep. at 35–36).)

1050.6 Audit provisions are often used by regulatory agencies like DOJ and FTC to monitor both financial and non-financial terms, like those related to quality, confidentiality or firewalls. (RX6003 (Rock Trial Dep. at 36, 45–46).)

1050.7 The Public Company Accounting Oversight Board has published standards to ensure quality for compliance audits like those provided for in the Open Offer. (RX6003 (Rock Trial Dep. at 45).)

1050.8 Large CPA firms like the Big 4 have the relevant knowledge and experience to conduct an effective compliance audit. (RX6003 (Rock Trial Dep. at 45).) Additionally, CPAs very frequently review compliance with contract provisions and audit the effectiveness of internal controls. (RX6003 (Rock Trial Dep. at 45).) This experience can increase the effectiveness and value of an audit over time. (RX6003 (Rock Trial Dep. at 45).)

1051. The Open Offer's audit provision allows for effective audits of Illumina's compliance with the Open Offer's requirements. (RX6003 (Rock Trial Dep. at 31, 35, 44 –45, 50–72).)

1051.1 The Open Offer's audit provision will act as a preventive measure to encourage compliance. (RX6003 (Rock Trial Dep. at 44).) The Open Offer's audit provision will also serve as a detective measure by finding and reporting instances of noncompliance. (RX6003 (Rock Trial Dep. at 44–45).)

1051.2 Audits of the Open Offer provisions on pricing and access to products and services can ensure that Illumina's customers are not disadvantaged by enabling Illumina to improve its procedures to help prevent instances of noncompliance and by providing customers with information to help them decide whether arbitration is necessary. (RX6003 (Rock Trial Dep. at 62–63, 66–67).)

1051.3 Audits of the Open Offer firewall provision will effectively ensure customers are not disadvantaged even if it does not address every customer concern because the audits provide information to improve Illumina's internal procedures to help prevent instances of non-compliance and to help customers decide whether action is necessary to remedy non-compliance. (RX6003 (Rock Trial Dep. at 71–72).)

1052. Illumina has a contract with Deloitte Consulting to help them operationalize the terms of the Open Offer. [redacted], 896.) This engagement will help Illumina improve its systems to allow for maximally effective audits. (PX7135 (Rock Dep. at 90).)

1052.1 Bringing in an outside consultant to assist with operationalizing the Open Offer is a positive step from an audit perspective. (PX7135 (Rock Dep. at 91–93).)

1053. In addition to the audit provision, Illumina also has unilaterally committed to grant the FTC similar monitoring, oversight, and access authority in connection with the proposed acquisition through the Consent Principles. (RX3155 (Illumina) at 4.) The Consent Principles, for example, authorize the FTC to appoint a monitor trustee, to require an annual

verified written report of Illumina's manner and form of compliance, and to access to Illumina's books, records, directors, officers, and employees. (RX3155 (Illumina) at 4–5.)

b. Arbitration

1054. Illumina also agrees to binding arbitration in the event that a dispute arises under the agreement. (Rabinowitz (Natera) Tr. 444; deSouza (Illumina) Tr. 2405; PX0064 (Illumina) at 10–11; PX7076 (Berry (Illumina) Dep. at 282–83).)

1054.1 The Open Offer explicitly requires 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 10.)

1054.2 Illumina aims to get through any arbitration as fast as possible and to use the most accelerated process available. (deSouza (Illumina) Tr. 2460–61.) Illumina is open to soliciting feedback and improving the arbitration process to make it more expeditious if possible. (deSouza (Illumina) Tr. 2460–61.)

1054.3 Prior to any binding arbitration, the Open Offer also provides for an immediate dispute resolution process: "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 10.)

1054.4 This immediate dispute resolution mechanism helps address any concern about the time and expense of arbitration. (RX6002 (Guerin-Calvert Trial Dep. at 90–91).)

1054.5 Illumina's interest is to resolve any disputes under the Open Offer quickly. (deSouza (Illumina) Tr. 2460–61.)

1055. The arbitrator may order any relief necessary to restore the status quo prior to Illumina's breach, including monetary and/or injunctive relief, and must follow the Commercial Arbitration Rules of the American Arbitration Association (AAA). (PX0064 (Illumina) at 10; RX3935 (Illumina) at 3; deSouza (Illumina) Tr. 2451–52.)

1055.1 The Open Offer requires that "[i]f the Arbitrator determines that Illumina has breached any provision of the Supply Agreement, the Arbitrator may order any relief necessary to restore the status quo prior to Illumina's breach, including monetary and/or injunctive relief." (RX3935 (Illumina) at 3.)

1056. The arbitrator's decision is required to reflect the fact that the purpose of the Open Offer is to allay any concerns relating to the Illumina-GRAIL transaction. (RX3935 (Illumina) at 3.)

1056.1 Specifically, the Open Offer requires 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 3.)

1057. The arbitration provision addresses the foreclosure 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).)

1057.1 MCED test developers would not be disadvantaged relative to GRAIL while arbitration is taking place. (RX6002 (Guerin-Calvert Trial Dep. at 91–92).)

D. Status of the Open Offer

1058. [redacted]

1059. [redacted]

1060. [redacted]

1061. [redacted]

1062. [redacted]

1063. [redacted]

1064. [redacted]

1065. [redacted]

1066. [redacted]

1067. [redacted]

1068. [redacted]

1069. In addition to the protections afforded by 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).)

1069.1 The Consent Principles would (i) permit the FTC to appoint a monitor trustee, (ii) provide for submission of an annual verified written report to the FTC regarding Illumina's compliance with the Consent Principles and (iii) grant FTC access to Illumina books, records, officers, directors and employees to determine or secure compliance with the Consent Principles. (RX3155 (Illumina) at 4–5.)

1069.2 Because the Consent Principles in essence convert the Open Offer into a consent format, the Consent Principles are consistent with the Open Offer. (RX6002 (Guerin-Calvert Trial Dep. at 95–96).)

1069.3 The Consent Principles' additional provisions are also "FTC friendly" and add provisions that the FTC has previously used in their own consent provisions. (RX6002 (Guerin-Calvert Trial Dep. at 96).)

1069.4 The enforcement provisions under the Consent Principles, including the monitor trustee commitment, the annual report commitment and the FTC access commitment (as well as those provided in the Open Offer), represent a comprehensive set of enforcement provisions across typical consent decrees in the FTC's past practice. (RX6002 (Guerin-Calvert Trial Dep. at 97–98).)

1069.5 The Consent Principles demonstrate that Illumina is willing to be subject to oversight by a monitor with respect to its compliance with the Open Offer terms. (RX6002 (Guerin-Calvert Trial Dep. at 98).)

E. [redacted]

1070. [redacted]

1071. [redacted]

1072. [redacted]

1072.1 Consent decrees are effective measures for resolving antitrust disputes and have been used by the FTC and other regulatory agencies for many years. (RX6002 (Guerin-Calvert Trial Dep. at 105).)

F. The Open Offer Addresses All Potential Criticisms and Concerns that Complaint Counsel and Certain Customers Have Raised

1. Customers' Alleged Concerns Regarding the Open Offer Are Unreliable

1073. Kevin Conroy, the Chairman and Chief Executive Officer of Exact, criticized the Open Offer, but had not actually read the Open Offer and, beyond what counsel had described to him, did not know what the Open Offer requires Illumina to do. (Conroy (Exact/Thrive) Tr. 1725–27 ("Q. So you haven't read the open offer, right? A. That's what I just testified to.").)

1073.1 For example, Mr. Conroy did not know whether the Open Offer commits Illumina to providing Exact access for purchase to any Pre-Release Sequencing Product to which GRAIL or any For-Profit Entity has access. (Conroy (Exact/Thrive) Tr. 1726.)

1073.2 Mr. Conroy did not know whether the Open Offer commits Illumina to enter into a separate development agreement on commercially reasonable terms, including the design or modification of any Supplied Product. (Conroy (Exact/Thrive) Tr. 1726.)

1073.3 Mr. Conroy did not know whether the Open Offer requires Illumina to allocate supply in an equitable manner in the event of a supply shortage. (Conroy (Exact/Thrive) Tr. 1726.)

1073.4 Mr. Conroy did not know the substance of the Open Offer's intellectual property provisions. (Conroy (Exact/Thrive) Tr. 1728–29.)

1073.5 [redacted]

1073.5.1 [redacted]; PX8388 (Illumina) at 3.)

1073.5.2 [redacted]

1074. [redacted]

1074.1 [redacted]

1074.2 [redacted]

1074.3 [redacted]

1074.4 [redacted]

1074.5 [redacted]

1074.6 [redacted]

1075. [redacted]

1075.1 [redacted]

1075.2 [redacted]

1075.3 [redacted]

1075.4 Guardant attached the amended supply agreement to its 2020 10–K because the amended agreement represented a material and important contract for Guardant. (Getty (Guardant) Tr. 2668–69; PX0060 (Guardant) at 151.)

1075.5 In its negotiations with Illumina, Guardant never indicated to Illumina that Guardant viewed its amended supply agreement as, in substance, unenforceable or worthless. (Getty (Guardant) Tr. 2669.)

1076. [redacted]

2. The Open Offer Does Not Contain "Loopholes" and Is Likely To be An Effective Contract Over its 12–year Term

1077. Contrary to the testimony of certain customers, the Open Offer does not contain too many "loopholes" to be effective; it contains the economically necessary set of terms to prevent the alleged competitive harms arising from the merger in both the short and the long term. (RX6002 (Guerin-Calvert Trial Dep. at 21–22).)

1077.1 In concluding that Illumina would be able to materially disadvantage GRAIL rivals after the Transaction, Complaint Counsel's expert, 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).)

1077.2 [redacted]

1078. Contrary to the opinion of Dr. Scott Morton, the theory of incomplete contracts does not, from an economic standpoint, mean that contracts cannot be written or that parties cannot enter into contracts that address unforeseen circumstances. (RX6002 (Guerin-Calvert Trial Dep. at 99–102); RX6000 (Carlton Trial Dep. at 50, 84–85).)

1078.1 Contracts can be written to take away Illumina's ability to disadvantage GRAIL rivals. (RX6002 (Guerin-Calvert Trial Dep. at 104–05).) Indeed, behavioral remedies like the Open Offer have been used by the FTC and DOJ since the 1970s in a wide variety of industries and cases. (RX6002 (Guerin-Calvert Trial Dep. at 105).) A retrospective study by the FTC of many consent decrees in horizontal and vertical

mergers found that behavioral remedies were effective in the mergers studied. (RX6002 (Guerin-Calvert Trial Dep. at 81–82).)

1078.2 Dr. Scott Morton's opinion that the Open Offer is inadequate because it cannot anticipate every contingency that could arise ignores the fact that this is true of all contracts. (RX6000 (Carlton Trial Dep. at 49–50).) In fact, Dr. Scott Morton assumes that, absent the merger, sophisticated contracts could be written that would enable the efficiencies of the merger but places no confidence in the Open Offer's ability to protect GRAIL rivals, even though the Open Offer is a private contract that is privately enforceable. (RX6000 (Carlton Trial Dep. at 49–50).)

1078.3 Under the theory of incomplete contracts, economists can still evaluate the terms of the Open Offer to determine whether the terms provide customers with adequate protection. (RX6002 (Guerin-Calvert Trial Dep. at 100–01).) Economists have evaluated the Open Offer and concluded that it is a comprehensive contract that sufficiently addresses and anticipates issues that are likely to arise over time. (RX6002 (Guerin-Calvert Trial Dep. at 21–22, 103–04); RX6000 (Carlton Trial Dep. at 84–85).)

1079. Contrary to the opinion of Dr. Scott Morton, behavioral remedies can function effectively in innovation markets by including, as the Open Offer does, terms that can adapt to changed circumstances in evolving marketplaces. (RX6002 (Guerin-Calvert Trial Dep. at 103–04).)

1079.1 For example, the Open Offer's provisions on pricing for new Supplied Products or new versions of materially improved Supplied Products require that the prices are "commercially reasonable" and empower an arbitrator to evaluate the commercial reasonableness of the prices. (RX3935 (Illumina) at 2–3.)

1080. Contrary to the testimony of certain customers, the Open Offer is not about optics; it is about actually working with customers to assure them that they will not be disadvantaged after the transaction. (Berry (Illumina) Tr. 856; *see also* Fiedler (FMI) Tr. 4479.)

1080.1 For example, the provisions of the Open Offer came about based on what individual customers said would make them more comfortable after the Transaction. (Berry (Illumina) Tr. 857, 942–47.)

1080.2 [redacted]

1080.3 [redacted]

1080.4 Working with customers to ensure they are comfortable with their relationship with Illumina after the Transaction aligns with Illumina's core business strategy of creating an open platform environment to broaden the market for sequencing products. (deSouza (Illumina) Tr. 2378–82.)

1081. Contrary the testimony of certain customers, the reason the Open Offer provides a standardized set of terms for customers is to ensure fairness, transparency and equitable treatment for customers. (*See* Berry (Illumina) Tr. 869; Goswami (Illumina) Tr. 3206–07; [redacted] 2392, 2401, 2403.)

1082. Contrary to the opinion of Dr. Scott Morton, the Open Offer fully addresses any alleged incentives by Illumina to foreclose GRAIL rivals. (RX6002 (Guerin-Calvert Trial Dep. at 20–21, 108–09).)

1082.1 The most important issue with regard to the efficacy of the Open Offer is whether it sufficiently prevents Illumina from acting on any incentive to foreclose GRAIL rivals. (*See* RX6002 (Guerin-Calvert Trial Dep. at 20–21, 109).)

1082.2 Separate from Illumina's ability to foreclose, the Open Offer's provisions in their totality also ensure that Illumina's incentives are to support GRAIL's rivals. (*See* RX6002 (Guerin-Calvert Trial Dep. at 20–22, 108–09; RX6000 (Carlton Trial Dep. at 84–85).)

1082.3 [redacted]

1082.4 Further, the Open Offer, as a private contract, creates an incentive for Illumina customers to take advantage of it and enforce it. (RX6000 (Carlton Trial Dep. at 84).)

1082.5 In addition, Complaint Counsel's expert improperly assumes 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, 109).) To the contrary, absent the merger, Illumina would have an incentive to favor GRAIL. (RX6000 (Carlton Trial Dep. at 45–46).) In the world absent the merger, Illumina would own roughly 12% of GRAIL, so it would make much more money by favoring GRAIL over GRAIL's rivals. (RX6000 (Carlton Trial Dep. at 45–46).)

3. The Open Offer Addresses Any Concerns or Requests Likely to Arise During the 12–year Term

1083. Contrary to the opinions of certain customers, the Open Offer fully addresses the competitive concerns that would be likely to arise over a 12–year term. (RX6002 (Guerin-Calvert Trial Dep. at 103–04).)

1083.1 The Open Offer accomplishes this by using flexible terms that can respond to changes over time. (*See* RX6002 (Guerin-Calvert Trial Dep. at 103–04).)

1083.2 For example, rather than prescribing specific types of assistance, the FDA provision requires Illumina to provide whatever documentation is needed for FDA approval. (RX6002 (Guerin-Calvert Trial Dep. at 103–04).) This allows the provision to

be effective even if FDA requirements change over time. (*See* RX6002 (Guerin-Calvert Trial Dep. at 104).)

1083.3 Moreover, customers have acknowledged that no contract is perfect and no contract can address all potential issues that might eventualize over the long term. (*See, e.g.*, [redacted] Nonetheless, these customers enter into contracts all the time. [redacted] Conroy (Exact/Thrive) Tr. 1723; Getty (Guardant) Tr. 2614; [redacted]

4. **The Open Offer Addresses Any Concerns Relating to Access to Services**

1084. Contrary to the testimony of certain customers, under the Open Offer, Illumina cannot delay or provide lower quality technical support services in a way that would (meaningfully) affect customers. (RX6002 (Guerin-Calvert Trial Dep. at 57–59, 67).)

1084.1 Illumina cannot delay technical support in a way that would affect customer's development of screening tests. (RX6002 (Guerin-Calvert Trial Dep. at 65, 67).)

1084.2 Delaying services or providing worse services to a customer who signed the Open Offer would be a breach of the Open Offer. (Berry (Illumina) Tr. 871, 878–79.)

1084.3 Illumina tracks the services that customers order, trains technicians extensively and tracks individual cases to ensure consistent quality of services, including the speed with which the services were provided. (Berry (Illumina) Tr. 866–69.) Therefore, any deterioration in the quality of services would be verifiable through the audit provision in the Open Offer. (*See* RX6003 (Rock Trial Dep. at 59–62).)

1084.4 Moreover, delaying or refusing to service instruments would hurt Illumina's overall business because customers would stop buying sequencing consumables from Illumina. (Berry (Illumina) Tr. 871–72.)

1084.5 Under the Open Offer, Illumina is prohibited from sending a deliberately inexperienced technician to address a service call at a test developer that is a GRAIL rival. (Berry (Illumina) Tr. 869.)

1085. Contrary to the testimony of certain customers, customers will receive access to the same level of service that they received premerger. (RX6002 (Guerin-Calvert Trial Dep. at 57–58, 63).)

1085.1 The Open Offer ensures that there will not be a diminution of the sets of services available to customers relative to those available before the merger. (RX6002 (Guerin-Calvert Trial Dep. at 58).)

1086. Contrary to the testimony of certain customers, customers will receive access to the same level of service that GRAIL receives. (RX6002 (Guerin-Calvert Trial Dep. at 57–58, 63).)

1086.1 [redacted]

1086.2 Under the Open Offer, Illumina could not provide lower quality services to customers who did not also purchase Galleri. (Berry (Illumina) Tr. at 878–79.)

1086.3 [redacted]

1086.4 Customers will also be aware of the services provided to GRAIL because Illumina is required to publish on the "Oncology Contract Terms" website the service plans that GRAIL purchases. (RX3935 (Illumina) at 2; RX4003 (Illumina) at 1; RX3960 (Illumina).) Illumina is also required to update this website within 5 days of entry of any service contract by GRAIL. (RX3935 (Illumina) at 2.)

1086.5 The publication of the services provided to GRAIL will also assist with the audit procedure. (RX6003 (Rock Trial Dep. at 59–61).)

5. The Open Offer Addresses Any Concerns Relating to Access to Sequencing Instruments and Core Consumables

1087. Contrary to the testimony of certain customers, under the Open Offer, customers have access to the same sequencing instruments and core consumables as GRAIL, including any improvements or future products that Illumina may release. (Berry (Illumina) Tr. 875–76.)

1087.1 Illumina cannot define what counts as a new product for purposes of the access provisions in a way that meaningfully disadvantages GRAIL rivals because Illumina's adherence to this provision will be subject to regular audits. (RX6003 (Rock Trial Dep. at 56, 59–61).)

1087.2 To the extent Illumina introduces a new product or a new version of an existing product, "[t]he price for a new Supplied Product or a new version of a materially improved Supplied Product must be commercially reasonable. For any materially improved Supplied Product, the price of the new version must take into account the value of the improvement." (RX3935 (Illumina) at 2.)

1087.3 [redacted]

1087.4 [redacted]

1088. Contrary to the testimony of certain customers, under the Open Offer, Illumina cannot develop a new product that only works for GRAIL and disadvantages other test developers. (deSouza (Illumina) Tr. 2433–35.)

1088.1 Similarly, Illumina could not make improvements to its products available only to GRAIL without breaching the Open Offer. (deSouza (Illumina) Tr. 2446–47.)

1089. Contrary to the testimony of certain customers, under the Open Offer, Illumina cannot discontinue access to products because the no-obsolescence provision explicitly prohibits this behavior. (Rabinowitz (Natera) Tr. 421–22; Berry (Illumina) Tr. 883; PX0064 (Illumina) at 6; (RX6002 (Guerin-Calvert Trial Dep. at 71–72); [redacted]

1089.1 Under the Grandfathered Pricing provision of the Open Offer, Illumina must also allow customers to continue paying the same pre-merger price for any products that customers continue to purchase. (PX0064 (Illumina) at 7.)

1090. Contrary to the testimony of certain customers, under the Open Offer, Illumina cannot disadvantage GRAIL rivals by delaying access to information about new or pipeline products because the Open Offer specifically requires equitable access to information about final product specifications of new or pipeline products within 5 days of when GRAIL receives access. (deSouza (Illumina) Tr. 2407–08; RX3935 (Illumina) at 2.)

1090.1 Additionally, when Illumina releases a new product, customers tend to wait for a period to see how that product performs in the market before adopting it. (deSouza (Illumina) Tr. 2409.) Clinical customers typically wait a year or more to see if there are any modifications to the product and to get a sense of the product's performance characteristics. (deSouza (Illumina) Tr. 2409–10.)

1090.2 Once a customer decides to adopt a sequencing product, they typically purchase a single sequencer to validate the workflows they have and to train their employees. (deSouza (Illumina) Tr. 2410.) This validation process typically takes months or quarters. (deSouza (Illumina) Tr. 2410.) Only after this process will the customer start to roll out their product tests on the new sequencer. (deSouza (Illumina) Tr. 2410–11.)

1090.3 Thus, it is not uncommon for customers to adopt a new sequencer 3 or more years after the sequencer is released. (deSouza (Illumina) Tr. 2410.) For example, 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. 2410.)

1091. Contrary to the testimony of certain customers, under the Open Offer, Illumina cannot delay access to products in a way that would meaningfully disadvantage GRAIL rivals. (RX6002 (Guerin-Calvert Trial Dep. at 60, 65).)

1091.1 The Open Offer requires that customers receive access to Supplied Products and Pre-Release Sequencing Products within 5 days of when GRAIL or Equivalent customers receive access. (RX3935 (Illumina) at 2.) [redacted]

1091.2 Considering the length of time that it takes to develop a test on a sequencing platform, 5 days is "a very inconsequential amount of time" for a developer making a test. (*see* Aravanis (Illumina) Tr. 1930; *see also* Berry (Illumina) Tr. 702–03; [redacted]

1091.3 Customers will be aware when the "clock starts running" for the access provisions because, under the Open Offer, customers must be notified when a product is made available. (RX6002 (Guerin-Calvert Trial Dep. at 64).)

1091.4 Under the Open Offer, Illumina could not provide lower quality sequencing instruments or core consumables to customers who did not also purchase Galleri. (Berry (Illumina) Tr. at 879.)

1092. Contrary to the testimony of certain customers, Illumina cannot "monkey" with supply by providing customers with lower quality reagents. (RX6002 (Guerin-Calvert Trial Dep. at 62).)

1092.1 If Illumina "monkeyed" with 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.)

6. The Open Offer Addresses Any Concerns Relating to Pricing of Services, Sequencing Instruments or Core Consumables

1093. Contrary to the testimony of certain customers, Illumina cannot avoid its obligations under the pricing provisions by defining what counts as a material improvement or new product. (RX3935 (Illumina) at 2–3.)

1093.1 The Open Offer specifically prohibits price increases (other than those due to inflation or factors outside of Illumina's control) unless a new product or new version results in a material improvement. (PX0064 (Illumina) at 7.)

1093.2 Illumina's ability to raise prices based on material improvements is constrained. (RX3935 (Illumina) at 2–3.) The price of any new version must take into account the value of the improvement. (RX3935 (Illumina) at 2–3.)

1093.3 In any arbitration over pricing of new products or new version of products, the arbitrator "is empowered to determine the reasonableness of the price, including the value of the . . . improvement in performance or capability, and to require that Illumina charge a price that is commensurate with the improvement, as well as require any associated refunds to Customer." (RX3935 (Illumina) at 2–3.)

1094. Contrary to the testimony of certain customers, the 43% price reduction by January 1, 2025 is a significant price reduction and is based on Illumina's projections with respect to the prices GRAIL would pay in 2025. (Berry (Illumina) Tr. 711–12; deSouza (Illumina) Tr. 2338; [redacted]

1094.1 In concluding that the 43% reduction was unlikely to constrain Illumina from raising prices above what they would be absent the merger, Dr. Scott Morton improperly assumed that, in the world without the merger (1) Illumina would have succeed in sufficiently lowering its costs by 2025, (2) Illumina would have passed all of those reductions on to its customers and (3) Illumina would have provided any reductions to all customers equally. (RX6002 (Guerin-Calvert Trial Dep. at 50–52).)

1095. Contrary to the opinion of Dr. Scott Morton, charging customers the same prices as GRAIL is a meaningful pricing protection because, even though GRAIL and Illumina are affiliates, the P&L of each company will be reported separately. (deSouza (Illumina) Tr. 2465, 2467–69.)

1095.1 Indeed, GRAIL is a separate organization with its own budget. (deSouza (Illumina) Tr. 2468.) Thus, for all the items that GRAIL purchases from Illumina, GRAIL will be making a payment to Illumina. (deSouza (Illumina) Tr. 2468.)

7. The Open Offer Addresses Any Concerns Relating to IVD Agreements and FDA Documentation

1096. Contrary to the testimony of certain customers, the Open Offer's requirement that Illumina provide FDA documentation is sufficiently long to address customers' concerns with respect to FDA approval of their tests. (*See* RX6002 (Guerin-Calvert Trial Dep. at 28, 73–75).)

1097. Contrary to the testimony of certain customers, under the Open Offer, Illumina could not decide to withhold support or documentation for regulatory approval from a test developer that was a potential GRAIL rival. (Berry (Illumina) Tr. 915–16.)

8. The Open Offer Addresses Any Concerns Relating to Intellectual Property

1098. Contrary to the testimony of certain customers, the Open Offer's intellectual property provisions adequately cover both Core IP and Application Specific IP. (RX6002 (Guerin-Calvert Trial Dep. at 77–79).)

1098.1 Illumina cannot cease shipping a product based solely on a claim of infringement for both Core and Application Specific IP. (RX6002 (Guerin-Calvert Trial Dep. at 78).)

1098.2 The Open Offer provides an additional assurance by promising customers that they will receive rights to use Illumina's Core IP. (RX6002 (Guerin-Calvert Trial Dep. at 78–79).)

1099. Contrary to the testimony of certain customers, Illumina does not wield its intellectual property in a non-competitive manner. (*See* deSouza (Illumina) Tr. 2470–71.)

1099.1 When Illumina has sued entities based on Illumina's intellectual property, it has done so because those entities infringed Illumina's intellectual property. (deSouza (Illumina) Tr. 2470.)

1099.2 Indeed, when Illumina sued Natera for infringement, Illumina was obligated to sue because Illumina is the custodian of a patent pool with multiple patentholders. (deSouza (Illumina) Tr. 2470–71.)

1099.3 Illumina's efforts in creating this patent pool helped prevent the non-competitive use of intellectual property rights in the market for non-invasive prenatal tests (NIPT.) (*See* PX7089 (Naclerio (Illumina) Dep. at 49–50, 57–58, 150).)

1099.4 In the nascent NIPT market that existed before Illumina acquired Verinata, several companies, such as Verinata, Sequenom and Ariosa, were engaged in ongoing intellectual property litigation. (PX7089 (Naclerio (Illumina) Dep. at 49).) These disputes led to exceedingly high prices for NIPT tests for patients. (PX7089 (Naclerio (Illumina) Dep. at 49–50).) Illumina recognized that these disputes held back the NIPT market. (PX7089 (Naclerio (Illumina) Dep. at 49–50).)

1099.5 Illumina chose to acquire Verinata in part to accelerate adoption of NIPT by settling this intellectual property litigation. (PX7089 (Naclerio (Illumina) Dep. at 57–58).) Illumina recognized that it could accomplish this because Illumina could help bring the companies in disputes to the negotiating table. (PX7089 (Naclerio (Illumina) Dep. at 57–59).)

1099.7 [redacted]

9. The Open Offer Addresses Any Concerns Relating to Firewalls and Confidential Information

1100. Contrary to the testimony of certain customers and the opinion of Dr. Scott Morton, the GRAIL firewall can be effectively implemented and provides adequate protection for customers' confidential information. (RX6002 (Guerin-Calvert Trial Dep. at 84–85).)

1100.1 Illumina is currently implementing the confidentiality provisions of the Open Offer by operating GRAIL as a completely separate and distinct organization and by thoroughly reviewing any interface points with GRAIL. (Berry (Illumina) Tr. 917–18.)

1100.2 The firewall under the Open Offer will have all of the necessary characteristics of an effective firewall, including clear policies around confidentiality, a means to enforce the firewall and a means to disseminate confidentiality policies to relevant personnel. (*See* RX6002 (Guerin-Calvert Trial Dep. at 84–85).)

1100.3 These types of firewalls have been implemented by the FTC (and other antitrust agencies or regulatory agencies) in vertical transactions with success since at least the 1970s. (RX6002 (Guerin-Calvert Trial Dep. at 81–82); *see also* RX3082 (*In re Broadcom Ltd.* Decision and Order) at 5–7; RX3192 (*In re Evanston Northwestern Healthcare Corp.* Final Order) at 5–7; RX3527 (*In re Northrop Grumman* Decision and Order) at 9–13; RX 3557 (*In re PepsiCo, Inc.* Decision and Order) at 6–9; RX3664 (*In re Sycamore Partners II* Analysis of Agreement Containing Consent Order) at 3–4.)

1100.4 The Open Offer's firewall and confidentiality provisions are consistent with and provide the essential features of those used in actual consent decrees and guidelines from the American Bar Association, the ICN Merger Guides and other merger remedy guides. (RX6002 (Guerin-Calvert Trial Dep. at 84–85).)

1100.5 Illumina's customers, such as FMI, have implemented firewalls in the past and have complied with their obligations. (Fiedler (FMI) Tr. 4488.) Dr. Fiedler of FMI also testified that based on historical experience, he had no reason not to trust that Illumina would comply with its firewall obligations. (Fiedler (FMI) Tr. 4487–88.)

10. The Open Offer Addresses Any Concerns Relating to Its Enforcement Provisions

1101. Contrary to the testimony of certain customers, audits under the Open Offer occur with sufficient regularity to ensure Illumina adheres to its obligations under the Open Offer. (Nolan (Freenome) Tr. 2844–45; RX3935 (Illumina) at 3; [redacted]

1101.1 [redacted]

1101.2 To provide customers with even greater security, the Open Offer provides for regular audits twice a year. (RX3935 (Illumina) at 3.)

1102. Contrary to the testimony of certain customers, there is no indication that the selected auditor would be biased in favor of Illumina because the Open Offer requires "an independent third-party auditor" selected "from among the 'Big 4' accounting firms". (PX0064 (Illumina) at 10.)

1103. Contrary to the testimony of certain customers and the opinion of Dr. Scott Morton, the provisions of the Open Offer can be audited effectively. (*See* RX6003 (Rock Trial Dep. at 50–55, 59–65, 67–71).)

1103.1 The theory of incomplete contracting does not suggest that the audit provisions are ineffective because audit provisions in contracts can function effectively even if they (like all contracts) cannot anticipate every possible contingency. (RX6002 (Guerin-Calvert Trial Dep. at 102–04).)

1103.2 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).)

1103.3 Illumina is contractually committed to cooperating in any audits under the Open Offer. (PX0064 (Illumina) at 10.) This enhances the efficacy of the audit. (RX6002 (Guerin-Calvert Trial Dep. at 86–87).)

1103.4 The policies, procedures and reporting processes for an audit can be tailored to each assurance area specified in the Open Offer. (RX6003 (Rock Trial Dep. at 31).)

1103.5 An independent auditor can audit the access to services and products provisions by publishing a comprehensive catalog of services and products, issuing notices when the catalog is updated and having the auditor perform procedures to test whether the catalog is updated, accurate and timely. (RX6003 (Rock Trial Dep. at 59–62); *see also* RX6002 (Guerin-Calvert Trial Dep. at 158–161); PX7076 (Berry (Illumina) Dep. at 294).)

1103.6 An independent auditor can audit the pricing provisions by ensuring that the population of data audited is complete, ensuring accuracy of net prices and discount tiers and ensuring reporting and compliance with the no-price-increase commitment. (RX6003 (Rock Trial Dep. at 63–65); *see also* RX6002 (Guerin-Calvert Trial Dep. at 159); PX7076 (Berry (Illumina) Dep. at 284, 290).)

1103.7 An independent auditor can 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).)

1104. The Open Offer adequately addresses the concern of certain customers that Illumina would get to decide whether there was a good-faith basis for requesting an additional audit because customers must be notified of any potential noncompliance with Illumina's obligations. (RX3935 (Illumina) at 2–3.)

1105. Contrary to the testimony of certain customers and the opinion of Dr. Scott Morton, the arbitration provisions of the Open Offer are not excessively costly or time-consuming. (RX6002 (Guerin-Calvert Trial Dep. at 90–92).)

1105.1 Customers will be willing to undertake arbitration in circumstances where it is cost-effective. (RX6002 (Guerin-Calvert Trial Dep. at 90–92).)

1105.2 Moreover, many steps of the arbitration process can occur in parallel. (deSouza (Illumina) Tr. 2460.) Additionally, Illumina aims to get through any arbitration as fast as possible and to use the most accelerated process available. (deSouza (Illumina) Tr. 2460–61.) Illumina is open to soliciting feedback and improving the arbitration process to make it more expeditious if possible. (deSouza (Illumina) Tr. 2460–61.)

1105.3 Prior to any binding arbitration, the Open Offer also provides for an immediate dispute resolution process, which helps address any concern about the time and expense of arbitration. (PX0064 (Illumina) at 10; RX6002 (Guerin-Calvert Trial Dep. at 89–91).)

VIII. THE BENEFITS OF THE TRANSACTION MORE THAN OFFSET THE ALLEGED HARM

1106. Respondents have offered unrefuted evidence that the reunion will lead to merger specific efficiencies including (1) saving of thousands of lives, (2) acceleration of market access to Galleri, (3) R&D efficiencies, (4) reduction of GRAIL's royalty burden, (5) elimination of double marginalization and (6) supply chain efficiencies, operational efficiencies and acceleration of international expansion of Galleri. (*See* deSouza (Illumina) Tr. 2341–80; Aravanis (Illumina) Tr. 1934–70; Febbo (Illumina) Tr. 4332–72; Qadan (Illumina) Tr. 4158–63; Flatley (Illumina) Tr. 4082–89; Bishop (GRAIL) Tr. 1415–32; Ofman (GRAIL) Tr. 3283–84; 3307–08; 3320–21; Della Porta (GRAIL) Tr. 538–41; Freidin (GRAIL) Tr. 2973–74, 2986, 2999, 3007–08.)

1107. While Complaint Counsel has argued that the efficiencies of the Transaction are unsubstantiated, each was supported by every Illumina and GRAIL witness to testify about them. (*See* deSouza (Illumina) Tr. 2341–80; Aravanis (Illumina) Tr. 1934–70; Febbo (Illumina) Tr. 4332–72; Qadan (Illumina) Tr. 4158–63; Flatley (Illumina) Tr. 4082–89; Bishop (GRAIL) Tr. 1415–32; Ofman (GRAIL) Tr. 3307–08, 3320–21, 3283–84; Freidin (GRAIL) Tr. 2973–74, 2986, 2999, 3007–08; Della Porta (GRAIL) Tr. 538–41; [redacted]

1108. That includes the trial testimony of Francis deSouza (President and Chief Executive Officer of Illumina), Dr. Alex Aravanis (Chief Technology Officer of Illumina and former head of R&D at GRAIL), Dr. Phil Febbo (Chief Medical Officer of Illumina), Ammar Qadan (Vice President and Global Head of Market Access at Illumina), Jay Flatley (former CEO and Chairman of the Illumina Board of Directors at the time of the Transaction), Hans Bishop (CEO of GRAIL), Dr. Joshua Ofman (President and Chief Medical Officer and then-Head of External Affairs of GRAIL), Aaron Freidin (Senior Vice President of Finance at GRAIL), Christopher Della Porta (Senior Director of Commercial Partnerships and then-Director of Growth Strategy at GRAIL) and Dr. Arash Jamshidi (then-Senior Vice President of Data Sciences at GRAIL). (*See* deSouza (Illumina) Tr. 2341–80; Aravanis (Illumina) Tr. 1934–70; Febbo (Illumina) Tr. 4332–72; Qadan (Illumina) Tr. 4158–63; Flatley (Illumina) Tr. 4082–89; Bishop (GRAIL) Tr. 1415–32; Ofman (GRAIL) Tr. 3307–08, 3320–21, 3283–84; Freidin (GRAIL) Tr. 2973–74, 2986, 2999, 3007–08; [redacted]

1109. Complaint Counsel either conducted no cross examination of these witnesses on the Transaction or its questioning readily affirmed the efficiencies.

1110. What is more, the former Chairman of Illumina (Jay Flatley), who is no longer affiliated with the company, testified—without contradiction—that the Illumina Board came to the unanimous conclusion that the Transaction will generate specific efficiencies, including accelerating the adoption of Galleri, streamlining the supply chain, streamlining operations, accelerating international expansion, generating R&D efficiencies and, most importantly, saving lives. (Flatley (Illumina) Tr. 4081–97.)

1111. At the time the Illumina Board approved the Transaction, it was comprised of a Nobel Laureate, former FDA commissioner, financial experts and experienced veterans in the biotech industry. (PX0159 (Illumina) at 9–18.)

1112. Each of the individuals came to his or her conclusion—based on a wealth of experience, that the Transaction will generate efficiencies. (Flatley (Illumina) Tr. 4081–82.)

1113. Mr. Bishop, at the time CEO of GRAIL, testified that the members of the GRAIL Board also unanimously decided to be acquired by Illumina because they had determined that the transaction would result in the best outcome for patients and reduce the risks of the challenges ahead of GRAIL. (Bishop (GRAIL) Tr. 1423; 1515.)

1114. The GRAIL board had deep experience in contemplating the different paths ahead and had done so multiple times with different companies; and employed the advice of expert advisors. (Bishop (GRAIL) Tr. 1422.)

1115. [redacted]

1116. On the flip side, Complaint Counsel offered no fact evidence—not a single witness—to say otherwise. The proof of efficiencies was conclusive.

A. The Reunion of Illumina and GRAIL Will Save Lives

1117. It is undisputed that accelerating consumer access to Galleri will save lives.

1117.1 All agree that cancer screening saves lives. (*See* Conroy (Exact/Thrive) Tr. 1737; [redacted]

1117.2 All agree that accelerating the adoption of a cancer screening test will save more lives. (*See e.g.* Conroy (Exact/Thrive) Tr. 1739; Chahine (Helio) Tr. 1132–33; [redacted]; Fiedler (FMI) Tr. 4474.)

1117.3 The unrefuted evidence shows that reuniting Illumina and GRAIL will accelerate the adoption of the Galleri test. (*See e.g.* deSouza (Illumina) Tr. 2411; [redacted]

1118. Cancer kills about 600,000 people annually in the U.S. alone and more than 9.5 million lives annually worldwide. (RX3030 (ACS) at 3, 55); RX3103 (CDC) at 1; RX3869 (Cote Expert Report) ¶ 25; CC Pre-Trial Br. at 1.)

1119. Cancer screening will save lives. (Conroy (Exact/Thrive) Tr. 1737; [redacted]

1119.1 Numerous fact witnesses, including those called by Complaint Counsel, testified that cancer screening will reduce these numbers and save lives. (Conroy

(Exact/Thrive) Tr. 1737 ("Q. The widespread adoption, sir, of an MCED test, a multicancer early detection test, will save lives. Do you agree with that? A. I do agree with that."); [redacted]

1119.2 Complaint Counsel agrees that cancer screening save lives. (Complaint Counsel Opening Statement, Tr. 11 ("[W]e agree that the technology at issue here, MCED tests, will save lives"); Compl. ¶ 2.)

1120. Accelerating the adoption of a screening test like Galleri will save still more lives. (Conroy (Exact/Thrive) Tr. 1739; *see also* Chahine (Helio) Tr. 1132–33; Nolan (Freenome) Tr. 2725; [redacted]; Fiedler (FMI) Tr. 4474.)

1120.1 Every fact witness to address the issue, including witnesses called by Complaint Counsel, testified that accelerating the adoption of a cancer screening test will save lives. For example, Kevin Conroy, the CEO of Exact Sciences, said that "the acceleration of any [cancer screening] test will save lives". (Conroy (Exact/Thrive) Tr. 1739; *see also* Chahine (Helio) Tr. 1132–33; Nolan (Freenome) Tr. 2725; [redacted]; Fiedler (FMI) Tr. 4474 ("Q. And will the acceleration of a multicancer screening test on the market save lives? A. Yes, it will.").) Complaint Counsel's lead economist agreed. [redacted] *see also* PX7139 (Navathe Trial Dep. at 136 ("Q. If more Galleri tests are conducted, more cancers will be found at earlier stages; right? A. I think as a hypothetical, holding all other factors constant, yes. Q. And that would be better for patient outcomes; right? A. Yes. Q. It will – specifically, it will extend patients' lives right? A. Yes.")).)

1120.2 The parties' experts agree that accelerating the widespread adoption of a screening test like Galleri will save more lives. (Carlton, Tr. 58–62, 72–79; [redacted]

1120.3 Complaint Counsel does not dispute that accelerating the adoption of a screening test like Galleri will save even more lives. (*See* Complaint Counsel Opening Statement, Tr. 11.)

1121. The Transaction will accelerate Galleri and thus save lives. (*See e.g.* deSouza (Illumina) Tr. 2411.)

1121.1 Illumina and GRAIL witnesses testified—without refutation—that the reunion of Illumina and GRAIL will accelerate Galleri and save lives in the U.S. and worldwide. (deSouza (Illumina) Tr. 2411; Aravanis (Illumina) Tr. 1942; Febbo

(Illumina) Tr. 4327; Flatley (Illumina) Tr. 4089; [redacted]; Ofman (GRAIL) Tr. 3283, 3309; Freidin (GRAIL) Tr. 2999; [redacted]; *see also* Compl. ¶ 2.)

1121.2 Francis deSouza, Illumina's President and Chief Executive Officer, testified that "[t]his transaction has the potential to fundamentally dent the mortality curve in cancer and save many, many thousands of lives around the world. Illumina can accelerate global access to this life-saving test by making this test more available." (deSouza (Illumina) Tr. 2411.)

1121.3 Dr. Aravanis, Chief Technology Officer of Illumina and former head of R&D at GRAIL, testified that the Transaction "will lead to millions of more tests performed, tens of thousands of additional lives saved, reduction in the cost of the Galleri test, much broader access". (Aravanis (Illumina) Tr. 1942.)

1121.4 Dr. Febbo, Chief Medical Officer of Illumina, testified that he recommended the approval of the Transaction because "earlier detection has the opportunity to save a lot of lives, and when I started looking at the work we were doing, it became very clear to me that Illumina reacquiring GRAIL, bringing GRAIL back into Illumina could accelerate the speed with which patients would have access to that test through multiple activities." (Febbo (Illumina) Tr. 4327.)

1121.5 Jay Flatley, the Chairman of the Illumina Board of Directors at the time of the Transaction, testified that "[t]he board's collective judgment, as we took a final unanimous vote on this, was that not only was this in the interest of our shareholders but that for all the reasons I just discussed, this would have a dramatic impact on the rate with which we could deploy the Galleri test and, therefore, save the lives of cancer patients who don't know they have cancer". (Flatley (Illumina) Tr. 4089.)

1121.6 [redacted]

1121.7 [redacted]

[redacted]

1121.8 Aaron Freidin, Senior Vice President of Finance at GRAIL, testified that acceleration of Galleri by Illumina means that GRAIL "will do it faster. We will save more lives." (Freidin (GRAIL) Tr. 2999.)

1121.9 [redacted]

1121.10 The parties' experts testified that the reunion of Illumina and GRAIL will accelerate the widespread adoption of the Galleri test. (RX6000 (Carlton, Trial Dep. at 58–62, 72–79; RX6001 (Deverka Trial Dep. at 62–64).)

1121.11 Complaint Counsel has conceded, at least implicitly, that accelerating the reunion of Illumina and GRAIL will accelerate adoption of the Galleri test. (Complaint Counsel Opening Statement, Tr. 11; [redacted]

1122. The Transaction is estimated to accelerate the adoption of Galleri by at least one year. (*See e.g.* Febbo (Illumina) Tr. 4360.)

1122.1 Although it is difficult to quantify the extent to which the Transaction will accelerate the adoption of Galleri, Illumina has estimated that a reunited Illumina and GRAIL will accelerate Galleri's adoption by at least one year. (Febbo (Illumina) Tr. 4360 ("We determined that, in aggregate, these efficiencies will accelerate the adoption and availability of the Galleri test by approximately at least one year."); PX7073 (Aravanis (Illumina) IHT at 77) ("We conservatively estimate that the combined benefits would be at least a year of acceleration in the overall rate of test adoption that we had in the deal model absent these efficiencies."); PX6066 (Illumina) at 8 ("Illumina expects that, as a result of the efficiencies summarized above, after the Proposed Transaction, it will be able to accelerate Galleri reaching patients at scale by at least one year."); PX2613 (Illumina) (applying an acceleration of one year to calculate lives saved).)

1122.2 [redacted]

1123. The lives saved by the Transaction are valued at no less than $37 billion. (*See* RX6000 (Carlton Trial Dep. at 73–75).)

1123.1 Acknowledging the difficulty of valuing human life in monetary terms but using valuations routinely used by the government, Dr. Dennis Carlton (a professor of economics at the University of Chicago Booth School of Business and former Deputy Assistant Attorney General for Economic Analysis, Antitrust Division at the Department of Justice) testified that the value of an acceleration of one year is at least $37 billion. (RX6000 (Carlton Trial Dep. at 73–75).)

1123.2 Dr. Carlton estimated that a one-year acceleration would lead to an additional 10 million tests performed in the U.S. over a nine-year period (2022–2030). (RX6000 (Carlton Trial Dep. at 73–75); [redacted]

1123.3 As shown in the chart below, Dr. Carlton then used "estimates in the literature about how Galleri testing will save lives" and arrived at a "range . . . from 7,429 to 10,441" lives saved from the acceleration. (RX6000 (Carlton Trial Dep. at 73–75); [redacted]

Table 11

Table 3: Baseline tests projected in deal model and impact of one-year acceleration in U.S.

Year	Standalone Tests Sold (Million)	Accelerated Tests Sold (Million)	Additional Tests Sold (Million)	Lives Saved (74 per 100k Tests)	Lives Saved (104 per 100k Tests)
2022	0.1	0.1	0.0	30	43
2023	0.1	0.4	0.3	188	265
2024	0.4	0.9	0.5	374	525
2025	0.9	2.1	1.2	897	1,261
2026	2.1	3.7	1.6	1,207	1,696
2027	3.7	6.1	2.4	1,744	2,451
2028	6.1	7.6	1.5	1,109	1,558
2029	7.6	8.8	1.2	872	1,226
2030	8.8	10.1	1.4	1,007	1,416
Total	**29.9**	**40.0**	**10.0**	**7,429**	**10,441**

Source: Deal Model; Hubbell, et al.

(RX3864 (Carlton Expert Report) ¶ 119, Table 3.)

1123.4 Using a low estimate of $5 million for the value of lives saved, Dr. Carlton estimated a low end value of the efficiencies of $37 billion. (RX6000 (Carlton Trial Dep. at 74) ("I use $5 million, and I use the lower estimate of lives saved, what will I get? And the answer is you get $37 billion."); RX3864 (Carlton Expert Report) ¶ 120.)

1124. Dr. Carlton's estimate of the value of lives saves is conservative. (RX6000 (Carlton Trial Dep. at 74).)

1124.1 For example, the estimate uses the lower end of lives saved and the value of lives saved. Using the higher estimate of lives saved results in a value of over $100 billion. (RX 6000 (Carlton, Trial Dep. at 74) ("If I used the higher estimate [of lives saved], the 10,441," the higher estimate of the value of a live saved is "roughly $10 million, then you get over $100 billion."); [redacted]

1124.2 In addition, the estimate does not include the value of international acceleration, which would double the benefits. (RX6000 (Carlton Trial Dep. at 200); RX3864 (Carlton Expert Report) ¶ 119 n.291 ("My calculations include U.S. lives only. Acceleration will also save lives in other countries. With a one-year acceleration, an additional 10.4 million tests would be performed outside of the U.S. over the nine-year period 2022–2030. If the lives saved by these tests are valued the same as lives saved in the U.S., then the total benefits from acceleration would be more than double what I calculate.").)

1124.3 Dr. Carlton's estimate also does not include the fact that acceleration of GRAIL's sales will allow GRAIL to improve the quality of the Galleri test by generating data quicker. (RX6000 (Carlton Trial Dep. at 78); RX3864 (Carlton Expert Report) at 82.)

1125. The size of the lives saved efficiency is also validated by alternative calculation methods. (RX 6000 (Carlton, Trial Dep. at 76–78).)

1125.1 Dr. Carlton calculated the value of life-years saved by valuing a life year at between $100,000 and $150,000. Using this calculation, the lives saved from a one year acceleration in the U.S. were still valued at least between $11.5 and $17 billion. (RX 6000 (Carlton, Trial Dep. at 76–78); [redacted]

1126. The lives saved efficiency was not refuted by Complaint Counsel.

1126.1 [redacted]

1126.2 [redacted] is directly contradicted by the Department of Health and Human Services and FDA guidance which states that "[t]he approach for valuing mortality risk reductions is generally based on estimates of the value per statistical life". (RX3967 (U.S. Dept. Health and Human Services) at 13; PX7139 (Navathe Trial Dep. at 142–45); *see also* RX3968 (Mammography Quality Standards Act; Amendments to Part 900 Regulations)

(quantifying the benefits derived from reduced mortality from a revised rule regarding breast cancer screening using the value of a statistical life); PX7139 (Navathe Trial Dep. at 146–48).)

1126.3 [redacted]; PX0221 (Hubbell et. al 2021 Supplementary Methods and Materials) at 4 ("As the holdout demonstrated the average performance was compatible with the cross-validated training set, we use here the training set sensitivities which allow resolution of individual cancer type sensitivities by stage"); RX6000 (Carlton Trial Dep. at 77) ("My understanding from the article, as well as discussions with Dr. Hubbell, is that there is no bias.").)

1126.4 Dr. Navathe's claim that Dr. Carlton should not have assumed perfect compliance with the Galleri testing regime overlooks the fact that doing so makes Dr. Carlton's estimate more conservative, not less. (RX6000 (Carlton Trial Dep. at 78).)

1126.5 Moreover, and most notably, none of Dr. Navathe's criticisms change the fundamentals of Dr. Carlton's conclusion: thousands of lives will be saved by the Transaction and the value of those lives is in the billions of dollars. (*See* RX 6000 (Carlton, Trial Dep. at 73–75).) None of Complaint Counsel's experts reliably refute this assertion.

1126.6 Complaint Counsel's economist, Dr. Fiona Scott Morton, speculates that, but for the Transaction, other MCED tests currently in development could be better and therefore might result in more lives saved. ([redacted], 232–33).)

1126.7 However, not only is this argument not supported by the factual evidence but also it asks this Court to accept speculation regarding potential MCED tests over factual evidence regarding existing efficiencies. It is undisputed that Galleri is the only MCED test on the market. (*See*, *e.g.*, Complaint Counsel Opening Statement, Tr. 11 ("[W]e agree that MCED tests is a developing market, meaning, GRAIL is the only company that is offering MCED tests for sale in even a limited capacity.").) Also, there is unrefuted evidence that Illumina will accelerate Galleri and thereby save more lives. (deSouza (Illumina) Tr. 2411; Aravanis (Illumina) Tr. 1942; Febbo (Illumina) Tr. 4327; Flatley (Illumina) Tr. 4089; [redacted]; Ofman (GRAIL) Tr. 3283, 3309; Freidin (GRAIL) Tr. 2999; [redacted] *see also* Complaint Counsel Opening Statement, Tr. 11; Conroy (Exact/Thrive) Tr. 1739; Chahine (Helio) Tr. 1132–33; Nolan (Freenome) Tr. 2725; [redacted]; Fiedler (FMI) Tr. 4474.) In contrast, there is no guarantee that any other MCED test will ever be released much less that they will be able to save the same number of lives as GRAIL or save those lives sooner. Dr. Scott Morton's claims about the effects of other tests are thus baseless speculation.

B. The Reunion of Illumina and GRAIL will Accelerate Market Access to a Life Saving Test

1127. The reunion of Illumina and GRAIL will accelerate market access to Galleri.

1127.1 To achieve widespread adoption, GRAIL will need to achieve regulatory approval and payor coverage for Galleri. (Bishop (GRAIL) Tr. 1343–45; Conroy (Exact/Thrive) Tr. 1734–35; Gao (Singlera) Tr. 2889–91; [redacted]; Rabinowitz (Natera) Tr. 298–99.)

1127.2 While Galleri was launched in June 2021, it has a long way to go in order to obtain widespread market adoption. (Bishop (GRAIL) Tr. 1322–23, 1344–45; [redacted]; Aravanis (Illumina) Tr. 1892, 1943, 1947.)

1127.3 GRAIL is a new company with no expertise or experience in achieving regulatory approval and payor coverage for an NGS test. [redacted]; Freidin (GRAIL) Tr. 2980; Aravanis (Illumina) Tr. 1943, 1947; PX6001 (Deverka Trial Dep. at 67).)

1127.4 Illumina, in contrast, has unique experience and capabilities that will enable the acceleration of market access for Galleri. (deSouza (Illumina) Tr. 2348, 2351–52; Aravanis (Illumina) Tr. 1943–44, 1947; Qadan (Illumina) Tr. 4158–59; [redacted]; Freidin (GRAIL) Tr. 2980; PX6001 (Deverka Trial Dep. at 63).)

1127.5 Hence, the reunion of Illumina and GRAIL will substantially accelerate market access for Galleri. (deSouza (Illumina) Tr. 2343–44; Aravanis (Illumina) Tr. 1945, 1948; Febbo (Illumina) Tr. 4345–46, 4360; Qadan (Illumina) Tr. 4158–59; Flatley (Illumina) Tr. 4082; Bishop (GRAIL) Tr. 1417; [redacted]; Freidin (GRAIL) Tr. 2980; [redacted]; RX6001 (Deverka Trial Dep. at 81); RX3867 (Deverka Expert Report) ¶¶ 112 n.217; 121 RX3867 (Deverka Expert Report) ¶ 112 n.217; RX6001 (Deverka Trial Dep. at 64–86).)

1128. GRAIL currently has limited availability.

1128.1 GRAIL launched Galleri as an LDT in June 2021. (Bishop (GRAIL) Tr. 1322, 1344–45; [redacted] Aravanis (Illumina) Tr. 1892 ("The Galleri test was launched as an LDT").)

1128.2 Galleri is currently available for $949, a price that many individuals cannot afford. (Bishop (GRAIL) Tr. 1322 ("Q. What is the current list price for Galleri? A. $949."); deSouza (Illumina) Tr. 2342 ("Today, the Galleri test is available for $950, and it's a self-pay test primarily. There is a part of the American population that can afford that as a regular test, but there is a lot of this country that cannot afford a thousand-dollar test, and so we feel a sense of urgency to drive reimbursement as quickly as possible.").)

1128.3 Galleri is not approved by the FDA or covered by CMS or private payors. (Bishop (GRAIL) Tr. 1323 ("Q. GRAIL's Galleri test is not currently covered by Medicare; is that right? A. That's right. Q. And Galleri is not widely reimbursed by private insurers yet either; right? A. To my knowledge, it's not reimbursed by any private insurers as of today."); [redacted]; Aravanis (Illumina) Tr. 1943, 1947.)

1128.4 At the time of live hearing, Galleri has only had limited sales of approximately three to four thousand tests. [redacted] Freidin (GRAIL) Tr. 2969 ("I think we're around the 3,000–ish range.").)

1129. Widespread market access to Galleri will depend on FDA, CMS and payor approval.

1129.1 Numerous fact witnesses, including third-party witnesses called by Complaint Counsel, testified that widespread adoption of an MCED test like Galleri will require FDA, CMS and payor approval. (Bishop (GRAIL) Tr. 1343–45; Conroy (Exact/Thrive) Tr. 1734–35; Gao (Singlera) Tr. 2889–91; [redacted] Rabinowitz (Natera) Tr. 298–99.)

1129.2 [redacted]

1129.3 As Dr. Deverka further explained: A novel test like Galleri "needs to have a premarket authorization, so clearance by the FDA. And how that's relevant for payers is that for the Medicare pathway it's actually a requirement to have an FDA-approved or cleared test. And while private payers can choose to pay for a laboratory-developed test, they sometimes pay addition- – give additional weight to the fact that a test has received FDA approval because it's essentially an imprimatur of quality and that the FDA with its rigorous process has approved the test." (RX 6001 (Deverka Trial Dep. at 39).)

1129.4 [redacted]

1129.5 [redacted]

1130. GRAIL is inexperienced in obtaining FDA approval, CMS coverage and private payor approval.

1130.1 [redacted]

1130.2 Aaron Freidin, Vice President of Finances at GRAIL, testified that Illumina has more experience "[c]ompared to what GRAIL's internal capabilities are and what our history is with the FDA today." (Freidin (GRAIL) Tr. 2980.)

1130.3 Dr. Aravanis, former head of R&D at GRAIL, testified that GRAIL has no experience getting FDA approval and payor coverage. (Aravanis (Illumina) Tr. 1943, 1947.)

1130.4 [redacted]

1130.5 Complaint Counsel did not put forward any fact witness that disagreed with this assessment.

1130.6 [redacted]

1131. Illumina is highly experienced in obtaining FDA approval, CMS coverage and private payor approval for NGS products.

1131.1 Illumina draws on a number of functions to support its regulatory and market access efforts. (Febbo (Illumina) Tr. 4317; (RX6001 (Deverka Trial Dep. at 65).)

1131.2 Illumina has built up teams with a large number of experienced individuals able to focus on regulatory and market access activities. (Febbo (Illumina) Tr. 4319, Qadan, Tr. 4113; (RX6001 (Deverka Trial Dep. at 65).)

1131.3 In the past 3–4 years, Illumina's medical team has grown from 25 to 160 individuals. This required selecting employees with relevant expertise and training them in the relevant technologies, which can take 6 to 12 months per employee. (Febbo (Illumina) Tr. 4319.)

1131.4 In the past 3–4 years, Illumina has also built up a market access group consisting of three functions: (1) strategy and operations, (2) health economics and (3) outcomes and payer partners. (Qadan Tr. 4113–14.) Illumina created this group to facilitate coverage and reimbursement for genomics in clinical practice. (Qadan (Illumina) Tr. 4113.) The team contains employees with many different areas of

expertise, including health economists, individuals with experience working with payors and individuals with experience in genomics. (Qadan (Illumina) Tr. 4115.) Illumina is continuing to expand its budget and headcount in the market access group. (Qadan (Illumina) Tr. 4118–19.)

1131.5 Illumina's regulatory and market access teams have extensive and deep experience working with regulators and payors in the U.S. and internationally. (Febbo (Illumina) Tr. 4338–43.)

1131.6 Illumina's regulatory team has extensive expertise obtaining FDA clearances and approvals for diagnostic tests. Illumina has successfully obtained 510(k) clearance for a cystic fibrosis test and a PMA in cancer treatment selection for an extended RAS panel called Praxis. (Febbo (Illumina) Tr. 4338–43; 4113.) Illumina has been working on the approval of a PMA in NIPT and therapy selection. (Febbo Tr. 4381–92.) Illumina also has experience bringing its next-generation sequencing products through FDA clearance. (Febbo (Illumina) Tr. 4338–39.)

1131.7 Illumina frequently interacts with the FDA, including through an educational program to teach the FDA about next-generation sequencing. (Febbo Tr. 4341.) Dr. Febbo testified that "both through my personal interactions and discussions with the FDA and FDA leaders, I have compliments that we have helped them understand next-generation sequencing, and I've seen -- you know, I have seen evolution and improvements in their approach to next-generation sequencing." (Febbo Tr. 4342–43.)

1131.8 Illumina has also developed a quality management system compliant with the requirements of the FDA. (Febbo Tr. 4347.) This system took over seven years to develop and can be used on new projects. (*Id.*)

1131.9 Illumina's market access team has extensive experience working with CMS and private payors. (Qadan (Illumina) Tr. 4154.) Illumina has extensive experience working on clinical studies and developing real world data necessary to show clinical utility. (Qadan (Illumina) Tr. 4156.) Through its partnerships and models Illumina can help show economic value of Galleri. (Qadan (Illumina) Tr. 4156–57.)

1131.10 Illumina has also built up a reputation in market access over three to four years. (Qadan (Illumina) Tr. 4118.) Illumina's broad experience with genomics and its longstanding relationships with payors such as Genomics England allow it to easily develop partnerships with payors. (Qadan (Illumina) Tr. 4416–17.) In addition, Illumina's growing reputation in the field has enabled it to attract the best talent. (Qadan (Illumina) Tr. 4117.)

1131.11 The market access group is currently working on NIPT, tumor comprehensive and whole genome sequencing. (Qadan (Illumina) Tr. 4121.)

1131.12 In NIPT, Illumina spearheaded a risk-sharing agreement with Harvard Pilgrim Health Care to develop the evidence needed to expand coverage of NIPT tests for all pregnancies. (Qadan (Illumina) Tr. 4123–24.) The publication of the work

with Harvard Pilgrim has increased Illumina's reputation and resulted in a significant increase in coverage for NIPT. (Qadan (Illumina) Tr. 4125–26.) Illumina also has a partnership with Providence HealthCare. (Qadan (Illumina) Tr. 4126.)

1131.13 In tumor genomic comprehensive genomic profiling, Illumina has developed partnerships with Providence in the U.S., the Belgian Society of Oncology, University of Melbourne and partnerships in Japan. (Qadan (Illumina) Tr. 4132.) The total number of patients globally covered for tumor comprehensive genomic profiling increased by almost six times. (Qadan (Illumina) Tr. 4133.)

1131.14 In whole genome sequencing, Illumina has worked closely with partners to develop evidence of clinical utility through publications. Illumina has also spent significant time developing evidence of economic utility as well as a model of economic utility. (Qadan (Illumina) Tr. 4134.) Illumina also has partnerships with many U.S. hospitals such as Rady Children's Hospital in San Diego, Medicaid in California and Michigan and countries and healthcare systems outside the U.S. such as Genomics England, the State of Queensland in Australia, in Taiwan and in Israel. (Qadan (Illumina) Tr. 4134–35.) Illumina has also entered into risk sharing agreements with Harvard Pilgrim and the State of Queensland in Australia. (Qadan (Illumina) Tr. 4136.) Coverage for whole genome sequencing has increased from nothing to 32–36 million in the U.S and over 1 billion worldwide. (Qadan (Illumina) Tr. 4137–38.)

1131.15 Illumina has also developed a budget model for NIPT and whole genome sequencing which can be used as a part of entering into partnerships with payors in the future and with payors outside the U.S. This took one to two years to develop. (Qadan (Illumina) Tr. 4128.) This budget model can be used to aid for future models in cancer screening. (Qadan (Illumina) Tr. 4129–30.)

1131.16 [redacted] The partnership currently plans on working on whole genome sequencing in oncology and polyvascular disease. (Qadan (Illumina) Tr. 4187–88.) [redacted]

1131.17 Illumina also has unique expertise in NGS technology. This expertise is critical when it comes to engaging in market access and regulatory efforts for a new technology, such as cancer screening. As Dr. Febbo testified "our technology is

still relatively new to all of the stakeholders, to payers, to regulators, to governments, and while there's early recognition of the promise and, you know, people are starting to see the benefits of genomics, there's really a lack of understanding and certainly a lack of deep knowledge. So it's really important that as we bring the story forward, we have expertise on the technology. We are the experts that can educate, that can engage, and help them understand. And the reason that is is that we're asking them and the payers to write a coverage policy on a technology, and for them to be comfortable with the policy, they have to be comfortable that the technology is analytically, clinically valid and has clinical utility. The regulators have to be convinced that they understand the technology enough to know it's safe and effective and can be the back -- the foundation for safe and effective tests. And so by having that expertise in genomics, you're in a much better position to help the regulators understand and help regulators evolve their approach to approval or payers evolve their approach to positive policy decisions covering those tests." (Febbo (Illumina) Tr. 4318–19.)

1132. Numerous witnesses testified to Illumina's experience and expertise in these areas.

1132.1 Illumina's Chief Executive Officer, Francis deSouza testified that "we have now, you know, closing in on about ten years' experience working with the FDA. We have since got[ten] other sequencers approved. . . . And on the test side, we're working on getting approval for our TSO 500, we're working on getting approval for our NIPT assay here in the U.S., and we're looking at getting approval for a genetic disease diagnosis workflow as well." (deSouza (Illumina) Tr. 2348.)

1132.2 With respect to payor coverage, Mr. deSouza testified Illumina "ha[s] been working with payers in the U.S. and around the world, again, for almost a decade. We have a very talented team that has expertise in working with payers and is – and has the right innovation focus to come up with new models to accelerate the evidence generation needed to get payers on board." (deSouza (Illumina) Tr. 2351–52.)

1132.3 Dr. Aravanis, Chief Technology Officer at Illumina and former head of R&D at GRAIL, testified that "Illumina received the first FDA clearance for a next-generation sequencer. It's received over 70 clearances and registrations around the world in 45 countries. It's received multiple clearances and a PMA approval in the United States." (Aravanis (Illumina) Tr. 1943–44.)

1132.4 Dr. Aravanis also testified that "Illumina has pioneered multiple approaches to market access, resulting in over 100 million additional patients worldwide covered for whole genome testing for genetic disease over the last two years. In the United States, we have now achieved 200 million people who can receive coverage for comprehensive genomic profiling using NGS technology. These were largely driven by Illumina's market access efforts." (Aravanis (Illumina) Tr. 1947.)

1132.5 Mr. Ammar Qadan, Vice President and Global Head of Market Access at Illumina, provided a detailed overview of Illumina's extensive market access capabilities

and the success they have had working with payors in the NGS space. (Qadan (Illumina) Tr. 4158–59.)

1132.6 [redacted]

1132.7 Aaron Freidin, Senior Vice President of Finance at GRAIL, testified that "Illumina has those resources to do those things and have demonstrated doing it in the past." (Freidin (GRAIL) Tr. 2980.)

1132.8 Dr. Deverka testified that Illumina has "a track of a market access team having generated the requisite evidence of clinical utility and engagement with payers, both in the U.S. and internationally, to support the use of next-generation sequencing-based tests, so it's really their – their objective track record." (PX6001 (Deverka Trial Dep. at 63).)

1132.9 Complaint Counsel did not put forward any fact witness that disagreed with this assessment, and its expert witnesses lack the expertise to opine on the issue. [redacted] PX7139 (Navathe Trial Dep. at 97–103); PX7140 (Rothman Trial Dep. at 42–44).)

1132.10 The Transaction will accelerate FDA, CMS and payor coverage of Galleri. (deSouza (Illumina) Tr. 2343–44; Aravanis (Illumina) Tr. 1945, 1948; Febbo (Illumina) Tr. 4345–46, 4360; Qadan (Illumina) Tr. 4158–59; Flatley (Illumina) Tr. 4082; Bishop (GRAIL) Tr. 1417; Ofman (GRAIL) Tr. 3346, 3371; Freidin (GRAIL) Tr. 2980; [redacted]

1133. Numerous Illumina and GRAIL fact witnesses testified that the reunion of Illumina and GRAIL will accelerate Galleri's path to FDA approval and CMS and private payor coverage.

1133.1 Francis deSouza, Chief Executive Officer and President of Illumina, testified that: "We also have deep expertise working with payers. We have created innovative programs like risk-sharing agreements with insurance companies where we contribute resources and offer a test to a segment of the population to gather the clinical data as well as the economic data to build the case for the insurance company to cover the test. . . . Now, that's stuff we can just plug the GRAIL, you know, work into and accelerate the adoption of GRAIL, so there's a lot of work we can do on market access. . . . our teams have deep experience, nearing now a decade, on working with regulators to get cleared tests and to get cleared sequencers. We're working that in oncology now and we're working that for genetic disease now and hope to get the first – you know, to progress that as well." (deSouza (Illumina) Tr. 2343–44.)

1133.2 Dr. Aravanis, Chief Technology Officer at Illumina and former head of R&D at GRAIL, testified that: "Illumina has made applications and has multiple pending applications for first-in-kind products for next-generation sequencing. In doing that, it's broken new ground working with the FDA on how to develop applications for these types of processes. They're very complex diagnostics. The applications are complex, and it's learned a tremendous amount in doing that and incorporated those into the current processes and templates for making applications. Those benefits will be conferred to GRAIL as part of the acquisition" and that Illumina's plan is "[to] apply the same approaches that Illumina used in other areas where it's increased market access and reimbursement." (Aravanis (Illumina) Tr. 1945, 1948.)

1133.3 Dr. Febbo, Chief Medical Officer at Illumina, testified that "I've seen our regulatory team. I've seen our broad teams come together to address multiple challenges, regulatory challenges as well as others. I know the incredible depth – how the incredible depth of expertise we have at Illumina is brought to bear and how we can motivate and really engage and execute on strategies to address challenges and to accelerate those timelines. . . . We determined that, in aggregate, these efficiencies will accelerate the adoption and availability of the Galleri test by approximately at least one year". (Febbo (Illumina) Tr. 4345–46, 4360.)

1133.4 Ammar Qadan, Vice President and Head of Market Access at Illumina, testified that "[t]hrough some of the partnerships that we have today, we will be able to accelerate the development, for example, with commercial payers in the U.S. We – in fact, we can do a lot. We can also accelerate, though it's not my area of expertise, but we can accelerate hopefully the regulatory approval, resulting in an accelerated path for CMS coverage and reimbursement." (Qadan (Illumina) Tr. 4158–59.)

1133.5 Jay Flatley, Chairman of the Board of Illumina at the time the transaction was entered into, testified that Illumina "has the ability to accelerate the adoption of this test or the approval of the test through the FDA. We also have the ability, because of the size and scope of the company, to establish reimbursement much more quickly than GRAIL would have the ability to do." (Flatley (Illumina) Tr. 4082.)

1133.6 Hans Bishop, Chief Executive Officer at GRAIL, testified that "deep expertise in interacting with regulators derisks and maybe speeds up the speed at which we can get the regulatory approvals, which are often – certainly that's true in the United States – a prerequisite to getting reimbursement. . . . [W]e have to be concerned about government and payers' ability to pay, and being part of Illumina will help us accelerate the speed at which we can drop the price of our tests." (Bishop (GRAIL) Tr. 1417.)

1133.7 [redacted]

[redacted]

1133.8 Aaron Freidin, Senior Vice President of Finance at GRAIL, testified that "a large inflection point to creating value and saving lives is going to be getting broad reimbursement. And this population we're addressing is between 50 and 80, of which, you know, the majority – a lot of those people are on public government pay, whether it's Medicare or something else. So to go down that path we'd have to have a PMA and get reimbursement, and so on. You know, Illumina has those resources to do those things and have demonstrated doing it in the past." (Freidin (GRAIL) Tr. 2980.)

1133.9 [redacted]

1133.10 [redacted]

1133.11 Mr. Qadan provided further information regarding the ways in which Illumina can accelerate market access for Galleri.

1133.12 Illumina has developed a plan to achieve the acceleration of market access. "[I]n the U.S., we will be working on accelerating CMS approval through clinical utility data and through accelerating the regulatory approval . . . Outside the U.S., there will be a lot of work needed with single-payer healthcare systems and countries, like what we have done, for example, with Genomics England, like what we have done with Germany, to accelerate the availability of Galleri in Europe, and third, as I mentioned, also the work that we can do in China to accelerate the availability of Galleri in China considering that there is a favorable environment in China for lab-developed tests now that did not exist before. So there are many things. Our group's experience then based on what we have done so far and the expertise we have developed, we can take many of those initiatives to accelerate Galleri's availability and reimbursement in the different markets." (Qadan (Illumina) Tr. 4163.)

1133.13 With regard to clinical utility, Mr. Qadan explained that Illumina has "a broad expertise in terms of developing those clinical studies, whether it is real-world data, as what we have just described with NIPT, the work that we're doing with whole genome sequencing, or even developing data from scratch like the work that we have done with NICUSeq study, which is double-blinded type of study, so more complicated. So we have experience building real-world data, we have experience building sophisticated clinical trials, and we have relationships, whether with healthcare systems or with payers, that would enable us to do both things as well."

1133.14 With regard to economic utility, Mr. Qadan explained that Illumina could use its experience to help assess budget impacts and also help in "finding innovative partnerships that would enable us to gather data for the test that will inform the clinical utility of the test". (Qadan (Illumina) Tr. 4157.)

1133.15 Illumina also plans to leverage the use of Galleri as a diagnostic aid to cancer ("DAC") in order to increase payer confidence and adoption of Galleri in the general population. As Mr. Qadan explained: "So diagnostic aid to cancer is one of the applications of Galleri, so it's the same test, Galleri. However, it is the use of Galleri in patients who could have started developing signs and symptoms of cancer. Because the test performs better in more advanced disease, we can expect the test to perform better in those patients. The value of this is that the clinical utility will be ruling out or ruling in whether those patients have cancer so that they do not go into multiple other tests and then they can hopefully start therapies. And the second is, there could be cost savings for the system to do one test that rules out or rules in cancer rather than multiple tests initially. So as we know payers around clinical utility and economic utility, there is clinical utility for DAC, and the economic utility could be even cost saving. So that will initially enable us to introduce Galleri into the marketplace while not having a huge budget impact for payers to resist. Through that entry, we can go into phase two, which is developing the data around the risk factors associated with those patients who tend to be positive for cancer, what do they share in common. And so that data will enable us then to go back and expand the use of Galleri in those patients with those risk factors to screen them first, so that will then expand the use of Galleri with an acceptable budget impact hopefully. And then the third phase hopefully will be once all of the clinical utility studies that GRAIL is doing or we will be doing start reporting results, that then can expand the use of Galleri in the general population above the age of 50, so it's a phasing of the Galleri budget impact knowing that payers might resist a test with high budget impact, so that's our plan." (Qadan (Illumina) Tr. 4163–64.)

1133.16 [redacted]

1133.17 [redacted]

[redacted]

1133.18 [redacted]

1133.19 [redacted]

1133.20 [redacted]

1133.21 As Mr. Qadan further explained "in Europe we can work with single-payer systems and health technology assessment agencies to start understanding their needs to deliver on their needs, the same thing in countries like Australia and Japan. And then in a major market like China, we could start some of the work around patient or people willingness to pay for screening, for cancer screening, types of studies that can inform Galleri's launch. So we can work on all of that and hopefully, you know, accelerate Galleri launch in all of those countries." [redacted] 4158–59; [redacted]

1133.22 Complaint Counsel did not present any contrary fact witness testimony and none of its experts are qualified to address the subject. (*See* [redacted]; PX7139 (Navathe Trial Dep. at 97–103); PX7140 (Rothman Trial Dep. at 42–44).)

1133.23 Echoing the unrefuted fact testimony, Dr. Deverka testified that the reunion of Illumina and GRAIL will accelerate GRAIL's FDA approval, CMS coverage and payor coverage. (RX6001 (Deverka Trial Dep. at 62–64).)

1133.24 Specifically, Dr. Deverka testified that Illumina's relationships with health systems and payors, its knowledge of payor evidence expectations and its ability to invest in large prospective studies that can be replicated across settings contribute and that "the acquisition will accelerate market access for Galleri." (RX6001 (Deverka Trial Dep. at 62–64).)

1133.25 In addition, "if Illumina's resources and prior experience dealing with the FDA are brought to bear with the merged companies that I predict that the – that could accelerate regulatory approval for Galleri, which would then have the downstream impact of further accelerating payer and Medicare coverage." (RX6001 (Deverka Trial Dep. at 81); RX3867 (Deverka Expert Report) ¶ 121 (noting Illumina's "experienced regulatory and quality teams that can work to accelerate FDA and other approvals").)

1133.26 The following table compares GRAIL's and Illumina's capabilities in relevant responses and summarizes how the reunion of the companies will accelerate FDA, CMS and private payor coverage:

Table 12

Capability	GRAIL	Illumina	Expected Efficiencies
Dedicated staff	[redacted]	13 focused on market access; 18 in medical affairs; 17 in clinical affairs; 23 in regulatory affairs; 11 in biostatistics	[redacted]
Experience with private and public payors	[redacted]	Extensive and international. Established coverage track record for multiple NGS test categories (not in CA screening tests)	[redacted]
Health system partnerships	[redacted]	Extensive and international. Track record of success with NIPT, CGP and RUGD	[redacted]

Capability	GRAIL	Illumina	Expected Efficiencies
			[redacted]
De-risking of reimbursement challenges	[redacted]	Harvard Pilgrim/NIPT case Harvard Pilgrim/WGS case Queensland Australia WGS for RUGD case	[redacted]
Regulatory experience with PMA	[redacted]	Extensive	[redacted]
Distributed version of test (requires FDA/regulatory approval)	[redacted]	Area of established expertise for Illumina	[redacted]
Global presence and expertise	[redacted]	Extensive	[redacted]
Resources to support appropriate real-world use of Galleri, fit into clinical workflow	[redacted]	Experience with educating patients and providers through pre-competitive collaborations (CAPS). Existing partnership with Genome Medical providing education to individuals, health care providers, and employers nationwide	[redacted]
Value assessment methods development	[redacted]	Experience with funding methods research for value assessments of	[redacted]

Capability	GRAIL	Illumina	Expected Efficiencies
		NGS-based tests (GEECS)	
Technical solutions such as process efficiencies working with laboratories, supply chains and automation	[redacted]	Extensive	[redacted]

(RX3867 (Deverka Expert Report) ¶ 112 n.217; RX6001 (Deverka Trial Dep. at 64–86) (explaining how each of the factors in the above table contribute to Illumina's ability to accelerate Galleri).)

1134. The evidence of regulatory and market access efficiencies is essentially unrefuted.

1134.1 Complaint Counsel does not dispute that GRAIL is far from being widely available.

1134.2 Nor does Complaint Counsel dispute that GRAIL has limited regulatory and market access capabilities.

1134.3 Instead, it relies on the testimony of two purported experts, Dr. Rothman and Dr. Navathe, for the proposition that Illumina's ability to accelerate Galleri is not properly substantiated.

1134.4 However, neither Dr. Rothman nor Dr. Navathe has relevant expertise to assess these efficiencies. (PX7139 (Navathe Trial Dep. at 97–102) (admitting that he lacks expertise in seeking FDA approval for an MCED test, how the FDA will evaluate an MCED test, seeking payor coverage for an MCED test and how payors will evaluate an MCED test); PX7140 (Rothman Trial Dep. at 42–46) (admitting that he lacks expertise with respect to FDA approval or payor reimbursement).)

1134.5 Dr. Navathe also made clear that he does not have an opinion on the expected timing of Galleri with or without the Transaction and that he had no opinion on acceleration. (PX7139 (Navathe Trial Dep. at 130, 132) (testifying that he "would not be able to predict timing" and has not drawn any conclusion of his own as to when Galleri is likely to get FDA approval with or without the Transaction).)

1134.6 Moreover, neither Dr. Navathe nor Dr. Rothman attempts to undermine the undisputed testimony (described above).

1134.7 [redacted]

1134.8 Moreover, unrefuted fact witness testimony (presented at trial) shows Illumina will benefit from acceleration (PX5027 (Illumina) at 36 (noting that a potential transaction would both accelerate adoption of screening market and increase share of revenue)), and that Illumina intends to implement plans to accelerate Galleri (*see e.g.* deSouza (Illumina) Tr. 2343–44). The government's experts ignored this testimony altogether.

1134.9 [redacted] However, speculation regarding future legislation does nothing to undermine the acceleration Illumina can create today, and Dr. Navathe pointed to no evidence that the potential legislation would actually benefit GRAIL in the same ways the Transaction would.

1135. Illumina's fact and expert witnesses provided detailed testimony regarding Illumina's plans to accelerate Galleri's regulatory approval.

C. Reuniting Illumina and GRAIL Will Lead to R&D Efficiencies

1136. In addition to accelerating market access, the Transaction will lead to significant R&D efficiencies, through the combination of GRAIL's expertise in methylation, data science and software development and Illumina's complementary expertise in sequencing and bioinformatics. (deSouza (Illumina) Tr. 2355–56; Aravanis (Illumina) Tr. 1952–54; Febbo (Illumina) Tr. 4356–60; Flatley (Illumina) Tr. 4082, 4088–89; Bishop (GRAIL) Tr. 1416; Jamshidi (GRAIL) Tr. 4048, [redacted].)

1137. Respondents presented extensive fact testimony in support of this efficiency, whereas Complaint Counsel presented no fact witness to refute it. (deSouza (Illumina) Tr. 2355–56; Aravanis (Illumina) Tr. 1952–54; Febbo (Illumina) Tr. 4356–60; Flatley (Illumina) Tr. 4082, 4088–89; Bishop (GRAIL) Tr. 1416; [redacted].)

1138. GRAIL is a relatively small company without the resources to focus on all of the R&D projects that it might otherwise be interested in pursuing. (Flatley (Illumina) Tr. 4088 ("GRAIL is a company with much more limited resources than what Illumina has, and as such, they were appropriately focused on delivering the Galleri test to the market and getting that as advanced as they possibly could"); Bishop (GRAIL) Tr. 1367 ("The investments we need to continue to make in R&D continue to be very significant."); [redacted]

1139. Illumina is a larger company with the financial resources to focus on R&D. (Flatley (Illumina) Tr. 4088.)

1139.1 In fact, R&D is a core component of Illumina's business. (Aravanis (Illumina) Tr. 1948 ("At Illumina, you know, innovation is incredibly important to the company, and we invest tremendously in research and development."); deSouza (Illumina) Tr. 2353 ("Q. . . . What role does R&D play in Illumina's business generally? A. R&D is absolutely critical at Illumina. Q. Why is that? A. We believe that innovation is going to be critical to, you know, unlock the future markets for genomics, that to unlock the next set of markets we need to continue to deliver lower prices into the market."); Aravanis (Illumina) Tr. 1950 ("[O]f the approximately 1800 people in the core research and development group at Illumina, about a quarter of those, you know, close to 500, have advanced scientific or advanced engineering degrees.").)

1139.2 Illumina spends "over $600 million in R&D" annually "which is about twice as much as a percentage of our revenue on R&D as the industry average." (deSouza (Illumina) Tr. 2354.)

1139.3 Illumina has been widely recognized for its R&D work. (deSouza (Illumina) Tr. 2354 (Illumina has been "recognized as one of the hundred most influential companies by TIME. . . . MIT Technology Review recognized us as the number one smartest company in the world a while ago. So we've received a number of awards over the last few years for our R&D work.").)

1140. The reunion of Illumina and GRAIL will lead to significant R&D efficiencies both related to the Galleri test and related to other technologies.

1140.1 As Jay Flatley testified, "We had some opportunities in the R&D side, because when you put brilliant people together like we have at GRAIL and Illumina, sparks fly." (PX7079 (Flatley (Illumina) Dep. at 31).)

1141. Illumina and GRAIL witnesses testified—without contradiction—that Galleri-specific efficiencies will arise from the reunion of Illumina and GRAIL.

1141.1 Francis deSouza, Chief Executive Officer and President of Illumina, testified that: "Our team has deep experience over – over a decade now in optimizing workflows in the processing of genomic tests. We have been running genomic tests at scale for over a decade now. What that means is our R&D teams are very good at optimizing, you know, how samples come in, so sample accessioning, how samples are prepared for sequencing, so both the sample extraction as well as library preparation. And then our teams are very good at creating high-throughput bioinformatics pipelines to process the data, and so our teams are very good at creating lower-cost, high-throughput workflows to process samples, and that will benefit Galleri." (deSouza (Illumina) Tr. 2355–56.)

1141.2 Alex Aravanis, Chief Technology at Illumina and former head of R&D at GRAIL, testified that: "So Illumina is developing applications in multiple areas: noninvasive prenatal testing, genetic disease testing, therapy selection. We believe that

some of those innovations that we're making in those other areas we will be able to apply also to future versions of the Galleri test, improving the performance and, therefore, increasing the clinical value of the test. Another type of R&D efficiency will be to lower the cost of the Galleri test faster. Illumina has significant experience and capabilities in miniaturizing assays, simplifying assays, developing new components for assays that can lower cost, internalizing manufacturing of expensive components, and by internalizing the manufacturing of them, reducing the cost of the overall test. Illumina can manufacture its own enzymes and, therefore, this makes the internalization and manufacturing at lower cost possible." (Aravanis (Illumina) Tr. 1952.)

1141.3 Phil Febbo, Chief Medical Officer at Illumina, testified that "Well, what I've seen and I'm excited about occurring as the companies come together is that as you expand your testing, as you scale testing and you test hundreds, thousands, tens of thousands of patients, you end up getting data that really helps you understand the test to a degree that's even deeper than initially. It also gives you data where you can bring in your biostatisticians and biostatistics reports to me, you can bring in your – you know, your – your medical experts, and together to work with your product development folks that is in core R&D under Alex Aravanis and look at those signals and look at how to improve the test itself, improve the performance, improve the efficiency." (Febbo (Illumina) Tr. 4356–57.)

1141.4 Jay Flatley, Chairman of the Board of Illumina at the time the transaction was entered into, testified that the Board of Directors of Illumina determined that "we could take advantage of the data that's coming from the international expansion, integrate that data, and use the deep learning algorithms to improve the accuracy of the Galleri test and to improve the number of cancers that it – that it addresses. So we would accelerate the improvement of the Galleri test on the one hand. (Flatley (Illumina) Tr. 4082.)

1141.5 Hans Bishop, then-Chief Executive Officer of GRAIL, testified that "ongoing access to funding is more secure as part of a large, successful, profitable company, and I believe that Illumina, as an outstanding technical innovation company, deeply understand[s] the importance of ongoing investment in research and development. That's how they've been successful, by continuing to do that. So I believe that the resources that we need to be reliably continuing to make those sorts of investments are greatly secured. I also believe that certain technical abilities that Illumina have will contribute to our performance in that area." (Bishop (GRAIL) Tr. 1416.)

1141.6 [redacted]

1141.7 Complaint Counsel did not even try to undermine this testimony through cross examination. It stands unrefuted.

1142. Similarly, party witnesses have testified that the Transaction will generate a number of non-Galleri related R&D efficiencies.

1142.1 Francis deSouza, Chief Executive Officer and President of Illumina, testified that: "We believe that – (inaudible) – once we – once we're allowed to merge, we will bring our R&D teams together and immediately start the work necessary to identify the genomic biomarkers in blood for other conditions, like fatty liver disease, neurological conditions like Alzheimer's and Parkinson's. We believe – we will get the teams working on it, and we would love to get a blood test screen for those conditions in addition to this cancer screen." (deSouza (Illumina) Tr. 2356.)

1142.2 Alex Aravanis, Chief Technology Officer at Illumina and former head of R&D at GRAIL testified that: "There's a couple ways that we think the transaction will lead to R&D benefits to the larger Illumina. One is novel discoveries. So our experience, for example, in noninvasive prenatal testing is that when you operate a clinical test as a large service, you will have additional findings. Those could give insights into other types of diseases that GRAIL's technology could be useful for. For example, fatty liver disease or neurodegenerative disease. Those are other applications Illumina would pursue. In addition, we've found that there's significant cross-pollination between applications, meaning that there's aspects of GRAIL's methylation technology that could be useful for noninvasive prenatal testing or genetic disease testing." (Aravanis (Illumina) Tr. 1954.)

1142.3 Phil Febbo, Chief Medical Officer at Illumina, testified that "I see this kind of platform as having significant impact certainly in cancer testing. We'll see screening, which is what we're talking about. We'll also see these kind of signals helpful in cancer monitoring, but outside of cancer, we know that these signals could pick up on metabolic disease. So in the United States, obesity is a major challenge. There's fatty acid – fatty changes in the liver, or NASH, causing NASH, an increasing healthcare concern, and I am confident – I don't know which application will go first, whether it's cardiovascular disease, metabolic disease, inflammatory disease – but I'm quite confident that as we look at these outliers, we'll see opportunities to build tests that serve as many, if not – as many patients as the screening test can serve." (Febbo Tr. 4359–60.)

1142.4 Jay Flatley, Chairman of the Board of Illumina at the time the transaction was entered into, testified that the Board of Directors of Illumina determined that "we could take advantage of the data that's coming from the international expansion, human blood carries markers for all kinds of diseases, some of those yet to be discovered, but we do know that there are markers in the blood for neurologic diseases, such as Alzheimer's, markers for conditions like diabetes, and because GRAIL, again, has to be so focused on the Galleri test, they don't have the ability to move rapidly to develop these other tests, where in combination with Illumina, we could delegate resources to work on these other tests and bring follow-on, complementary tests to the market much more quickly." (Flatley (Illumina) Tr. 4088–89.)

1142.5 Here, again, Complaint Counsel did not put on any fact witnesses that undermined or even attempted to contradict this testimony.

1143. Respondents' experts corroborated the undisputed fact testimony that R&D efficiencies will arise from the reunion of Illumina and GRAIL.

1143.1 As Dr. Carlton has explained: "simply put, you put some scientists who know one thing with scientists who know another thing, you put them together, and out of that collaboration comes new products, new ideas, new ways of doing things that could not just lower costs but create — create new products. . . But my understanding is that the possibility for such types of R&D discoveries is a real one as a result of this transaction and that some of these possibilities include being able to do screening not just for cancer, but for neurodegenerative diseases, like Alzheimer's, fatty liver disease, cardiovascular disease. So all of these, it's my understanding, are possible benefits from this R&D collaboration". (RX6000 (Carlton Trial, Dep. at 61–62).)

1144. The evidence of R&D efficiencies is unrefuted.

1144.1 [redacted]

1144.2 Instead, Dr. Rothman states that the efficiency is not cognizable because Dr. Carlton did not assess the specific efficiencies that will be created or the cost of those efficiencies. (RX3854 (Rothman Dep. at 25–34).)

1144.3 However, Dr. Rothman fails altogether to account for the undisputed fact testimony illustrated above; he simply ignores it.

1144.4 Dr. Rothman also does not explain why understanding the exact costs of these efficiencies is necessary in order for them to be cognizable.

1144.5 Moreover, Dr. Rothman admittedly only assessed the evidence in Dr. Carlton's report and did not assess any other evidence, including affirmative testimony offered by Respondents' witnesses at trial. (RX3854 (Rothman, Dep. at 74–78) ("A.. . My analysis is of the claims that – – certain claims that Dr. Carlton, Dr. Deverka and Mr. Serafin Make in their reports. . . . Q So if – you don't know whether there is additional evidence out there that supports any of those claimed efficiencies beyond what they cited, do you? . . . A. My analysis was of what they offered as substantiation for certain claimed efficiencies. . . . Q. GRAIL and Illumina's witnesses have not yet offered their direct testimony at trial, have they? We can agree on that? A. Yes. Q. Okay. You don't know what those witnesses are going to say under direct examination, by definition, right? A. That's correct".)).

1144.6 [redacted] However, the firewall in the Open Offer is designed to protect against the sharing of third party

confidential information and does not prevent Illumina and GRAIL from engaging in R&D activities. (RX3340 (Illumina Open Offer at 7–8) ("Illumina shall establish a firewall designed to prevent any GRAIL personnel (and any Illumina personnel carrying out activities with respect to the GRAIL business or products) from accessing any Confidential Information obtained by or made available to Illumina relating to Customer or its business or products, whether pursuant to this Supply Agreement or otherwise".).) Thus, it has no bearing on the R&D efficiencies shown at trial.

1145. Complaint Counsel also ignores Illumina's track record of generating R&D efficiencies in a vertical transaction.

1145.1 Illumina's track record of generating R&D efficiencies in a vertical transaction substantiates the R&D efficiencies.

1145.2 The idea for Galleri came from another vertical transaction: Illumina's acquisition of Verinata, a company in the non-invasive prenatal testing business. (Aravanis (Illumina) Tr. 1868–69; PX7048 (Klausner (GRAIL) IHT at 49–54).)

1145.3 In the first hundred thousand women that received Illumina's noninvasive prenatal test, some unusual signals were identified. (Aravanis (Illumina) Tr. 1868–69; PX7048 (Klausner (GRAIL) IHT at 49–54).)

1145.4 Illumina formed a team and a program to evaluate early cancer detection signals and to follow up with patients and their prescribing physicians, which led to the discovery that the women with the unusual NIPT results had undiagnosed cancers. (Aravanis (Illumina) Tr. 1869–70; PX7048, (Klausner (GRAIL) IHT at 49–54).)

1145.5 It is that discovery that ultimately led Illumina to pursue development of an early cancer detection test and to found GRAIL. (Aravanis (Illumina) Tr. 1871; PX7048 (Klausner (GRAIL) IHT at 43–44, 69–72).)

1145.6 As Jay Flatley testified: "If you go back to the origin of GRAIL, one of the most important things that happened there was our acquisition of Verinata because it was that work that really was the light bulb moment that I think I described to you last time, about the actual failures in a number of cases of the NIPT test that caused us to realize that you can detect cancer by screening the blood. So those kinds of magical moments happen when you put people together that are working in related areas. So certainly some great opportunities would evolve there". (PX7079 **(**Flatley (Illumina) Dep. at 31–32).) This project was enabled by Illumina's acquisition of Verinata.

1145.7 Similarly, Rick Klausner, one of the founders of GRAIL, testified that: "So very soon after I had started at Illumina, I received either an e-mail or a phone call from a pathologist named Meredith Miller, who had been working at a company called Verinata that Illumina had at that time I think relatively recently acquired. And this was a company that was performing an LDT called NIPT for noninvasive prenatal testing, which is basically a liquid biopsy company I guess of sorts, but it's . . . not a company. It's a technology that measures the same type of circulating fragments of DNA that we now have been looking at for early cancer detection. And she had known of me. I think I

had met her in the past. But told me a story that . . . she was the pathologist who was reading and signing off on the NIPT results and told me that she had collected a small number, less than 15 . . . of, as she described them, really weird results. And she didn't understand the results. She told me that she had basically concluded that the test didn't work, but to her great, you know, I think it's terrific that she was puzzled by and kept them. She wondered what they were. This was all happening very quickly because the scaleup of very long NIPT by multiple companies, including Verinata and then Illumina, had just gone very rapidly, hundreds of thousands of these tests, you know, quite extraordinary, and that was important, because of the hundred to thousand I don't remember the precise number that they had run, she only had these 12 to 15 that were, quote, this similar weird pattern. And she asked me if she could bring them by to show me these genomic readouts to see if I had any ideas about what was going on. So that was the framing of what was then going to change my mind about the possibility of a multicancer detection test." (PX7048 (Klausner (GRAIL) IHT at 43-44).)

1145.8 Verinata did not have the resources to research and develop an early cancer detection test on its own, and but for Illumina acquiring Verinata no one would have developed an early cancer test research and development program despite the potential benefits of such a test. (Aravanis (Illumina) Tr. 1873–74.)

1145.9 Illumina's track record of generating R&D efficiencies in connection with a vertical transaction corroborates the R&D efficiencies proven here. (deSouza (Illumina) Tr. 2345 ("we believe that there are R&D synergies between the two teams, so just like our team discovered the possibility to see cancer in blood because we were processing NIPT samples, we believe that it is going to be possible to develop a diagnostic test, a blood diagnostic test, to look for fatty liver disease, Alzheimer's, Parkinson's. But that requires the capabilities of the two companies to be brought together, and so we believe there are R&D synergies there".); PX7079 (Flatley (Illumina) Dep. at 31–32) ("If you go back to the origin of GRAIL, one of the most important things that happened there was our acquisition of Verinata because it was that work that really was the light bulb moment . . . that caused us to realize that you can detect cancer by screening the blood. . . . So certainly some great opportunities would evolve there".).)

D. The Reunion of Illumina and GRAIL Has Already Reduced GRAIL's Royalty Burden.

1146. The Transaction will lead to significant efficiencies by reducing royalties that GRAIL was required to pay Illumina before the Transaction.

1146.1 [redacted] PX7073 (Aravanis (Illumina) IHT at 27).)

1146.2 [redacted]

1147. [redacted]

1147.1 [redacted]

1147.2 [redacted]

1147.3 [redacted]

1148. [redacted]

1148.1 [redacted]

1148.2 [redacted]

1148.3 [redacted]

1148.4 [redacted]

1148.5 [redacted]

1149. Royalty savings will be passed on to consumers.

1149.1 The reduction of royalties resulting from the Transaction will be passed on to consumers in the form of lower prices. (Freidin (GRAIL) Tr. 2975–77; **{3029–30}**.)

1149.2 [redacted] (Freidin (GRAIL) Tr. 2975–77; **{3029–30}**.)

1149.3 [redacted] PX7073 (Aravanis (Illumina) IHT at 27).)

1149.4 Dr. Aravanis testified that "[i]t is Illumina's plan to pass 100% of those efficiency savings on to payers of the test, so, you know, physicians – or sorry – patients and, you know, other payers of the test". (PX7065 (Aravanis (Illumina) IHT at 27).)

1149.5 [redacted]

1150. [redacted]

1150.1 [redacted]

1151. The royalty efficiency is unrefuted.

1151.1 Complaint Counsel does not offer any fact witness testimony to the effect that the Transaction did not reduce GRAIL's royalty obligation.

1151.2 Moreover, Complaint Counsel's experts do not opine on this efficiency in their reports.

1151.3 [redacted]

1151.4 [redacted]

1151.5 [redacted] (Aravanis (Illumina) Tr. 1959–61; deSouza (Illumina) Tr. 2358–70; Freidin (GRAIL) Tr. 2977; PX7065 (Aravanis (Illumina) IHT at 55–56)) and [redacted]

E. Illumina and GRAIL Reunification Will Result in the Elimination of Double Marginalization

1152. Elimination of Double Marginalization or EDM is a well-documented efficiency from a vertical transaction that occurs when an upstream firm acquires a downstream firm to which it supplies inputs. (PFF ¶¶ 1152.1–1152.2.)

1152.1 [redacted]

1152.2 As explained by Dr. Carlton: "EDM benefits arise when an upstream firm with market power acquires a downstream firm with market power to which it supplies inputs. As separate entities, each firm maximizes its profits by setting its price such that the marginal revenue from an additional sale equals the marginal cost of an additional sale. When the upstream and downstream firms operate in markets that are not perfectly competitive, each firm sets its optimal price at a markup over marginal cost. . . . When the upstream and downstream firms merge, there is a single firm with the marginal costs

of what was formerly the upstream firm and which faces the same demand curve as the former downstream firm. Thus, the margin of the upstream firm is internalized and there is an effective reduction in the marginal cost of producing the downstream product; put differently, the merger leads a profit maximizing firm to eliminate the upstream margin from its downstream pricing decision and to reduce the price of the downstream good". (RX3864 (Carlton Expert Report) ¶ 102–.)

1153. The conditions for elimination of double marginalization are present in this Transaction.

1153.1 Before the Transaction closed, Illumina charged a margin to GRAIL on sales of its NGS products, and GRAIL projected a margin on its products. (deSouza (Illumina) Tr. 2359–60; Aravanis (Illumina) Tr. 1960.)

1153.2 As Dr. Carlton testified "[i]f you look at the data, if you look, for example, at the deal model, what is Illumina projecting is going to be happening, say, in – you know, in the future, there's double-marginalization, period. That's what the evidence is. What about now? Yes. There is just no question, double-marginalization is going on now, double-marginalization in the sense that price that is being charged to GRAIL is not marginal cost. That's just crystal clear in the data. So they haven't gotten rid of double-marginalization. As far as I can tell, Illumina has never gotten rid of double-marginalization with GRAIL or any of these third-party MCED developers. There's always a margin. But just look at the deal model. That is really excellent evidence. The deal model is telling you, absent the merger, here are Illumina's projections. No question, crystal clear, there is a margin that Illumina is charging to GRAIL". (RX6000 (Carlton Trial Dep. at 66–67).)

1154. [redacted]

[redacted]

1155. The EDM efficiency is unrefuted.

1155.1 Complaint Counsel does not present any factual testimony or other evidence suggesting that there were not two margins prior to the Transaction or that the elimination of double marginalization will not be achieved.

1155.2 Rather, Complaint Counsel's economic expert argues that EDM will not be achieved here because Respondents could have achieved these procompetitive benefits before the Transaction, given the complex contracts that already existed between the parties, and chose not to do so. (RX3852 (Scott Morton Dep. at 224).)

1155.3 This assertion, however, follows from Dr. Scott Morton's unsupported assumption that EDM can easily be eliminated by contract, and hence, if double marginalization is not eliminated by contract, then the current pricing structure that exists must be efficient and would not be improved upon post-merger. (RX3852 (Scott Morton Dep. at 215–18).)

1155.4 But this reasoning, if true, would eliminate the rationale for every vertical merger, as all EDM benefits (as well as any other efficiencies) could be achieved by contract under Dr. Scott Morton's theory. In fact, Dr. Scott Morton's assumption flies in the face of longstanding economic literature, case law, and the Vertical Merger Guidelines. *See e.g., United States v. AT&T Inc.*, 310 F. Supp. 3d 161, 193 (D.C. Cir

2018) ("EDM effect is 'generally accepted as a potential procompetitive benefit resulting from vertical mergers'") (quoting the DOJ's proposed findings of fact.)

1155.5 Even if EDM could be eliminated by contract in certain circumstances, the undisputed evidence shows that it was not and would not have been eliminated here. (deSouza (Illumina) Tr. 2359–60 (noting that Illumina and GRAIL each charged a margin prior to the transaction); Aravanis (Illumina) Tr. 1960 (same); *see also* RX6000 (Carlton Trial Dep. at 67–68) ("Well, you can say anything can happen. The fact of the matter is it hasn't happened. The reason why the evidence in this case is so strong, I think, to refute what Dr. Scott Morton is saying, is because it's obvious that, absent the merger, Illumina will charge GRAIL and does charge GRAIL and expects to charge GRAIL a price above its marginal cost, period. It's crystal clear from the documents".).)

F. Reuniting Illumina and GRAIL Will to Lead to Supply, Operational and International Expansion

1156. The Transaction will not just save lives, accelerate market access, generate R&D efficiencies, reduce GRAIL's royalty burden and eliminate double marginalization. The reunion of Illumina and GRAIL will also (1) lead to supply chain and operational efficiencies and (2) accelerate the international expansion of Galleri.

1. The Reunion of Illumina and GRAIL Will Lead to Supply Chain and Operational Efficiencies.

1157. Reuniting Illumina and GRAIL will allow them to achieve significant supply chain and operational efficiencies. (deSouza (Illumina) Tr. 2371–72; Aravanis (Illumina) Tr. 1961; Flatley (Illumina) Tr. 4086; Bishop (GRAIL) Tr. 1405.)

1158. The evidence of this is entirely one-sided, fully favoring Respondents. Complaint Counsel presented no fact witness or other evidence rebutting the testimony of Respondents' fact witnesses on these efficiencies.

1159. Illumina has been operating in the NGS space for over a decade. During that time, Illumina has developed relationships with suppliers from whom it purchases in large volumes. (Flatley (Illumina) Tr. 4085 ("That supply chain is very deep. It goes all the way back to primary formulations of products".).)

1160. These relationships allow Illumina to purchase inputs at a significant discount. (Aravanis (Illumina) Tr. 1960–61.); PX7073 (Aravanis (Illumina) 2.7(h) IHT) at 49–50.)

1161. By contrast, GRAIL is a young company that has only one product on the market with very limited sales. (Bishop (GRAIL) Tr. 1362–75, 1420.)

1162. It is well recognized that purchasing in large volume can generate cost saving to the supplier and that can lead to volume discounts. The reunion of Illumina and GRAIL will allow GRAIL to benefit from Illumina's prices and relationships in areas of common products.

1162.1 Multiple witnesses addressed these efficiencies:

1162.2 Francis deSouza, CEO and President of Illumina, testified that: "We have supply contracts with a large number of suppliers, and we purchase a number of raw materials in – that GRAIL also uses in much higher quantities than GRAIL does. So what that means is we are able to get deeper discounts for those raw materials than GRAIL is able to do. And so by consolidating purchasing for these materials between GRAIL and Illumina, GRAIL would enjoy bigger discounts than it gets today for a lot of the materials that it has. In addition, we have conducted — just because we have a lot more experience and a bigger team, we have been able to identify vendors that provide superior cost performance points across the products that we buy, and because we have been able to do that, you know, more extensively than GRAIL has so far, there are areas where we've identified vendors that offer superior cost performance than the vendors that GRAIL would use, and so they're able to take advantage of those capabilities as well. And then as a global company, we're able to enjoy the benefits of leveraging a supply chain that is global, and so, again, that gives us access to a superior cost performance supply chain than GRAIL would have on its own". (deSouza (Illumina) Tr. 2369.)

1162.3 Alex Aravanis, CTO at Illumina and former head of R&D at GRAIL, testified that: "[D]uring the due diligence process, we identified common suppliers for core components of the Galleri assay. Again, these are common to components that Illumina purchases today at a very large scale, a very large volume. . . The cost reductions associated with volume that Illumina benefits from could be shared with GRAIL as part of an integrated company. Therefore, the cost of goods for the Galleri test would decrease". (Aravanis (Illumina) Tr. 1960–61.)

1162.4 Jay Flatley, Chairman of the Board of Illumina at the time the transaction was entered into, testified that the Board of Directors of Illumina determined that "Illumina and GRAIL both buy significant amounts of reagents and chemicals from third parties. That supply chain is very deep. It goes all the way back to primary formulations of products. Together, we'd have the ability to combine volumes and, therefore, reduce the prices that we paid for those reagents, because many of the reagents are common in the kind of tests that GRAIL runs versus some of the tests that Illumina runs. We also would have the ability to have increased purchasing power. So at times where supplies are constrained, like they were during the COVID era — continuing, in fact — we would have more purchasing power as a combined entity than either of us would as individual entities". (Flatley (Illumina) Tr. 4085.)

1162.5 Hans Bishop, CEO of GRAIL, testified that "As part of Illumina, I think we'll scale faster, and scale brings cost benefits." (Bishop (GRAIL) Tr. 1404.)

1162.6 Complaint Counsel did nothing on cross examination to undermine this testimony; nor did it offer any fact witness testimony to the contrary.

1162.7 Evidence of this efficiency is therefore unrefuted.

1163. Illumina has significant experience managing laboratories that operate NGS tests at scale.

1163.1 As Francis deSouza explained, Illumina has been operating laboratories at scale "for well over a decade now. We have labs in the U.S. but also outside the U.S. . . Our labs have already been delivering tests in the millions of tests a year to consumers and have been doing that for a while". (deSouza (Illumina) Tr. 2371.)

1163.2 Illumina operates genomic tests for cancer therapy selection, genetic disease diagnosis and other uses. (deSouza (Illumina) Tr. 2371.)

1163.3 Illumina has also optimized its work flow from a cost and safety perspective. (deSouza T. 2371–72; *see also* Aravanis (Illumina) Tr. 1961–62 ("Illumina has developed automation capabilities to automate assays and reduce cost. It's also developed the capabilities to dynamically staff large sequencing operations and by doing so reducing labor costs associated with that. It's also developed the ability to efficiently use real estate and laboratories".).)

1164. GRAIL, in contrast, only has one laboratory and limited experience operating that lab. (deSouza (Illumina) Tr. 2370; Bishop (GRAIL) Tr. 1376; Aravanis (Illumina) Tr. 1892.)

1165. Combining Illumina and GRAIL will allow GRAIL to benefit from Illumina's lab operations capabilities.

1165.1 Undisputed fact testimony established this efficiency.

1165.2 Francis deSouza, CEO and President of Illumina, testified that: "[W]e already have the lab facilities, the real estate facilities. We already have the equipment in the labs. We already have the personnel that are trained to run genomics, and it requires a certain level of sophistication to run a genomics pipeline. In addition to that, we have optimized the work flows associated with running a genomics lab, things like that sample accessioning, how do you bring in, you know, from a logistics perspective but then also, on the facility itself, how do you unpack a lot of samples? How do you maintain a chain of custody with integrity as a sample comes in to your position all the way, you know, until you return data? We have also been able to optimize the work flow end to end from a safety perspective, from a supply chain — sorry, chain of custody perspective, and from a cost perspective. We've also developed the custom automation tools it takes to run a highly automated lab. We've also developed the software pipeline it takes to analyze the data in a very high throughput way coming off those samples. So, you know, all of those operational capabilities are benefits that GRAIL will enjoy, and it will take GRAIL years to develop that capability themselves" (deSouza (Illumina) Tr. 2371–72.)

1165.3 Alex Aravanis, CTO at Illumina and former head of R&D at GRAIL, testified that: "So Illumina has developed automation capabilities to automate assays and reduce cost. It's also developed the capabilities to dynamically staff large sequencing operations and by doing so reducing labor costs associated with that. It's also developed the ability to efficiently use real estate and laboratories. We believe that will lower the facilities costs that GRAIL will incur, and those, again, costs can be passed on to people purchasing the test". (Aravanis (Illumina) Tr. 1961.)

1165.4 Jay Flatley, Chairman of the Board of Illumina at the time the transaction was entered into, testified that the Board of Directors of Illumina determined that "Well, both companies run laboratories. GRAIL has one. Illumina has several of these around the world. And to the extent that we could integrate those lab operations, we would have much more consistent protocols, much more consistent software, both on the — how we bring samples into the laboratory and how we control the samples and build the databases around the sample information, but also on the reporting side, as well as the what are called lab information management systems, which control sample processing through the overall laboratory. Separate, those systems would be very divergent, and patients would get different types of reports, and the sample control and the data sets would be independent. In a combined company, we would have the ability to integrate that in a very important way and leverage the data across multiple tests for a given patient and have much more unified software structures and reporting". (Flatley (Illumina) Tr. 4086.)

1165.5 Hans Bishop, CEO of GRAIL testified that "Illumina has established operations and the relevant teams of experts and laboratories in certain instances in many countries around the world" that will help GRAIL scale. (Bishop (GRAIL) Tr. 1405.)

1165.6 Here again, Complaint Counsel failed to undermine this testimony in cross and it offered no fact witness testimony to the contrary.

1166. Illumina has quantified the monetary cost savings from supply chain and operational efficiencies as at least $140M over a 10–year period. (RX6000 (Carlton Trial Dep. at 71); PX2613 (Illumina) at 4.) The government offered no evidence to the contrary.

1167. The supply chain and operational efficiencies are unrefuted.

1167.1 Complaint Counsel does not dispute that supply chain and operational efficiencies may arise from a vertical transaction.

1167.2 Nor did it call any witness to dispute the testimony from Illumina and GRAIL witnesses.

1167.3 [redacted]

1167.4 However, Respondents do not depend on either Dr. Carlton or the document he cited for this efficiency.

1167.5 [redacted] and did not independently assess any other evidence regarding this efficiency, including the direct testimony regarding these efficiencies outlined above. (RX3854 (Rothman Dep. at 74–78); [redacted]

2. The Reunion of Illumina and GRAIL Will Accelerate the International Expansion of Galleri.

1168. The Transaction will accelerate the international expansion of Galleri because it will put Illumina in a position to leverage its significant international resources for GRAIL.

1168.1 Complaint Counsel did not present any fact witnesses or evidence to rebut the testimony of Respondents' fact witnesses on this efficiency.

1168.2 Illumina has a strong international presence with platforms and/or tests registered in over 140 countries around the world. (deSouza (Illumina) Tr. 2374; PX6066 (Illumina).)

1168.3 As Mr. deSouza explained, "[Illumina has] a strong international presence. In fact, more than half of Illumina's revenue today comes from outside the U.S., and so the countries outside the U.S. represent the majority of Illumina's business today . . . Today, we've placed products in over 140 countries around the world. We have clear products in dozens of countries around the world. . . . We have partners, we have sales teams, we have in-market surveillance teams to make sure that we are quick to recognize if there's any issue our customers are having and be able to respond. We're able to market into those countries". (deSouza (Illumina) Tr. 2374; PX6066 (Illumina).)

1168.4 Illumina has significant experience working with foreign regulators and payors and with obtaining regulatory approvals. (deSouza 2374; Febbo (Illumina) Tr. 4351–52.)

1169. GRAIL has no presence outside of the United States and the United Kingdom. (Freidin (GRAIL) Tr. 3008–09 ("GRAIL has been focused on the U.S. domestic market. We do have a study in the U.K. with the NHS. Other than that, our long-range plan for the next ten years, you know, really ignores anything international. We don't have any international operations other than, you know, 10–20 people in the U.K. to facilitate the NHS study".); RX3282 (GRAIL).)

1169.1 Due to its limited international presence, GRAIL has not made plans to expand internationally in the near future and in fact has been unable to accept offers to provide its Galleri product to other countries due to a lack of capacity. (Freidin (GRAIL) Tr. 3009 ("Q. And what ability do you have to develop international sales today? A. Yeah. So we've got a very small corporate development team of three people, and we — we have people — we have enough people to talk to people but not enough to actually do anything, so we've often in a position of people reaching out to do things and us, you know, being polite and having to say we just can't take it on right now".).)

1170. Through the proposed transaction, Illumina will dramatically increase GRAIL's ability to access international markets and to achieve regulatory and payor approvals outside the United States.

1170.1 The fact testimony on this score was undisputed.

1170.2 Francis deSouza, CEO and President of Illumina, testified that: "I do know what impact international expansion will have on the GRAIL test. By accessing larger sample sets, by accessing the genomes from more patients or more consumers around the world, the GRAIL test will become more and more accurate, and this is a test that's based on a learning algorithm, and so accessing larger sample sets will improve the GRAIL test for people here in the U.S. In addition, accessing more diverse genomes than are available in the U.S., which you will get access to as you enter, you know, continents like Africa or Asia or Latin America, or even in the European Union, accessing the more diverse – the bigger biodiversity associated with those genomes will improve the test for people here in the U.S. This is a special issue in genomics because the cohorts that are used here in the U.S. to develop genomic tests are predominantly Caucasian cohorts. What that means is if you are an African-American person in the U.S. or a number of other minorities, the genomic tests just simply aren't as good for you as they are for Caucasians, and that's just a health inequity we're dealing with in the U.S. that we will be able to address more fully as we expand the cohorts to include cohorts from Africa and from Asia". (deSouza (Illumina) Tr. 2375–76.)

1170.3 Alex Aravanis, CTO at Illumina and former head of R&D at GRAIL, testified that: "The basis of the determination is, number one, our plans for making the Galleri test available in the many countries around the world that we operate, that GRAIL does not operate today, so that's our basis of the determination, that the test will be available worldwide, much faster than GRAIL could given that it has no operations in those countries. With offering that test in many countries in the world, that will generate a significant amount of testing data. We know that that testing data will be useful in payer discussions around the questions they'll have around clinical utility. We also know that that data will be useful in creating future versions of the Galleri test. We also know that that data will be useful in discussions with the FDA around FDA approval". (Aravanis (Illumina) Tr. 19666–67.)

1170.4 Jay Flatley, Chairman of the Board of Illumina at the time the transaction was entered into, testified that the Board of Directors of Illumina determined that "Going into international markets is complicated. It requires often the setup of subsidiaries and legal entities. It requires hiring and employees and, therefore, setting up tax structures and all of the structures around how stock options get issued to employees. It's quite a complicated and expensive process to set up subsidiaries in countries around the world. Illumina has this in place in all of the major countries of the world, and GRAIL would have the ability to leverage that very directly even if the sales force were separate, which in some cases it would be. In some cases where we have distributors, distributors might sell both products directly to the customer, but the infrastructure that Illumina has in place would dramatically accelerate GRAIL's ability to bring Galleri to other markets of the world and to do that quite quickly". (Flatley (Illumina) Tr. 4087–88.)

1170.5 Hans Bishop, CEO of GRAIL, testified that "first of all, selling Galleri more broadly, you know, outside the United States will have a series of country-specific regulatory approvals. We don't have a team today that has any experience of that. Illumina already has those people. Secondly, to supply a particular country requires you to have a business and capabilities in that country. And outside of the U.K., we don't

have any offices around the world. Illumina has many. Thirdly, the financial resources and engineering expertise to build the infrastructure that's needed on top of what they already have is a much easier step than as a standalone company today with a very limited footprint outside the U.S.". (Bishop (GRAIL) Tr. 1406.).

1170.6 Aaron Freidin, Senior Vice President of Finance at GRAIL, testified that "GRAIL has been focused on the U.S. domestic market. We do have a study in the U.K. with the NHS. Other than that, our long-range plan for the next ten years, you know, really ignores anything international. We don't have any international operations other than, you know, 10–20 people in the U.K. to facilitate the NHS study. And you know, you compare that to, as I said, a multinational, billion-dollar-plus company with multiple products, locations all over the globe, and it's pretty obvious to me that they could accelerate us internationally if they have the infrastructure already". (Freidin (GRAIL) Tr. 3008.)

1171. International expansion will have a positive effect on Galleri's operations in the United States, because it will allow Galleri to gather data from more patients in less time and will allow Galleri to ensure a more representative and diverse dataset that can be used to accelerate clinical validation for GRAIL's PMA submission as well as provide clinical utility evidence for payor adoption and reimbursement in the United States. (deSouza (Illumina) Tr. 2375–78; Aravanis (Illumina) Tr. 1963–65.)

1172. International acceleration will also help improve the Galleri test. As Francis deSouza testified: "by accessing a bigger market, you get a better test because the algorithms continue to get refined, and you get better and better accuracy in the test the more samples you run. This is especially true if the samples are genomically diverse. . . . the benefit you get from running this test globally is not just driven by the fact that you are running more tests and that gives you more accurate performance. Running more tests in regions where there's high genomic biodiversity, you know, in Africa, for example, in Asia, for example, or even just extending from the UK into the rest of the European Union, or going into Latin America, gives you a more diverse set of genomes. That gives you a better test. And so long term, global expansion is important to the success of the MCED test in at least those two dimensions". (deSouza (Illumina) Tr. 2373.)

1173. The international acceleration efficiency is unrefuted.

1173.1 Complaint Counsel did not call any fact witness who undermined the testimony from Illumina and GRAIL witnesses.

1173.2 [redacted]

1173.3 Thus, there is no actual dispute that the Transaction will accelerate international adoption of Galleri.

G. The Benefits of the Transaction Are Merger Specific.

1174. Each of the efficiencies arising from the Transaction is merger specific because each was not, and could not have been, achieved but for the Transaction.

1175. The acceleration efficiencies are merger specific because it would not be possible to achieve these efficiencies without the Transaction.

1175.1 As numerous Illumina and GRAIL fact witnesses testified, Illumina's capabilities with regulatory approval, market access and international expansion are a product of years of work and cannot be easily replicated. (deSouza (Illumina) Tr. 2377–78; Aravanis (Illumina) Tr. 1947–48; Ofman (GRAIL) Tr. 3308 ("our ability to scale the business is limited if we are doing this on our own. It will take a long time. And if we're part of Illumina, I firmly believe that that time will be greatly accelerated, and so our ability to achieve our aspiration will not only be accelerated but actually, you know, fortified by being part of a company with the magnitude and the capabilities of Illumina").)

1175.2 Fact witnesses with personal knowledge also testified that GRAIL could not achieve these efficiencies by hiring additional personnel or outside consultants because the pool of individuals with such experience is limited and it can take a long time for consultants to get up to speed on the specific needs in a new area such as screening. (PFF ¶¶ 1175.1–1175.2.4.)

1175.2.1 Dr. Febbo testified that "I know through our use of consultants and our hiring of individuals into regulatory, into market access, across our personnel, is that there's just not a deep, rich bench of experience available for consultants, and the model of a consultant driving that just doesn't work as effectively as having internal employees". (Febbo (Illumina) Tr. 4365.)

1175.2.2 As Mr. Qadan explained, "you build institutional capability over time internally that might not be the subject-matter expertise of those consultants, because, again, consultants are teams that come and go, so they do not have that institutional expertise. . . . [T]hat's really the main reason why . . . a group of consultants cannot do the work with companies. And our, again, experience when we needed to use consultants even for strategy work, it has been a steep learning curve in many cases when it comes to the applications or clinical applications we're dealing with". (Qadan (Illumina) Tr. 4167–68.)

1175.2.3 [redacted]

1175.2.4 [redacted]

1175.3 Finally, Illumina and GRAIL witnesses testified that they could not contract for these efficiencies if they were separate entities because Illumina does not provide such services to any third party entities and doing so would require GRAIL to share its confidential information with Illumina. (Aravanis (Illumina) Tr. 1969–70 ("It would require GRAIL to share, you know, its knowledge of all of its technology, its assays, its bioinformatics. On the payer and FDA aspects of the efficiencies, they would need to share details of its clinical trials, the results, you know, of them, you know, how they were conducted, proprietary information that it wouldn't necessarily – it wouldn't otherwise share".); Febbo (Illumina) Tr. 4369 ("you don't see total alignment between two companies, and nor can you get into the depth of understanding of the processes and the special sauce that a lot of these companies, including Illumina, have in order to fully realize efficiencies, fully realize where you have the best opportunity to improve a test, to improve or speed regulatory, improve reimbursement. You just don't see the layer of engagement that's necessary to get to the full realization of those benefits through partnerships".); [redacted]

1175.4 The fact testimony was corroborated by unrefuted expert testimony: As Dr. Carlton explained, the acceleration efficiencies are merger specific because:

> 1175.4.1 Illumina Does Not Offer Regulatory or Market Access Assistance to Third Parties. "Illumina does not offer regulatory help or market access services to customers. My understanding is Illumina would not provide, in absence of this transaction, a service to GRAIL to help it get FDA approval or payer approval". (RX6000 (Carlton Trial Dep. at 60).)
>
> 1175.4.2 GRAIL Would Not Share Confidential Information. "GRAIL would not tell Illumina in absence of this transaction, a lot of information that would be useful for Illumina to know to accelerate the improve – the approval. In particular, GRAIL is very concerned about its proprietary information in its machine-learning algorithm, and it's not going to give that information to Illumina if this transaction doesn't go through". (RX6000 (Carlton Trial Dep. at 60–61).)
>
> 1175.4.3 Illumina and GRAIL Testimony Supports Merger Specificity. "[B]oth Mr. deSouza and Bishop have told me that this acceleration won't be achieved by, you know, just hiring consultants or outside staff". (RX6000 (Carlton Trial Dep. at 61).)

1175.5 Complaint Counsel argued the Transaction's acceleration benefits are not merger specific, but it presented no evidence to support the assertion.

1176. Similarly, the R&D efficiencies described above are merger specific because they could not be achieved without the Transaction.

1176.1 Every single fact witness to address the issue testified—without exception—that it would take GRAIL years to develop the R&D capabilities Illumina has. (Aravanis (Illumina) Tr. 1967; deSouza (Illumina) Tr. 2354–57; Flatley (Illumina) Tr. 4086–87.)

1176.2 Illumina and GRAIL could not achieve the efficiencies at issue by contract because Illumina does not offer such services to third parties and GRAIL would be unwilling to collaborate on R&D projects with a third party because doing so would require GRAIL to share its "secret sauce" with Illumina. (Febbo (Illumina) Tr. 4369–70 ("without understanding in depth the specifics of the sequencing that's performed, the specifics of the bioinformatics that goes from that sequencing and pulls out the methylation patterns that – and then the machine-learning that's used to identify that cancer detection signal, to identify that tissue of origin of signal, without deeply understanding that, it's almost impossible for our scientists, who know the technology better than any other company, to realize efficiencies. So you have to get to that deep, fundamental understanding and exchange in order to realize the full benefit of coming together and the full efficiencies".); [redacted]

1176.3 Here again, the undisputed fact witness testimony is corroborated by Dr. Carlton's testimony regarding why the acceleration efficiencies are merger specific:

1176.3.1 Illumina and GRAIL Would Not Share Confidential Information With Third Parties. "[P]robably the simplest reason is it's very well established in the economics literature, it's very hard to transact in information, and those are exactly the circumstances when vertical integration makes sense. That aligns exactly with what I told you earlier about how GRAIL is worried about proprietary information". (RX6000 (Carlton Trial Dep. at 62–63).)

1176.3.2 Illumina Does Not Provide R&D Consulting Services. "Illumina does not provide R&D consulting to its clinical customers. As I've told you, GRAIL has explained that they will not share proprietary information in an arm's length negotiation with Illumina, in particular proprietary information about its machine-learning algorithm, and it is not the case, based on my understanding of the evidence, that there's any possibility that these R&D efficiencies could be achieved by contract, by hiring outside – outside people". (RX6000 (Carlton Trial Dep. at 63).)

1176.4 Following now-familiar form, Complaint Counsel presented no fact evidence that suggests that the acceleration benefits are not merger specific, and its experts did not meaningfully contend with the evidence summarized above.

1177. The remaining cost-saving efficiencies are merger specific, because they too have not occurred, and would not occur, absent the Transaction.

1177.1 [redacted]

1177.2 As explained, both Illumina and GRAIL have an incentive to eliminate double marginalization.

1177.3 If it were feasible to achieve EDM through contract, Illumina and GRAIL would have already done so pre-merger.

1177.4 The fact that they didn't is proof that there is no evidentiary basis to speculate that this efficiency would be achievable by contract absent the merger.

1177.5 [redacted] and the supply chain and operational efficiencies (RX6000 (Carlton Trial Dep. at 128) ("I'm not aware of any, you know, contracting, nor does she cite any, that's been done to achieve those efficiencies").)

1177.6 Dr. Scott Morton provided no reason why the parties would not have achieved these efficiencies through contract if it were feasible to do so.

H. The Contentions of Complaint Counsel's Experts Miss the Mark.

1178. Complaint Counsel's only real response to the overwhelming and undisputed evidence that the Transaction will generate sizeable efficiencies is to fall back on its experts' assertions that the efficiencies are unsubstantiated.

1178.1 Complaint Counsel's experts arrive at their conclusions by weighing the evidence, crediting the testimony that fit Complaint Counsel's thesis and dismissing the evidence that did not. (PX3852 (Scott Morton Dep. at 212) (stating that she "weighed [witness statements] according to the information they had, the role they play in the company and the type of competition in which they are engaged.").)

1179. Any continued claim that the efficiencies of the transaction were unsubstantiated is contradicted by the sworn testimony of no less than ten trial witnesses: Francis deSouza (President and CEO of Illumina), Dr. Alex Aravanis (Chief Technology Officer of Illumina and former head of R&D at GRAIL), Dr. Phil Febbo (Chief Medical Officer of Illumina), Ammar Qadan (Vice President and Global Head of Market Access at Illumina), Jay Flatley (former CEO

and Chairman of the Illumina Board of Directors at the time of the Transaction), Hans Bishop (CEO of GRAIL), Dr. Joshua Ofman (Chief Medical Officer of GRAIL), Aaron Freidin (Senior Vice President of Finance at GRAIL), Chris Della Porta (Director, Growth Strategy, at GRAIL) and Dr. Arash Jamshidi (Senior Vice President of Data Sciences at GRAIL). It is also counter to the independent judgments of Illumina Board member knowledgeable about the industry: Dr. Frances Arnold (Director, Chairperson of Science and Technology and Nominating); Francis deSouza (Director, CEO), Caroline Dorsa (Director, Chair of Audit Committee), Dr. Robert Epstein (Director, Chair of Governance Committee), Jay Flatley (Chairman and former CEO), Dr. Scott Gottlieb (Director), Dr. Gary Guthart (Director, Chair of Compensation Committee), Philip Schiller (Director), Susan Siegel (Director) and John Thompson (Lead Independent Director).

IX. COMPLAINT COUNSEL'S CHALLENGE TO THE TRANSACTION VIOLATES THE U.S. CONSTITUTION

A. The FTC Violates Article II.

1180. Article II of the U.S. Constitution vests "[t]he executive Power . . . in a President of the United States of America", who must "take Care that the Laws be faithfully executed". U.S. Const. Art II, § 1, cl. 1, § 3.

1181. FTC ALJs enjoy two layers of protection from the President. FTC ALJs may be removed only "for good cause established and determined by" someone other than the President, namely the Merit Systems Protection Board ("MSPB"). 5 U.S.C. § 7521(a).

1182. Merit System Protection Board members may be removed by the President only for "inefficiency, neglect of duty, or malfeasance in office." 5 U.S.C. § 1202(d).

1183. Neither the President, nor anyone directly responsible to him, nor even an officer whose conduct he may review only for good cause, has full control over FTC ALJs. 5 U.S.C. §§ 7521(a), 1202(d).

1184. In prior challenges under Article II, the FTC has argued that the dual-level of protection afforded to FTC ALJs is of no constitutional moment because they are not "Officers of the United States". (*See In re LabMD, Inc.*, Compl. Counsel's Opp'n to Resp't's Mot. to Amend Affirmative Defenses and to Dismiss this Proceeding, Dkt. No. 9537 (Jul. 24, 2015), 3 n.3.)

1185. Like SEC ALJs, FTC ALJs are "Officers of the United States". *See Lucia v. SEC*, 138 S. Ct. 2044, 2053–54 (2018); 5 U.S.C. § 3105; 16 C.F.R. § 3.42(c); 16 C.F.R. §§ 3.42(c)(9), 3.52(a)(1) (FTC ALJs); 17 C.F.R. § 201.360(a)(1) (SEC ALJs); 16 C.F.R. § 3.42(c) (FTC ALJs); 17 C.F.R. §§ 201.111, 200.14(a) (SEC ALJs).

1185.1 Both may be "appoint[ed]" by their respective Commissions. 5 U.S.C. § 3105.

1185.2 Both exercise significant authority pursuant to the laws of the United States, by exercising the authority needed to ensure fair and orderly adversarial hearings. 16 C.F.R. § 3.42(c) (empowering FTC ALJs to, among other things, "receive evidence", "conduct … hearings", "administer oaths", "rule upon … motions", and "regulate the course of the hearings and the conduct of the parties and their counsel").

1185.3 Both take testimony, conduct trials, administer oaths, rule on motions, and regulate the course of hearings, as well as the conduct of parties and counsel. 16 C.F.R. § 3.42(c) (empowering FTC ALJs to, among other things, "receive evidence", "conduct … hearings", "administer oaths", "rule upon … motions", and "regulate the course of the hearings and the conduct of the parties and their counsel").

1185.4 Both are empowered to make and file initial decisions, which may then be appealed to the respective full Commission. 16 C.F.R. §§ 3.42(c)(9), 3.52(a)(1) (FTC ALJs); *accord* 17 C.F.R. § 201.360(a)(1) (SEC ALJs).

1185.5 Both "have all powers necessary" to "dispos[e] of" the proceedings over which they preside. 16 C.F.R. § 3.42(c) (FTC ALJs); *accord* 17 C.F.R. §§ 201.111, 200.14(a) (SEC ALJs).

1186. FTC ALJs have both adjudicative and policymaking functions.

1186.1 In addition to their adjudicative functions, FTC ALJs engage in some policymaking by conducting rulemaking proceedings, compiling the hearing record, resolving disputes, making recommendations to the Commission based on their findings and conclusions as to all relevant and material evidence, and ensuring that the rulemaking proceeds in an orderly fashion. *See* 16 C.F.R. § 1.13.

1187. While the Commission may review an ALJ's decision, the Commission may also decide not to review an ALJ decision at all, in which case the ALJ's decision becomes final. 16 C.F.R. § 3.52(a)(1).

1188. In the past 26 years, the FTC has never reversed a decision in which an FTC ALJ found liability. (RX3993 (Wright 2015) at 6.)

1189. The FTC's dual-protection structure for ALJs vests significant governmental power in the hands of a single individual who is neither elected by the people nor controlled through the threat of removal by someone who is. *See* 5 U.S.C. §§ 7521(a), 1202(d).

1190. In addition, FTC Commissioners are protected by a single-layer good cause removal provision. 15 U.S.C. § 41.

B. The FTC's Internal Administrative Process Violates the Due Process Clause.

1191. Commissioners Rebecca Slaughter, Noah Phillips, Christine Wilson, and Rohit Chopra voted out the complaint against Respondents. (*See* Compl., *In re Illumina, Inc., & GRAIL, Inc.*, Dkt. No. 9401 (Mar. 30, 2021).)

1192. Chairperson Khan was not on the Commission at the time the Complaint was issued, but she subsequently joined the Commission on June 15, 2021 and authorized this matter to proceed in lieu of litigation in federal court. (*See* RX4018 (FTC) at 1; 15 U.S.C. § 45(b).)

1193. Ms. Kahn's articles were presented to Respondents' experts during depositions. (PX7134 (Carlton Dep. at 55).)

1194. Absent an unprecedented change in the composition of the Commission, the Commission will pass judgment on itself. *See* 16 C.F.R. §§ 3.11(a), 3.52(a)(1).

1195. Four of the five Commissioners participated in the prosecution of this case by interviewing witnesses and rejecting settlement offers by Respondents prior to filing the complaint.

1195.1 Commissioners Rebecca Slaughter, Noah Phillips, Christine Wilson, and Rohit Chopra each individually sought out witnesses and made judgments about their credibility before voting out the complaint in both the FTC and federal court. (*See* RX0496 (FTC) at 3; RX0497 (FTC) at 1; RX0498 (FTC) at 1–2; RX0499 (FTC) at 1; RX0500 (FTC) at 2; RX0501 (FTC) at 3; Compl., *In re Ilumina, Inc., & GRAIL, Inc.*, Dkt. No. 9401 (Mar. 30, 2021).)

1195.2 Interviewing witnesses is precisely what prosecutors are authorized to do and what judges are prohibited from doing. ABA Standards for Criminal Justice § 3–3.4(c) ("The prosecutor . . . should seek to interview all witnesses"); Model Code of Jud. Conduct r. 2.9 (Am. Bar. Ass'n 2020) ("A judge shall not investigate facts in a matter independently . . . .").

1195.3 Before filing complaints in the FTC and federal court, all four of the Commissioners at the time also acted as prosecutors by rejecting Illumina's efforts to resolve the case and instead insisting on proceeding to trial. (*See* Mot. for Conference to Facilitate Settlement, 3–4; Fed. R. Crim. P. 11(c)(1) ("An attorney for the government . . . may discuss and reach a plea agreement. The court must not participate in these discussions").)

1195.4 Commissioners Rebecca Slaughter, Noah Phillips, Christine Wilson, and Rohit Chopra rejected settlement offers by Respondents prior to filing the complaint and instead insisted on proceeding to trial. [redacted] RX3155 (Illumina) at 1–7; Compl. at 1–2, *Fed. Trade Comm'n v. Illumina, Inc.*, No. 21–cv-873 (D.D.C. Apr. 1, 2021) ECF No. 14; Compl. Counsel's Mem. in Opp. to Resp'ts' Request for Expedited Consideration, Dkt. No. 9401 (July 15, 2021) at 1.)

1195.5 In July 2021, Respondents moved this administrative tribunal to convene a settlement conference to facilitate a negotiated resolution to the dispute. (*See* Resp'ts' Mot. for Conference to Facilitate Settlement, Dkt. No. 9401 (July 2, 2021) at 3–4.)

1195.6 Complaint counsel opposed that motion, declaring any settlement conference "a waste of time". (Compl. Counsel's Mem. in Opp. to Resp'ts' Request for Expedited Consideration, Dkt. No. 9401 (July 15, 2021) at 1.)

1196. All of the Commissioners agreed to withdraw the federal case that would have allowed a federal district judge to decide whether the Transaction should stand, reserving that right to themselves. (*See* RX4018 (FTC) at 1 (announcing that the Commission authorized its staff—including Complaint Counsel—to dismiss the complaint in federal court).)

1196.1 Just as prosecutors are free to withdraw their charges at any time, Commissioners can withdraw their complaint at any time by vote rather than by a motion to withdraw or dismiss. 15 U.S.C. § 45(b).

1196.2 The parties agreed to work together to complete litigation over the preliminary injunction before September 20, 2021, when termination rights would kick in under the merger agreement. (*See* Opp. to FTC's Mot. to Dismiss, at 7, *Fed. Trade Comm'n v. Illumina*, *Inc.*, (S.D. Cal. 2021) (No. 21–cv-00800–CAB-BGS).)

1196.3 To facilitate this process, the parties agreed to a temporary restraining order and commenced expedited fact discovery. **(**Plaintiff Federal Trade Commission's Unopposed Mot. for Entry of a Temporary Restraining Order, at 2, *Fed. Trade Comm'n v. Illumina*, *Inc.*, (S.D. Cal. 2021) (No. 21–cv-00800–CAB-BGS); Case Management and Scheduling Order, at 2, *Fed. Trade Comm'n v. Illumina*, *Inc.*, (S.D. Cal. 2021) (No. 21–cv-00800–CAB-BGS).)

1196.4 But only weeks before the scheduled conclusion of fact discovery, the FTC moved to dismiss its own complaint. (*See* Memo in Support of Plaintiffs' Ex Parte Application to Dismiss, *FTC v. Illumina*, *Inc.*, (S.D. Cal. 2021) (No. 21–cv-00800–CAB-BGS).)

1197. An accuser lacks the necessary neutrality to determine the merits of its own allegations.

1197.1 A study of SEC adjudications showed that when the SEC judged cases in which it brought charges in fiscal years 2007 through 2015, the SEC won against over 89% of defendants. (*See* RX4013 (Velikonja 2017) at 349 tbl.4.)

1197.2 A research project concerning potential bias at the FTC in merger challenges decided between 1956 and 1992 found that the "ability of commissioners to act as both prosecutor and judge in a particular matter can significantly increase the likelihood of a merger order". (*See* RX4014 (Coate et al 1998) at 9.)

1197.3 A study of the legal profession found that lawyers tend to view the merits of their clients' cases too favorably. (*See* RX4015 (Eigen et al) at 1.)

1197.4 Once the Commission votes out a complaint, it finds in favor of itself 100% of the time. (RX3993 (Wright 2015) at 6.)

1197.5 As former FTC Commissioner Wright stated: "The FTC has voted out a number of complaints in administrative adjudication that have been tried by administrative law judges in the past nearly twenty years. In each of those cases, after the administrative decision is appealed to the Commission, the Commission has ruled in favor of FTC staff and found liability. In other words, in 100 percent of cases where the administrative law judge ruled in favor of the FTC staff, the Commission affirmed liability; and in 100 percent of the cases in which the administrative law judge [] found no liability, the Commission reversed. This is a strong sign of an unhealthy and biased institutional process. By way of contrast, when the antitrust decisions of federal district

court judges are appealed to the federal courts of appeal, plaintiffs do not come anywhere close to a 100 percent success rate—indeed, the win rate is much closer to 50 percent." (RX3993 (Wright 2015) at 6.)

1197.6 To this day, the FTC has never decided against itself in any merger challenge. (Mot. of Resp't Axon Enter., Inc., to Stay Ex. 2A at 1–5, *In re Axon Enter., Inc.*, No. 9389 (FTC Jan. 10, 2020) (Chart of Federal Trade Commission Adjudicative Proceedings).)

1197.7 Similarly, a former SEC Commissioner has admitted that despite needing to act with the "cold neutrality of an impartial judge" when acting in a judicial capacity, after prosecuting violations, the SEC had "a vested interest in ensuring that a particular result [was] reached [and] that particular policies [were] protected and advanced" such that "fairness and the appearance of fairness . . . [were] left behind". (RX4016 (Fleischman 1993) at 10.)

1198. The unusual posture of this case further highlights the way that investigative and adjudicative powers have been mingled in this case.

1198.1 Unlike most cases where the FTC has notice of a Transaction, the Transaction has already been consummated and Complaint Counsel seeks to unwind it. (*See* RX0377 (Illumina).)

1198.2 This is no accident. Complaint Counsel initially filed a complaint in federal court seeking to enjoin the Transaction—but then unilaterally moved to dismiss its own complaint, apparently believing that the Office of Administrative Law Judges would be a friendlier forum. (*See* Compl. at 1–2, *Fed. Trade Comm'n v. Illumina, Inc.*, No. 21–cv-873 (D.D.C. Apr. 1, 2021) ECF No. 14; RX4018 (Press Release on FTC's Motion to Dismiss, May 2021) at 1 (announcing that the Commission authorized its staff—including Complaint Counsel—to dismiss the complaint in federal court).)

1198.3 In its papers supporting the motion to dismiss, Complaint Counsel openly admitted that it knew Respondents did not agree that they were "prohibited from closing", and chose to dismiss its own case anyway. (*See* Pls.' Ex Parte Application to Dismiss the Compl. Without Prejudice at 5, *Fed. Trade Comm'n v. Illumina, Inc.*, No. 21–cv-873 (D.D.C. Apr. 1, 2021) ECF No. 120–1.)

1198.4 Complaint Counsel specifically reserved the right to re-file its federal action "if the [Respondents] attempt to close", but Respondents actually did close—and Complaint Counsel still chose not to re-file. (*See* Pls.' Ex Parte Application to Dismiss the Compl. Without Prejudice at 15, *Fed. Trade Comm'n v. Illumina, Inc.*, No. 21–cv-873 (D.D.C. Apr. 1, 2021) ECF No. 120–1.)

1198.5 Then, in the middle of trial in this action, which was the first-ever challenge under the 2020 Vertical Merger Guidelines, a divided F.T.C. suddenly withdrew its own Vertical Merger Guidelines, further trying to slant the playing field in Complaint Counsel's favor by changing the rules mid-trial. (*See* RX3953 (Press Release on FTC's Withdrawal from Vertical Merger Guidelines, Sep. 2021) at 1–2.)

1198.6 Complaint Counsel opted to try this case "on its own turf" in an administrative proceeding in which the Commission will act as the final administrative arbiter. (*See* RX3953 (Press Release on FTC's Withdrawal from Vertical Merger Guidelines, Sep. 2021) at 1–2.)

C. The FTC's Structure and Procedural Rules Violate the Equal Protection Clause.

1199. The Equal Protection Clause of the Fifth Amendment commands that the government shall not "deny to any person within its jurisdiction the equal protection of the laws". U.S. Const. amend. XIV, § 1.

1200. The parties to a merger challenged by the FTC are treated very differently from the parties to a merger challenged by DOJ. For example:

1201. The parties to a merger challenged by DOJ are entitled to have the challenge adjudicated in a U.S. district court. 15 U.S.C. § 25. In contrast, the parties to a merger challenged by the FTC are not entitled to have the matter adjudicated in federal district court; they can be compelled to litigate in an internal administrative proceeding, U.S. district court, or both—at the FTC's election. 15 U.S.C. § 45(b).

1202. The parties to a merger challenged by DOJ cannot be preliminarily enjoined except upon the traditional four-part showing under the common law. Dep't of Justice, Antitrust Div., Antitrust Division Manual IV-14 (5th ed. 2012); *United States v. Gillette Co.*, 828 F. Supp. 78, 80 (D.D.C. 1993). The parties to a merger challenged by the FTC, however, can be enjoined upon a lesser showing. *See* 15 U.S.C. § 53(b)(2) ("Upon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, . . . a preliminary injunction may be granted"); *FTC v. H.J. Heinz Co.*, 246 F.3d 708, 714 (D.C. Cir. 2001); RX4017 (Report of the Antitrust Modernization Commission, Apr. 2017) at 141–42.

1203. The parties to a merger challenged by DOJ are guided by the Vertical Merger Guidelines. (*See* RX2598 (FTC and DOJ Vertical Merger Guidelines) at 1.) However, the parties to a merger challenged by the FTC may not be, as a majority of the current FTC Commissioners repudiated the Vertical Merger Guidelines during the pendency of this proceeding. (*See* RX3953 (Press Release on FTC's Withdrawal from Vertical Merger Guidelines, Sep. 2021) at 1–2.)

1204. The parties to a merger challenged by DOJ are subject to a single proceeding in which DOJ has no legal recourse in the event it loses, except to appeal to the circuit court. 28 U.S.C. § 1291; Fed. R. App. P. 3(a)(1). In contrast, the parties to a merger challenged by the FTC run the risk of the FTC proceeding in two forums simultaneously (federal court and an administrative proceeding) or challenging the merger in U.S. district court and if the court rules against the challenge, retrying the entire merits proceeding in an administrative proceeding within the FTC itself. 15 U.S.C. §§ 45(b), 53(b). The FTC possesses a significant advantage that DOJ lacks in negotiating a settlement; few parties will want to litigate a full administrative trial and face the risk of expensive and disruptive divestitures. In addition, if the FTC loses

before an FTC ALJ it may reverse that decision as to both factual and legal findings. 16 C.F.R. § 3.54(b).

1205. The parties to a merger challenged by DOJ are entitled to an independent factfinder—an Article III judge appointed by the President and confirmed by the Senate, with no allegiance to DOJ. 15 U.S.C. § 25. In contrast, parties to a merger challenged by the FTC in an internal administrative proceeding face an ALJ whom the FTC can replace at any time and can reverse on a de novo review, and appeal the very Commissioners who voted out the complaint and directed its prosecution. 16 C.F.R. §§ 3.42(a), 3.54.

1206. The parties to a merger challenged by DOJ are entitled to the protections of the Federal Rules of Civil Procedure and the Federal Rules of Evidence. *See* 15 U.S.C. § 25. Failure by DOJ to abide by the applicable procedural rules results in exclusion of evidence and potential sanctions against DOJ. *See* Fed. R. Evid. 103(d); Fed. R. Civ. P. 37. In contrast, the parties to a merger challenged by the FTC are subject to rules created by the FTC itself, do not necessarily enjoy the protections of the Federal Rules of Civil Procedure or the Federal Rules of Evidence, and must petition their accuser for relief from subpoenas and Civil Investigative Demands. 16 C.F.R. § 2.7(k). The FTC has even changed procedural rules when ALJs have ruled against it. (*See* Final Pretrial Hearing, Tr. 66 ("In fact, a lot of the rules that we abide by were – let's just say the rules were changed after I came to the Federal Trade Commission because of rulings I continually made applying Federal Rule of Evidence. That's all I'll say about that. But just remember, there's no jury. It's a bench trial.").)

1207. The parties to a merger challenged by DOJ are entitled to litigate the issue in federal court alone, often in a consolidated proceeding at which the issue of preliminary and permanent injunctive relief are decided at the same time. *See* 15 U.S.C. § 25. By contrast, the parties to a merger challenged by the FTC must litigate preliminary injunctions in federal district court and permanent injunctions in an administrative proceeding subject to review by the FTC. *See* 15 U.S.C. § 53(b).

1208. The parties to a merger challenged by DOJ face no risk that DOJ will change the district court's merits decision before appeal to the circuit court, as DOJ has no power to do so. *See Catlin v. United States*, 324 U.S. 229, 233 (1945); 28 U.S.C. § 1291. By contrast, the parties to a merger challenge in the FTC's administrative proceedings run the significant risk that the FTC will change a merits decision, including a decision that is adverse to the FTC, prior to appeal to the circuit court. 15 U.S.C. § 45(c); 16 C.F.R. § 3.54(b). The Commission is empowered to ignore an ALJ's determinations in their entirety and substitute the Commission's own legal and factual findings prior to appeal. 16 C.F.R. § 3.54. In fact, in the past 20 years, the FTC has reversed all but one decision in which this Court ruled in favor of a defendant. (RX3993 (Wright 2015) at 6); *see, e.g.*, *In re Schering-Plough Corporation*, Dkt. No. 9297 (Dec. 8, 2003); *In re Union Oil Co. of Cal.*, Dkt. No. 9305 (Jul. 6, 2004); *In re Rambus Inc.*, Dkt. No. 9302 (Jul. 31, 2006); *In re Realcomp II, Ltd.*, Dkt. No. 9320 (Oct. 30, 2009); *In re LabMD, Inc.*, Dkt. No. 9357 (Jul. 28, 2016); *In re Impax Labys, Inc.*, Dkt. No. 9373 (Mar. 28, 2019).

1209. The parties to a merger challenged by DOJ are entitled to factual review under the clearly erroneous standard. *United States v. Baker Hughes, Inc.*, 908 F.2d 981, 983 (D.C. Cir. 1990) (citing Fed. R. Civ. P. 52(a)). In contrast, parties to a merger challenged by the FTC are

subject to factual review under the lesser, substantial-evidence standard. *Hosp. Corp. of Am. v. F.T.C.*, 807 F.2d 1381, 1385 (7th Cir. 1986) ("Our only function is to determine whether the [FTC's] analysis of the probable effects of these acquisitions . . . is so implausible, so feebly supported by the record, that it flunks even the deferential test of substantial evidence.").

1210. The choice of whether a challenge is brought by DOJ or the FTC is sorted out by the agencies themselves through an informal, non-public, unwritten process called "clearance". (RX4012 (Muris 2005) at 4.)

1211. At times, the FTC and DOJ have decided which agency will handle a case by a coin flip. (RX4011 (Koenig 2020) at 1.)

1212. Even when the choice of reviewing agency is not the product of a coin toss, the clearance process is "opaque at best", often resulting in clearance disputes rather than an allocation based on reason. (RX4012 (Muris 2005) at 4.)

1213. Former director of the FTC's Bureau of Competition from 2013 to 2017 has stated that "every deal [she had] worked on [had] been mired in a clearance dispute between the agencies . . even for industries . . . she would have thought would clearly fall into one agency's particular expertise". (RX4011 (Koenig 2020) at 1–2.)

1214. While a 2002 Clearance Agreement reformed the clearance process and sought to capitalize on each agency's "industry-specific knowledge", allocating merging parties based on past industry-specific knowledge is no less arbitrary. (RX4012 (Muris 2005) at 9, 11.)

1215. Which agency has expertise in a particular industry is an accident of history. (*See* RX4012 (Muris 2005) at 9) ("[T]he new [2002 clearance] agreement recognized historical patterns of enforcement activity and expertise.").)

X. TESTIMONIAL EVIDENCE

A. Illumina

1. Francis deSouza

a. Background

1216. Francis deSouza is the CEO of Illumina and has served in that role since July 2016. (deSouza (Illumina) Tr. 2306.) Mr. deSouza's responsibilities include setting the long-term strategy and vision for Illumina, managing the operations of Illumina and overseeing building of products and various teams such as the commercial, regulatory affairs, market access, clinical affairs, finance, human resources and legal teams. (deSouza (Illumina) Tr. 2306, 2309.)

1217. Mr. deSouza joined Illumina in 2013 as President of the company and he was responsible for running Illumina's product development, engineering, manufacturing, and quality teams. (deSouza (Illumina) Tr. 2308–09.) Mr. deSouza's role as President involved overseeing Illumina's entire portfolio of products, including Illumina's sequencers, library preparation kits, IVD cystic fibrosis assay and software products. (deSouza (Illumina) Tr. 2309.) Mr. deSouza was President of Illumina at the time that GRAIL was created and spun off and CEO of Illumina at the time that Illumina decided to reacquire GRAIL. (deSouza (Illumina) Tr. 2308–09, 2194–95.)

1218. Mr. deSouza has a bachelor's degree in electrical engineering and a master's degree in electrical engineering and computer science, both from the Massachusetts Institute of Technology (MIT). (deSouza (Illumina) Tr. 2307.)

b. Testimony

1219. The Transaction. Mr. deSouza testified that: Illumina decided to acquire GRAIL because Illumina believed it could dramatically accelerate the availability of Galleri around the world and dramatically improve the accessibility of Galleri to people around the world, which not only benefits the public writ large, but also aligned with Illumina's mission and allowed Illumina to create significant value for Illumina's shareholders, (deSouza (Illumina) Tr. 2334–35); the impact of the Transaction is the potential to "fundamentally dent the mortality curve related to cancer and save many, many thousands of lives around the world" by Illumina accelerating access in the United States and across the globe to the life-saving Galleri test through leveraging Illumina's broad experience and capabilities, (deSouza (Illumina) Tr. 2411–12).

1220. Efficiencies. Mr. deSouza testified that Illumina's acquisition of GRAIL will result in numerous efficiencies, including: saving lives, accelerating market access to Galleri, research and development efficiencies, the elimination of double marginalization, the elimination of the royalty GRAIL owes to Illumina, supply chain and operational efficiencies, and accelerating international availability of Galleri. (deSouza (Illumina) Tr. 2342–78.) Despite Complaint Counsel's attempts to impeach Mr. deSouza with his IH testimony in an attempt to undermine his trial testimony on efficiencies, Mr. deSouza emphasized the IH testimony used by

Complaint Counsel was taken out of context and does not in any way change his conviction that the Transaction will result in significant efficiencies. (deSouza, Tr. 2426–27.)

1221. *Saving Lives.* Mr. deSouza testified that by accelerating access to Galleri the Transaction has the potential to "fundamentally dent the mortality curve in cancer" and save over 10,000 lives in the U.S. alone over the next nine years. (deSouza (Illumina) Tr. 2411–12.)

1222. Mr. deSouza explained that Illumina will make Galleri more accessible globally, more quickly than GRAIL and that GRAIL only plans to launch its product in the U.S., UK and Canada but Illumina will expand the test to other less wealthy countries, such as India and countries in Africa. (deSouza (Illumina) Tr. 2412–13.)

1223. *Accelerating Market Access to Galleri*. Mr. deSouza testified that FDA approval allows for an MCED test to be run in hospital and healthcare systems in addition to a GRAIL central laboratory thereby increasing patient access to the test, (deSouza (Illumina) Tr. 2346); CMS approval broadens access of Galleri to communities that are traditionally underserved by the healthcare system and payer approval will be absolutely critical in the adoption of Galleri, (deSouza (Illumina) Tr. 2346–47, 2350).

1224. Mr. deSouza explained that Galleri currently costs $950, which is a price many Americans cannot afford and makes payer coverage and reimbursement of Galleri absolutely critical to enabling widespread adoption and availability. (deSouza (Illumina) Tr. 2350–51.)

1225. Mr. deSouza provided testimony about Illumina's experience in obtaining FDA and CMS approval of products that it can leverage to accelerate FDA and CMS approval of Galleri, including that: Illumina has nearly a decade of experience working with the FDA and CMS on obtain approval for products, (deSouza (Illumina) Tr. 2347); the FDA's clearance in 2013 of Illumina's MiSeqDx next generation sequencer as an open platform next generation sequencer was the first such approval by the FDA, (deSouza (Illumina) Tr. 2344, 2347); Illumina has also obtained FDA approval of its NextSeqDx sequencer and is working on obtaining approval of its NovaSeq sequencer, (deSouza (Illumina) Tr. 2348); Michigan became the first state in the United States in which Medicaid covers rapid whole genome sequencing for critically ill children in the NICU and that breakthrough is due to work that Illumina has done over the past few years, (deSouza (Illumina) Tr. 2342); in 2013, Illumina's cystic fibrosis test was the first NGS-based test cleared by the FDA, (deSouza (Illumina) Tr. 2344); and partly because of Illumina's risk-sharing agreements with insurance companies, insurance coverage for NIPT has gone from being nearly nonexistent to covering over 190 million people, (deSouza (Illumina) Tr. 2343).

1226. Mr. deSouza explained that Illumina can accelerate payer coverage and reimbursement of Galleri because: Illumina has nearly a decade of experience working with payers to obtain approval of genomic tests and will utilize its experience and relationships for approval of Galleri, (deSouza (Illumina) Tr. 2351–53); Illumina has helped one billion people around the world obtain payer reimbursement for genomic tests and has deep expertise, innovative tools and deep relationship that it can utilize to accelerate payer coverage of Galleri; (deSouza (Illumina) Tr. 2342–43); and Illumina's experience with entering into risk-sharing agreements with insurance companies enables Illumina to work effectively with insurance

companies on building the data necessary for insurance companies to cover a test, (deSouza (Illumina) Tr. 2343).

1227. Mr. deSouza testified that in comparison to Illumina, GRAIL has a tiny team dedicated to FDA and CMS approval, (deSouza (Illumina) Tr. 2348); and the GRAIL team focused on payer approval has only nascent experience, (deSouza (Illumina) Tr. 2352).

1228. Mr. deSouza explained that after consummation of the merger, Illumina plans to quickly start the large-scale evidence generation and initiation of studies required to obtain FDA, CMS and payer approval for Galleri, (deSouza (Illumina) Tr. 2349–50); and that Illumina plans to leverage its existing models from its experience in obtaining payer approval of prior products (in NIPT, genetic disease diagnosis and cancer therapy selection) to help accelerate payer approval of Galleri (deSouza (Illumina) Tr. 2349).

1229. *Research and Development Efficiencies*. Mr. deSouza testified about Illumina's commitment to research and development to expand market opportunities for Illumina's business, including that research and development is absolutely critical to Illumina because innovation will unlock the future markets for genomics, (deSouza (Illumina) Tr. 2353); in 2020, Illumina invested $600 million in research and development, (deSouza (Illumina) Tr. 2354); Illumina has focused on driving the cost of sequencing down because the lower the prices are to consumers, the more opportunities to utilize sequencing for products opens up, (deSouza (Illumina) Tr. 2353); and innovation will allow for genomic tests to be easier for patients and physicians to understand and Illumina is focused on innovating to create simplicity that will grow the genomics market, (deSouza (Illumina) Tr. 2353–54).

1230. Mr. deSouza testified that the Transaction will create research and development efficiencies, for example: Illumina has over a decade of experience in optimizing workflows for the processing of genomic tests and will utilize that experience to optimize the workflow for Galleri, and optimizing the Galleri workflow will allow an increased number of tests to be run in a production environment and eliminate waste, which will result in lowering the cost per test for Galleri, (deSouza (Illumina) Tr. 2356–58); and the Illumina and GRAIL teams can work together on research and development of new genomic tests by, among other things, seeking to identify genomic biomarkers in the blood for conditions such as fatty liver disease, Alzheimer's Disease and Parkinson's Disease, (deSouza (Illumina) Tr. 2356).

1231. Mr. deSouza explained that absent the merger, GRAIL's team would be unable to focus on developing new genomic tests because their team is fully focused on scaling Galleri, GRAIL's diagnostic cancer test and GRAIL's MRD test and will not have the time and resources needed to develop new genomic tests. (deSouza (Illumina) Tr. 2357.)

1232. *Elimination of Royalties*. Mr. deSouza testified that the Transaction will generate cost saving synergies, including that: before the Transaction, GRAIL owed Illumina a royalty and after the close the Transaction, GRAIL no longer owes that royalty. (deSouza (Illumina) Tr. 2358.)

1233. *Elimination of Double Marginalization*. Mr. deSouza testified that Illumina charged a margin to GRAIL on next generation sequencing products prior to the Transaction and

GRAIL projected that margin into the future, but the Transaction will eliminate double marginalization. (deSouza (Illumina) Tr. 2359–60.)

1234. *Supply Chain and Operational Efficiencies*. Mr. deSouza testified to the supply chain and operational efficiencies the Transaction will create, including that: compared to GRAIL, Illumina is a much larger purchaser of materials needed for Galleri and will be able to deeper discounts for those materials, which will lower the cost of Galleri, (deSouza (Illumina) Tr. 2345); Illumina is a large purchaser of raw materials, and consolidating the quantity of raw materials that Illumina purchases with the quantity of raw materials that GRAIL purchases will generate even larger discounts for Illumina, which discounts are already larger than GRAIL's, and the discounts will result in a lower price to consumers for Galleri, (deSouza (Illumina) Tr. 2369–70); and Illumina has deeper experience than GRAIL in relation to purchasing raw materials and will be better able to identify suppliers that provide superior cost performance of inputs for the Galleri test, which will result in a lower price to consumers for Galleri, (deSouza (Illumina) Tr. 2369–70).

1235. Mr. deSouza testified to the lab operation efficiencies the Transaction will create, including that: Illumina already has high-throughput genomic testing laboratories in operation and can leverage its facilities, equipment and personnel to ramp up production of Galleri, (deSouza (Illumina) Tr. 2341); GRAIL runs Galleri out its development laboratory in Menlo Park, California, but Illumina has production laboratories in the United States and abroad that are able to run millions of tests and accelerate scaling Galleri, (deSouza (Illumina) Tr. 2370–71); a "certain level of sophistication" is required to run genomic testing pipeline, and Illumina already has the facilities, equipment and personnel needed to bring Galleri to scale, (deSouza (Illumina) Tr. 2371); Illumina has developed custom automation tools to run highly automated laboratories and software pipelines to analyze data from samples in a high throughput manner, (deSouza (Illumina) Tr. 2371–72); and it would take years for GRAIL to develop operational capabilities similar to the capabilities Illumina has and that GRAIL will be able to take advantage of as a result of the Transaction, (deSouza (Illumina) Tr. 2372).

1236. *Expanding International Availability*. Mr. deSouza testified to facts regarding Illumina's ability to accelerate international availability of the Galleri, including that: Illumina has a strong international presence and more than half of Illumina's revenue is generated in countries other than the United States, (deSouza (Illumina) Tr. 2374); Illumina has placed products in over 140 countries around the world and has obtained clearance of products in dozens of countries, which creates a connection between Illumina and the medical communities and regulatory bodies in the countries in which Illumina operates, (deSouza (Illumina) Tr. 2374); and Illumina's presence and experience internationally allows Illumina to be able to identify and respond to customer issues quickly, (deSouza (Illumina) Tr. 2374).

1237. Mr. deSouza explained that GRAIL only recently hired someone in the United Kingdom and does not have a presence in any countries around the world other than the United Kingdom and United States, (deSouza (Illumina) Tr. 2374–75); and absent the merger, GRAIL's plan is to make Galleri available only in the United States, Canada and the United Kingdom in the next five years, (deSouza (Illumina) Tr. 2375).

1238. Mr. deSouza pointed out that on its own, GRAIL will not get the test to countries such as Africa and India even over the next decade; that Illumina feels a sense of urgency to get the test on the market and that Illumina will make Galleri available globally and more accessible globally than GRAIL would on its own. (deSouza (Illumina) Tr. 2412–13.)

1239. Mr. deSouza noted that Galleri being available around the world will improve the test because the algorithms get more refined and the test become more accurate based on more tests being run and analyzing diverse samples, (deSouza (Illumina) Tr. 2373); and cancer is a global disease and expanding availability around the globe faster will result in additional saved lives, (deSouza (Illumina) Tr. 2372–73).

1240. For the efficiencies Mr. deSouza testified to, he explained that GRAIL would not be able to achieve those efficiencies absent the merger because: no other company or consulting firm can match Illumina's expertise in market access, clinical affairs, commercialization, regulatory approval and international expansion for genomics tests; customers are unwilling to share proprietary information with Illumina; and Illumina is not set up to be a consulting firm that makes its expertise available on fee basis. (deSouza (Illumina) Tr. 2377–78.)

1241. [redacted]

1242. *Raising GRAIL Rivals' Costs*. Mr. deSouza explained that: Illumina's core business is to sell sequencers and consumables to customers that include government institutions, researchers, academic medical centers, hospitals and healthcare systems, laboratories and private companies that provide genetic tests, (deSouza (Illumina) Tr. 2313–14, 2378); Illumina's customers use Illumina's products for a wide range of applications, (deSouza (Illumina) Tr. 2322–23); even in areas where Illumina provides a competing test, such as NIPT and cancer therapy selection, Illumina earns significantly more revenue by selling sequencers and consumables than it does selling tests, (deSouza (Illumina) Tr. 2378–79); [redacted]

1243. Mr. deSouza testified that: Illumina does not have any incentive to raise prices to any GRAIL rival or potential GRAIL rival because that would jeopardize Illumina's core business of selling sequencers and consumables, (deSouza (Illumina) Tr. 2378–79, 2387–88); if Illumina raised prices to GRAIL's rivals or potential rivals, the companies would switch to another platform such as those provided by Thermo Fisher or BGI, (deSouza (Illumina) Tr. 2379–80); and companies performing genomic analysis have a number of choices and can decide

to use short-read sequencers, long-read sequencers, microarrays or PCR platforms. (deSouza (Illumina) Tr. 2323–26.)

1244. Mr. deSouza noted that Illumina's revenue from selling sequencers and consumables to companies who provide cancer therapy selection tests is fourteen times higher than Illumina's revenue from selling its own cancer therapy selection test, (deSouza (Illumina) Tr. 2379); and Illumina's revenue from selling sequencers and consumables to companies who provide NIPTs is eight times higher than Illumina's revenue for selling its own NIPT, (deSouza (Illumina) Tr. 2379).

1245. Mr. deSouza explained that the projected size of the profit pool for MCED tests does not provide Illumina with an incentive to favor GRAIL over GRAIL's rivals or potential rivals because: Illumina is not projected to earn a profit on the GRAIL transaction until after 2030, which means Illumina must continue to rely on its sequencing sales to drive profitability, (deSouza (Illumina) Tr. 2382–83); and the profitability margin for testing is not projected to be larger than the profitability margin for sequencing sales, (deSouza (Illumina) Tr. 2385–86).

1246. *Small Cost of Sequencing Inputs.* Mr. deSouza testified to facts showing that Illumina raising the costs of sequencing would be ineffective due to the small percentage of sequencing costs in the overall cost of an MCED test, because: in 2007, the cost to sequence a human genome cost approximately $150,000 and currently the cost to sequence a human genome on Illumina's NovaSeq is $600, representing an over 99% reduction in the price of sequencing over that time span, (deSouza (Illumina) Tr. 2327–28); Illumina has driven down the cost of sequencing by focusing on research and development as well as technology innovation that drive down costs, and lower sequencing costs has, among other things, vastly expanded the number of applications that use sequencing technologies and made clinical tests affordable to a broader population, (deSouza (Illumina) Tr. 2328–29); Illumina plans to reduce the cost of sequencing further by increasing the density of its flow cells, reducing the wavelength of the light in the optical assembly, speeding up the platform's chemistry and accelerating it algorithms and data paths, which Illumina is doing to reach a point where it can provide a solution that sequences a genome for one hundred dollars, (deSouza (Illumina) Tr. 2330–31, 2397–98); and sequencing costs today represent about ten percent of the price of Galleri and Illumina projects the percentage to be less than four percent by 2025, (deSouza (Illumina) Tr. 2388).

1247. *Not Cooperating With GRAIL Rivals*. Mr. deSouza provided testimony about Illumina's business strategy to expand the use of its products by cooperating with test providers, including that: Illumina's ethos and strategy has always been to be an open systems platform to allow customers to not only use Illumina's suite of products, but also to use other companies' sequencing products for one part of the sequencing workflow and Illumina's products in another, [redacted]); and Illumina wants to expand the market for NGS-based testing and cooperating with potential GRAIL rivals expands the market for selling sequencers and consumables, (deSouza (Illumina) Tr. 2390).

1248. Mr. deSouza noted that: Illumina does not have any history of foreclosing potential competition after acquiring a testing company, (deSouza (Illumina) Tr. 2393–94); following Illumina's acquisition of Verinata (an NIPT provider) in 2013, Illumina did not take any steps to foreclose Natera with respect to the provision of NIPTs, (deSouza (Illumina) Tr.

2393); and while the number of NIPTs ordered has increased since 2013, Illumina's share of NIPT sales have decreased since 2013, (deSouza (Illumina) Tr. 2393–94).

1249. Mr. deSouza testified that Illumina does not have an incentive to not cooperate with any potential GRAIL rival because: Illumina's open platform ethos and strategy allows customer to switch to another sequencer, but continue to use the same data management platform and library preparation kits, (deSouza (Illumina) Tr. 2386–87); customers who observe Illumina's foreclosure conduct, regardless of whether that customer provides an MCED test or not, will cease doing business with Illumina, (deSouza (Illumina) Tr. 2380–82, 2387–88); if Illumina did not cooperate with a potential GRAIL rival to advantage GRAIL, it would have ripple effects across Illumina's customer base and negatively affect Illumina's core sequencing business, (deSouza (Illumina) Tr. 2390); and Illumina's current contracts with customers prevent Illumina from failing to cooperate with customers because Illumina is required to provide support services under the contracts, (deSouza (Illumina) Tr. 2391).

1250. *Inability To Capture Diverted Sales.* Mr. deSouza explained that Illumina would not be able to make up for sales it lost from engaging in foreclosure activities because: Galleri and other MCED tests will not be substitutes for one another, (deSouza (Illumina) Tr. 2380–82, 2387–88); Illumina employees and Mr. deSouza talked to a number of doctors who informed Illumina that a fifty-cancer test like Galleri will serve different needs than tests that screen for one cancer type or ten or fewer cancer types and that a cancer screening test that detects cancer signal of origin will not compete with a cancer screening test that does not detect cancer signal of origin, (deSouza (Illumina) Tr. 2336–37); and a customer is likely to switch to a non-NGS-based test as opposed to another NGS-based test, (deSouza (Illumina) Tr. 2380–82).

1251. *Investment Activity*. Mr. deSouza testified to facts showing that investment activity reflects a lack of investor concern of Illumina foreclosing competition after consummation of the transaction, including that: after the announcement of the merger, investment in the MCED market significantly ramped up, (deSouza (Illumina) Tr. 2392); following the announcement of the Illumina-GRAIL transaction Exact acquired Thrive, which had no commercially available product and no revenue, (deSouza (Illumina) Tr. 2392); and in the past, Illumina has seen similarly increased investments in potential rival NIPT companies after acquiring Verinata, (deSouza (Illumina) Tr. 2392–93).

1252. Open Offer. Mr. deSouza provided testimony about Illumina's Open Offer and explained that: Illumina drafted the Open Offer to resolve the objections to the Transaction raised by Complaint Counsel and customers, (deSouza (Illumina) Tr. 2338, 2401); following the announcement of the Transaction, Illumina reached out to customers to quell concerns about the Transaction, (deSouza (Illumina) Tr. 2290); certain Illumina customers executed long-term supply agreements with Illumina to quell their concerns about the Transaction, (deSouza (Illumina) Tr. 2290); and after Illumina published the original Open Offer, Illumina amended the Open Offer to address additional concerns customers and Complaint Counsel raised during the course of the trial, (deSouza (Illumina) Tr. 2407–09).

1252.1 Complaint Counsel also attempted to undermine the benefits of the Open Offer but Mr. deSouza reaffirmed that Illumina is committed to abiding by the terms of

the Open Offer and to treating all its oncology customers equally. (deSouza, Tr. 2431-41.)

1253. Mr. deSouza explained that the Open Offer is a 12–year-long contract that Illumina has made available to any oncology customer and contractually commits Illumina to, among other things, guarantee to oncology customers the same access to products and services as GRAIL or any other Illumina customer, (deSouza (Illumina) Tr. 2400–01); and an oncology customer who enters into the Open Offer can exit the agreement at any time for any reason, but Illumina cannot exit the agreement, (deSouza (Illumina) Tr. 2402).

1254. Mr. deSouza testified that to ensure that Illumina cannot offer disadvantageous pricing to any potential GRAIL rival: Illumina commits in the Open Offer to publish the products and services that GRAIL purchased, publish the pricing sheet that Illumina provided to GRAIL, participating in bi-annual audits to ensure compliance, and engage in binding arbitration to resolve any disputes, (deSouza (Illumina) Tr. 2402–03); the Open Offer contains a universal pricing grid, the purpose of which is to provide transparency around the prices that GRAIL is paying for products and services that that GRAIL purchases from Illumina, aid customers in developing multiyear business plans and ensure customers that everyone is on an even playing field, (deSouza (Illumina) Tr. 2403–04).

1255. Mr. deSouza testified that the Open Offer commits Illumina to providing customers with access to any products GRAIL has access to within five days of GRAIL having access to the products. (deSouza (Illumina) Tr. 2407–08.)

1256. Mr. deSouza explained that the Open Offer guarantees that Illumina will lower the price of sequencing by at least forty-three percent by 2025. (deSouza (Illumina) Tr. 2403.)

1257. Mr. deSouza noted that the Open Offer commits Illumina to enter into IVD agreements with customers who want to enter IVD agreements and support customers in developing an IVD if the customer wants to develop an IVD. (deSouza (Illumina) Tr. 2404.)

1258. Mr. deSouza testified that the Open Offer commits Illumina to license to any oncology testing customer any intellectual property that is licensed to GRAIL or another oncology customer for use in an oncology test. (deSouza (Illumina) Tr. 2405.)

1259. Mr. deSouza explained that the Open Offer commits Illumina to erecting a firewall between Illumina and GRAIL that ensures Illumina cannot share a customer's confidential information with anyone at Illumina or GRAIL who works with GRAIL's business; (deSouza (Illumina) Tr. 2404–05); and that the Open Offer provides audit and binding arbitration mechanisms to ensure Illumina's compliance with the Open Offer, (deSouza (Illumina) Tr. 2405). Mr. deSouza also testified that he was willing to change the arbitration in any way if Complaint Counsel felt it was still insufficient. (deSouza (Illumina) Tr. 2460–61.)

2. Alex Aravanis

a. Background

1260. Dr. Alex Aravanis is the Chief Technology Officer and Head of R&D at Illumina. (Aravanis (Illumina) Tr. 1809). Dr. Aravanis's responsibilities include directing the research and product development programs, managing the teams that are responsible for both, and helping develop Illumina's strategies in those areas. He also participates as a member of the executive team representing research and development. (Aravanis (Illumina) Tr. 1809–10).

1261. In early 2013, Dr. Aravanis joined Illumina as the Senior Director of R&D. At that time, he was responsible for directing and managing research projects and led efforts to develop new sequencing approaches for therapy selection in cancer and noninvasive prenatal testing. He also worked on improvements to fundamental sequencing technologies, new sequencing chemistries, new sequencing detection methods, new materials for using sequencing, and also development of software to analyze sequencing data. (Aravanis (Illumina) Tr. 1814–15).

1262. In 2015, Dr. Aravanis served as a cofounder of GRAIL. (Aravanis (Illumina) Tr. 1815.) In March 2016, Dr. Aravanis left Illumina to join GRAIL. Dr. Aravanis served as Vice President of Research and Development. In that role he built, managed and developed the research and development program at GRAIL and was involved in the initial research to develop the Galleri test. (Aravanis Tr., 1817–18.) After a few years, Dr. Aravanis was promoted to Chief Scientific Officer of GRAIL. As Chief Scientific Officer, Dr. Aravanis's duties expanded to include lab operations and clinical development. Dr. Aravanis held that role until he rejoined Illumina in May 2020. (Aravanis (Illumina) Tr. 1818–19.) Dr. Aravanis rejoined Illumina as head of research, he then became Chief Technology Officer in June of 2020 and head of product development in May of 2021. (Aravanis (Illumina) Tr. 1810.)

1263. Dr. Aravanis has a bachelor's degree in electrical engineering from the University of California at Berkeley. He also holds a master's and a Ph.D in electrical engineering, and a medical degree from Stanford University. (Aravanis (Illumina), Tr. 1810–11.) After graduating from Berkeley, and prior to joining Illumina, Dr. Aravanis amassed experience working in laboratories and medical device companies. He oversaw research and development at Pria Diagnostics, a company developing an at-home diagnostic fertility and thyroid hormone test, and Epoc Biosciences, a company developing medical devices for intensive care patients. He also served as Chief Scientific Officer at Sapphire, a company developing synthetic biology tools. (Aravanis (Illumina), Tr. 1812–13.) Dr. Aravanis has over 20 U.S. patents and 40 U.S. patent applications in his name and hundreds internationally. (Aravanis (Illumina) Tr. 1820.)

b. Testimony

1264. Background on DNA and Sequencing. Dr. Aravanis provided background facts on DNA, genes and the genome. (Aravanis (Illumina) Tr. 1823–27.)

1265. He explained that DNA sequencing is a technology to read DNA; there are many purposes of DNA sequencing in almost every area of life science or clinical medicine; and a

good application is finding the right therapy for a cancer patient. (Aravanis (Illumina) Tr. 1827–28.)

1266. Dr. Aravanis noted that Next-Generation Sequencing ("NGS") is a higher throughput type of sequencing; first generation sequencing might be able to sequence a hundred molecules on one instrument per run; NGS instruments today can simultaneously sequence millions or even billions of sequences in a single run; there are many applications to NGS for different areas of science and medicine with new applications being published almost every day; some exciting clinical applications for NGS are currently being used, for example therapy selection, but even in those areas there is a long way to go to get the full benefit of the technology; it is still early in seeing how NGS can benefit medicine (Aravanis (Illumina) Tr. 1841–42).

1267. Dr. Aravanis described the different oncology applications for which sequencing is used today including: many research applications where people sequence cancer cells to understand cancer biology and how cancer is behaving and how you might treat it; therapy selection applications where you sequence a tumor to understand whether or not any of the mutations that are present might be targetable by a drug; applications for monitoring, sometimes called minimal residual disease, used to determine how effective the treatment will be for a given cancer patient; early cancer detection in individuals who are asymptomatic and do not have cancer (Aravanis (Illumina) Tr. 1843).

1268. He testified regarding the Illumina sequencing work flow: the first step is to isolate and extract DNA; the second step is called library prep, which consists of preparing the DNA in special ways, and the last step is sequencing the DNA and analyzing the data. (Aravanis (Illumina) Tr. 1829–33.) He also testified that it is possible to process multiple DNA samples at the same time on the same flow cell (Aravanis (Illumina) Tr. 1829–33) and that the consumables, the chemistries and flow cells used in sequencing are not customized, they are generic (Aravanis (Illumina) Tr. 1842).

1269. He explained that the sequencer itself is entirely generic and that the tailoring for a cancer application versus genetic disease testing is all about library prep and data analysis; different MCED tests would use the same instrument and consumable; the unique aspects of any given MCED test would be in the up-front workflow or after the sequencer when analyzing the data. (Aravanis (Illumina) Tr. 1832–33; 1837–40.)

1270. Illumina's Business. Dr. Aravanis testified as to Illumina's business model, including that Illumina develops and commercializes genomics technologies for the purposes of basic research and clinical applications and that Illumina's mission is to unlock the power of the genome, which means understanding how human biology and diseases work and detecting diseases earlier. (Aravanis (Illumina) Tr. 1821.)

1271. Dr. Aravanis testified that: "Illumina's core business is to constantly innovate, improve sequencing, you know, create new sequencing technologies, develop them and commercialize them so that, you know, these customers who want to do science, who want to do clinical applications are -- have better and better tools to unlock the genome." (Aravanis (Illumina) Tr. 1844.) "[B]y making the technologies that enable the information the -- the

genome to be accessed, at lower cost, with more accuracy, with more speed and in different ways we feel furthers that mission of unlocking the power and ultimately improving human health." (Aravanis (Illumina) Tr. 1821.)

1272. Illumina sells eight instruments: the NovaSeq 6000, the NextSeq 1000/2000, the NextSeq 550, the MiSeq, the MiniSeq, the iSeq 100, the NextSeq 550Dx, and the HiSeqDx. (Aravanis (Illumina) Tr. 1845.)

1273. Dr Aravanis explained that consumables are the materials consumed in a sequencing run; consumables include liquid reagents; for each instrument Illumina sells there are a handful of different consumables. (Aravanis (Illumina) Tr. 1845-46.)

1274. Dr. Aravanis noted that flow cells are glass slides where the actual sequencing is done; they have evolved over time, getting larger with more surface area to do more sequencing on the, the density has increased so that the number of DNA sequences you can have on a small area are increased. (Aravanis (Illumina) Tr. 1847.)

1275. The Founding of GRAIL. Dr. Aravanis testified that the idea for GRAIL came from a couple of projects that Illumina was doing. (Aravanis (Illumina) Tr. 1869–77.)

1276. *First*, Illumina was operating Verinata, a noninvasive prenatal testing business Illumina had recently purchased, and in the first hundred thousand women that received that noninvasive prenatal test some unusual signs were identified. It turned out these signals were undiagnosed cancer. This led to the discovery that cancer detection from the blood might be possible. (Aravanis (Illumina) Tr. 1869.)

1277. Dr. Aravanis explained "the laboratory director at Illumina who was responsible for the testing collected these unusual signals. She approached leadership at Illumina about them, including the chief medical officer and also myself, you know, and told us, you know, that we should look into it in more detail. We ultimately formed a team and a program to, you know, evaluate these signals, to follow up with patients carefully and their prescribing physicians, which eventually led to the discovery that these women had undiagnosed cancers." (Aravanis (Illumina) Tr. 1869–70.)

1278. *Second*, Illumina was developing liquid biopsy technology to look at cancer signals in late-stage cancer for the purposes of therapy selection and there was data from that that applied to some early-stage cancer samples that also suggested that early-stage cancer detection might be possible. (Aravanis (Illumina) Tr. 1870.)

1279. Dr. Aravanis testified that Illumina developed a hypothesis that multicancer early detection might be possible but also appreciated the significant amount of research and clinical development would be required; at the time no other companies were exploring development of NGS-based multicancer early detection tests; Dr. Aravanis, the other founders of GRAIL and Illumina's board came to the conclusion that to pursue this application in the research phases and maximize the changes of success it made sense to found GRAIL as an independent company; at the time, the industry was very skeptical about the concept. (Aravanis (Illumina) Tr. 1870–72.)

1280. Dr. Aravanis testified that Verinata would not have pursued this application if they had not been acquired by Illumina; that Meredith Halks-Miller, the laboratory director who had seen the initial signs of cancer in the blood, told him that prior to the acquisition no one at Verinata would listen to her about pursuing this research, that it was a distraction and that Verinata did not have the resources to do this and that but for Illumina no one would have developed a program in this area and without GRAIL this interesting discovery and the potential benefits might never be realized. (Aravanis (Illumina) Tr. 1873–74.)

1281. Dr. Aravanis explained that Illumina's ownership interest in GRAIL subsequently decreased to around 20%; at that time the relationship between the companies became one of vendor and important customer; that Illumina's interest eventually dropped to 12%; that aside from certain holdover projects there were no further interactions between the companies aside from vendor and customer; Illumina did not customize NGS products for GRAIL prior to the spinout and only did minor customization after the spinout. (Aravanis (Illumina) Tr. 1876–77.)

1282. Development of the Galleri Test. Dr. Aravanis testified that he wrote the research and development plan and led the research and development program to develop Galleri. (Aravanis (Illumina) Tr. 1877.)

1283. Dr. Aravanis explained that the steps involved in developing an MCED test are a research phase, a test development phase, a clinical trial and a commercial launch. (Aravanis (Illumina) Tr. 1878.)

1284. Dr. Aravanis testified that the research phase for Galleri was a multiyear process involving hundreds of employees that included: understanding the types of signals in every major cancer; looking at tens of millions of biomarkers, including mutations, chromosomal changes, RNA signals; recruiting hundreds of individuals for each major cancer type and stage and recruiting individuals without cancer and determining the technology needed to effectively detect the signal. (Aravanis (Illumina) Tr. 1878–81.)

1285. Dr. Aravanis explained that the most promising signals were methylation signals; that Galleri uses a million such markers; that it would not be possible to create a test using far fewer methylation markers; that different cancer types do not use the same methylation marker. (Aravanis (Illumina) Tr. 1882–83.)

1286. Dr. Aravanis testified that the test development phase for Galleri was a multiyear process involving hundreds of employees that included: constructing an assay, including library prep and analysis that performs the test, finding or inventing the right chemistries to manipulate and prepare the DNA, miniaturizing the relevant processes, developing an analysis of the signals and verifying and validating the system. (Aravanis (Illumina) Tr. 1885–86.)

1287. Dr. Aravanis explained that the GRAIL developed a targeted methylation assay and a method for doing high-throughput automated extraction, a method for library prep, a proprietary machine learning algorithms to take the signals and make a prediction about whether or not a patient has cancer and what type of cancer they have. (Aravanis (Illumina) Tr. 1887.)

1288. Dr. Aravanis testified that in the clinical trial phase GRAIL has released results for the CCGA and PATHFINDER studies. (Aravanis (Illumina) Tr. 1891.)

1289. The CCGA study initial results showed that multicancer early detection could be possible and that methylation was the most promising result; later results shows that a much lower-cost targeted methylation assay could achieve high performance for multicancer early detection. (Aravanis (Illumina) Tr. 1891.)

1290. The PATHFINDER study showed that in an interventional clinical trial Galleri could find early stage cancer in significant numbers with a low false positive rate and 90% accuracy. (Aravanis (Illumina) Tr. 1891–92.)

1291. Dr. Aravanis testified that there are two ways to commercially launch a test: a laboratory developed test or LDT and an FDA-approved IVD. (Aravanis (Illumina) Tr. 1892.)

1292. GRAIL launched the Galleri test as an LDT in June of 2021; GRAIL chose to launch as an LDT to make the potentially lifesaving technology available as soon as possible and because data from an LDT could be used to support and supplement a PMA application; GRAIL plans to seek FDA approval through a PMA because it will help with reimbursement and adoption. (Aravanis (Illumina) Tr. 1892–93.)

1293. Dr. Aravanis testified that GRAIL considered developing a single cancer test as a route to multicancer but abandoned it because it would take far too long; building a multicancer test by developing single cancer tests could take four or five years for each cancer; in order to develop a 50–cancer test one cancer at a time a developer would need to do a research study, discovery study and collect relevant samples, determine the right technology, go into a new test development phase and clinical trials for each new cancer; GRAIL was able to develop a 50 cancer test directly by undergoing a much larger process that developed a test for 50 cancers at the same time. (Aravanis (Illumina) Tr. 1895–97.)

1294. Dr. Aravanis testified that it would be difficult to develop a test by simply collecting samples from sample banks without a clinical trial because you would end up finding signals that are an artifact of the collection methods. (Aravanis (Illumina) Tr. 1899–1901.)

1295. The Galleri Test. Dr. Aravanis testified that the Galleri test works by detecting methylation signals in the blood that are coming from a cancer, it the predicts whether or not there is a cancer present or not and the type of cancer and a report is provided to the patient. (Aravanis (Illumina) Tr. 1901–02.)

1296. He explained that the Galleri test can detect 50 types of cancer; it can detect every major cancer including lung, stomach, head and neck, liver, ovarian and pancreatic cancer. (Aravanis (Illumina) Tr. 1894–95, 1902.)

1297. The specificity of the marketed version of Galleri is 99.5%, which is higher than the specificity of other screening tests that are in the 80s or low 90s. (Aravanis (Illumina) Tr. 1903.)

1298. The sensitivity of the marketed version of Galleri varies by cancer type and stage; the sensitivity for the subgroup of particularly deadly cancers in early stages is 70 percent. (Aravanis (Illumina) Tr. 1904.)

1299. Dr. Aravanis testified that Galleri has detected cancer in asymptomatic individuals and actually resulted in curative therapy for certain patients. (Aravanis (Illumina) Tr. 1904.)

1300. Other Purported MCED Tests. Dr. Aravanis testified that there are several obstacles to developing a test like Galleri: it is not possible to perform a discovery study for an MCED test like Galleri using samples stored in a biobank; you need samples that were actually collected that are relevant to what you are trying to detect, including early stages of specific cancers which are rarely found in biobanks; it would be difficult to develop an MCED test using biomarkers identified from a commercial MRD or therapy selection tests because they focus on a small number of cancers and later stage cancers; there are few precedents for running clinical trials for cancers that do not currently have screening methodologies. (Aravanis (Illumina) Tr. 1915–18.)

1301. Dr. Aravanis testified if a company was within five years of launching an MCED test Dr. Aravanis would expect to see reports, publications, meeting presentations, clinical trials registered on ClinicalTrials.gov and peer reviewed publications; he would also expect a company to disclose that it obtained an investigational device exemption; it would take a couple of years from registration on ClinicalTrials.gov to actual results. (Aravanis (Illumina) Tr. 1908–15.)

1302. Dr. Aravanis testified that he keeps track of other companies developing cancer screening tests and that: there appear to be some tests in early research phases; he is not aware of any tests that are comparable to Galleri; he is not aware of any tests comparable to Galleri that have disclosed a clinical trial on ClinicalTrials.gov; he is not aware of any peer-reviewed articles that describe a test that does what Galleri does; it turns out that companies that Illumina had at one time tracked as potential competitors to Galleri are not in fact developing anything that would be a substitute or a competitive product. (Aravanis (Illumina) Tr. 1908–20.)

1303. Dr. Aravanis explained that Galleri does not compete with any single cancer tests because they are intended to be used in current standard of care applications while Galleri is not; Galleri is unlikely to compete with cancer tests detecting less than 10 cancers; Galleri will not compete with a test that does not identify tumor of origin because they would be used in a different clinical context, for example with an imaging modality. (Aravanis (Illumina) Tr. 1921–22.)

1304. Upstream Competition. Dr. Aravanis testified that numerous companies make NGS sequencers including BGI, Thermo Fisher, Oxford Nanopore and Pacific Biosciences and a couple dozen companies are developing NGS sequencing instruments. (Aravanis (Illumina) Tr. 1848.)

1305. *Thermo Fisher.* Dr. Aravanis stated that Thermo Fisher makes and instrument called the Ion Torrent; that the Ion Torrent uses a different type of sequencing chemistry and a different detection mechanism than Illumina but it produces similar types of sequencing data; that the Ion Torrent can be us as an alternative for many Illumina applications; that the Ion Torrent platform is adequate in terms of the type of sequencing data it produces, the accuracy and the cost and that Thermo Fisher markets the Ion Torrent as an alternative to Illumina. (Aravanis (Illumina) Tr. 1848–52.)

1306. *BGI.* Dr. Aravanis explained that BGI manufactures multiple sequencing instruments and consumables; they have an array of instruments very similar to Illumina's offerings in terms of the different categories of high throughput , mid throughput, low throughput; the instruments are comparable in terms of sequencing output; BGI's systems are used for liquid biopsy applications; BGI has an NGS sequencing product that could be used for multicancer screening; BGI competes with Illumina for liquid biopsy applications in the countries in which it operates; BGI markets its NGS offerings as an alternative to Illumina; the patents that are currently blocking BGI from entering the U.S. will expire in 2023; Illumina projects BGI will enter the U.S. in 2023. (Aravanis (Illumina) Tr. 1852–54.)

1307. *PacBio.* Dr. Aravanis testified that PacBio has an NGS sequencing product in development that could be used for multicancer screening; PacBio markets its NGS offering as an alternative to Illumina; PacBio's acquisition of Omniome will increase competition for NGS sequencers; PacBio has said that they plan to offer NGS products based on their acquisition of Omniome in 2023 at a very attractive price and that its NGS sequencing will be superior to Illumina. (Aravanis (Illumina) Tr. 1855–56.)

1308. *Oxford Nanopore.* Dr. Aravanis testified that Oxford Nanopore is a company that develops and commercializes NGS products; they are known for a type of sequencing called nanopore sequencing; it is possible to do short-read sequencing on Oxford Nanopore's platforms; doing short-read sequencing on Oxford Nanopore's systems today would be very low cost; the Oxford Nanopore platform is a very high-output sequencing platform; the amount of data and cost per data is comparable to the high-end Illumina systems; Oxford Nanopore's NGS sequencing product can be used and have been for liquid biopsy oncology testing; Oxford Nanopore markets its NGS offering as an alternative to Illumina and Illumina views Oxford Nanopore as a competitor in NGS sequencing. (Aravanis (Illumina) Tr. 1856–59.)

1309. *Genapsys*. Dr. Aravanis testified that Genapsys is a company that develops and commercializes NGS products; Genapsys sells an NGS instrument and consumable; Genapsys's NGS offering is different from Illumina's but produces the type of data that could be used as a substitute to Illumina for some applications; if Genapsys is able to deliver on its product roadmap then its NGS sequencing product could be used for multicancer screening; Genapsys markets its NGS offering as an alternative to Illumina. (Aravanis (Illumina) Tr. 1860.)

1310. *Singular.* Dr. Aravanis testified that Singular is a public sequencing company developing an NGS sequencing product; they will launch their product in 2023. (Aravanis (Illumina) Tr. 1861.)

1311. *Switching Platforms.* Dr. Aravanis testified that when he was at GRAIL, GRAIL considered using BGI, Thermo Fisher and Oxford Nanopore; GRAIL evaluated these platforms and determined that many of them would be a viable alternative. (Aravanis (Illumina) Tr. 1863.)

1312. Dr. Aravanis noted that that customers switch from one Illumina NGS platform to another every few years; in order to switch from an Illumina NGS platform to another NGS platform, GRAIL would need to do an analytical bridging study to demonstrate that the test performs similarly on an alternative sequencing platform, there might be other steps where minor modifications to some of the library prep or analysis would also be required; an alternative NGS

platform would not need FDA approval before it could be used for development or commercialization of an MCED test like Galleri; if the platform produces very similar data it would take a couple of months and a few hundred thousand dollars to switch and if the platforms had more substantially different data it could take six to twelve months and millions of dollars to switch. (Aravanis (Illumina) Tr. 1861–65.)

1313. Dr. Aravanis testified that Illumina has projected what the competitive landscape for NGS will look like over the next five to ten years; there are going to be many new sequencing platforms and a tremendous intensification of competition; the many platforms available today will become more competitive and there will be even more platforms in the coming years. (Aravanis (Illumina) Tr. 1866.)

1314. Dr. Aravanis explained that, in large part due to Illumina, the cost of sequencing the genome went from $3 billion to several hundred million dollars to now $600 dollars; Illumina plans to eventually get to a hundred dollar genome. (Aravanis (Illumina) Tr. 1867.)

1315. Alleged Foreclosure. Dr. Aravanis provided testimony that debunked Complaint Counsel's foreclosure theories.

1316. *Raising GRAIL Rivals' Costs*. Dr. Aravanis explained that Illumina does not plan on raising costs to GRAIL's rivals as Illumina's business is based on growing sequencing markets and lowering the cost to allow people to do more sequencing; Illumina plans to decrease costs going forward; foreclosing GRAIL rivals would decrease Illumina's revenue; foreclosing GRAIL's rivals would be very detrimental to Illumina's reputation, would jeopardize current and future customer relationships and would be inconsistent with Illumina's mission and values; customers have alternative sequencing options today. (Aravanis (Illumina) Tr. 1921–27.)

1317. *Small Cost of Sequencing Inputs.* Dr. Aravanis testified to facts showing that Illumina raising the costs of sequencing would be ineffective due to the small percentage of sequencing costs in the overall cost of an MCED test, which facts include: the cost of sequencing is currently less than 10% of revenue from Galleri and will go down to 5% or less in the future; MCED test developers will rely on less sequencing in the future. (Aravanis (Illumina) Tr. 1924–25.)

1318. *Not Cooperating With GRAIL Rivals*. Dr. Aravanis testified that Illumina does not have the ability to harm other test developers by withholding cooperation because: Illumina does not provide more than ordinary course customer support, servicing of instruments and maintenance to customers; a test developer developing an FDA-approved IVD distributable kit with Illumina needs very little support from Illumina; GRAIL is not developing its test as an IVD distributable kit because it believes that an LDT and a site-specific PMA are what the market needs in the foreseeable future. (Aravanis (Illumina) Tr. 1926–28.)

1319. *Optimizing Sequencers for GRAIL*. Dr. Aravanis testified that Illumina does not have any incentive to optimize its sequencing systems that are optimized for Galleri but do not work for a rival third-party test; Illumina has not optimized any of its products for Galleri; Illumina does not have any pattern or practice of optimizing its sequencers for particular applications. (Aravanis (Illumina) Tr. 1928.)

1320. *Investment in the Market.* Dr. Aravanis testified that Illumina monitors investment in MCED testing; since the announcement of the Transaction multiple companies raise additional money to develop MCED tests and new companies have been founded and financed; Illumina believes the Transaction will significantly increase innovation in the field; impeding innovation would be detrimental to Illumina's reputation, business model and ability to retain talent. (Aravanis (Illumina) Tr. 1931–33.)

1321. *The Verinata Transaction and NIPT.* Dr. Aravanis testified regarding Illumina's experience in the NIPT space which belies the government's assertion that a vertically integrated Illumina will foreclose its rivals. Dr. Aravanis testified that since Illumina's acquisition of Verinata in 2013, Verinata's market share decreased, the cost of NIPT tests decreased by over 90%, the number of tests performed has gone up by a factor of a hundred, the number of companies offering NIPT tests has increased significantly, the coverage of patients for NIPT tests has increased by at least 100 million women and there have been a significant number of new entrants. (Aravanis (Illumina) Tr. 1933–34.)

1322. The Transaction. Dr. Aravanis testified that: In September 2020, Illumina decided to acquire GRAIL; Dr. Aravanis supported the acquisition because if Galleri is widely deployed there is the opportunity to save many thousands of lives, there are few things in cancer diagnostics or therapeutics that have the same potential to avert deaths from cancer, Illumina is in a unique position to accelerate adoption of the GRAIL Galleri test and by accelerating access to the test many additional thousands of lives will be saved; in addition the Transaction would give Illumina access to additional clinical data and test data that could lead to new breakthroughs and could provide other business benefits. (Aravanis (Illumina) Tr. 1905–06.)

1323. Dr. Aravanis testified that the strategic rationale for the acquisition "[f]irst and foremost was to, through the acquisition, to accelerate the adoption of Galleri, and by doing so, increasing the number of tests, you know, performed for patients by millions than would otherwise happen in the absence of the acquisition, by doing additional millions of tests, potentially saving tens of thousands of additional lives." (Aravanis (Illumina) Tr. 1934.)

1324. Dr. Aravanis testified that the decision to reacquire GRAIL was consistent with the decision to spin off and reduce Illumina's stake in GRAIL because GRAIL was set up to do early stage R&D but GRAIL was not set up to do commercial development, regulatory processes; it was always contemplated that Illumina would bring GRAIL back in the future; at this point clinical results and product development have been accomplished and the focus for Galleri will need to be market access and increased R&D resources, which Illumina can provide. (Aravanis (Illumina) Tr. 1907–08.)

1325. Efficiencies. Dr. Aravanis testified that Illumina's acquisition of GRAIL will result in numerous efficiencies, including: saving lives, accelerating market access to Galleri, research and development efficiencies, the elimination of double marginalization, the elimination of the royalty GRAIL owes to Illumina, supply chain and operational efficiencies, and accelerating international availability of Galleri. (Aravanis (Illumina) Tr. 1935.)

1325.1 Complaint Counsel did not challenge any of Dr. Aravanis' testimony on efficiencies. (Aravanis (Illumina) Tr**. {1770–1809}**, 1971–77.)

1326. *Saving Lives.* Dr. Aravanis testified that cancer screening from Galleri will significantly reduce the number of cancer deaths because it will enable the ability to screen for 45 cancers that currently have no screening method; Dr. Aravanis authored a study in a peer review journal which estimated that in a population of 100,000 individuals Galleri would find approximately 500 cancers earlier than they would be found otherwise and avert 100 deaths; the PATHFINDER study showed that multiple individuals had early cancers detected by the Galleri test; by accelerating the adoption of the Galleri test by one year approximately 20,000 additional lives could be saved. (Aravanis (Illumina) Tr. 1938–42.)

1327. *Accelerating Market Access to Galleri*. Dr. Aravanis testified that widespread adoption of the Galleri test will require FDA approval and coverage by public payors like Medicare and Medicaid. (Aravanis (Illumina) Tr. 1943.)

1328. Dr. Aravanis explained that in order to get FDA approval GRAIL will need to demonstrate that Galleri was developed and will be operated in accordance or in compliance with FDA quality system regulations and clinical evidence demonstrating the performance of Galleri. (Aravanis (Illumina) Tr. 1943.)

1329. Dr. Aravanis noted that GRAIL has no experience getting FDA approval whereas Illumina received the first FDA clearance for an NGS sequencer, received over 70 clearances and registrations around the world in 45 countries and received multiple clearances and a PMA approval; Illumina has a large regulatory team experienced in FDA submissions, processes, templates, infrastructure for doing and writing and submitting PMA applications; Illumina has broken new ground and learned from past difficulties obtaining FDA approval. (Aravanis (Illumina) Tr. 1943–44.)

1330. Dr. Aravanis testified that Illumina plans to give GRAIL capabilities that are known to be a gap in its regulatory approval, for example, a sophisticated quality management system, support for additional studies, templates and processes that it doesn't have or that are currently deficient; and Illumina can provide these capabilities immediately whereas GRAIL would need to develop them. (Aravanis (Illumina) Tr. 1946.)

1331. Dr. Aravanis testified that payor approval required clinical utility evidence showing the benefit of Galleri. (Aravanis (Illumina) Tr. 1947.)

1332. Illumina has pioneered multiple approaches to market access, resulting in over 100 million additional patients worldwide covered for whole genome testing over the last few years and over 200 million people in the United States receiving coverage for comprehensive genomic profiling. (Aravanis (Illumina) Tr. 1947.)

1333. GRAIL has no experience in obtaining payor coverage and it would be difficult for GRAIL to gain similar capabilities to Illumina because it lacks the expertise, processes, infrastructure, reputation, track record, size of business that would be required. (Aravanis (Illumina) Tr. 1948.)

1334. Dr. Aravanis testified that Illumina would apply its approaches to market access to Galleri and help it achieve similar success. (Aravanis (Illumina) Tr. 1948.)

1335. Dr. Aravanis testified that the firewall that Illumina has put in place with the Open Offer will not affect the acceleration. (Aravanis (Illumina) Tr. 1946, 1948.)

1336. Dr. Aravanis testified that GRAIL could not achieve the market access efficiencies by hiring additional personnel because there are only a small number of individuals with direct experience doing NGS submissions, working with the FDA on those types of applications and pioneering market access for NGS products; it would take GRAIL a significant amount of time to hire and train staff for this purpose whereas Illumina has them. (Aravanis (Illumina) Tr. 1968–69.)

1337. *Research and Development Efficiencies*. Dr. Aravanis testified that innovation is incredibly important to Illumina; Illumina invests tremendously in research and development, investing close to 20% of its revenue or $650 million in research and development last year; Illumina's level of R&D is higher than comparable companies in the space; Illumina has approximately 1800 people in the core research and development group and a quarter have advanced degrees. (Aravanis (Illumina) Tr. 1948–50.)

1338. Dr. Aravanis testified that the transaction will create research and development efficiencies. *First*, the Transaction will improve the Galleri test because Illumina will be able to apply innovations from other clinical applications to the Galleri test, thereby increasing the clinical value of the test and Illumina will be able to lower the cost of the Galleri test faster by means of its significant experience miniaturizing assays, simplifying assays, developing new components for assays that can lower costs, internalizing manufacturing and reducing the overall cost. (Aravanis (Illumina) Tr. 1951–53). These efficiencies could not be achieved without the Transaction because they would require GRAIL to share its proprietary information with Illumina. (Aravanis (Illumina) Tr. 1953–54.)

1339. *Second*, the Transaction will lead to R&D benefits to the larger Illumina by creating novel discoveries, insights into other types of diseases such as fatty liver disease, diabetes, cardiovascular disease and neurodegenerative disease and significant cross pollination between applications. (Aravanis (Illumina) Tr. 1954–56.) It would be very difficult for GRAIL to pursue these on its own. (Aravanis (Illumina) Tr. 1957.)

1340. Dr. Aravanis also testified that these efficiencies will lead to cost reductions which also occurred when Illumina purchased Verinata in the NIPT space. (Aravanis (Illumina) Tr. 1957–58.)

1341. Dr. Aravanis testified that GRAIL could not achieve the R&D efficiencies by hiring additional employees and experts because creating R&D capabilities takes a substantial amount of time to hire the individuals and develop the programs and teams that can execute on these types of projects. (Aravanis (Illumina) Tr. 1967.)

1342. *Elimination of Royalties*. Dr. Aravanis testified that the Transaction will result in the elimination of the royalty GRAIL owes to Illumina. (Aravanis (Illumina) Tr. 1959.)

1343. *Elimination of Double Marginalization*. Dr. Aravanis testified that Illumina charged a margin to GRAIL on next generation sequencing products prior to the Transaction and

GRAIL projected that margin into the future, but the Transaction will eliminate double marginalization. (Aravanis (Illumina) Tr. 1960–61.)

1344. *Supply Chain and Operational Efficiencies*. Dr. Aravanis testified to the supply chain and operational efficiencies the Transaction will create, including that: during the due diligence process Illumina identified common suppliers for core components of the Galleri assay which Illumina purchases at a large scale and at volume discounts which it could share with Galleri (Aravanis (Illumina) Tr. 1960–61); Illumina operates multiple clinical laboratories, has operated genomic testing at a very large scale and has developed sophisticated laboratory operations that can be shared with GRAIL to lower their laboratory operations costs and lower turnaround time (Aravanis (Illumina) Tr. 1961–65).

1345. *Expanding International Availability*. Dr. Aravanis testified to facts regarding Illumina's ability to accelerate international availability of Galleri, including: Illumina operates its business in the majority of countries around the world; Illumina has a commercial, regulatory, product support in approximately 100 countries worldwide; Illumina can ship and sell products into all those countries, support products around the globe and pursue regulatory filings and clearances around the world; GRAIL has a small presence in the U.K. with no other international capabilities. (Aravanis (Illumina) Tr. 1965.)

1346. Dr. Aravanis explained that international expansion of Galleri will benefit patients in many ways, including: other countries in the world will benefit from the Galleri test much sooner than they otherwise would; a very large number of people around the world can benefit from this; a larger amount of testing will generate significant data on test performance for clinical utility information enabling coverage much sooner and this data can also be used with the FDA to accelerate regulatory approval. (Aravanis (Illumina) Tr. 1963–67.)

1347. For the efficiencies Dr. Aravanis testified to, he explained that GRAIL would not be able to achieve those efficiencies by contract because "[i]t would require GRAIL to share its knowledge of all of its technology, its assays, its bioinformatics . . . details of its clinical trials, including the results . . . how they were conducted, proprietary information that it wouldn't . . . otherwise share". (Aravanis (Illumina) Tr. 1969–70.)

1348. Open Offer. Dr. Aravanis provided testimony about Illumina's Open Offer and explained that: Illumina has committed that companies may develop similar products to Galleri and others in the oncology space, commits that prices will never be raised; guarantees a price reduction over time of at least 43% (Aravanis (Illumina) Tr. 1926); Illumina cannot disadvantage GRAIL's rivals because the Open Offer requires Illumina to give them access to pre-release NGS products until 45 days after those products are accessible to Galleri (Aravanis (Illumina) Tr. 1930).

3. Jay Flatley

a. Background

1349. Mr. Flatley is the former CEO and Executive Chairman of Illumina. (Flatley (Illumina) Tr. 4074–78.)

1350. Mr. Flatley was CEO of Illumina from 1999 to July 2016, Executive Chairman of the Board of Illumina from July 2016 to January 1, 2020 and Chairman of the Board of Illumina from January 2020 to May 2021. (Flatley (Illumina) Tr. 4074–78.) As CEO, Mr. Flatley was in charge of the overall general management of Illumina. (Flatley (Illumina) Tr. 4076.) As Executive Chairman, Mr. Flatley was a resource to Mr. deSouza, worked on certain special projects, including projects on population genomics, and worked with the market access group. (Flatley Tr. 4076–78.) As Chairman, Mr. Flatley ran board meetings, coordinated overall board room conversation and called for votes of the Board of Directors. (Flatley (Illumina) Tr. 4081.) At the time that the Board voted on the Transaction, Mr. Flatley was chairman of the Board of Directors and coordinated the overall board room conversation about the acquisition and called the ultimate vote to proceed with the deal. (Flatley (Illumina) Tr. 4081.)

1351. Mr. Flatley is currently the CEO of Zymergen, a materials science company based in California. (Flatley (Illumina) Tr. 4073–74). He also serves on the boards of several companies: Coherent, Denali (working on neurologic therapeutics), Iridia (working on a solution to store data in DNA), Wellcome Leap, and Rivian. (Flatley (Illumina) Tr. 4078–80.)

1352. He is on the board of trustees of the Salk Research Institute in San Diego. Salk is a research center in San Diego that works in plant genomics, an effort to take carbon out of the atmosphere and have plants sequester that carbon in soil. They also perform research in oncology, neurologic, and infectious diseases. (Flatley (Illumina) Tr. 4078–4081.)

1353. He is also on the advisory board to UC San Diego Moores Cancer Center. The board of advisors meets every couple months to get a report out on what are the latest developments in the cancer research, and for the board to advise the leadership of Moores on how to continue to evolve its cancer research. (Flatley (Illumina) Tr. 4080.)

1354. Mr. Flatley has a B.A. in economics from Claremont McKenna College as well as a B.Sc. and M.Sc. in industrial engineering from Stanford University. (Flatley (Illumina) Tr. 4074.) He has spent most of his career in the instrumentation industry including positions at Spectra Physics, Manning Technologies, Plexus Computers, and Molecular Dynamics. (Flatley (Illumina) Tr. 4074–75.)

b. Testimony

1355. The Transaction. Mr. Flatley testified that: after considering the Transaction for quite some time, the Illumina Board of Directors made the final decision to reacquire GRAIL in the fall of 2020; the Board's decision to reacquire GRAIL was unanimous; and the Board voted to reacquire GRAIL because it was a great deal for Illumina's shareholders, had the ability to accelerate the adoption of Galleri and that acceleration was going to be very important in saving lives. (Flatley (Illumina) Tr. 4081–82.)

1356. Efficiencies. Mr. Flatley testified that the Board voted to approve the Transaction because it would result in a number of efficiencies, including: saving lives, accelerating market access to Galleri, research and development efficiencies and accelerating international availability of Galleri. (Flatley (Illumina) Tr. 4082–84.)

1357. *Saving Lives.* Mr. Flatley testified that the Board concluded that the reunion of Illumina and GRAIL would save lives because it would have a dramatic impact on the rate with which the combined company could deploy the Galleri test and, therefore, save the lives of cancer patients who don't know they have cancer. (Flatley (Illumina) Tr. 4082, 4089.)

1358. *Accelerating Market Access to Galleri*. Mr. Flatley testified that one of the most significant constraints to adoption of a clinical test is reimbursement for that test so that physicians will use the test and ultimately get paid for the test performance; getting FDA approval is challenging, requires a tremendous amount of clinical work, documentation and procedural work and demands that you have the right kinds of relationships and interactions with the FDA; the payor system is quite complicated; there are many different health systems who all operate differently and every country in the world has a different type of payor system, some of those centralized, some of them decentralized like the United States; and the payor system is a very complex matrix or mosaic of people that are involved in getting reimbursement. (Flatley (Illumina) Tr. 4084–85.)

1359. Mr. Flatley explained that Illumina has been developing FDA capabilities inside the company for over a decade; Illumina has invested in the payor area for over a decade; and Illumina has a very large market access group whose sole function is to identify and work with payor groups around the world. (Flatley (Illumina) Tr. 4084–85.)

1360. Mr. Flatley explained that GRAIL is a very young company with limited resources, a quite limited ability to create an FDA submission and to put Galleri through the process of the FDA and has limited resources to put Galleri through the payor reimbursement process. (Flatley (Illumina) Tr. 4084–85.)

1361. Mr. Flatley testified that Illumina has the ability to accelerate the approval of Galleri through the FDA; that Illumina has to ability to establish reimbursement much more quickly than GRAIL; and that Illumina has the ability to get in front of payors and do submissions and supply clinical data at a rate much faster than GRAIL. (Flatley (Illumina) Tr. 4084–85.)

1362. *Research and Development Efficiencies.* Mr. Flatley explained that GRAIL is a company with much more limited resources than Illumina; that GRAIL has been focused on delivering Galleri to the market and making that test as advanced as possible as opposed to other avenues of research; and that Illumina has vastly deeper R&D resources. (Flatley (Illumina) Tr. 4088.)

1363. Mr. Flatley testified that the Transaction will create research and development efficiencies, for example: a combined company would lead to R&D efficiencies that would both improve the existing Galleri test and also improve the speed of development of subsequent tests to Galleri that would address other types of indications (Flatley (Illumina) Tr. 4083); a combined

company would accelerate the improvement of the Galleri test by taking advantage of the data coming from international expansion, integrating the data and using deep learning algorithms to improve the accuracy of the Galleri test and to improve the number of cancers that it addresses (Flatley (Illumina) Tr. 4088); a combined company could delegate resources to work on other tests including other tests involving markers in the blood such as Alzheimers, neurologic diseases and diabetes and bring follow-on, complementary tests to the market much more quickly (Flatley (Illumina) Tr. 4088–89).

1364. *Supply Chain and Operational Efficiencies*. Mr. Flatley testified to the supply chain efficiencies the Transaction will create, including that: Illumina's supply chain is deep and goes all the way back to primary formulations of products; Illumina and GRAIL both buy significant amounts of reagents and chemicals from third parties; because Illumina and GRAIL use many of the same reagents a combined company would have the ability to combine volumes and reduce the prices paid for those reagents; and a combined company would also have increased purchasing power. (Flatley (Illumina) Tr. 4085.)

1365. Mr. Flatley also testified to lab operation efficiencies the Transaction will create, including that: Illumina has several labs around the world; GRAIL has only one lab; integration of those lab operations could lead to much more consistent protocols, much more consistent software, and more consistent lab information management systems; the reunion of Illumina and GRAIL would allow a combined company to integrate and leverage data across multiple tests for a given patient and have much more unified software structures and reporting. (Flatley (Illumina) Tr. 4086.)

1366. *Expanding International Availability*. Mr. Flatley testified that Illumina has an international presence in all major countries of the world (Flatley (Illumina) Tr. 4087) and Illumina has a much larger sales force than GRAIL (Flatley (Illumina) Tr. 4083).

1367. Mr. Flatley noted that GRAIL has limited resources; plan to launch Galleri only in the US, UK and Canada; and expansion beyond those countries was not even contemplated as an option for the next several years prior to the Transaction. (Flatley (Illumina) Tr. 4087.)

1368. Mr. Flatley testified that Illumina would be able to leverage its international presence very directly even if the sales force were separate and that Illumina's infrastructure would dramatically accelerate GRAIL's ability to bring Galleri to other markets of the world and to do that quite quickly. (Flatley (Illumina) Tr. 4087–88.)

4. Phil Febbo

a. Background

1369. Dr. Febbo is currently the Chief Medical Officer at Illumina. (Febbo (Illumina) Tr. 4301.)

1370. As the Chief Medical Officer, Dr. Febbo oversees Illumina's clinical and medical strategy and he manages the teams that report in to the chief medical officer organization. (Febbo (Illumina) Tr. 4301.) At Illumina, Dr. Febbo has eight functions that reports to him: the

medical genomics research, biostatistics, clinical affairs, regulatory affairs, government affairs, payor community affairs, medical affairs and scientific affairs. (Febbo (Illumina) Tr. 4314–16.)

1371. Prior to Illumina, Dr. Febbo was employed at the Duke University Medical Center where he saw medical oncology patients in the genitourinary oncology clinic for six years and the University of California, San Francisco where he was a professor of medicine in urology and ran a lab that worked on the genomics of cancer. (Febbo (Illumina) Tr. 4302–03.) Dr. Febbo also had previous experiences with clinical trials, the FDA, payors, peer-reviewed publications, and NGS products. (Febbo (Illumina) Tr. 4304–08).

1372. Dr. Febbo received his bachelor's degree in biology from Dartmouth and he obtained his medical degree from the University of California, San Francisco. After medical school, Dr. Febbo trained in internal medicine and oncology within the Harvard Medical System at the Brigham and Women's Hospital. Furthermore, Dr. Febbo completed a medical oncology fellowship at the Dana-Farber Cancer Institute. (Febbo (Illumina) Tr. 4302.)

b. Testimony

1373. Background on Regulatory Approval for NGS Products. *Illumina's Clinical, Regulatory and Market Access Expertise.* Dr. Febbo testified that he oversees approximately 160 employees across eight functions, each of which contribute to Illumina's regulatory and market access initiatives: medical genomics research, biostatistics, clinical affairs, regulatory affairs, medical affairs, scientific affairs, government affairs and market access; (Febbo (Illumina) Tr. 4313-14) his team's experience in and expertise with genomics is critical, because Illumina's technology is still relatively new to payors, regulators and governments, so it is important to have experts that can help educate those stakeholders and convince them that NGS tests should be approved and covered. (Febbo (Illumina) Tr. 4317–18.)

1374. Dr. Febbo provide an overview of each of the functions he oversees: clinical affairs executes on the clinical studies required to support the regulatory filings for clinical tests; regulatory affairs oversees and provides guidance on the those clinical studies; biostatistics ensures the studies are scientifically rigorous and can demonstrate the performance of the tests; medical affairs provides medical input during the development of tests, educates healthcare providers and healthcare provider societies about genomics and generates evidence about the clinical validation and utility of Illumina's tests; scientific affairs develops presentations, abstracts and publications for the studies that Illumina performs, and assists with submissions to payers and regulatory authorities; market access engages with payers to cover Illumina's clinical tests; and government affairs works with governments to advocate for the use of Illumina's technology. (Febbo (Illumina) Tr. 4314–16.)

1375. *Importance of Clinical Evidence.* Dr. Febbo testified that it is important for an LDT to have clinical evidence that backs its performance: test developers and labs require CLIA certification to offer their tests, and after initial certification, labs undergo routine audits in which the clinical data supporting their tests and the claims that they put on their reports are reviewed; labs put their CLIA license at risk if they don't have sufficient data supporting their tests. (Febbo (Illumina) Tr. 4322–23.)

1376. Dr. Febbo testified that diagnostic tests can obtain payer reimbursement without FDA approval. For instance, NIPT is run exclusively under the LDT framework and is routinely covered by payers. (Febbo (Illumina) Tr. 4323–24.) In addition Dr. Febbo testified that certain breast and prostate cancer therapy selection tests, as well as special stains in pathology are offered as LDTs and regularly reimbursed. (Febbo (Illumina) Tr. 4323–24.)

1377. Dr. Febbo testified that he has experience switching an LDT from one platform to another, and in his experience, this takes approximately six to 12 months; the process is not that different if the test already has premarket approval from the FDA, but Dr. Febbo testified that you must also submit data to the FDA to secure approval to switch platforms, which could take an additional three to six months. (Febbo (Illumina) Tr. 4325–26.)

1378. Efficiencies. Dr. Febbo testified that Illumina's acquisition of GRAIL will result in numerous efficiencies, including: saving lives, accelerating market access to Galleri, research and development efficiencies, supply chain and operational efficiencies, and accelerating international availability of Galleri. (Febbo (Illumina) Tr. 4333–75.)

1379. Dr. Febbo explained that this acceleration effect is not reflected in the base case of Illumina's deal model for the merger, because the model was created to determine the acquisition price, and did not reflect the value that Illumina believed it could bring to GRAIL. (Febbo (Illumina) Tr. 4361.)

1380. *Lives Saved*. Dr. Febbo testified that the efficiencies will accelerate the adoption and availability of Galleri by approximately at least one year (Febbo (Illumina) Tr. 4360) and that he believes the resulting one-year acceleration of access to Galleri will save lives. (Febbo (Illumina) Tr. 4362–63.)

1381. *Accelerating Market Access to Galleri*. Dr. Febbo testified that a single-site PMA approval from the FDA has several benefits: because a PMA requires additional review, additional data and FDA approval it is seen as another assessment of the quality of the evidence supporting the test; the FDA has very strong credibility with which to attest to the safety and efficacy of testing in other areas such as therapy selection where there is now a national coverage decision linked with FDA approval; having a single-site PMA and a companion diagnostic claim compels reimbursement by Medicare. (Febbo (Illumina) Tr. 4337–38.)

1382. FDA approval of an NGS test is a big challenge for the FDA because the agency is generally used to reviewing a test that measure one or a small number of analytes or variables to determine the state of a patient to help in a single indication and one in which additional education will be needed. (Febbo (Illumina) Tr. 4341–43.)

1383. Dr. Febbo testified that Illumina has experience clearing both tests and devices with the FDA: Illumina obtained a 510(k) for its cystic fibrosis test, a PMA in cancer therapy selection for the Praxis extended RAS panel, and also cleared the MiSeq Dx and NextSeq Dx sequencers. (Febbo (Illumina) Tr. 4338–39.) Illumina is also in the midst of PMA submissions for its NIPT and therapy selection tests, as well as for a cleared version of its NovaSeq platform. (Febbo (Illumina) Tr. 4339.)

1384. Dr. Febbo testified that Illumina also has additional experience interacting with FDA officials and educating the agency about NGS technology, including: Illumina officials have held educational sessions about particular aspects of NGS during the "presubmission" stage of the PMA process, and also hosted 15 FDA employees for a two-day onsite session about the different components of NGS, including tutorials on sample preparation, sequencing samples and the back-end bioinformatics work. (Febbo (Illumina) Tr. 4339–41.) In addition, Illumina is a member of BloodPAC, an organization that advocates for the use of NGS-based clinical tests, which the FDA also participates in. (Febbo (Illumina) Tr. 4341.)

1385. Dr. Febbo testified that as Illumina has taken products through the FDA over the last decade, "we've established a cadence, an understanding. We've helped the FDA understand, and we feel we know where we need to continue to help them move and understand our technology in a way that's scalable and will help realize the potential of precision medicine." (Febbo (Illumina) Tr. 4344.) In addition, Dr. Febbo testified that Illumina's own teams have gained a better understanding of the requirements that are evolving from the FDA, which will also contribute to accelerating Galleri's PMA. (Febbo (Illumina) Tr. 4344.)

1386. Dr. Febbo testified that: Illumina's quality management system ("QMS"), which is compliant with FDA and foreign regulators, will also help accelerate Galleri (Febbo (Illumina) Tr. 4346–49); a QMS "is foundational to the work you do to develop, validate, and provide and manufacture a test", as it ensures 'consistency in the manufacturing of a test so that the performance of each test produced is similar to the performance of the test when it was going through clinical validation" (Febbo (Illumina) Tr. 4346–47); it has taken Illumina seven years to develop its QMS, and over that time Illumina has improved and refined its processes as it's gone through routine audits from FDA and other regulators (Febbo (Illumina) Tr. 4347–48); Illumina has "had a quality management system longer than GRAIL's been a company, and so those -- that learning, that evolution, and those -- those procedures and documentations that are foundational to the quality systems, as well as some of the software infrastructure, can be incorporated in the leverage to GRAIL's benefit." (Febbo (Illumina) Tr. 4348–49.).

1387. Dr. Febbo testified that GRAIL does not have FDA experience comparable to Illumina's. (Febbo (Illumina) Tr. 4344.)

1388. Dr. Febbo testified that Illumina's experience will accelerate the FDA approval and PMA process for Galleri and that GRAIL would be able to leverage Illumina's already existing QMS for its own FDA efforts. (Febbo (Illumina) Tr. 4344–45, 4348–49.)

1389. Dr. Febbo explained that Ammar Qadan, who reports to Dr. Febbo, is responsible for the plan to accelerate Galleri's adoption by payors, but testified that Illumina will commit to investing between $500 million and $1 billion over the next five to ten years to generate the clinical evidence necessary to secure broad payor coverage. (Febbo (Illumina) Tr. 4349–51.)

1390. *Research & Development Efficiencies*. Dr. Febbo testified that there are two categories of R&D efficiencies that the Transaction will generate. *First*, as testing of Galleri scales, the combined company will have access to more data that his biostatistics team and the

product development team can use to refine the test and improve its performance over time. (Febbo (Illumina) Tr. 4356–57.)

1391. *Second*, Dr. Febbo testified that Illumina can generate R&D efficiencies relating to new clinical applications, similar to Illumina's early cancer signal discovery with NIPT: Dr. Febbo explained that as the volume of Galleri tests increases, it will become more likely that some outlier signal gets observed, and Illumina has a "growing bench of experts who can look at these outliers, look at these signals, and help determine what's happening" and then take that observation to hypothesis, then proof of concept study and eventually a clinical test. (Febbo (Illumina) Tr. 4357–59.)

1392. *Supply Chain and Operational Efficiencies*. Dr. Febbo testified that finding the most efficient way to process samples, including through increased automation in a test's workflow, is critical to the success of any clinical test, both because it results in improved analytic performance and decreased operational burden (Febbo (Illumina) Tr. 4334); Illumina has lab operations expertise through its Verinata acquisition and because of that, Illumina has "more experience . . . than any other organization" in scaling a clinical test on Illumina sequencers. (Febbo (Illumina) Tr. 4334.)

1393. *Expanding International Availability*. Dr. Febbo testified that Illumina has a significant international presence and experience, including that: Illumina does business in over 120 countries, has regulated products and meaningful reimbursement in over 30 countries, has relationships with international laboratories and health systems, all of which is meaningful experience Illumina can bring to bear to help GRAIL. (Febbo (Illumina) Tr. 4351–52.)

1394. Dr. Febbo testified that Illumina will be able to accelerate Galleri's international expansion. (Febbo (Illumina) Tr. 4351–53.)

1395. Dr. Febbo explained that accelerating Galleri's international adoption will have a positive impact on patients in the United States because: by evaluating the performance of Galleri in countries with ethnic distribution different than the United States, Illumina will be able to better understand Galleri's performance in those populations within the United States, where they might be underrepresented in clinical studies international expansion will result in a higher volume of real-world evidence on Galleri's performance, which can be used to help convince payors to increase coverage for Galleri. (Febbo (Illumina) Tr. 4353–54.)

1396. Dr. Febbo also testified that while GRAIL's engagement with NHS in the United Kingdom is important, it does not demonstrate that GRAIL can expand internationally just as easily without Illumina: Dr. Febbo explained that the United Kingdom is particularly forward-thinking with genomics, and in Illumina's experience, success there does not automatically lead to success in other countries. (Febbo (Illumina) Tr. 4354–55.)

1397. *Efficiencies and the Firewall.* Dr. Febbo testified that the firewall provisions in the Open Offer would not impede Illumina from achieving the efficiencies he testified about because the regulatory, market access and R&D efficiencies are "not dependent at all on having any knowledge about what other customers are doing in screening or what GRAIL's commercial success is"; none of the teams that report to him have access to confidential information of

Illumina's oncology customers and Illumina is not involved in the single-site PMA applications of its customers, nor does the FDA seek information from Illumina in connection with the review of a third party's single-site PMA application for tests running on Illumina instruments. (Febbo (Illumina) Tr. 4363–64.)

1398. *The Efficiencies Are Merger-Specific*. Dr. Febbo testified that based on his time and experience and Illumina GRAIL could not achieve the acceleration benefits he described by hiring FDA consultants because a company needs an internal core team that has experience with the authorities and there is "just not a deep, rich bench of experience available for consultants, and the model of a consultant driving [the regulatory submission process] just doesn't work as effectively as having internal employees." (Febbo (Illumina) Tr. 4365.)

1399. Dr. Febbo also testified that GRAIL could not just hire Illumina's regulatory and market access personnel because Illumina has taken a cross-functional, multidisciplinary approach, creating a "critical mass that have worked over the years to generate this institutional insight that is not dependent on any single employee." (Febbo (Illumina) Tr. 4366.)

1400. Dr. Febbo explained that Illumina and GRAIL could not achieve the efficiencies that the merger will create via contract, because with partnerships, "you don't see total alignment between two companies . . . nor can you get into the depth of understanding of the processes and the special sauce that a lot of these companies, including Illumina, have in order to fully realize efficiencies, fully realize where you have the best opportunity to improve a test, to improve or speed regulatory, improve reimbursement. You just don't see the layer of engagement that's necessary to get to the full realization of those benefits through partnerships." (Febbo (Illumina) Tr. 4369.)

1401. Dr. Febbo testified that Illumina needs access to GRAIL's proprietary "secret sauce" to achieve the efficiencies of the Transaction; in terms of R&D efficiencies, "without understanding in depth the specifics of the sequencing that's performed, the specifics of the bioinformatics that goes from that sequencing and pulls out the methylation patterns [and] the machine-learning that's used to identify that cancer detection signal, to identify that tissue of origin of signal . . . it's almost impossible for our scientists, who know the technology better than any other company, to realize efficiencies"; in terms of regulatory efficiencies, Dr. Febbo testified that Illumina needs to have a deep assessment of GRAIL's full regulatory filings and all of its communications with FDA in order to engage with GRAIL, identify gaps based on Illumina's experience with FDA, so that they can "supplement those gaps, mitigate those risks, and find a path to acceleration." (Febbo (Illumina) Tr. 4369–71.)

1402. Alleged Foreclosure. Dr. Febbo testified to facts that debunk Complaint Counsel's theory of alleged foreclosure:

1403. The Transaction would not give Illumina an incentive to impede innovation in cancer screening test development because cancer screening represents a major market opportunity and will be a highly competitive landscape, and Illumina has a great incentive to be the platform of choice for any company interested in developing a cancer screening test (Febbo (Illumina) Tr. 4330); "it is in [Illumina's] best interest to make sure that we continue to create an environment where laboratories are excited to use our platform to develop screening tests for

cancer, as well as all the other applications we see happening" (Febbo (Illumina) Tr. 4331); sequencing will play an important clinical role in other areas of medicine, such as cardiovascular, metabolic, neurologic and inflammatory diseases, and if Illumina behaved in a way that disincentivized companies from using Illumina's platform in cancer screening, that would disincentivize other companies and laboratories from performing the early R&D work in those other areas on Illumina platforms (Febbo (Illumina) Tr. 4331).

5. Joydeep Goswami

a. Background

1404. Joydeep Goswami is the chief strategy and corporate development officer at Illumina. (Goswami (Illumina) Tr. 3181.)

1405. Dr. Goswami joined Illumina in late September 2019. (Goswami (Illumina) Tr. 3183.) Dr. Goswami reports to Illumina's CEO, Francis deSouza, and his responsibilities include helping formulate the company's annual five-year strategic plan, overseeing key strategic projects undertaken by the company, involvement with mergers and acquisitions and business development. (Goswami (Illumina) Tr. 3181–84.) With respect to business development, Dr. Goswami is involved with Illumina's licensing business and partnerships, including pharmaceutical partnerships with companies and academic institutions for companion diagnostics, research and development and in vitro diagnostic ("IVD") agreements. (Goswami (Illumina) Tr. 3183–85.)

1406. Prior to joining Illumina, Dr. Goswami worked with next generation sequencing platforms and genomic tests for approximately sixteen years for Thermo Fisher directly or companies who were later acquired by Thermo Fisher. (Goswami (Illumina) Tr. 3181–82.)

1407. Dr. Goswami has a Ph.D. in chemical and biochemical engineering and an M.B.A. (Goswami (Illumina) Tr. 3183.)

b. Testimony

1408. Background on IVD Distributed Tests or IVD Kits. Dr. Goswami testified that if a company wants to introduce a clinical test, the company can provide the test as a Laboratory Developed Test ("LDT"), a single-site Pre-Market Approval ("PMA") or single-site IVD test, or an IVD distributed kit. (Goswami (Illumina) Tr. 3185–87.)

1409. LDTs are the most common offering and involves a company clinically and analytically validating the test and then running the test in a single laboratory that has received CLIA/CAP certification. (Goswami (Illumina) Tr. 3185, 3195–96.)

1410. A single-site PMA test is run in a single lab, but the test has been clinically and analytically validated under the FDA's PMA regulations. (Goswami (Illumina) Tr. 3186.)

1411. An IVD distributed test or IVD kit involves a kit that is developed and manufactured by a test manufacturer and after receiving FDA approval, the test can be run in various labs provided that the labs are CLIA/CAP certified (Goswami (Illumina) Tr. 3186–87);

the manufacturer of an IVD distributed test, not the lab running the test, bears the burden of continuing to manufacture the test, distributing the test and supporting the test in accordance with FDA guidelines (Goswami (Illumina) Tr. 3187).

1412. Dr. Goswami pointed out that an IVD kit offering is rare and due to the burdens associated with IVD kits and test developers often choose to stay with an LDT model as opposed to seeking to provide an IVD kit; for example, the longest available molecular test, the BRCA test, was introduced in the 1990s and has never been offered as an IVD kit—neither has Exact Sciences' Cologuard test. (Goswami (Illumina) Tr. 3196.)

1413. Alleged Foreclosure. Dr. Goswami provided testimony that debunked Complaint Counsel's foreclosure theories, including that Illumina has a minimal role in providing support to test developers developing an LDT, IVD or IVD kitted test; the use of IVD kitted tests in the U.S. is rare; Illumina receives little information from a test developer developing a kitted test and what information it does receive is kept confidential; Illumina has provided IVD rights to test developers in therapy selection where it is vertically integrated. (Goswami (Illumina) Tr. 3187–89.)

1414. *Test Developers Do Not Need Support from Illumina.* Dr. Goswami testified that where a test developer utilizes an Illumina sequencing platform for an LDT or single-site IVD test, Illumina has a "very minimal role" of providing instruments and reagents and the test developer has the sole responsibility of developing, designing, qualifying and maintaining quality control of the test. (Goswami (Illumina) Tr. 3187–88.) Illumina's role is "mostly as a supplier". (Goswami (Illumina) Tr. 3188.)

1415. Dr. Goswami explained that Illumina also has a minimal role in IVD kit development: Illumina provides a Dx 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).

1416. *IVD Kit Tests Are Rare in the United States.* Dr. Goswami testified that it was rare for a test developer to seek an IVD kitted test; that IVD kits are most suitable for tests that have precious samples, present shipping challenges and require fast turnaround times and that early cancer screening is not one of these types of tests. (Goswami (Illumina) Tr. 3196–3200.)

1417. Dr. Goswami also testified that GRAIL has not expressed any intent to pursue a distributed IVD kit. (Goswami (Illumina) Tr. 3273.)

1418. *IVD Kit Test Developers Do Not Provide Illumina With Proprietary Information and That Information Is Kept Confidential.* Dr. Goswami testified that Illumina has no ability to disadvantage its IVD partners because customers who enter IVD agreements with Illumina do not share any proprietary information with Illumina; the information shared with Illumina is limited to: the geographic location of the distribution and the timing of launch and FDA submission to ensure products are timely delivered and support is available, (Goswami

(Illumina) Tr. 3219–20, 3227); and the size of the panel of the test, (Goswami (Illumina) Tr. 3226).

1419. Dr. Goswami noted that for the information test developers provide to Illumina related to IVD kit development: Illumina's agreements contain confidentiality provisions to protect the shared information; Illumina employees are required to sign separate agreements to commit to protect customer's sensitive information; Illumina maintains a separation among teams working with customers who have similar products; limitations are placed on the information shared with employees and upper management, including restrictions on sharing of documents with sensitive customer information; and employees consult with Illumina's legal team on what information may be shared with specific Illumina employees. (Goswami (Illumina) Tr. 3328–31.)

1420. [redacted]

1421. Illumina's intent in entering IVD agreements is to lower the cost of kitted oncology assays in order to make the kits more widely available and spur innovation by allowing customers to rely on Illumina's platforms and infrastructure instead of spending the time and money required to develop their own. (Goswami (Illumina) Tr. 3217–18.)

1422. Illumina supports the development of IVD kits on Illumina's sequencing platforms regardless of whether the test developer is seeking to develop an IVD kit for a test that competes with a test Illumina offers, (Goswami (Illumina) Tr. 3202–03) and because: it aligns with Illumina's missions to NGS available to a broad swath of customers who can develop solutions to help human health and economically genomic testing customers are more apt to adopt an FDA approved diagnostic platform. (Goswami (Illumina) Tr. 3201–02.)

1423. [redacted]

1424. [redacted]

1425. Dr. Goswami pointed out that not all platform providers support IVD kit development on their platforms. (Goswami (Illumina) Tr. 3202.)

1426. Open Offer IVD Terms and Related Provisions. Dr. Goswami testified that any alleged foreclosure related to IVD Kits is impossible due to the terms of the Open Offer. (Goswami (Illumina) Tr. 3207–35.)

1427. Illumina's Open Offer commits Illumina to assisting customers, including MCED test developers, who want to develop IVD kits and allows customers to enter an IVD agreement with Illumina at any time from the close of the Transaction until six years after the close of the Transaction. (Goswami (Illumina) Tr. 3207, 3234–35.)

1428. The IVD terms of the Open Offer are available to oncology test developers who want to enter into an IVD agreement with Illumina and provides test developers with the power to select the terms and platform it would utilize and begin negotiations with Illumina with the Open Offer terms as a floor of what is available. (Goswami (Illumina) Tr. 3204–06, 3208.)

1429. The IVD provisions of the Open Offer are based on prior IVD agreements between Illumina and test developers (Goswami (Illumina) Tr. 3206) and are intended to provide clarity to Illumina's oncology customers, address concerns with the transaction raised by Complaint Counsel and ensure an even playing filed for all of Illumina's oncology customers (Goswami (Illumina) Tr. 3206–07).

1430. The IVD provisions of the Open Offer: limit development of IVD kits to three different tests, but do not place a cap on the number of IVD kits for a particular test a customer can offer, which terms are in accordance with Illumina's prior IVD agreements, (Goswami (Illumina) Tr. 3208–09); allow for IVD kit distribution in any geographic area in which Illumina's sequencers have approval for IVD usage, (Goswami (Illumina) Tr. 3209–10); and ten-year term for IVD agreements related to the NextSeq and NovaSeq platforms and for all-platform agreements the term is fifteen years, (Goswami (Illumina) Tr. 3210).

1431. The Open Offer's IVD provisions commit Illumina to maintaining the diagnostic platforms for the length of the IVD agreements. (Goswami (Illumina) Tr. 3211–12.)

1432. The financial terms of the IVD provisions of the Open Offer are fairly standard in Illumina's industry and include the technology access fee, milestone payments and revenue sharing terms (Goswami (Illumina) Tr. 3212) and the terms do not differ based on whether the test developer offers a test that competes with a test Illumina offers, (Goswami (Illumina) Tr. 3216).

1433. The technology access fee is an up-front payment of $25 million for all-platform development, which is based on: the fact that Illumina has to invest years and millions of dollars to develop diagnostic platforms and the investments are made at Illumina's risk as the FDA may not approve the platform and customers have not yet committed to adopt the diagnostic platform for IVD kit usage; and customer feedback on acceptable range of a technology access fee. (Goswami (Illumina) Tr. 3213–14.)

1434. Customers who do not want an all-platform agreement for IVD kits have the option of entering an agreement specific to NovaSeq or NextSeq platforms that have technology access fees of $15 million and $3 million, respectively. (Goswami (Illumina) Tr. 3214-15.)

1435. The revenue share term is due after a test developer commercially launches an IVD kit, (Goswami (Illumina) Tr. 3212); the revenue share is a six percent, which falls between the four and ten percent revenue share term that is fairly common in the life sciences and diagnostics industries, (Goswami (Illumina) Tr. 3215); and Illumina arrived at the six percent figure after discussing with customers to obtain their views on an acceptable revenue share term, (Goswami (Illumina) Tr. 3215.)

1436. The milestone payments are due when a test developer reaches certain stages of development of an IVD kit, which prevents the test developer from making payments before achieving certain significant progress on developing an IVD kit, (Goswami (Illumina) Tr. 3212, 3215–16); and Illumina arrived at the milestone payment figures after considering the infrastructure and maintenance investments related to optimizing platforms for usage with IVD kits and discussions with customers on fair figures, (Goswami (Illumina) Tr. 3216).

1437. Other Open Offer Provisions. The Open Offer contains a firewall provision to assure customers that Illumina will not directly allow GRAIL personnel or Illumina employees, including upper-level executives of both GRAIL and Illumina, who interact with GRAIL to access confidential information of Illumina's customers who provide offerings similar to GRAIL's offerings. (Goswami (Illumina) Tr. 3231–32.)

1438. Illumina has codified procedures to discipline Illumina employees for sharing confidential information with GRAIL employees. (Goswami (Illumina) Tr. 3232–33.)

1439. The audit provisions of the Open Offer are designed to identify any breaches of confidentiality that Illumina's internal controls do not detect. (Goswami (Illumina) Tr. 3233.)

1440. Notification requirements in the Open Offer require Illumina to promptly notify the customer if Illumina becomes aware that of a breach of confidentiality concerning the customer's confidential information either via an audit or Illumina's internal procedures. (Goswami (Illumina) Tr. 3233.)

6. Ammar Qadan

a. Background

1441. Mr. Qadan is the Vice President and Global Head of Market Access at Illumina. He joined Illumina in November of 2016. (Qadan (Illumina) Tr. 4098–99, 4105.)

1442. As a team leader of the market access team, Qadan is responsible for understanding the unmet needs of the payor community. (Qadan (Illumina) Tr. 4105–06.) By understanding the needs of the payors, he and his team can develop the evidence necessary to deliver on those needs and communicate the outcomes through publications and other channels. (Qadan (Illumina) Tr. 4106.)

1443. He has a bachelor's degree in pharmaceutical science from the University of Jordan in Amman, Jordan. (Qadan (Illumina) Tr. 4099.) Prior to joining Illumina, Mr. Qadan spent the majority of his career at Bristol-Myers Squibb and a short time at Halozyme Therapeutics. (Qadan (Illumina) Tr. 4099.)

1444. Mr. Qadan started his career at Bristol-Myers Squibb in July of 1990 and remained there for around 24 years. (Qadan (Illumina) Tr. 4099.) The market access activities Mr. Qadan was involved in at Bristol-Myers Squibb included coverage and reimbursement, marketing, initiatives for oncology drugs, diabetes payor marketing, and market access work on hepatitis C. (Qadan (Illumina) Tr. 4101–02.) In July of 2014 Mr. Qadan joined Halozyme Therapeutics, where he was the market access and value lead for their lead product for the treatment of pancreatic cancer, and later became the lead for the development and commercialization for that product. (Qadan (Illumina) Tr. 4103–04.)

b. Testimony

1445. Illumina's Market Access Capabilities. Mr. Qadan provided testimony about Illumina's market access function and explained that: the organization's goal is to increase coverage and reimbursement across clinical applications for genomics, which he measures by the number of lives covered globally by reimbursement authorities (Qadan (Illumina) Tr. 4110); the organization's functions include strategy and operations, health economics and outcomes research—which is the "power engine" of the organization that develops clinical and economic utility evidence—and payor relationships (Qadan (Illumina) Tr. 4109); and it is important for the market access team to work cross-functionally with other departments within Illumina in order to develop evidence of clinical and economic utility. (Qadan (Illumina) Tr. 4107–08.)

1446. Mr. Qadan explained how and why Illumina's market access function came into existence and expanded thereafter: the function was created with his hire (Qadan (Illumina) Tr. 4112); Illumina created the function because reimbursement is critical to achieve wide-scale adoption for genomics in clinical practice (Qadan (Illumina) Tr. 4113); and Mr. Qadan was tasked with identifying the structure needed to develop the market access team and then to recruit people into roles around the globe. (Qadan (Illumina) Tr. 4113–14.)

1447. Mr. Qadan explained: that expanding the market access team was a "steep process" that took three to four years to get everything into a steady state (Qadan (Illumina) Tr. 4114); that building out the team required hiring those trained as health economists for the health outcomes and research roles, and experience working with payors for the payor partner team (Qadan (Illumina) Tr. 4114–15); that having expertise in genomics is an important quality, because building the case for clinical and economic utility is more complicated than it is in pharmaceuticals (Qadan (Illumina) Tr. 4115); and that it took him six to nine months and a steep learning curve to gain a detailed understanding of genomics. (Qadan (Illumina) Tr. 4115–16.)

1448. Mr. Qadan testified about the importance Illumina's reputation plays in shaping its ability to gain market access for genomic tests, explaining that: unlike most companies in genomics, which focus on one or two main applications, Illumina plays a broader role in the field, and since payors must deal with genomics in the same broader sense, it is important for Illumina to develop partnerships with payors (Qadan (Illumina) Tr. 4116–17); Illumina has improved its reputation with payors through its early projects with payors like Genomics England (Qadan (Illumina) Tr. 4117); based on the reputation Illumina has built in market access, it has become less and less difficult to find talented applicants when recruiting for new roles (Qadan (Illumina) Tr. 4117); and, based on his work and experience, it has taken Illumina three to four years to build this reputation in market access. (Qadan (Illumina) Tr. 4118.)

1449. In addition to building the market access group's reputation, Mr. Qadan testified that he has overseen an increase in its budget: due to the expansion of clinical applications the group will cover; the expansion of Illumina's geographic footprint into the Middle East, Africa and Latin America; and the expansion of Illumina's evidence generation partnerships, Illumina's budget has increased from $3 million to $11 million annually, excluding headcount, during Mr. Qadan's tenure. (Qadan (Illumina) Tr. 4118–19.)

1450. Mr. Qadan explained that so far, the market access group's focus has been on three particular clinical applications: noninvasive prenatal testing ("NIPT"), tumor comprehensive genomic profiling ("CGP") and whole genome sequencing in rare and undiagnosed genetic diseases ("RUGD"). (Qadan (Illumina) Tr. 4121.)

1451. *NIPT.* Mr. Qadan testified that Illumina's efforts to expand market access for NIPT have included building evidence of clinical and economic utility and working with health technology assessment agencies and single-payer systems outside the U.S. (Qadan (Illumina) Tr. 4122); previously, payors had only covered NIPT for high-risk pregnancies (defined as pregnant women above the age of 35) and what Illumina found was that there was little clinical or economic utility data for average-risk pregnancies. (Qadan (Illumina) Tr. 4122–23.)

1452. Mr. Qadan explained that Illumina signed a risk-sharing agreement with payor Harvard Pilgrim Health Care to help generate the clinical and economic utility data: Harvard Pilgrim would cover NIPT for all pregnancies and Illumina would help cover the cost as well as gather the evidence around what clinical utility was created as a result of that expansion and at what cost, with the intention of publishing the results. (Qadan (Illumina) Tr. 4123–24.)

1453. Mr. Qadan explained that the partnership was a success: *first,* Illumina and Harvard Pilgrim demonstrated that there is clinical utility of expanding the use of NIPT to average or lower-risk pregnancies by lowering the number of unnecessary invasive tests in that population (Qadan (Illumina) Tr. 4124); *second*, from an economic utility point of view, there was an increase in cost of only 2.6 cents per member per month, which is very low cost for any payor to absorb (Qadan (Illumina) Tr. 4124); and *third*, those who used NIPT did not duplicate testing with older methods that were used before in that population, such as traditional serum screening, which is less sensitive than NIPT. (Qadan (Illumina) Tr. 4124.)

1454. Mr. Qadan testified about the impact of publishing the results of this study: Illumina is using the economic utility findings in its discussions with Medicaid so that they can understand the budget impact of expanding NIPT in Medicaid pregnancies (Qadan (Illumina) Tr. 4125); following the study, the American College of Obstetricians and Gynecologists ("ACOG") changed their guidelines to recommend NIPT in all pregnancies (Qadan (Illumina) Tr. 4125); and Illumina shared the results of their Harvard Pilgrim work with some commercial payors, like UnitedHealthcare, such that, by the end of 2020, around an additional 55 million lives were covered by payors for NIPT in lower-risk pregnancies. (Qadan (Illumina) Tr. 4125–26.)

1455. After successfully convincing commercial payors to expand market access, Mr. Qadan testified that Illumina's work in NIPT still continues: in the U.S., Illumina's focus now is on Medicaid plans, specifically in California, Texas and New York, to reduce disparities in healthcare in that population (Qadan (Illumina) Tr. 4130); while internationally, Illumina

continues to make submissions in a number of different countries and has been able to expand coverage over the past couple of years. (Qadan (Illumina) Tr. 4130–31.)

1456. Mr. Qadan explained that Illumina's work to expand coverage of NIPT applies to all NIPT tests, not just Illumina's: if payors are convinced that they need to cover a test, they develop a medical policy that says NIPT is medically necessary, and that applies across the board at an application level. (Qadan (Illumina) Tr. 4131.)

1457. *CGP.* Mr. Qadan testified that Illumina's market access work has helped expand coverage of CGP: Illumina has developed partnerships with Providence Healthcare in the U.S., the Belgian Society of Oncology, the University of Melbourne in Australia, and in Japan, to develop clinical utility evidence that supports the use of tumor comprehensive genomic profiling instead of the standard of care today, which is single-gene tests and small genomic panels (Qadan (Illumina) Tr. 4132–33); and over the past two to three years, the number of patients globally who have been covered for tumor comprehensive genomic profiling has increased nearly sixfold. (Qadan (Illumina) Tr. 4133.)

1458. *RUGD.* Mr. Qadan testified that Illumina's market access work has helped expand coverage of RUGD and has involved: partnering with Rady Children's Hospital in San Diego and other hospitals in the U.S., the California and Michigan state Medicaid systems and with countries and healthcare systems outside the U.S., including Genomics England, the State of Queensland in Australia, Taiwan and Israel, in order to develop clinical and economic utility evidence for RUGD (Qadan (Illumina) Tr. 4135); spending significant time building an economic utility model demonstrating that whole genome sequencing of rare and undiagnosed genetic diseases could be cost-saving for healthcare systems, which is slated for publication in a peer-reviewed scientific journal (Qadan (Illumina) Tr. 4134–35); and entering risk-sharing agreements with Harvard Pilgrim Health Care to study real-world effects of coverage for whole genome sequencing and with the state of Queensland in Australia to study the economic and clinical utility of providing every child with undiagnosed genetic disease whole genome sequencing as a first-line test. (Qadan (Illumina) Tr. 4136–37.)

1459. Mr. Qadan testified that in the past two to three years, Illumina's efforts have resulted in 36 million covered lives for whole genome sequencing in the U.S. and a fivefold increase overall. (Qadan (Illumina) Tr. 4137.)

1460. Mr. Qadan testified that across the 21 countries and three applications Illumina's market access team is focused on, they have secured more than one billion covered lives. (Qadan (Illumina) Tr. 4137–38.)

1461. *Risk-Sharing Agreements*. Mr. Qadan explained generally how risk-sharing agreements work: a risk-sharing agreement is a form of value-based contract whereby the payment or the decision by the payor is tied to the value provided by the test (Qadan (Illumina) Tr. 4138); for instance, in Illumina's case with Harvard Pilgrim, in order to get clinical utility data, Illumina shared the economic risks associated with expanding coverage for NIPT by covering Harvard Pilgrim's increased costs up to a capped amount as Illumina developed the data, and allowing Harvard Pilgrim to carry the risk if that cap were exceeded. (Qadan (Illumina) Tr. 4138–39.)

1462. Mr. Qadan testified that Illumina has entered into three risk-sharing agreements in total: the NIPT agreement with Harvard Pilgrim, a risk-sharing agreement with Harvard Pilgrim regarding whole genome sequencing and an agreement with the state of Queensland in Australia for whole genome sequencing. (Qadan (Illumina) Tr. 4140.)

1463. Mr. Qadan testified: that to his knowledge, no manufacturer had entered into a risk-sharing agreement involving NGS prior to Illumina; that risk-sharing agreements are not common between manufacturers and payors or health systems, and are rather more common between payors and healthcare providers, because they are easier to administer; that when there are risk-sharing agreements involving a manufacturer, they typically involve pharmaceuticals, rather than genomics or diagnostics; that risk-sharing agreements are not common in diagnostics and genomics because the data associated with genomics is much more complicated than that of pharmaceuticals. (Qadan, (Illumina) Tr. 4140–43.)

1464. Mr. Qadan explained that he was principally involved in negotiating the NIPT risk-sharing agreement with Harvard Pilgrim; that negotiations spanned from April 2017 until the agreement was signed in February 2018; and that there was no guarantee the arrangement was going to be successful from the outset, given the complexities of the data involved. (Qadan (Illumina) Tr. 4143–44.)

1465. Mr. Qadan testified that the success of the initial NIPT risk-sharing agreement with Harvard Pilgrim enabled Illumina and Harvard Pilgrim to enter into another risk-sharing agreement in RUGD. (Qadan (Illumina) Tr. 4145.)

1466. Mr. Qadan testified that Illumina's work with risk-sharing agreements is relevant to improving market access for Galleri, due to the reduced learning curve for any future agreements: while the NIPT agreement took 10 months to negotiate, the agreement for RUGD took roughly half the time despite the fact that Illumina had to analyze over 2,000 billing codes. (Qadan (Illumina) Tr. 4146.)

1467. *Budget Impact Modeling.* Mr. Qadan testified about Illumina's expertise in building budget impact models and their importance, explaining that: a budget impact model enables Illumina, before getting into a risk-sharing agreement, to understand what type of liability it might have and is very critical in managing the risk associated with risk-sharing agreements (Qadan (Illumina) Tr. 4127–28); in Illumina's submissions to single-payer systems outside the U.S., the economic utility component of those submissions is usually informed by its budget impact model (Qadan (Illumina) Tr. 4128); and it took one year to develop its budget impact model for NIPT and two years for RUGD. (Qadan (Illumina) Tr. 4128.)

1468. Mr. Qadan explained that the broad work Illumina has done across the different applications is very important to inform its expertise of how to look at other models in the future: for example, for RUGD, in which there are over six to seven thousand genetic diseases, Illumina had to review 2,000 diagnosis codes to properly build a budget impact model (Qadan (Illumina) Tr. 4129); in CGP, the analysis Illumina has done on the impact of diagnosis on survival of cancer patients can be used in other cancer applications. (Qadan (Illumina) Tr. 4130.)

1469. GRAIL and Galleri. Mr. Qadan explained some of the market access challenges that GRAIL and Galleri would face. (Qadan (Illumina) Tr. 4151–55.)

1470. *Medicare Adoption.* Mr. Qadan testified that: coverage by Medicare will be important in obtaining market access for Galleri, because the Medicare population, ages 65 and above, is at a higher risk of cancer; in order for Medicare to cover Galleri, Congress will likely need to pass new legislation enabling a pathway for CMS to cover multicancer screening tests; and after that pathway is created, CMS will look for FDA approval and for additional evidence of clinical utility before granting coverage. (Qadan (Illumina) Tr. 4151–53.)

1471. Mr. Qadan explained that his market access team has significant experience interfacing with CMS regarding Medicare coverage and that Illumina will "interact with [CMS] in a face-to-face, in different ways needed, to make sure that they understand our point of view." (Qadan (Illumina) Tr. 4153–54.)

1472. *Private Payor Adoption.* Mr. Qadan testified that: coverage by private payors will also be important for Galleri's widespread adoption, since private payors insure most people between ages 50 and 65 who are a critical part of Galleri's target population; private payors require evidence of both clinical utility and economic utility. (Qadan (Illumina) Tr. 4154–55.)

1473. Illumina's Acceleration of Galleri's Market Access. Mr. Qadan explained that Illumina would be able to help develop clinical utility evidence for Galleri by using the partnerships Illumina has in place, by working with healthcare systems and countries outside the U.S. that Illumina has worked with before and by defining a population, especially in the U.S., that could be a good entry point with commercial payors rather than just screening everybody above the age of 50 from the outset. (Qadan (Illumina) Tr. 4155.)

1474. Mr. Qadan testified that "we have experience building real-world data, we have experience building sophisticated clinical trials, and we have relationships, whether with healthcare systems or with payors, that would enable us to do both things as well." (Qadan (Illumina) Tr. 4156.)

1475. Mr. Qadan also explained that Illumina could help develop economic utility evidence for Galleri using its experience from the work its done on budget impact studies and finding innovative partnerships that would enable Illumina to gather data. (Qadan (Illumina) Tr. 4156–57.)

1476. Mr. Qadan explained that based on his experience, Illumina is capable of contributing to the development of evidence of clinical and economic utility in a way that will accelerate the availability of Galleri on a large scale: in the U.S., Illumina will utilize the partnerships it has today to accelerate adoption by private payors; outside the U.S., in Europe, Australia and Japan, Illumina will work with single-payer systems and health technology assessment agencies to start understanding their needs; in China, Illumina could start some of the work around patient willingness to pay for cancer screening as well as other types of studies that can inform Galleri's launch. (Qadan (Illumina) Tr. 4158–59.)

1477. Mr. Qadan testified that private payors consider the budget impact of new tests when making coverage decisions; that budget impact can delay the uptake of any new drug or

test; that the budget impact of Galleri is going to be high; and that Illumina is capable of contributing to the development of evidence of economic value and cost-effectiveness of Galleri. (Qadan (Illumina) Tr. 4159–60.)

1478. Mr. Qadan testified that based on his experience, Illumina is capable of generating evidence of the economic value and cost-effectiveness of Galleri in a way that will help to accelerate the availability of Galleri on a broad scale; that Illumina has had a plan for that acceleration in place since before this litigation commenced; that this planning work started with due diligence on Galleri when Illumina was considering buying GRAIL; and that Illumina had had discussions with partners around a pathway to accelerate Galleri's development that could reduce the budget impact of the test. (Qadan (Illumina) Tr. 4160–62.)

1479. Mr. Qadan explained that Illumina's plan for market access acceleration applied to both public and private payors; that within the U.S., Illumina would work on accelerating CMS approval through clinical utility data and accelerating regulatory approval; that outside of the U.S. work would be needed with single-payer healthcare systems, like work done with Genomics England and work done in Germany; and that work would also be done in China as a result of the favorable environment for lab-developed tests that previously did not exist. (Qadan (Illumina) Tr. 4162–63.)

1480. Mr. Qadan testified that a diagnostic aid to cancer (or DAC) could be an excellent entry point for a test like Galleri; that a DAC is a test used on patients who have started developing signs and symptoms of cancer; that Galleri performs better in patients with more advanced disease, so the test would rule out or rule in whether those patients have cancer to avoid multiple other tests; that Galleri ruling in or ruling out cancer has economic utility in that it saves money for the system in terms of further tests not being required; and that using Galleri as a DAC would initially enable Illumina to introduce Galleri into the marketplace without it having a huge impact on payors. (Qadan (Illumina) Tr. 4163–64.)

1481. Mr. Qadan explained that the data developed around risk factors associated with patients who tend to be positive for cancer from Galleri's use as a DAC would allow Illumina to expand its use to patients with those risk factors; that this would hopefully have an acceptable budget impact; that the third phase of this plan would be expanding the use of Galleri to the general population over the age of 50; and that the phased plan was developed with the knowledge that payors might otherwise resist a test with a high budget impact. (Qadan (Illumina) Tr. 4164–65.)

1482. *Illumina's Use of Consultants.* Mr. Qadan explained that in his work at Illumina and beforehand, he had used consultants: first, to build strategy and second, to build metrics to evaluate whether that strategy is working or not; and that he could not use consultants for execution, *i.e.*, to go and talk to payors on Illumina's behalf. (Qadan (Illumina) Tr. 4165.)

1483. Mr. Qadan testified that Illumina had used Real Endpoints as a consultant for its risk-sharing agreement with Harvard Pilgrim on NIPT; that Real Endpoints had conducted market research on why payors were not covering NIPT in certain pregnancies; that Real Endpoints had also managed the financial arrangement involved in the risk-sharing agreement as a third party; and that in his experience, consultants are unable to engage with payors or health

systems to negotiate partnerships on behalf of their clients due to confidentiality issues associated with such negotiations. (Qadan (Illumina) Tr. 4166–67.)

1484. Mr. Qadan explained that a team of consultants could not provide the functionality for Illumina that its market access group provides; that consultants are teams that come and go, and do not have institutional expertise that is built up over time; and that, even for strategy work, it is a steep learning curve for consultants to develop the required understanding. (Qadan (Illumina) Tr. 4167–68.)

1485. Mr. Qadan testified that Illumina does not provide market access consulting services to other companies, as it focused its resources on its own products and could not accommodate other things; and that he was not aware of other players in the market providing consulting services for market access. (Qadan (Illumina) Tr. 4168.)

1486. Mr. Qadan testified that market access was a high-demand, limited-supply function, particularly in genomics, and that it would be very difficult to replicate Illumina's market access functionalities because: first, there is a learning curve, especially coming to work in genomics; second, it has taken Illumina a long time to fill the roles in market access, taking two to three years before the team was in a steady state; third, Illumina's image was one of demonstrated success in this field, which could not simply be moved with an employee; and fourth, the institutional knowledge and relationships developed over time would be very hard to replicate from one company to another. (Qadan (Illumina) Tr. 4169–71.)

1487. Mr. Qadan testified that he was aware of GRAIL hiring two Illumina employees in the past, but neither was from the market access function; that Gautam Kollu was involved in Illumina's risk-sharing agreement with Harvard Pilgrim from the market development side of the process; that market development deals with things other than payors, including, for example, societies that are responsible for clinical guidelines; and that market access deals mainly with payor customers around the world. (Qadan (Illumina) Tr. 4171–73.)

1488. Mr. Qadan testified that although Illumina's market access employees are currently working on projects unrelated to Galleri, they could be redeployed to focus on expanding market access for Galleri upon Illumina and GRAIL integrating. (Qadan (Illumina) Tr. 4173–74.)

1489. Mr. Qadan testified that to his knowledge, GRAIL has not achieved coverage from any payors for Galleri so far; that agreements with self-insured employers would not necessarily lead to GRAIL being covered by insurance companies; that an agreement with a health system like Providence would not necessarily lead to coverage by insurance companies; that agreements with concierge medicine providers would not necessarily lead to coverage by insurance companies; that agreements with life insurers to use Galleri would not have any impact on the willingness of private health insurers to cover the test; that risk-sharing agreements related to Galleri would not ensure that it would be able to gain market access; and that payors are not influenced in their coverage decision by how innovative a test is or by public pressure. (Qadan (Illumina) Tr. 4174–78.)

1490. [redacted]

1491. [redacted]

1492. [redacted]

1493. [redacted]

1494. [redacted]

[redacted]

1495. Mr. Qadan testified that partnerships with healthcare providers would not necessarily generate the clinical utility data required for a payor to cover a test, as physicians and payors differ in what they need. (Qadan (Illumina) Tr. 4297–98.)

1496. Mr. Qadan testified that Illumina's expertise with NIPT could inform Galleri; that NIPT could be an analog for Galleri in terms of payor uptake; that Illumina's understanding of budgetary impact on payor uptake could be transferred from NIPT to Galleri; and that Illumina's expertise with building risk-sharing agreements and using historical data will inform the work for Galleri. (Qadan (Illumina) Tr. 4297–4300.)

7. Nicole Berry

a. Background

1497. Nicole Berry is the Senior Vice President and General Manager of The Americas Commercial Region of Illumina. (Berry (Illumina) Tr. 833.)

1498. Her team's responsibilities include customer-facing actives to drive revenue and customer success with Illumina's technology. (Berry (Illumina) Tr. 833–34.) Overall, the sales organization is responsible for acquiring new customers, management of existing customers as it relates to their purchases and post-sale support. (Berry (Illumina) Tr. 834.)

1499. Ms. Berry possesses a bachelor's degree in biology from the University of Rochester. (Berry (Illumina) Tr. 829–30.)

1500. Prior to joining Illumina, Ms. Berry worked for Memorial Sloan Kettering Hospital in New York City in their cancer research lab and subsequently at Eastman Kodak Company and then Applied Biosystems. (Berry (Illumina) Tr. 828–29.) She worked in the Scientific Imaging Division at Eastman Kodak and was a district sales manager for Applied Biosystems. (Berry (Illumina) Tr. 828.)

b. Testimony

1501. The Transaction. Ms. Berry testified that the Transaction will not change the way that Ms. Berry's team or Illumina as a whole interacts with its customers because, in order to achieve its goal of unlocking the power of the genome, Illumina must expand access to NGS. (Berry (Illumina) Tr. 836–39.)

1502. Alleged Foreclosure. Ms. Berry provided testimony that debunks Complaint Counsel's theories of foreclosure, including that: Illumina has competitors who recognize the market opportunity that exists for genomics technology and this competition will only become more intensive over time (Berry (Illumina) Tr. 813); Illumina has driven down the cost of sequencing and continues to do so (Berry (Illumina) Tr. 809–12); and Illumina's products and services are only involved in certain steps of a multi-step sequencing process. (Berry (Illumina) Tr. 813–22.)

1503. Ms. Berry testified to facts supporting the fact that Illumina's ability to withhold support from customers is limited, including: Illumina does not typically customize its sequencing instruments or core consumables for different customers (Berry (Illumina) Tr. 844); customers typically do not come to Illumina for advice on the development of their assays (Berry (Illumina) Tr. 844–45); and, outside of providing necessary documentation to regulators, Illumina does not typically provide support to customers in their efforts to get regulatory approval for their assays. (Berry (Illumina) Tr. 847–49.)

1504. Ms. Berry testified to facts supporting the fact that Illumina receives limited confidential information from customers, including that: the primary categories of confidential information that Illumina receives from its customers are their order history, some order forecasting for certain customers who choose to disclose it, certain financial information to evaluate customers' creditworthiness, and quality management records relating to troubleshooting Illumina's instruments (Berry (Illumina) Tr. 849–50); Illumina does not collect customers' sequencing data to conduct troubleshooting (Berry (Illumina) Tr. 852–53); and customers have to opt in to Illumina's troubleshooting software. (Berry (Illumina) Tr. 853.)

1505. Ms. Berry testified to facts supporting the fact that Illumina treats customer information confidentially: Illumina takes extensive measures to protect any customer information that it treats as confidential, including employee training and viewing restrictions on data stored in databases (Berry (Illumina) Tr. 853–55); and Illumina's customers cannot access the data of other customers. (Berry (Illumina) Tr. 855–56.)

1506. The Open Offer. Ms. Berry testified that the Open Offer was intended as a formal documentation obligating Illumina to provide certain terms and conditions ensuring customers will not be disadvantaged relative to GRAIL, and that the cover letter specifically notes that the purpose of the Open Offer is to allay concerns relating to the Transaction. (Berry (Illumina) Tr. 856, 859.)

1507. Ms. Berry testified that after the announcement of the Transaction, Illumina engaged in proactive outreach to certain customers through calls and letters of intent and that the Open Offer was developed based on what Illumina learned during this outreach. (Berry (Illumina) Tr. 857, [redacted]

1508. [redacted]

1509. [redacted]

[redacted]

1510. [redacted]

1511. [redacted]

1512. *Term and Termination*. Ms. Berry testified that: the Open Offer has a twelve-year term, which was chosen to assure customers that Illumina is invested in maintaining longstanding, positive relationships with its customers (Berry (Illumina) Tr. 861–62); customers can continue to sign the Open Offer for six years after the close of the Transaction (Berry (Illumina) Tr. 861); customers can exit the Open Offer agreement at any time and for any reason (Berry (Illumina) Tr. 862–63); and Illumina cannot terminate the agreement for convenience or for a claim that a customer is infringing Illumina's IP. (Berry (Illumina) Tr. 863–64.)

1513. *Access to Services and Products*. Ms. Berry testified that: the Open Offer obligates Illumina to provide customers access to the same services to which they had access before the Transaction and to which GRAIL has access (Berry (Illumina) Tr. 865–66); Illumina can ensure adherence to this provision because Illumina's services come from a standard catalog of orderable SKUs and Illumina tracks KPIs relating to customer support functions to ensure consistent treatment (Berry (Illumina) Tr. 867–71); and Illumina would breach the Open Offer if it deliberately delayed or refused to service a customer's instrument. (Berry (Illumina) Tr. 871.)

1514. Ms. Berry testified that: the Open Offer requires that customers have access for purchase to the same sequencing instruments and core consumables to which they had access to before Transaction or to which GRAIL has access (Berry (Illumina) Tr. 865–66, 874–75); the Open Offer also requires that customers receive access to future versions of sequencing instruments and core consumables at substantially the same time as GRAIL or equivalent customers (Berry (Illumina) Tr. 876–78); and, under the Open Offer's access provisions, Illumina could not deliberately send low quality reagents, delay fulfilling a purchase order or "monkey" with supply. (Berry (Illumina) Tr. 878–79.)

1515. Ms. Berry testified that the Open Offer requires Illumina, on customer request, to modify its sequencing instruments and core consumables to work more effectively with a given customer's tests (Berry (Illumina) Tr. 881); and that, even though this is not something that Illumina typically does, it was included in the Open Offer to be as customer-friendly as possible and to accommodate all possible requests Illumina might receive over the twelve-year term. (Berry (Illumina) Tr. 882.)

1516. Ms. Berry testified that the Open Offer prohibits Illumina from obsolescing a sequencing instrument or core consumable as long as at least one customer continues to purchase that product (Berry (Illumina) Tr. 883.); and that this was included to ensure that customers never felt forced to transition to a new product, even if that product was better and cheaper. (Berry (Illumina) Tr. 884–85.)

1517. Ms. Berry testified that the Open Offer requires that, in the event of a supply shortage, Illumina must allocate any short supply in an equitable manner, rather than favoring specific customers, such as GRAIL. (Berry (Illumina) Tr. 885–86.)

1518. *Pricing*. Ms. Berry testified that: the Open Offer allows customers to choose between their legacy pricing ("Grandfathered Pricing") or pricing under a universal grid ("Universal Pricing") (Berry (Illumina) Tr. 888–90); customers can choose Grandfathered Pricing for some products and Universal Pricing for others (Berry (Illumina) Tr. 892); customers who choose Universal Pricing have access to two "most-favored-nation" clauses, which ensure that they will receive pricing that is no less favorable than the pricing received by GRAIL or an equivalent customer (Berry (Illumina) Tr. 893); and if one of these most-favored-nation clauses is triggered for a customer, Illumina would be obligated to reduce the price to that customer to match the lower price received by GRAIL or an equivalent customer. (Berry (Illumina) Tr. 894.)

1519. Ms. Berry testified that the Open Offer prevents Illumina from raising prices beyond inflation or cost of goods sold for existing products or new products that do not reflect material improvements. (Berry (Illumina) Tr. 899–901.)

1520. Ms. Berry explained that the no-price-increase provision interacts with the no obsolescence provision and the Grandfathered Pricing provision to ensure that customers can continue to purchase the same products they received before the Transaction at the same prices. (Berry (Illumina) Tr. 902–03.)

1521. Ms. Berry testified that: the Open Offer further requires Illumina to reduce the price per gigabase of sequencing using the highest throughput flow cell on the highest throughput instrument by at least 43% by 2025 (Berry (Illumina) Tr. 903–04); and by reducing the price per gigabase of sequencing, Illumina would necessarily reduce the price per sample. (Berry (Illumina) Tr. 905–06.)

1522. Ms. Berry testified that: the Open Offer allows for short-term project pricing that allows customers to access uniquely low pricing for unique situations (Berry (Illumina) Tr. 909–10); and this pricing cannot be accessed for ordinary course purchases, so if, for example, GRAIL received a discretionary discount for ordinary course purchases, that discount would trigger the most-favored-nation protections under the normal Universal Pricing grid. (Berry (Illumina) Tr. 913–14.)

1523. *Regulatory Support*. Ms. Berry testified that the Open Offer obligates Illumina to provide support that is reasonably required for a customer to secure FDA approval of the customer's tests. (Berry (Illumina) Tr. 914.)

1524. *Confidentiality*. Ms. Berry testified that the Open Offer requires Illumina to keep customers' confidential information completely separate from GRAIL and from Illumina employees who work within GRAIL. (Berry (Illumina) Tr. 916–17.)

1525. *Enforcement*. Ms. Berry testified that the Open Offer provides for monitoring and enforcement mechanisms including regular audits by an external accounting firm to ensure Illumina's compliance with the Open Offer. (Berry (Illumina) Tr. 920–21.)

1526. [redacted]

1527. [redacted]

1528. [redacted]

1528.1 [redacted]

1529. [redacted]

1530. [redacted]

1531. [redacted]

1532. [redacted]

1533. [redacted]

8. **John Leite (Illumina/InterVenn)**

a. Background

1534. Dr. John Leite is the Chief Business Officer at InterVenn, a company that develops a glycoproteomic platform for life scientists and the development of diagnostic tests. (Leite (Illumina/InterVenn) Tr. 2073, 2166.) As Chief Business Officer, Mr. Leite is responsible for major partnership transactions, commercial activities, corporate strategy and corporate development. (Leite (Illumina/InterVenn) Tr. 2166–67.)

1535. Prior to joining InterVenn, Dr. Leite was employed at Illumina in both the Product Marketing and Development organizations. (Leite (Illumina/InterVenn) Tr. 2073, 2079–80.) In Product Marketing, Dr. Leite was responsible for the design and marketing of new diagnostic products in the Oncology Business Unit. (Leite (Illumina/InterVenn) Tr. 2073–74.) His responsibilities included Illumina's TSO-500 test, a therapy selection test. (Leite (Illumina/InterVenn) Tr. 2076.) As Vice President of Clinical Business Development, Dr. Leite was responsible for major partnership transactions with IVD providers and pharmaceutical companies. (Leite (Illumina/InterVenn) Tr. 2073.) This included the negotiation of collaboration agreements with pharmaceutical partners and IVD companies. (Leite (Illumina/InterVenn) Tr. 2080.)

1536. Dr. Leite has a bachelor's degree in biochemistry from Rutgers University, a Ph.D. in biochemistry and molecular genetics from the University of Pittsburgh and a post-doctoral fellowship from Caltech. (Leite (Illumina/InterVenn) Tr. 2071.)

b. Testimony

1537. Downstream Competition. Dr. Leite testified that InterVenn specializes in a proprietary platform in glycoproteomics, a technology that does not use next generation sequencing. (Leite (Illumina/InterVenn) Tr. 2167–68.)

1538. Dr. Leite explained that InterVenn is developing several assays on its glycoproteomics platform including an ovarian cancer screening test, a predictive test for late-stage cancer patients who are being considered for immunotherapies and an assay for colorectal cancer screening. (Leite (Illumina/InterVenn) Tr. 2168–69.)

1539. Dr. Leite explained that InterVenn has several blood-based early cancer screening tests in development, the tests are based on glycoproteomics, none of them use Illumina's NGS platform and each of these tests can be run in sequence off of the same sample. (Leite (Illumina/InterVenn) Tr. 2175, 2188–89.)

1540. InterVenn recently raised $201 million in Series C financing. (Leite (Illumina/InterVenn) Tr. 2177–78.)

1541. Illumina's IVD Program. During Complaint Counsel's direct examination, Dr. Leite testified that an IVD test is a type of test used for diagnosis, prognosis or therapy selection that is associated with an FDA approval for a single-site or distributable application and that IVD tests are distinguished from research-use-only or laboratory-developed test ("LDT") applications. (Leite (Illumina/InterVenn) Tr. 2075–76.)

1542. Alleged Foreclosure. Dr. Leite directly undermined Complaint Counsel's theories about Illumina's IVD strategy by testifying that Illumina never used the IVD agreements to raise the prices of kitted oncology assays, diminish innovation in kitted oncology assays or restrict competition among kitted oncology assays. (Leite (Illumina/InterVenn) Tr. 2161–62.)

1543. [redacted]

1544. [redacted]

1545. [redacted]

1546. [redacted]

1547. [redacted]

1548. [redacted]

B. GRAIL

1. Hans Bishop

a. Background

1549. Hans Bishop has served as the Chief Executive Officer of GRAIL since 2019. (Bishop (GRAIL) Tr. 1316.) He is also a member of GRAIL's board of directors. (Bishop (GRAIL) Tr. 1316.)

1550. Bishop has spent the majority of his career involved in oncology. (Bishop (GRAIL) Tr. 1361–62.) Prior to joining GRAIL, Bishop was the cofounder of June Therapeutics, which was then developing blood cancer therapies; the Chief Operating Officer of Dendreon, which was then developing a prostate cancer therapeutic; the President of Specialty Medicine at Bayer, where he oversaw an oncology portfolio; and the Global Commercial Head of Chiron, which was then developing a cancer treatment. (Bishop (GRAIL) Tr. 1361, 1365.)

1551. Bishop is the chairman of the board of Sana Biotherapeutics, which develops cancer treatments. He is also a member of the boards of Lyell Immunopharma and JW Therapeutics, both of which develop cancer treatments, as well as of Agilent Technologies, a scientific instrument and reagent company. (Bishop (GRAIL) Tr. 1361–62.)

b. Testimony

1552. Background on GRAIL. Mr. Bishop testified that GRAIL is a company whose single mission is to detect cancer early when the chances of cures are greatly increased. (Bishop (GRAIL) Tr. 1362.)

1553. Mr. Bishop testified that: GRAIL started at Illumina; the triggering event was a curious pathologist who noticed in data from pregnant women some very unusual sequences; after discussions with Illumina's chief medical officer, the pathologist concluded that the unusual data pointed to the fact that the women had cancer; and this led to the discovery of the possibility of detecting cancer in asymptomatic patients and to the formation of GRAIL. (Bishop (GRAIL) Tr. 1362–63.)

1554. Mr. Bishop explained that, after GRAIL was formed, Illumina recognized that it was an enormously risky endeavor and it would be right to form a separate company; Illumina very generously funded the company, provided it with some of its best scientists and engineers and granted it technology rights; and, a year or two after formation, Illumina reduced its ownership in GRAIL. (Bishop (GRAIL) Tr. 1363–64.)

1555. Mr. Bishop testified that: he joined the GRAIL Board in 2018 and became CEO in 2019; he joined because he believed that, if successful, GRAIL could make an enormous contribution and that it had the opportunity to reduce suffering and deaths from cancer in a cost-effective manner; and, since he joined GRAIL, GRAIL has validated the performance of Galleri in a trial approved by the FDA, built all of the infrastructure necessary to reliably deliver that test and made the Galleri test available to patients for the first time. (Bishop (GRAIL) Tr. 1364, 1366–67.)

1556. Mr. Bishop testified that GRAIL is now at a delicate and risky inflection point; GRAIL is now a commercial company and that comes with many new challenges, including the need to build different types of teams, to serve customers and to continue to develop technologies. (Bishop (GRAIL) Tr. 1367.)

1557. The Galleri Test. Mr. Bishop testified that: Galleri is a blood test that is intended to detect a cancer signal and enable the earlier diagnosis and treatment of cancer; the test looks at abnormalities in methylation regions in DNA that come from a tumor and is able to identify that as distinct and separate from healthy tissue; the test detects more than 50 types of cancer with a very low false positive rate and offers the doctor insight into the tissue of origin of the cancer; and GRAIL is optimistic it will be able to detect more cancers in the future. (Bishop (GRAIL) Tr. 1373, 1375.)

1558. Of the 50 cancers that Galleri can detect, only five—prostate, cervix, breast, colon and lung—have screening tests available. (Bishop (GRAIL) Tr. 1374.)

1559. Mr. Bishop testified that GRAIL currently only has one lab, but that it is building a second lab to invest in additional test capacity, invest in new cost-reducing technology and create new capacity for clinical trials. (Bishop (GRAIL) Tr. 1377–78.)

1560. Mr. Bishop testified that, while GRAIL uses the Illumina NovaSeq, the choice to use it relates mainly to the fact that it was used when Illumina founded GRAIL; GRAIL uses a variety of reagents and consumables and not all of these inputs are from Illumina; and Illumina has no role in running the Galleri test. (Bishop (GRAIL) Tr. 1381–82.)

1561. Mr. Bishop described the Galleri test process from a patient perspective: a doctor makes the decision as to whether or not it is appropriate to prescribe Galleri; a blood sample is collected; that blood sample is sent to GRAIL's laboratory in Northern California where all Galleri tests are processed; and then, once testing is complete, test results are returned to the doctor, who communicates them to the patient. (Bishop (GRAIL) Tr. 1375–76.)

1562. Mr. Bishop also described the Galleri test process at the laboratory: first, the DNA is chemically isolated from the patient's blood; next, the sample undergoes bisulfite conversion to essentially preserve the methylation or the epigenetic signature associated with that

DNA sample; then, in library preparation, plates are loaded with different samples from different patients; followed by a series of steps to enrich the signal that comes from each sample; then, the sequencing step, measuring the methylation; after that, duplexing and alignment to separate out the results before the methylation call is run; next, the computer algorithm makes a determination as to whether a cancer signal is detected or not; and, finally, a series of quality control steps to ensure that no samples have been contaminated. (Bishop (GRAIL) Tr. 1379–80.)

1563. The report provided to physicians contains information about whether a cancer signal has been detected; a prediction about the cancer signal of origin; and detail regarding the test's technical performance, including sensitivity, specificity and PPV. (Bishop (GRAIL) Tr. 1382.)

1564. Mr. Bishop testified that Galleri's sensitivity is a little less than 70% when the results from 12 prespecified important cancers are averaged and just under 45% when results from all 50 cancers are averaged; these numbers should not be compared to similar numbers for a single cancer tests because it is an apples-to-pears comparison. (Bishop (GRAIL) Tr. 1383–84.)

1565. Mr. Bishop testified that: a low false positive rate for a test like Galleri is very important, because a false positive can create enormous stress and having a positive test can come with medical risk and economic costs; and the PPV for Galleri is over 40% which is significantly higher than the PPV for mammograms and other single-cancer screening tests. (Bishop (GRAIL) Tr. 1385–86.)

1566. Mr. Bishop testified that detecting tumor of origin is important because it points the doctor to the right follow up, makes the test easier to use, speeds up time to diagnosis and can reduce unnecessary work-ups and whole-body imaging; the Galleri test correctly identifies tumor signal of origin approximately nine times out of ten; and Galleri detects tumor signal of origin though the blood and without a body scan. (Bishop (GRAIL) Tr. 1387–88.)

1567. Mr. Bishop testified that GRAIL is focused on three customer groups for Galleri: large, self-insured employers, integrated health systems and limited direct-to-physician channels called concierge practices; these are groups among which the test can be adopted even though it is not covered by a patient's insurance. (Bishop (GRAIL) Tr. 1401–03.) To expand beyond these groups, GRAIL would need to be successful with a PMA, achieve broad-based reimbursement, reduce test cost and increase production capacity. (Bishop (GRAIL) Tr. 1403.)

1568. Mr. Bishop testified that Galleri is currently priced at $949; Galleri's long-term goal is for this price to be reduced; and becoming part of Illumina will accomplish this goal by allowing Galleri to scale faster, invest in automation and robotics, reduce reliance on sequencing and reduce other costs. (Bishop (GRAIL) Tr. 1404–05.)

1569. Galleri's Alleged Competitors. Mr. Bishop testified that he has become familiar with other early detection liquid biopsy tests in development as a part of his job through expert colleagues, reading the literature, reading press reports and reading reports on data presented at medical meetings. (Bishop (GRAIL) Tr. 1388.)

1570. Mr. Bishop testified that, while he is aware of other companies developing single cancer tests, Galleri will complement, not compete with, single-cancer tests: single-cancer tests are optimized for detecting a single cancer, whereas Galleri's goal is to maximize the number of cancers we detect early; and single-cancer tests are used with individuals with an underlying risk, while Galleri is designed to be used with the general population. (Bishop (GRAIL) Tr. 1389–93.)

1571. Mr. Bishop explained that the more cancers a test can detect, the greater the clinical benefit for society and the patient; a test that detects a small number of cancers would be less helpful unless a patient was at an elevated risk for those cancers. (Bishop (GRAIL) Tr. 1400–01.)

1572. *Guardant*. Mr. Bishop testified that Guardant is focused on a blood-based, single-cancer test to detect colon cancer; he has not read any publications indicating that Guardant's test will detect more than one cancer; and this test will not compete against Galleri. (Bishop (GRAIL) Tr. 1389–93.)

1573. *Freenome*. Mr. Bishop testified that Freenome is developing a blood-based test for colorectal cancer; that he has not read anything that would suggest this test can detect any other cancers or that Freenome has another test that will identify other cancers; and that Galleri does not expect to compete with Freenome's test. (Bishop (GRAIL) Tr. 1393–94.)

1574. *Exact/Thrive*. Mr. Bishop testified that: there is no publicly available data on the latest iteration of Exact's test; the last reported results report approximately eight or ten cancers; Exact has been unable to replicate results from earlier trials; if Exact's technology is viable, the lack of published data on Exact's test is extraordinary; at least one of Exact's reported technologies would involve two sequential tests and a PET-CT scan; there is no data suggesting that Exact can identify cancer signal of origin; and it is currently not possible to understand whether Exact will compete with Galleri. (Bishop (GRAIL) Tr. 1394–97.)

1575. *Singlera*. Mr. Bishop testified Singlera has published clinical trials conducted in China regarding a multicancer test; that GRAIL's technical scientists follow the data carefully and are concerned that the data has confounding factors which suggest that the technology is still in early stages; and it is not possible to know, based on current data, whether Singlera's test would compete with Galleri. (Bishop (GRAIL) Tr. 1397–99.)

1576. Mr. Bishop testified that, today, GRAIL is not competing against any of the above companies. (Bishop (GRAIL) Tr. 1401.)

1577. Risks Faced By GRAIL. GRAIL met with Illumina to discuss a potential acquisition in the summer of 2020. (Bishop (GRAIL) Tr. 1407.) In 2020, GRAIL was also considering an IPO to fulfill ongoing needs for substantial amounts of capital to run operations. (Bishop (GRAIL) Tr. 1407.) While one other company had expressed interest in purchasing GRAIL, they never made an offer. (Bishop (GRAIL) Tr. 1407.)

1578. Mr. Bishop testified that, in deciding between an IPO and a transaction with Illumina, he had many meetings with investors and shareholders; there was substantial concern about an IPO because the pathway to reimbursement was unpredictable and long, investors did

not understand the scientific reports, investors were concerned that performance could deteriorate as results become more advanced and investors struggled to value GRAIL, given the lack of similar precedents. (Bishop (GRAIL) Tr. 1407–11.)

1579. Mr. Bishop testified that GRAIL's S-1 discloses many risks faced by GRAIL. (Bishop (GRAIL) Tr. 1411–22.)

1580. The Transaction. Mr. Bishop testified that there were multiple discussions by the GRAIL board regarding the Transaction; the GRAIL board had deep experience in contemplating the different paths ahead and had done so multiple times with different companies; and the GRAIL board employed the advice of expert advisors. (Bishop (GRAIL) Tr. 1422.)

1581. Mr. Bishop testified that the GRAIL Board unanimously decided to be acquired by Illumina because it had determined that it would result in the best outcome for patients and reduce the risks of the challenges ahead of GRAIL. (Bishop (GRAIL) Tr. 1423, **{1514–15.)}**

1582. [redacted]

1583. Mr. Bishop testified that he expects that GRAIL will be able to achieve its mission of detecting cancer early faster as part of Illumina. (Bishop (GRAIL) Tr. 1423.)

1584. Efficiencies. Mr. Bishop testified that Illumina's acquisition of GRAIL will result in numerous efficiencies, including: saving lives (Bishop (GRAIL) Tr. 1370–71); accelerating market access to Galleri (Bishop (GRAIL) Tr. 1368–72, 1403); research and development efficiencies (Bishop (GRAIL) Tr. 1367); supply chain and operational efficiencies (Bishop (GRAIL) Tr. 1372, 1404–05); and accelerating international availability of Galleri. (Bishop (GRAIL) Tr. 1406.)

1585. *Saving Lives.* Mr. Bishop testified that many cancers are diagnosed when it is very difficult or impossible to cure them; offering a test to all patients, regardless of financial means, will enable detection of cancer at an earlier stage, improving patients' probability of survival and reducing the cost of cancer treatment for those patients. (Bishop (GRAIL) Tr. 1370–71.)

1586. Mr. Bishop testified that combining with Illumina will increase GRAIL's likelihood of success and enable it to accomplish its goals faster. (Bishop (GRAIL) Tr. 1371–72.)

1587. *Acceleration of Market Access.* Mr. Bishop testified that GRAIL intends to seek a PMA approval from the FDA; that seeking a PMA approval is a long and complicated process; and that PMA approval is a prerequisite to getting payor and insurance coverage for Galleri. (Bishop (GRAIL) Tr. 1368, 1370, 1403.)

1588. Mr. Bishop testified that Illumina is a globally respected and experienced company when it comes to dealing with regulatory authorities (Bishop (GRAIL) Tr. 1372); the Transaction will increase GRAIL's chances of success with the PMA (Bishop (GRAIL) Tr. 1372); [redacted]

1589. Mr. Bishop testified that the path to reimbursement for preventative services, including screening tests, was unclear, but that obtaining widespread reimbursement was very important. (Bishop (GRAIL) Tr. 1417.)

1590. Mr. Bishop expects that Illumina's deep expertise interacting with regulators de-risks and maybe speeds up the speed at which regulatory approvals, which are a prerequisite for reimbursement, are achieved (Bishop (GRAIL) Tr. 1417–18, 1421–22); that Illumina will be able to help GRAIL reduce its costs, which will make Galleri more attractive to payors and healthcare organizations (Bishop (GRAIL) Tr. 1417–18); and that [redacted]

1591. *Research and Development Efficiencies.* Mr. Bishop explained that GRAIL has, as a very high priority, reducing the cost of its test and is investing heavily in robotics and other improvements (Bishop (GRAIL) Tr. 1368–69); Illumina has the experience and ability to make GRAIL's technology faster and cheaper to run (Bishop (GRAIL) Tr. 1372); Illumina understands the importance of ongoing investment in R&D (Bishop (GRAIL) Tr. 1416); after the Transaction GRAIL will no longer be at the whims of the market and will be part of a successful, profitable company that understands what it takes to invest and develop innovative science (Bishop (GRAIL) Tr. 1419); Illumina will give GRAIL the predictability needed to engage in ongoing investments in people and technology (Bishop (GRAIL) Tr. 1372–73); the resources needed for R&D will be greatly secured (Bishop (GRAIL) Tr. 1416); and Illumina has the technical capabilities to contribute to GRAIL's performance. (Bishop (GRAIL) Tr. 1415–16.)

1592. *Supply Chain and Operational Efficiencies.* Mr. Bishop testified that Illumina's experience and success in opening labs and producing complicated equipment will help GRAIL scale up (Bishop (GRAIL) Tr. 1372, 1404–05); and that [redacted]

1593. *Expanding International Availability*. Mr. Bishop testified that GRAIL will need to obtain regulatory approvals outside of the United States and that Illumina's commercial experience and relationships around the world will help GRAIL reach those customers faster. (Bishop (GRAIL) Tr. 1368, 1372, 1406–07.)

1594. As Mr. Bishop explained, "Before the Illumina transaction, [international expansion] was something that we had extraordinary limited plans on because we didn't have the team or financial resources to contemplate that outside of one market . . . Illumina has established operations and the relevant teams of experts and laboratories in certain instances in many countries around the world." (Bishop (GRAIL) Tr. 14056.)

1595. Mr. Bishop also testified that Illumina's sales, marketing and distribution infrastructure, which has been very successful at commercializing new technology, will enable GRAIL to commercialize Galleri at a faster scale. (Bishop (GRAIL) Tr. 1420–21, **{1513.)}**

2. **Josh Ofman**

a. Background

1596. Joshua Ofman is the Chief Medical Officer and Head of External Affairs at GRAIL. (Ofman (GRAIL) Tr. 3276.)

1597. Dr. Ofman joined GRAIL in July 2019. (Ofman (GRAIL) Tr. 3276.) As Chief Medical Officer and Head of External Affairs, Dr. Ofman oversees external affairs (including corporate communications and government affairs); clinical development; medical affairs; and the regulatory, quality and clinical compliance aspects of GRAIL. (Ofman (GRAIL) Tr. 3281.)

1598. Prior to joining GRAIL, Dr. Ofman worked at Amgen for about sixteen years in a variety of roles in clinical development, medical affairs and government affairs; for the last eight years of his time at Amgen, Dr. Ofman served as Worldwide Head of Market Access, Global Planning, Global Health Policy and Outcomes Research. (Ofman (GRAIL) Tr. 3276–77.)

1599. Dr. Ofman has authored over one hundred publications, focusing primarily on call technology assessment, which refers to the evaluation of human, clinical and economic harms and benefits associated with the introduction of innovative technology. (Ofman (GRAIL) Tr. 3278.)

1600. Dr. Ofman has a bachelor's degree from UC Berkeley and a medical decree from UC Irvine. He worked as an intern and resident in internal medicine and a fellow in digestive diseases at UCLA. He participated in the Robert Wood Johnson scholars program at the RAND/UCLA program and he received a master's of science in health services from the UCLA School of Public Health. (Ofman (GRAIL) Tr. 3277–78.)

b. Testimony

1601. The Galleri Test. Dr. Ofman testified that Galleri is GRAIL's first validated test. (Ofman (GRAIL) Tr. 3284.)

1602. Dr. Ofman testified regarding the process of the Galleri test: it starts with a simple blood draw from the participant; then plasma (in which circulating DNA resides) is isolated from the blood, amplified, and subjected to bisulfite sequencing, which reveals the patterns of methylation status of the DNA; Galleri looks at over a million of these methylation sites in over a hundred thousand regions of the genome and uses a machine learning algorithm to discriminate what is a cancer signal from what is a noncancer signal; and then, if a cancer signal gets detected, Galleri examines and weights different features from these patterns to predict the tissue of origin or where in the body the cancer signal arose. (Ofman (GRAIL) Tr. 3285–88.)

1603. Dr. Ofman testified that GRAIL has validated the Galleri test through the largest case-control study that's been done for early detection, called the Circulating Cell-free Genome

Atlas (CCGA) study; GRAIL is conducting two very large cohort noninterventional studies, STRIVE and SUMMIT, in women getting mammograms and men and women getting low-dose CT for high-risk lung cancer screening; GRAIL is conducting an interventional study, PATHFINDER, in 6,600 men and women screening eligible with no suspicion of cancer; GRAIL is also conducting the largest, real-world, pragmatic, randomized clinical trial ever done in the field of genomics, in the U.K. in 140,000 screening-eligible individuals. (Ofman (GRAIL) Tr. 3291–300.)

1604. [redacted]

1605. [redacted]

1606. [redacted]

1607. Dr. Ofman testified that GRAIL has locked version 2 of Galleri, which is the version currently available on the market, and is working on an updated version of Galleri that meets current performance standards while sequencing fewer regions of the genome, thereby reducing the cost of the test. (Ofman (GRAIL) Tr. 3301–03.)

1608. Dr. Ofman testified that, although GRAIL's Galleri test runs on NGS sequencers supplied by Illumina, Illumina has had no involvement in GRAIL's development of Galleri at all since Illumina spun out GRAIL; Illumina has had no involvement in any of GRAIL's clinical trials or studies; GRAIL has not been required to share information about Galleri's specifications or its algorithm with Illumina; and GRAIL developed its Galleri test without Illumina. (Ofman (GRAIL) Tr. 3306–07.)

1609. Dr. Ofman testified that Galleri received breakthrough device designation from the FDA in 2018 as well as investigational device exemption (IDE). (Ofman (GRAIL) Tr. 3305–06.)

1610. Other Alleged MCED Tests. Dr. Ofman testified that GRAIL developed the following criteria to evaluate whether a multicancer early detection test will be well-received by regulatory agencies and clinical entities: it needs to find the majority of deadly cancers; it has to have a very low false positive rate and a much higher positive predictive value (PPV) than what is typically seen with single-cancer screening tests; it has to be able to predict the tissue of

origin; it needs to be simple and easy to use; and there should be robust analytical and clinical validation at population scale to support the test's deployment in the population. (Ofman (GRAIL) Tr. 3288–91.)

1611. Dr. Ofman testified that Galleri is not competing with any of the single-cancer liquid biopsy tests in development by companies like Exact Sciences, Guardant Health and Freenome or with liquid biopsy tests that detect two or three cancers; the real value of Galleri is in detecting cancers for which people are not currently being screened. (Ofman (GRAIL) Tr. 3310–13.)

1612. Efficiencies. Dr. Ofman testified to the efficiencies that would arise from the Transaction.

1613. *Acceleration of Market Access to Galleri.* Dr. Ofman testified that Galleri is available in the market as a laboratory-developed test (LDT), but to achieve GRAIL's goal to provide broad access to Galleri to as many adult Americans as possible, GRAIL will not be able to get Medicare reimbursement or large U.S. payor coverage without FDA approval. (Ofman (GRAIL) Tr. 3317–20.)

1614. [redacted]

1615. Dr. Ofman testified that GRAIL is working on its PMA application submission to the FDA (Ofman (GRAIL) Tr. 3324); [redacted]

1616. Dr. Ofman testified that he is confident that Illumina will help GRAIL accelerate its FDA approval process (Ofman (GRAIL) Tr. 3455–56); [redacted]

[redacted]

1616.1 [redacted]

1617. *Acceleration of Galleri's International Availability.* Dr. Ofman testified that partnering with Illumina would enable GRAIL's mission and vision to be accelerated by getting to scale quickly and getting GRAIL's breakthrough technology into the hands of doctors and their patients on a global scale as soon as possible (Ofman (GRAIL) Tr. 3283); and that GRAIL will not be able to make its test accessible to as many patients as it wants to reach without Illumina, because GRAIL's ability to achieve its aspiration will not only be accelerated, but also fortified, by being part of a company with the magnitude and the capabilities of Illumina. (Ofman (GRAIL) Tr. 3307–08, 3320.)

1618. Dr. Ofman testified that, but for the lawsuit, Illumina and GRAIL would have begun to explore integration in affairs, quality management system (QMS), compliance, clinical development and medical affairs areas. (Ofman (GRAIL) Tr. 3457–58.)

3. Aaron Friedin

a. Background

1619. Aaron Freidin is the Senior Vice President of Finance at GRAIL. (Freidin (GRAIL) Tr. 2964.)

1620. Mr. Freidin assumed the role of Senior Vice President of Finance in January 2021. (Friedin (GRAIL) Tr. 2964.) As Senior Vice President of Finance, Freidin oversees accounting organization, financial planning and analysis. (Freidin (GRAIL) Tr. 2967.) He also oversees investor relations, corporate development, strategy, procurement, facilities and IT. (Freidin (GRAIL) Tr. 2967.) His primary responsibility is to roll up GRAIL's forecast for the year, develop the budget, assess headcount needs, put together GRAIL's long-range plan and understand and guide GRAIL's high-level strategy. (Freidin (GRAIL) Tr. 2967.)

1621. Friedin has also held the positions of Vice President of Finance, Senior Director of Finance and Director of Finance at GRAIL. (Freidin (GRAIL) Tr. 2964.)

1622. Prior to joining GRAIL, Freidin spent about two to three years at Counsyl, an NGS lab in South San Francisco; spent a couple of years at Cepheid, a molecular diagnostic public company; and spent the first ten years of his career at PricewaterhouseCoopers in San Jose as a senior manager in the audit practice, specifically in the semiconductor and life science area. (Freidin (GRAIL) Tr. 2965–66.)

b. Testimony

1623. The Galleri Test. Mr. Freidin testified that GRAIL launched Galleri in the U.S. in early June 2021; it is not commercially available outside the U.S.; and, as of the date of his testimony, Galleri had sold around 3,000 tests, which constitutes less than a tenth or a hundredth of a percent of the total addressable market of 108 million. (Freidin (GRAIL) Tr. 2968–69.)

1624. Alleged Foreclosure. Mr. Freidin testified to facts that show that Illumina will continue to have an incentive to support other test developers. Specifically, Mr. Freidin testified that GRAIL expects to penetrate only about 13 to 16 percent of the market in the next ten years because GRAIL expects there to be multiple winners in the market. (Freidin (GRAIL) Tr. 2970.)

1625. [redacted]

1626. The Transaction. As Vice President of Finance, Mr. Freidin was one of the four people at GRAIL who was deeply involved in negotiations over the transaction; he focused primarily on the financial implications of the transaction. (Freidin (GRAIL) Tr. 2972.)

1627. Mr. Freidin testified that, from a financial perspective, he concluded that GRAIL should be acquired by Illumina because it would accelerate the saving of lives, accelerate funding for GRAIL, be a great return for shareholders, derisk GRAIL's business and eliminate the royalty in GRAIL's supply agreement with Illumina. (Freidin (GRAIL) Tr. 2972–73.)

1628. Mr. Freidin testified that the best way to accomplish the goal of accelerating broad-scale adoption of Galleri is the acquisition of GRAIL because Illumina has greater expertise than GRAIL. (Freidin (GRAIL) Tr. 2971.)

1629. Efficiencies. Mr. Freidin testified that the reunion of Illumina and GRAIL would lead to at least seven benefits which led him to recommend acceptance of the Transaction: elimination of the royalty (Freidin (GRAIL) Tr. 2974); accelerating FDA, Medicare and public payor approval; accelerating private payor partnerships; securing long-term funding; accelerating commercialization at scale (Freidin (GRAIL) Tr. 3000–01); increased laboratory operation capabilities and automation and accelerating international expansion. (Freidin (GRAIL) Tr. 2974.) He also testified that the Transaction would save lives. (Freidin (GRAIL) Tr. 2999.)

1629.1 As Freidin explained: "We knew that we would have to go out and to raise a significant amount of capital and more than -- and more than once over the, you know, next five or six years, and so by Illumina acquiring us, you know, we don't have to worry about that anymore. Illumina is a, you know, multibillion-dollar, profitable business that generates cash flows. And if they ever ran out of cash flows or we needed to

spend more, they have successfully raised debt and done other offerings, so it -- in my view, it derisked our capital needs and accelerated our ability to put capital to work immediately and was another positive benefit of the acquisition." (Freidin (GRAIL) Tr. 3000.)

1630. *Acceleration of Market Access to Galleri.* Mr. Freidin testified that a large inflection point to creating value and saving lives is broad reimbursement; he identified two ways in which the Transaction would accelerate market access: accelerating FDA, Medicare and public payor approval and accelerating private payor approval. (Freidin (GRAIL) Tr. 2979–82, 2987.)

1631. *Accelerating FDA, Medicare and Public Payor Approval.* Mr. Freidin testified that the population Galleri is addressing is between 50 and 80; that a large portion of that population is on public government pay; and that FDA, CMS and Medicare approval are the path to allow those individuals to afford the test. (Freidin Tr. 2979–81.) Mr. Freidin also testified that, in order to obtain Medicare approval, Galleri would need to be approved by CMS; CMS approval requires both FDA approval and showing that the cost-benefit analysis weighs in favor of paying for the test. (Freidin (GRAIL) Tr. 2981–82.)

1632. Mr. Freidin testified that Illumina has demonstrated the ability to get tests approved by the FDA in the past; that Mr. deSouza provided details to GRAIL regarding Illumina's FDA capabilities, the team, the employees and their successes; that Mr. Friedin had also identified four examples in which Illumina had had success with the FDA: FDA-regulated NGS machines, FDA-cleared cystic fibrosis NGS test, FDA emergency use authorization for an NGS COVID-19 test and an NGS cancer therapy selection test; and that these examples substantiated what Mr. deSouza shared with GRAIL. (Freidin (GRAIL) Tr. 2984–85.)

1633. Mr. Freidin explained that GRAIL has comparably fewer resources, a smaller regulatory team and no FDA-approved tests. (Freidin (GRAIL) Tr. 2985–86.)

1634. Mr. Freidin explained that the Transaction would accelerate and increase the chances of FDA approval from what GRAIL's internal capabilities and history with the FDA are. (Freidin (GRAIL) Tr. 2980, 2986.)

1635. *Accelerating Private Payor Partnerships.* Mr. Freidin explained that millions of lives targeted by Galleri are covered by commercial or private insurance (Freidin (GRAIL) Tr. 2987); that 68% of individuals between 18 and 64 are covered by private and commercial insurance (Freidin (GRAIL) Tr. 2988); that no public or private payors currently reimburse for Galleri (Freidin (GRAIL) Tr. 2992); that FDA approval alone will not guarantee private coverage (Freidin (GRAIL) Tr. 2993); that recommendations of the USPSTF, commercial payors and other guideline bodies will be required to achieve broad private payor reimbursement (Freidin (GRAIL) Tr. 2993-94); and that the large addressable market means that private payors will require significant evidence before providing for reimbursement. (Freidin (GRAIL) Tr. 2996–97.)

1636. Mr. Freidin explained that GRAIL has no experience obtaining private insurer reimbursement, has a small team and lacks resources to pursue private payor reimbursement. (Freidin (GRAIL) Tr. 2997–98.)

1637. Mr. Freidin also testified that Illumina has capabilities and expertise as well as successful partnerships with government agencies and private payors, including Harvard Pilgrim, Blue Cross Blue Shield and the State of Michigan. (Freidin (GRAIL) Tr. 2999.)

1638. Mr. Freidin testified that Illumina is likely to derisk and accelerate GRAIL's private payor acceptance and reimbursement, which will save more lives. (Freidin (GRAIL) Tr. 2999.)

1639. *Securing Long-Term Funding.* Mr. Freidin testified that as part of GRAIL's long-range plan, the company estimated the amount of capital they would need to be self-sufficient and fund themselves; the company estimated it would need several large raises over the next five or six years; and that Illumina's acquisition removed that concern because Illumina is a multibillion-dollar, profitable business that generates cash flows and can raise money through debt and other offerings. (Freidin (GRAIL) Tr. 3000.)

1640. *Elimination of the Royalty.* [redacted]

1641. [redacted]

1642. *Supply Chain and Operational Efficiencies/Acceleration Commercialization at Scale.* Mr. Freidin testified that GRAIL is an R&D company with limited commercial sales experience and capabilities (Freidin (GRAIL) Tr. 3000–02); that [redacted]

1643. Mr. Freidin testified that Illumina is a multibillion-dollar, international company that sells products in various sections and has demonstrated capabilities and skill sets that GRAIL needs to build; that Illumina has a large software engineering function that has built similar systems to what GRAIL needs; and that Illumina has the ability to execute with vendors and customers. (Freidin (GRAIL) Tr. 3000–04, [redacted]

1644. Mr. Freidin testified that, in order to commercialize Galleri, GRAIL will need commercial sales experience and laboratory operations and automation, which includes high capacity manufacturing, software and customer management and quality control systems. (Freidin (GRAIL) Tr. 3002–04.)

1645. Mr. Freidin explained that, with regard to commercial sales experience, GRAIL only has three to four months of experience, whereas Illumina is a successful multibillion-dollar, international company with multiple products. (Freidin (GRAIL) Tr. 3004.) Mr. Freidin testified that Illumina will enable GRAIL to commercialize much faster than it would on its own. (Freidin (GRAIL) Tr. 3004.)

1646. Mr. Freidin testified that GRAIL is focusing on a centralized lab process due to the complexity of Galleri and because it is the fastest way to process millions of tests (Freidin (GRAIL) Tr. 3006–07); that automation and lab processes are key to getting costs down and keeping quality high (Freidin (GRAIL) Tr. 3005–06); that this will bring the cost of Galleri down (Freidin (GRAIL) Tr. 3006); that [redacted] (Freidin (GRAIL) Tr. [redacted]

1647. Mr. Freidin explained that, in Illumina's work with the Verinata NIPT and other tests, Illumina has run labs, processed lots of tests and demonstrated that they have capabilities that can accelerate Galleri. (Freidin (GRAIL) Tr. 3007–08.)

1648. *Expanding International Availability*. Mr. Freidin testified that GRAIL has been focused on the U.S. domestic market; that other than a study in the U.K. with the NHS, GRAIL's long-range plan ignores anything international; and that GRAIL does not have any international operations aside from 10–20 people in the U.K. to facilitate the NHS study. (Freidin (GRAIL) Tr. 3008.) [redacted]

1649. Mr. Freidin testified that Illumina is a multinational billion-dollar company with multiple products and locations over the globe; that 50 percent of Illumina's revenues are international; and that Illumina's 10–K confirms its international reach. (Freidin (GRAIL) Tr. 3008–11.)

1650. Mr. Freidin testified that Illumina could accelerate Galleri internationally and that international acceleration can save lives around the world. (Freidin (GRAIL) Tr. 3008–10.)

1651. Mr. Freidin testified that: in considering whether to proceed with the Transaction or the capital markets, GRAIL considered the above efficiencies and whether they could be achieved through an IPO or other capital markets raises; GRAIL concluded that, even if it were to successfully raise more money, this would not come with the expertise and infrastructure Illumina has; GRAIL determined that capital market raises have the potential for significant delay; additional private capital raises were not an alternative because of the potential for delay; an IPO was not an alternative because it would not provide the benefits of the Transaction, including the elimination of the royalty, acceleration of FDA, Medicare and public payor approvals, securing long term funding, accelerating commercialization, lab operations and international expansion; and an IPO was unlikely to equal the $2 billion that GRAIL needed to get to break even. (Freidin (GRAIL) Tr. 3011–22.)

1652. Mr. Freidin also testified that there was no guarantee that an IPO would have been successful; that, if a company doesn't execute and deliver after going public, their valuation decreases and shares are diluted, which makes it more difficult to raise funds going forward; that investors raised concerns regarding broad adoption and FDA approval, which would have hampered investment; that investors raised concerns that GRAIL had already raised a lot of money for a company without revenues; and that, based on meetings with investors, it appeared that an IPO was not certain. (Freidin (GRAIL) Tr. 3024–26.)

1653. [redacted]

1654. Mr. Freidin testified that GRAIL considered hiring outside consultants to achieve the above benefits; that consultants in general can provide high-level strategic roadmaps, but they don't stick around to watch the company grow and scale; that GRAIL needed help in operations and expertise in how to execute; that, in Mr. Freidin's experience, employees provide higher-quality product than consultants; that consultants can be more expensive overall because they do not stick around; and that consultants are not full-time, loyal employees. (Freidin (GRAIL) Tr. 3032–36.)

1655. [redacted]

1656. [redacted]

1657. Mr. Freidin testified that the lawsuit by Complaint Counsel caused all integration to cease. (Freidin (GRAIL) Tr. 3168.)

1658. Mr. Freidin testified that GRAIL did not believe it was necessary to formally model the acceleration benefits of the acquisition because "they were just obvious to us. You know, a royalty goes away, access increases, price can come down. You know, Illumina is a multinational, billion dollar, multiproduct company. They have got international operations. They have got commercial experience. Also, they have got FDA success, again, things that GRAIL does not have. So it was just obvious." (Freidin (GRAIL) Tr. 3167–68.) Further, when asked if he had modeled any dissynergies, he responded, "No. I can't think of any or couldn't think of any." (Freidin (GRAIL) Tr. 3168.)

4. Arash Jamshidi

a. Background

1659. Dr. Arash Jamshidi is the Senior Vice President of Data Sciences at GRAIL. He began his role near the end of 2020. Jamshidi also joined the executive leadership team about a year and a half ago. (Jamshidi (GRAIL) Tr. 4013–4014.)

1660. As Senior Vice President of Data Science, Dr. Jamshidi manages a team of about 90 individuals, that analyze GRAIL's data developed through clinical studies and develop machine-learning and classification algorithms from the data. His primary responsibility is managing groups around bioinformatics, data sciences, clinical data management and biostatistics. (Jamshidi (GRAIL) Tr. 4017.)

1661. Dr. Jamshidi has a master's and Ph.D. from UC Berkeley, where he also completed some post-doctoral work between 2005 and 2011. He completed his undergraduate studies at Simon Fraser University in Canada and did some university work at Sharif University in Iran. (Jamshidi (GRAIL) Tr. 4014.)

1662. Prior to joining GRAIL, Dr. Jamshidi spent about five years at Illumina in multiple positions, including Senior Staff Scientist, Staff Scientist and different scientific roles. His most recent position at Illumina was Associate Director of Research. (Jamshidi (GRAIL) Tr. 4015.)

1663. Before becoming Senior Vice President of Data Sciences, Dr. Jamshidi was the President of Bioinformatics and Data Sciences at GRAIL and was part of the founding group of GRAIL. (Jamshidi (GRAIL) Tr. 4015–4016.)

b. Testimony

1664. The Galleri Test. Dr. Jamshidi testified that Galleri is a multicancer early detection test which aims to be able to detect cancer early in an asymptomatic population that's generally at elevated risk, with a focus on adults ages 50 and above; and that the key performance attributes for Galleri include sensitivity, specificity, accuracy of calling the cancer signal origin, and positive predictive value. (Jamshidi (GRAIL) Tr. 4021–22.)

1665. [redacted]

1666. [redacted]

1667. [redacted]

1668. Efficiencies. [redacted]

1669. [redacted]

5. **Christopher Della Porta**

a. Background

1670. Christopher Della Porta is Director of Growth Strategy at GRAIL. (Della Porta (GRAIL) Tr. 453–454.) The Growth Strategy group was founded by Della Porta and functions primarily to develop new channels for the sale of Galleri by evaluating and approaching potential customers. (Della Porta (GRAIL) Tr. 455.) Della Porta has served as Director of Growth Strategy since September of 2020. (Della Porta (GRAIL) Tr. 454.)

1671. Prior to September of 2020, Della Porta served as Associate Director of Product Marketing, Senior Manager of Product Marketing and Product Marketing Manager. (Della Porta (GRAIL) Tr. 454.)

b. Testimony

1672. [redacted]

1673. GRAIL's Alleged Competitors. [redacted]

1674. [redacted]

1675. [redacted]

1676. [redacted]

1677. *Exact/Thrive*. [redacted]

1678. *Natera*. [redacted]

1679. *Guardant*. [redacted]

[redacted]

1680. *Freenome*. [redacted]

1681. *Singlera*. [redacted]

1682. *FMI*. [redacted]

1683. *Helio Health*. [redacted]

1684. Efficiencies. Mr. Della Porta testified that Illumina's acquisition of GRAIL will result in the acceleration of Galleri.

1685. *Acceleration of Galleri.* Mr. Della Porta testified that Galleri has been having challenges making sales; Illumina's previous experience launching products in NIPT and its additional resourcing across functions, including regulatory, market access and sales, would accelerate the adoption of Galleri; and Illumina could help increase Galleri's sales in the health system, employer and physician channels through its relationships, footprint, reputation and resources. [redacted], 588.)

1686. Mr. Della Porta testified that simply hiring employees from Illumina would not be sufficient to accelerate adoption by health systems and employers because the name, brand and scale of Illumina, combined with its significant talent pool, cannot be easily hired. (Della Porta (GRAIL) Tr. 588.)

1687. *Acceleration of DAC.* [redacted]

1688. *Acceleration of International Expansion.* [redacted]

C. Third Parties

1. Kevin Conroy (Exact)

a. Background

1689. Kevin Conroy is the Chairman and CEO of Exact Sciences. (Conroy (Exact/Thrive) Tr. 1526.)

1690. As Chairman, Mr. Conroy is responsible for setting the agenda for the board of directors. (Conroy (Exact/Thrive) Tr. 1527.)

1691. As CEO, he is responsible for the general operations of the company including the merger and acquisition strategy, strategic planning and commercialization planning. (Conroy (Exact/Thrive) Tr. 1527–29.)

b. Testimony

1692. Alleged relevant market. [redacted] the company may need to explore a number of different biomarker combinations and alternative candidate products and platform technologies accordingly, or repeat clinical studies before identifying a potentially successful candidate (Conroy (Exact/Thrive) Tr. 1717).

1693. [redacted]

1694. Mr. Conroy admitted that CancerSEEK is subject to considerable risk, as the long-term success of the various early cancer screening tests in development is going to depend significantly on a whole host of scientific and regulatory variables. (Conroy (Exact/Thrive) Tr. 1709, 1711.)

1695. Mr. Conroy admitted that candidate products that may initially show promise may fail to achieve the desired results in large clinical trials, they may not achieve acceptable levels of accuracy, and results from early studies or trials are not necessarily predictive of future clinical trial results. (Conroy (Exact/Thrive) Tr. 1712.) He admitted that if in a clinical study a candidate product fails to identify even a small number of cancer cases, the sensitivity rate may be materially and adversely affected. (Conroy (Exact/Thrive) Tr. 1716–17.)

1696. [redacted]

1697. [redacted] and healthcare providers may be reluctant to prescribe and patients may be reluctant to complete Exact's tests if they're not confident that patients will be reimbursed for those tests (Conroy (Exact/Thrive) Tr. 1719).

1698. Mr. Conroy admitted that product development is expensive and may take years to complete and can have uncertain outcomes, and failure can occur at any stage of development (Conroy (Exact/Thrive) Tr. 1717–18): if, after development, a candidate product appears successful, Exact may need to obtain FDA and other regulatory clearances or approvals before it can market the product, which are likely to involve significant time as well as additional research and development and clinical study expenditures (Conroy (Exact/Thrive) Tr. 1718); there can be no guarantee that the FDA would clear or approve any future product or service that Exact/Thrive may develop (Conroy (Exact/Thrive) Tr. 1718); and the commercial success of a product is going to depend upon a variety of factors, like acceptance in the medical community, patient acceptance and demand, and coverage and reimbursement by third-party payers (Conroy (Exact/Thrive) Tr. 1718–19).

1699. Mr. Conroy admitted that Exact/Thrive's CancerSEEK is not a substitute for, but is highly differentiated from, GRAIL's Galleri test, as the Galleri test is the only multicancer screening test based on DNA on the market (Conroy (Exact/Thrive) Tr. 1709); Exact/Thrive does not have evidence that CancerSEEK's detection technology will ultimately be able to detect the same amount of cancers as GRAIL's test (Conroy (Exact/Thrive) Tr. 1651); the Cohen study for the CancerSEEK test only focused on eight cancer types (Conroy (Exact/Thrive) Tr. 1699); and in the DETECT-A study, the CancerSEEK blood test identified only ten cancer types and failed to detect six cancers (Conroy (Exact/Thrive) Tr. 1706–07).

1700. [redacted]; and that the Cohen study found the PET-CT approach is not well suited to be a primary screening modality for the general population also because it is financially and operationally impractical (Conroy (Exact/Thrive) Tr. 1707–08).

1701. Mr. Conroy admitted that each one of the cancer screening tests in development could be different from one another based on types of cancer they detect, the technologies they use, their sensitivities and specificities, their different uses and their payer coverage. (Conroy (Exact/Thrive) Tr. 1709–10.)

1702. Mr. Conroy could not say with any certainty which of the tests in development will actually come to market and be commercially successful. (Conroy (Exact/Thrive) Tr. 1710.)

1703. Alleged foreclosure. [redacted]

1704. [redacted]

1705. [redacted]

1706. [redacted]

1707. [redacted]

1708. [redacted]

Exact/Thrive does not have any rights to the GRAIL IP or an IP license of any kind from GRAIL and has never had any expectation that it would be given access to GRAIL's IP as a mechanism to develop the CancerSEEK test (Conroy (Exact/Thrive) Tr. 1730); Exact/Thrive does not have any confidential information about Illumina's proprietary products or reagents (Conroy (Exact/Thrive) Tr. 1730); and Exact/Thrive does not currently share any pricing plans with, has never tried to purchase data from Illumina, and has no plans to purchase any data from Illumina in the future (Conroy (Exact/Thrive) Tr. 1733–34).

1709. Open Offer. [redacted] has not read Illumina's full open offer, and does not know the details of the open offer (Conroy (Exact/Thrive) Tr. 1725–26).

1710. Mr. Conroy admitted that when the Illumina/GRAIL transaction was announced, it was Exact's expectation that Exact could reach a long-term supply agreement that would be in the mutual best interests of both Illumina and Exact. (Conroy (Exact/Thrive) Tr. 1723–24.)

1711. Mr. Conroy admitted that through the Open Offer, Illumina has committed to lower the volume-based net price per gigabase of sequencing 43 percent by 2025. (Conroy (Exact/Thrive) Tr. 1732.)

1712. Mr. Conroy admitted that Exact relies on contracts to run its business, despite the fact that no contract is perfect and no contract can address all potential issues that might eventualize over a long term. (Conroy (Exact/Thrive) Tr. 1723.)

1713. Efficiencies. Complaint Counsel contends the Transaction will not generate efficiencies (Conroy (Exact/Thrive) Tr. 1683), but Mr. Conroy admitted that the widespread adoption of an MCED test will save lives and that the acceleration of any cancer screening test will save lives (Conroy (Exact/Thrive) Tr. 1737, 1739-40.)

1714. Mr. Conroy admitted that developing your cancer screening test requires a Herculean effort: from a practical perspective, getting paid under Medicare without FDA approval would be impossible, getting paid by commercial payers without FDA approval would be improbable and it would be very challenging for an MCED test to become viable long-term if it were ineligible for Medicare reimbursement, which is going to depend on a lot of factors, including the sufficiency of the sensitivity and specificity of the test and on whether the test is reliable, safe, effective, and medically necessary. (Conroy (Exact/Thrive) Tr. 1734–35.)

1715. [redacted]

[redacted]

1716. Bias. [redacted]

1717. [redacted]

1718. [redacted]

2. **Christopher Lengauer (Exact/Thrive/Third Rock)**

a. Background

1719. Dr. Lengauer was a cofounder and Chief Innovation Officer of Thrive, and is currently a consultant to Exact Sciences, overseeing strategy at Thrive and a part of Thrive's management leadership team involved in the progression of the CancerSEEK test. (Lengauer (Exact/Thrive) Tr. 156–57.)

b. Testimony

1720. Alleged Relevant Market. [redacted]

1721. [redacted]

1722. [redacted]

1723. Dr. Lengauer admitted that the DETECT-A prospective, interventional trial showed critical flaws with CancerSEEK test: CancerSEEK Alpha protocol as it was studied in the DETECT-A trial included two blood tests and also a PET-CT scan; the first step of the DETECT-A protocol was a baseline blood test that analyzed variant and protein biomarkers; the second step was a confirmation blood test to rule out an abnormal biomarker reading due to CHIP; only if both the baseline and the confirmatory blood tests were positive, then the overall blood test was considered positive; the participants with two positive blood tests were then reviewed by a multidisciplinary review committee which recommended whether a full body PET-CT scan would be performed in order to detect the origin of the cancer; and the diagnostic PET-CT scan was required to confirm the results of the blood testing and to localize the potential cancer. (Lengauer (Exact/Thrive) Tr. 246–48, 260.)

1724. Dr. Lengauer admitted that a diagnostic full-body PET-CT confers a higher radiation exposure than a standard CT; the radiation exposure from diagnostic PET-CT and follow-up imaging tests in the participants without cancer is a recognized source of potential harm associated with the DETECT-A CancerSEEK protocol (Lengauer (Exact/Thrive) Tr. 248–50); 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 (Lengauer (Exact/Thrive) Tr. 249-50).

1725. Dr. Lengauer admitted that in the DETECT-A trial, CancerSEEK showed the ability to detect cancers only in ten primary organs: appendix, breast, colorectal, kidney, lung, lymphoma, ovary, thyroid, and uterine cancers, and carcinoma of unknown primary. (Lengauer (Exact/Thrive) Tr. 243, 260–61.)

1726. Dr. Lengauer also admitted that the CancerSEEK blood test has a high false-positive rate: of the about 9,900 participants actually were tested with the baseline blood test in the DETECT-A trial, 490 participants had a positive baseline test; of the 490 participants who had a positive baseline test in the DETECT-A trial, only 134 participants had two positive blood tests and no CHIP; of the 134 participants who had two positive blood tests and no CHIP, 116

had a full-body PET-CT scan and 11 of them had other imaging; of the 127 participants who had imaging, 15 participants who had the PET-CT scan were found to have cancer and all of the 11 by other imaging have cancer; of the 490 participants who had a positive baseline test in the DETECT-A trial, only 26 cancers were actually detected. (Lengauer (Exact/Thrive) Tr. 251–53, 256.)

1727. [redacted] 257–59; 262.)

1728. Dr. Lengauer admitted that the elements and features of the CancerSEEK test have been continuously in flux since it was studied in DETECT-A, and Exact/Thrive is in the process of adding additional biomarkers, including aneuploidy. (Lengauer (Exact/Thrive) Tr. 212, 218.)

1729. [redacted]

1730. [redacted]

1730.1 [redacted] 244–45, 262–63.)

1731. [redacted]

1732. [redacted]

[redacted]

1733. [redacted]

1734. Alleged Foreclosure. [redacted]

1734.1 [redacted]

1734.2 [redacted]

1734.3 [redacted]

1735. [redacted]

[redacted]

1736. [redacted]

1737. [redacted]

1738. [redacted]

1739. [redacted]

1740. [redacted]

1741. [redacted]

[redacted]

1742. [redacted]

1743. [redacted]

1744. Bias. Complaint Counsel presented Dr. Lengauer as an unbiased witness, but Dr. Lengauer admitted that he met with the FTC four times without any representatives of Illumina or GRAIL before providing his testimony. (Lengauer (Exact/Thrive) Tr. 263–64.)

3. Konstantin Fiedler (FMI)

a. Background

1745. Dr. Konstantin Fiedler is the Chief Operating Officer of Foundation Medicine (FMI), a wholly owned subsidiary of Roche that specializes in diagnostic testing. (Fiedler (FMI) Tr. 4463–66.)

1746. As Chief Operating Officer, Dr. Fiedler oversees all aspects of operation, from sample arrival at FMI facilities through results reporting. (Fiedler (FMI) Tr. 4464–65.) Dr. Fiedler reports to FMI's CEO. (Fiedler (FMI) Tr. 4465.)

b. Testimony

1747. Alleged relevant market. [redacted]

1748. Dr. Fiedler also testified that the only multicancer screening test on the market is Galleri and that he does not know how the cancer screening market may look or evolve in 12 years. (Fiedler (FMI) Tr. 4468–69.)

1749. Alleged foreclosure. Complaint Counsel contends the reunion of Illumina and GRAIL will change Illumina's incentives toward its customers, but Dr. Fiedler testified that FMI, which competes with Illumina's TSO500 product, has never had any concerns in its relationship with Illumina. (Fiedler (FMI) Tr. 4469–70.) Specifically, Dr. Fiedler testified that: FMI has been a customer of Illumina since FMI was started; FMI's first supply agreement with Illumina was signed in 2013; since 2019, FMI has purchased well over a hundred million, probably 140 million, in NGS products from Illumina; and during the time that FMI has been an Illumina customer FMI has had no issues or problems with Illumina servicing the Illumina instruments that FMI uses. (Fiedler (FMI) Tr. 4470.) Dr. Fiedler has never known Illumina to delay providing services or replacement parts to FMI; Illumina has acted in good faith with respect to its obligations under the 2013 supply agreement; Illumina has never "monkeyed with supply"; Illumina has never interrupted supply to FMI because it claimed FMI had infringed on Illumina's intellectual property; Illumina has never reneged on a commitment it made to FMI; FMI is a satisfied customer and FMI trusts Illumina to abide by its commitments. (Fiedler (FMI) Tr. 4471–72.)

1750. Complaint Counsel argues that one way Illumina may disadvantage other test developers is to raise the cost of sequencing but Dr. Fiedler testified that since 2018, the costs of sequencing have gone down due to upgrades on the platform that Illumina provided to FMI with higher throughput, and he assumes the cost of sequencing will also go down in the future. (Fiedler (FMI) Tr. 4469.)

1751. [redacted]

1752. The Transaction. [redacted]

1753. [redacted]

1754. Fiedler Declaration. [redacted]

1755. The declaration states, among other things, that: "On March 4, 2021, FMI entered into an amended and restated supply agreement with Illumina incorporating these commitments. This agreement contains the following terms: Access to similar overall commercial terms. including pricing, to purchase Illumina's NGS products as those offered to similarly situated customers, including GRAIL. Access to a 12–year supply agreement with Illumina, including assurances that there shall be no interruption in supply of NGS products because of any claim for IP infringement. Access to pre-release sequencing products from Illumina at substantially the same time as GRAIL and other for-profit sequencing companies have access. Establishment of a firewall to prevent GRAIL and any of its employees from accessing any confidential information FMI is required, or elects, to share with Illumina after the acquisition of GRAIL. With these expanded protections under the amended and restated supply agreement, FMI believes it will continue to have access to the Illumina technology that is critical to FMI's tests over the term of the agreement. On that basis, FMI believes the concerns previously expressed to the FTC in connection with its investigation of Illumina's proposed acquisition of GRAIL have been adequately addressed."

1756. Open Offer / Amendment to the Illumina/FMI Supply Agreement. [redacted]

1757. [redacted]

1758. *Pricing Terms.* [redacted]

1759. [redacted]

1760. [redacted]

1761. Dr. Fiedler testified that he trusted Illumina that FMI would receive the same pricing as GRAIL under the supply agreement. (Fiedler (FMI) Tr. 4484.)

1762. *Supply Provisions.* [redacted]

1763. *Access to Pre-release Sequencing Products.* [redacted]

1764. [redacted]

1765. *Confidentiality/Firewall*. [redacted]

1766. [redacted]

1767. Efficiencies. Complaint Counsel contends the Transaction will not generate efficiencies, but Dr. Fiedler testified that it was beneficial to FMI to be acquired by Roche because it provided solid financial backing, allowed FMI to think more strategically and more long term, and FMI did not have to fulfill quarterly shareholder expectations. (Fiedler (FMI) Tr. 4472). Dr. Fiedler testified that he speculates that Illumina will help GRAIL makes its tests more widely available. (Fiedler (FMI) Tr. 4473.)

1768. Dr. Fiedler also testified that there are benefits to catching cancer early before it moves beyond stage one—where it is restricted to one organ—including that the patient can be treated very differently and the organ or parts of it can be removed; catching cancer early saves lives; multicancer screening tests can help catch cancer early; and the acceleration of a multicancer screening test on the market will save lives. (Fiedler (FMI) Tr. 4474.)

4. Michael Nolan (Freenome)

a. Background

1769. Mr. Nolan is the CEO of Freenome. (Nolan (Freenome) Tr. 2695.) He has held this position since the end of April 2021. (Nolan (Freenome) Tr. 2695.) Prior to becoming CEO, he served as the company's Chief Business Officer and Chief Commercial Officer. (Nolan (Freenome) Tr. 2695.)

b. Testimony

1770. Alleged Relevant Market. [redacted]

1771. [redacted]

1772. [redacted]

1773. [redacted]

1774. [redacted]

1775. [redacted]

1776. [redacted]

1777. [redacted]

1778. [redacted]

1779. Alleged Foreclosure. [redacted]

1780. [redacted]

1781. [redacted]

[redacted]

1782. [redacted]

1783. [redacted]

1784. Open Offer. [redacted]

1785. [redacted]

1786. [redacted]

1787. [redacted]

[redacted]

1788. [redacted]

1789. [redacted]

1790. [redacted]

5. **Darya Chudova (Guardant)**

a. Background

1791. Dr. Chudova is a senior vice president of technology at Guardant Health. (Chudova (Guardant) Tr. 1135–36.)

1792. In this role Dr. Chudova oversees technology development projects that contribute to Guardant's clinical diagnostic assays, with a focus on screening applications. (Chudova (Guardant) Tr. 1137.)

b. Testimony

1793. Alleged Relevant Market. [redacted]

[redacted]

1794. [redacted]

1795. [redacted]

1796. [redacted]

1797. [redacted]

1798. [redacted]

1799. [redacted]

[redacted]

1800. [redacted]

1801. [redacted]

1802. [redacted]

1803. [redacted]

1804. [redacted]

1805. Alleged foreclosure. [redacted]

1806. [redacted]

1807. [redacted]

1807.1 [redacted]

1808. [redacted]

1809. [redacted]

1810. [redacted]

1811. [redacted]

1812. [redacted]

1813. Bias. [redacted]

[redacted]

6. **William Getty (Guardant)**

a. Background

1814. Mr. Getty is the Senior Vice President of Commercial for Guardant Health's Screening Division. (Getty (Guardant) Tr. 2482.)

1815. In this position, Mr. Getty's responsibilities include to lead the commercialization of Guardant's screening product in development, the LUNAR-2, which encompasses sales, marketing, medical affairs, commercial development and all manners of activities that will support its commercialization. (Getty (Guardant), Tr. 2483.)

b. Testimony

1816. Alleged relevant market. [redacted]

1817. [redacted]

1818. [redacted]

1819. [redacted]

1820. Mr. Getty admitted that Guardant's ability to achieve commercial success with its tests depends on a number of factors including the timing and scope of intended use of FDA approval, the timing and scope of coverage by all payers including commercial insurance payers and Medicare; Guardant has not achieved FDA approval for the LUNAR-2 test and the IDE or investigational device exemption Guardant received would not allow Guardant to go to market with a new medical diagnostic; and FDA approval for LUNAR-2 is not guaranteed: FDA review of PMA applications can be extensive, uncertain and lengthy; generally takes between one and three years but may take significantly longer; and many devices are not approved. (Getty (Guardant) Tr. 2646–50, 2661.)

1821. Mr. Getty admitted that Guardant does not have payer coverage either with Medicare or with private insurers for LUNAR-2 yet, even though Guardant's revenue depends on achieving broad insurance coverage, including private insurance as well as Medicare, for its tests; it is not guaranteed that insurance coverage will in fact be available for LUNAR-2; and it is very difficult at this point in time to say which of the potential early cancer detection tests out there will achieve broad coverage by payers. (Getty (Guardant) Tr. 2661–62.)

1822. Mr. Getty admitted that Guardant cannot assure that it will continue to compete effectively: Guardant's product development process involves a high degree of risk; commercialization of LUNAR-2 is not guaranteed; LUNAR-2 may not perform as expected; the data that Guardant is seeking to develop now to validate LUNAR-2 may not validate it as hoped for; Guardant may not be able to produce the evidence that it needs to ensure that it gets private payer and Medicare coverage for LUNAR-2; and even if LUNAR-2 performs as Guardant hopes it will, it may not achieve market acceptance. (Getty (Guardant) Tr. 2664–65.)

1823. Alleged foreclosure. Complaint Counsel contends that Illumina is the only viable NGS platform for MCED test developers, including Guardant, but Mr. Getty admitted that Thermo Fisher Scientific Inc., and other companies developing next-generation sequencing platforms also provide NGS platforms that could be used for liquid biopsy testing. (Getty (Guardant) Tr. 2642.)

1824. Complaint Counsel contends that Illumina is essential to the development and commercialization of MCED tests, but Mr. Getty admitted that LUNAR-2 assay is proprietary to Guardant and Illumina did not help Guardant develop the LUNAR-2 assay, did not contribute to the scientific effort Guardant undertook in connection with the LUNAR-2 assay, and did not brainstorm with Guardant on how it could improve the LUNAR-2 assay; Illumina has not been involved in any FDA review or consideration of the LUNAR-2 assay; and Guardant will be the sponsor of a PMA application for the LUNAR-2 assay as a sole-source laboratory. (Getty (Guardant) Tr. 2645–46.)

1825. [redacted]

1826. Mr. Getty also admitted that it is difficult to predict whether clinicians will choose to order LUNAR-2 or Galleri; the patient's out-of-pocket cost will be a factor for primary care physicians choosing among cancer screening tests; workflow within primary care physicians' office will also be of importance; the performance characteristics of the various cancer screening tests will also be important to any clinician who is actually going to utilize these technologies; the number of cancers that the tests screen for likely will be part of the decision. (Getty (Guardant) Tr. 2670–72, 2674.)

1827. Open Offer and Negotiations with Illumina. Complaint Counsel contends that Illumina's Open Offer is insufficient to resolve its concerns about the reunion of Illumina and Grail, but Mr. Getty admitted that Guardant has not engaged with Illumina about the Open Offer. (Getty (Guardant) Tr. 2668.)

1828. [redacted]

1829. Complaint Counsel contends that the Open Offer contains holes and is difficult to enforce, but Mr. Getty admitted that Guardant has never told Illumina in substance that Amendment 5 is unenforceable and worthless. (Getty (Guardant) Tr. 2668.) [redacted]

1830. Efficiencies. Complaint Counsel contends the Transaction will not generate efficiencies, but Mr. Getty admitted the right multicancer early detection test may help to reduce mortality and the sooner a right multicancer early detection test becomes available on a widespread basis to the public, the better. (Getty (Guardant) Tr. 2637–38.)

1831. Bias. Complaint Counsel presented Mr. Getty as an unbiased witness, but Mr. Getty admitted that Guardant sees GRAIL as a competitor: there are first-mover advantages associated with being the first multicancer early detection test to market; it may be worth double the market share to be the first mover; and Guardant is not as far along as GRAIL on the path towards commercialization of a multicancer early detection test. Getty (Guardant) Tr. 2639–40.) Mr. Getty is a competitive person and would like to see Guardant come out on top in the marketplace of a multicancer early detection test. (Getty (Guardant) Tr. 2639–40).

7. Kenneth Chahine (Helio)

a. Background

1832. Dr. Chahine was the Chief Executive Officer of Helio Health until June 2021. (Chahine (Helio) Tr. 999.)

1833. Dr. Chahine is currently working for a New York based start-up, code name Cedar, and is the advisor to Helio Health. (Chahine (Helio) Tr. 998.)

1834. Dr. Chahine was previously employed at Ancestry.com as the Executive Vice President and General Manager at AncestryDNA. (Chahine (Helio) Tr. 1002.)

b. Testimony

1835. Alleged Relevant Market. [redacted]

1836. [redacted]

[redacted]

1837. [redacted]

1838. [redacted]

1839. Dr. Chahine admitted that the success of various early cancer screening tests will depend on various technical, scientific and regulatory variables; each of the MCED tests in development could ultimately be differentiated from one another, such as focusing on different types of cancers, using different technologies, having different levels of sensitivity or specificity, being approved by the FDA for different intended uses and being covered by third-party payers for different uses; there is no certainty about which MCED tests in development will actually come to market, which MCED tests in development will actually compete with GRAIL's multicancer test or which of the MCED tests in development will be the market leaders in the future; there is no way to predict five, ten or fifteen years from now which of these various companies developing early cancer screening tests is actually going to be successful in bringing an early cancer screening test to market; Helio's strategy in pursuing a series of tests for specific cancers, particularly liver cancer, potentially differentiates Helio from GRAIL and Thrive, who are developing blood tests to detect multiple types of cancer. (Chahine (Helio) Tr. 1125–27.)

1840. Alleged foreclosure. [redacted]

1841. [redacted]

[redacted]

1842. [redacted]

1843. The Transaction. [redacted]

1844. Efficiencies. Complaint Counsel contends that the Transaction will not generate efficiencies, but Dr. Chahine admitted that because the FDA follows precedence, if one company's MCED test is approved by the FDA, it could potentially make it easier for another company to bring a different MCED test to market; if GRAIL accelerates the process by which it gets FDA approval for its MCED test, that could possibly accelerate the process by which other companies get FDA approval for their cancer screening tests; that if one company's MCED test gets covered or reimbursed by Medicare, that can grease the skids for other companies who want to get reimbursement for similar tests, and so they will have an easier time; and one of the advantages of being second and following someone else who's ahead is it makes it easier to get reimbursement coverage. (Chahine (Helio) Tr. 1128–32.)

1845. Dr. Chahine admitted that if GRAIL gets its MCED test out to market at scale, that would be a positive for society and would potentially save lives; and the sooner any company gets its early cancer screening tests to market, the sooner those societal benefits will be realized. (Chahine (Helio) Tr. 1132–33.)

8. Matthew Strom (Morgan Stanley)

a. Background

1846. Matthew Strom is a managing director in Morgan Stanley's healthcare investment banking group. Morgan Stanley served as GRAIL's exclusive financial advisor from 2017 through Illumina's acquisition of GRAIL in 2021. (Strom (Morgan Stanley) Tr. 3473.)

1847. Specific to Illumina's acquisition of GRAIL, Morgan Stanley was asked to help GRAIL negotiate the transaction with Illumina and to evaluate potential alternatives, such as an IPO. Morgan Stanley was also tasked with providing financial perspective to GRAIL's board through valuation considerations and due diligence on the transaction. (Strom (Morgan Stanley) Tr. 3474.)

b. Testimony

1848. Alleged Relevant Market. Complaint Counsel contends that several companies are working on MCED tests, but Mr. Strom confirmed that Morgan Stanley's report shows that the large-scale clinical trials by Guardant Health, Exact Sciences and Freenome are all in colon cancer; there is no company other than GRAIL offering an MCED test relying on NGS in the market today. (Strom (Morgan Stanley) Tr. 3595–96.)

1849. [redacted]

1850. Alleged Foreclosure. Complaint Counsel contends that there are no alternatives to Illumina in the upstream NGS market, but Mr. Strom confirmed that the funding environment for NGS remains very robust: there was an announcement that ONT just raised a fairly significant amount of capital through an IPO in the London Stock Exchange and have publicly announced that they have launched that IPO to raise $350 million at a $3.5 billion valuation; Morgan Stanley also works with a number of clients in the NGS space in the private market who have raised private capital and are potentially evaluating accessing the public markets; and investors continue to be quite interested in the NGS space given the vast sort of opportunity out there. (Strom (Morgan Stanley) Tr. 3476–77, 3489–90.)

1851. While Complaint Counsel claims that the Transaction would inhibit innovation and entry into the MCED space, but Mr. Strom confirmed that there is significant investor interest in the cancer diagnostics space, which is probably the most interesting subsector of diagnostics to investors; Morgan Stanley has not seen investment interest in the diagnostics space slow down at all since Illumina announced its intention to acquire GRAIL in around September 2020: there has been a robust level of activity in the diagnostics space, both in the public and private markets and a lot of investors have seen the exit opportunity that GRAIL's investors had as a positive and validating moment for this space; Morgan Stanley has observed increased investor interest in other companies that are working in the cancer diagnostics space since the Illumina-GRAIL acquisition was announced; Natera's stock actually increased in value since Illumina closed the transaction and acquisition of GRAIL on August 18, 2021; and

Guardant's stock price continues to have good momentum as well. (Strom (Morgan Stanley) Tr. 3478–80.)

1852. NIPT. While Complaint Counsel claims that Illumina has successfully foreclosed rivals in the NIPT market, Mr. Strom confirmed that in the last six to nine months, the various societies that help put out clinical guidelines around reimbursement for different tests have recommended that all women who are pregnant receive NIPT testing and be reimbursed for that use—whereas before it was just for high-risk-deemed pregnancies—which was a meaningful growth in number of patients that it was recommended for and thus recommended to be reimbursed for; since Illumina acquired Verinata, the annual amount of NIPT testing that actually gets to patients has increased. (Strom (Morgan Stanley) Tr. 3486–87, 3492.)

1853. Mr. Strom confirmed that Natera's test has the biggest share of the NIPT market; Natera has been able to significantly increase its market share in NIPT over time despite the fact that Illumina owns Verinata; and Verinata's market share has decreased in the NIPT market in the time since Illumina acquired Verinata. (Strom (Morgan Stanley) Tr. 3492.)

1854. Mr. Strom confirmed that the costs of Illumina's sequencing products for NIPT applications has decreased significantly since Illumina acquired Verinata. (Strom (Morgan Stanley) Tr. 3492.)

1855. Efficiencies. [redacted]

1856. [redacted]

1857. [redacted]

[redacted]

1858. [redacted]

1859. [redacted]

1860. [redacted]

1861. [redacted]

1862. Mr. Strom confirmed that in Morgan Stanley's view, GRAIL needed to make it clear to investors that: GRAIL has used significant capital in the past and that they should expect that GRAIL will continue to use significant capital in the future; based on the market capitalization as well as cash balance and cash flow of Illumina, the transaction at issue today provide sufficient capital to provide for the needs of GRAIL given these significant net losses in the foreseeable future; GRAIL did not have institutional experience generating revenue from products and that in the near term any revenue GRAIL did generate would be too small to offset or cause it to break even on its level of expenses; and the Illumina-GRAIL transaction provides sufficient capital to provide for GRAIL's needs of significant capital in the foreseeable future. (Strom (Morgan Stanley) Tr. 3597–99.)

1863. Efficiencies. Mr. Strom testified that the transaction would lead to the elimination of GRAIL's royalty and accelerate market access to Galleri. (Strom (Morgan Stanley) Tr. 3599.)

1864. *Elimination of Royalty.*

1865.

1866.

1867.

1868. Mr. Strom testified that in Morgan Stanley's view, the proposed Illumina acquisition would remove that risk posed by the royalties owed to Illumina (Strom (Morgan

Stanley) Tr. 3536); the transaction eliminates the risk of the high-single-digit royalties owed to GRAIL and the impediment they posed to GRAIL's efforts to obtain profitability (Strom (Morgan Stanley) Tr. 3597–99).

1869. *Acceleration of Market Access to Galleri.* [redacted]

1870. [redacted]

9. **Matthew Rabinowitz (Natera)**

a. Background

1871. Dr. Rabinowitz serves as the executive chairman of Natera, a position he has held since 2019. (Rabinowitz (Natera) Tr. 284–85.)

1872. As chairman, Rabinowitz consults on issues concerning technology, strategy, and business development. (Rabinowitz (Natera) Tr. 286.)

b. Testimony

1873. Alleged Relevant Market. [redacted]

1874. [redacted]

1875. [redacted]

1876. [redacted]

1877. [redacted]

1878. Dr. Rabinowitz admitted that Natera told its shareholders that there are significant risks associated with Natera's development of an MCED test, including that:

1878.1 [redacted]

1878.2 [redacted]

[redacted]

1878.3 [redacted]

1878.4 [redacted]

1878.5 [redacted]

1879. Alleged Foreclosure. [redacted]

1880. [redacted]

1881. [redacted]

[redacted]

1881.1 In addition, Guardant has accused Natera of making false comparisons of its MRD test to Guardant's MRD test "[w]ith little or no concern for the [colorectal cancer] patients who could be harmed". (RX3297 (*Guardant Health v. Natera*, 3:21-cv-04062, Dkt. No. 1) ¶ 3.) CareDx, a rival to Natera in kidney transplant testing, has accused Natera of "making various false and misleading claims that [Natera's test] is superior to CareDx's AlloSure" kidney transplant test". RX3096 (*CareDx, Inc. v. Natera*, 1:19-cv-00662, Dkt. No. 1) ¶ 3.) [redacted]

1882. Open Offer. [redacted]

1883. [redacted]

1884. [redacted]

[redacted]

1885. Efficiencies. [redacted]

1886. Bias. [redacted]

10. **Gary Gao (Singlera)**

a. Background

1887. Dr. Yuan (Gary) Gao is a board member and a scientific advisor of Singlera and had served as Singlera's chairman from beginning of the company in July 2014 until June 2020. (Gao (Singlera) Tr. 2871.)

b. Testimony

1888. Alleged Relevant Market. Complaint Counsel contends that Singlera is working on an MCED test that will directly compete with Galleri, but Dr. Gao admitted that Singlera does not have an MCED test on the market; the ColonES test that Singlera is currently developing has a specific focus on early detection of only colorectal cancer in asymptomatic patients; Singlera does not have any clinical trial evidence that ColonES can detect more than one cancer; Singlera's PanSeer test can only detect five cancers, including lung, liver, esophageal, gastric, and colorectal cancers, for asymptomatic patients; Singlera's publication on PanSeer did not mention early detections of any other cancers; Singlera does not currently offer any form of the PanSeer early detection test for use in the U.S.; Singlera is a long way away from even starting clinical trials for PanSeer; Singlera has not even had discussions with the FDA about PanSeer; Singlera has not even begun designing a clinical trial plan for PanSeer or engaged FDA consultants for any FDA submissions related to PanSeer as it did for ColonES. (Gao (Singlera) Tr. 2914–15, 2917; 2917–18; 2926–27, 2942–43, 2949.)

1889. Dr. Gao admitted that Singlera does not have a clear timeline for when Singlera will be able to launch a single cancer ColonES test in the U.S.; Singlera intends to seek FDA approval for the ColonES test, but expects it will be several years' time before ColonES obtains FDA approval; Singlera does not yet have a partnership lined up with a U.S.-based company to conduct a clinical trial for ColonES to obtain FDA approval and is at least one year away from even starting clinical trials in the U.S. for ColonES; and to obtain FDA approval, a clinical trial for ColonES could take three to four years; Dr. Gao does not believe that Singlera or any other test developer will have a colorectal or other early cancer detection test based on NGS on the market within the next three years. (Gao (Singlera) Tr. 2911–12, 2920–23.)

1890. Dr. Gao also admitted that the investor have very little confidence in the current management team and in Dr. Gao being able to get FDA approval for the ColonES product and wanted to have a U.S. company directly involved in a clinical trial even of Singlera's colorectal cancer single screen test. (Gao (Singlera) Tr. 2910–11.)

1891. Dr. Gao admitted that Singlera expects to launch the ColonES product first before it launches PanSeer; Singlera sees ColonES as the first top priority for commercialization because Dr. Gao thinks it is much easier to demonstrate the validity of single-cancer detection test than to demonstrate the validity of an MCED test; the regulatory pathway for approval of colorectal cancer is easier than the pathway for multiple cancer detection; the fact that Exact has already gone through an FDA approval process for colorectal cancer benefits other companies developing colorectal cancer screening tests; when the FDA ultimately approves an MCED test, it will make it easier for other MCED test developers to follow in the same footsteps. (Gao (Singlera) Tr. 2918–19, 2924.)

1892. Dr. Gao believes that FDA would require a prospective pivotal trial for approval of a test for early cancer detection; doing clinical trials for a true MCED test will be a significant undertaking: a ten-year, 100,000–person study were only able to provide enough data to verify a five cancer test; to get FDA approval of a ten cancer test, a company would need to do a clinical study covering perhaps 200,000 people over eight to ten years; a company would need approximately ten years to do the clinical trial work to get the necessary results to get a ten cancer test approved by the FDA. (Gao (Singlera) Tr. 2919, 2924, 2926.)

1893. Alleged Foreclosure. Complaint Counsel contends the reunion of Illumina and Grail may foreclose GRAIL rivals, including Singlera, but Dr. Gao admitted that Singlera's PanSeer test was not designed to solely on Illumina equipment and it is compatible with Thermo Fisher's NGS systems, including the Ion Torrent S5. (Gao (Singlera) Tr. 2928.)

1894. Dr. Gao estimates that it would take about six months to a year to switch from Illumina to Thermo Fisher NGS equipment for the PanSeer test; if Singlera were to switch to Thermo Fisher equipment today, it would not have to rerun any clinical trial that it had previously run for PanSeer, would not even need any bridging study to revalidate any PanSeer trial results, and would not disrupt any ongoing clinical trial work for PanSeer. (Gao (Singlera) Tr. 2942–43.)

1894.1 Dr. Gao admitted that Singlera successfully raised $150 million, more money than Singlera had ever raised before, a few months after Illumina and GRAIL announced their merger. (Gao (Singlera) Tr. 2949–50.)

1895. Open Offer. Dr. Gao testified that he was "not even aware of the first open [...] offer until [his] lawyer told [him]", let alone the amended version. (Gao (Singlera) Tr. 2952 ("Q. And are you aware that that open offer was amended as of just last week to make certain improvements to it? A. Sir, to be frank, I am not even aware of the first open -- open offer until my lawyer told me, and I am not even aware of the one if you don't tell me a week ago.").)

1896. Efficiencies. Complaint Counsel contends the Transaction will not generate efficiencies, but Dr. Gao admitted that Singlera's investors expressed concern that the Illumina-

GRAIL merger will give GRAIL additional resources beyond what it has today and also strong financial backing from Illumina and give GRAIL the benefits of being part of a public company with unlimited resources, which will help GRAIL get the Galleri test approved sooner; in addition, having FDA experience in-house would save a company a significant amount of money. (Gao (Singlera) Tr. 2946–49.)

1897. Bias. Complaint Counsel presented Dr. Gao as an unbiased witness, but Dr. Gao admitted that he spoke with FTC lawyers two separate times in 2020; in these conversations, the FTC lawyers went over the questions that they were going to ask Dr. Gao without anyone from GRAIL or Illumina present on those calls. (Gao (Singlera) Tr. 2904–06.)

11. **Jorge Velarde (Singular)**

a. Background

1898. Mr. Velarde is the Senior Vice President of corporate development and strategy at Singular Genomics. In his role, Mr. Velarde oversees all of the external collaborations, evaluations of potential licensing, partnering, and other commercial aspects of Singular Genomics' business. (Velarde (Singular) Tr. 4511–12.)

1899. Mr. Velarde has a degree in molecular biology from Loyola University, as well as a master's degree in business administration from UC Irvine. (Velarde (Singular) Tr. 4512.)

1900. After earning his MBA, Mr. Velarde was a research associate at Gen-Probe. Mr. Velarde climbed through the ranks of Gen-Probe to science-focused positions before joining Illumina in 2001. (Velarde (Singular) Tr. 4512–13.)

1901. Mr. Velarde worked at Illumina in corporate business development from 2001 to 2012 (Velarde (Singular) Tr. 4513.)

b. Testimony

1902. Upstream Market. While Complaint Counsel contends that there are no alternatives to Illumina in the upstream NGS market, Mr. Velarde confirmed that Singular currently have two NGS products in development, including the G4 NGS sequencer and the PX multiomics platform system; Singular is also developing core consumables for use with the G4 NGS instrument. (Velarde (Singular) Tr. 4513–14, 4521.)

1903. Mr. Velarde confirmed that Singular is going to be commercially launching the G4 NGS sequencer at the end of 2021 and shipping the G4 NGS systems in the first half of 2022; Singular is currently on track to meet those target date to ship the G4 system in the first half of 2022. (Velarde (Singular) Tr. 4515–16, 4522.)

1904. [redacted]

[redacted] (Velarde (Singular) Tr. 4514, [redacted].)

1905. Mr. Velarde confirmed that Singular has developed the G4 systems and has completed beta testing for the G4 systems; Singular's beta testing occurred before its IPO by placing two different systems independently in Sanford Burnham and Fate Therapeutics, who successfully ran those systems with data published with Singular's IPO; Singular's beta test partners successfully used the sequencers themselves. (Velarde (Singular) Tr. 4516–17.)

1906. Mr. Velarde testified that Singular is conducting an early access program for the G4 systems by shipping the system to early access partners to generate data, technical notes, publications on the system to support the commercial launch at the end of 2021; Singular has completed one early access test with Beth Israel Deaconess Medical Center of Harvard Medical School, is in the process of another, and has just recently shipped the G4 system to a third early access partner; Singular expects to finish a number of early access tests before the end of 2021. (Velarde (Singular) Tr. 4516–19.)

1907. [redacted]

1908. Mr. Velarde confirmed that Singular is aggressively building out its sales and marketing force in preparation for the launch of the G4 system; Singular's sales and marketing force have a current head count of well over 200 right now. (Velarde (Singular) Tr. 4520–21.)

1909. [redacted] (Velarde (Singular) Tr. 4532, [redacted])

1910. [redacted] **(**Velarde (Singular) Tr. 4523–27, [redacted]

1911. Mr. Velarde confirmed that Singular designed its G4 NGS system in a way that would be the least disruptive to customers' workflow so Singular could offer the customers a system that would work for their needs; Singular's G4 NGS system was designed be compatible and work with a number of the library prep and bioinformatics workflows the customers have already developed for prior sequencing systems. (Velarde (Singular) Tr. 4532–34.)

1912. [redacted] (Velarde (Singular) Tr. 4522, [redacted]

1913. Mr. Velarde testified that he does not think Illumina's reacquisition of GRAIL will have an effect on Singular's ability to innovate in the NGS space and Singular does not project that Illumina's reacquisition of GRAIL will slow down Singular's commercialization plans. (Velarde (Singular) Tr. 4534.)

12. **William Cance (ACS)**

a. Background

1914. Dr. William Cance is the chief medical and scientific officer at the American Cancer Society (ACS) where he oversees the medical and scientific aspects of ACS's mission programs. (Cance (ACS) Tr. 591–92).

b. Testimony

1915. Background on Cancer Screening Guidelines. Dr. Cance testified that only five cancers are currently include in ACS's cancer screening guidelines, including breast, colorectal, lung, cervix, and prostate cancer: typically radiologic screening is used for breast cancer and for lung cancer; screening for cervical cancer is the Pap smear and also measuring human papilloma virus DNA in the blood; colorectal cancer can be screened through looking at blood or DNA in the stool, or using colonoscopy; prostate cancer can be screened through elevation of PSA (prostate -specific antigen), which can also be elevated in benign disease, such as inflammation in the prostate. (Cance (ACS) Tr. 606).

1916. Dr. Cance testified that ACS recommends cancer screening tests for certain patients to detect cancer at an earlier stage where it can be intercepted, treated more successfully, and has a higher cure rate. (Cance (ACS) Tr. 606.)

1917. Dr. Cance confirmed that surgical operations on earlier stage cancer patients detected by screens have the benefits that the operation is more well-tolerated by the patient, it is frequently less invasive, the recovery is faster, and it has better cure rate. (Cance (ACS) Tr. 607–08.)

1918. Alleged Relevant Market. Complaint Counsel contends that several companies compete or will compete directly with GRAIL, but Dr. Cance admitted that GRAIL is further ahead in its development process than other companies that are developing purported MCED tests; he is not aware of any other purported MCED test that is commercially available today; GRAIL's Galleri test can detect 50 cancer types and he does not know of other companies having the same number of cancers detected as GRAIL. (Cance (ACS) Tr. 631–33.)

1919. Cance Declaration. Complaint Counsel suggests that Dr. Cance's testimony supports their case, but Dr. Cance admitted that apart from the statement in the declaration that "ACS is an independent organization, and we do not take a position on the acquisition of GRAIL by Illumina," none of the statements in his declaration relate to Illumina's acquisition of GRAIL. (Cance (ACS) Tr. 638–40.)

1920. Dr. Cance testified that ACS takes no position on Illumina's acquisition of GRAIL: ACS takes no position on whether Illumina's acquisition of GRAIL will result in the loss of innovation in MCED tests, whether Illumina's acquisition of GRAIL will increase development costs for MCED tests, whether Illumina's acquisition of GRAIL will be harmful for patients, whether Illumina's acquisition of GRAIL will result in an injustice in health, whether Illumina's acquisition of GRAIL will increase the costs of healthcare, or whether Illumina's acquisition of GRAIL will reduce the supply of healthcare; ACS has not done any analysis to

show whether Illumina's acquisition of GRAIL would result in any loss of innovation in MCED tests, would raise the cost of developing MCED tests, would harm patients, would result in an injustice in health, or would affect the costs or supply of healthcare. (Cance (ACS) Tr. 629–30.)

1921. Dr. Cance does not believe that any multicancer early detection tests should be stalled at its launch phase just so that other multicancer early detection tests can catch up sometime in the future and agrees that accelerating an early cancer detection test's ability to commercialize at scale is consistent with ACS's mission. (Cance (ACS) Tr. 631.)

13. **Andrew Felton (Thermo Fisher)**

a. Background

1922. Dr. Felton is the vice president of product management, platform research, and applied markets at Thermo Fisher Scientific (Thermo Fisher). He has been in this position for approximately seven years. (Felton (Thermo Fisher) Tr. 1978–79.).

b. Testimony

1923. Alleged Relevant Market. [redacted]

1924. Upstream Market and Alleged Foreclosure. [redacted]

1925. [redacted]

[redacted]

1926. [redacted]

1927. [redacted]

1928. [redacted]

1929. [redacted]

1930. [redacted]

[redacted]

1931. [redacted]

1932. [redacted]

1933. [redacted]

D. Respondents' Experts

1. Dennis Carlton

a. Background

1934. Dennis W. Carlton, Ph.D is the David McDaniel Keller Professor of Economics at The University of Chicago Booth School of Business. Dr. Carlton received his A.B. in Applied Mathematics and Economics from Harvard University and his M.S. in Operations Research and Ph.D. in Economics from the Massachusetts Institute of Technology. Dr. Carlton 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); RX6000 (Carlton Trial Dep. at 5–7).)

1935. 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. Dr. Carlton is the co- author of the book Modern Industrial Organization, a leading text in the field of industrial organization, and he has published over 100 articles in academic journals and books. In addition, Dr. Carlton 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. Dr. Carlton has also served as an Associate Editor of the International Journal of Industrial Organization and Regional Science and Urban Studies,

and on the Editorial Board of Intellectual Property Fraud Reporter. Dr. Carlton was the 2014 Distinguished Fellow of the Industrial Organization Society. (RX3864 (Carlton Expert Report) ¶ 2); RX6000 (Carlton Trial Dep. at 7–9).)

1936. 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. Dr. Carlton's responsibilities included supervising approximately 50 Ph.D. economists, helping formulate antitrust policy toward ongoing proposed mergers, analyzing general antitrust policies both horizontal and vertical, and communicating such policies to foreign and domestic agencies, as well as to practitioners. Dr. Carlton also served as a Commissioner of the Antitrust Modernization Commission, created by Congress to evaluate U.S. antitrust laws. 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. (RX3864 (Carlton Expert Report) ¶ 3); RX6000 (Carlton Trial Dep. at 10–11).)

1937. Dr. Carlton also is a Senior Managing Director of Compass Lexecon, a consulting firm that specializes in the application of economics to legal and regulatory issues and for which he served as President (of Lexecon) for several years. Dr. Carlton has provided expert testimony before various U.S., state and federal courts, the U.S. Congress, a variety of state and federal regulatory agencies and foreign tribunals. Dr. Carlton has consulted to or testified for companies that were involved in vertical transactions, including offering economic expert testimony on behalf of AT&T in its recent acquisition of Time Warner. Dr. Carlton's curriculum vitae and a list of his testifying experience over the last four years is provided in Exhibit 1. Compass Lexecon bills for Dr. Carlton's time on this matter at his customary hourly rate, which is currently $1,800 per hour. Neither Dr. Carlton's compensation nor that of Compass Lexecon is dependent on the outcome of this proceeding. (RX3864 (Carlton Expert Report) ¶ 4); RX6000 (Carlton Trial Dep. at 12–13).)

b. Summary of Opinions

1938. Dr. Carlton testified that Illumina's acquisition of GRAIL is unlikely to lead to any adverse competitive effects as alleged by Complaint Counsel and is likely to generate efficiency benefits for customers of GRAIL and ultimately for patients. (RX3864 (Carlton Expert Report) ¶ 13; RX6000 (Carlton Trial Dep. at 15).) Specifically, Dr. Carlton concluded the following:

1939. Fully accounting for the effects of a vertical transaction requires an economic vertical model that simultaneously accounts for the countervailing forces of raising rivals' costs ("RRC") and the elimination of double marginalization ("EDM") and other efficiencies (which interact with each other in complicated ways) as well as the impact of constraints, including the Open Offer, reputation constraints, and the ability of MCED test providers to take steps to reduce

their reliance on Illumina. (RX3864 (Carlton Expert Report) ¶ 13); RX6000 (Carlton Trial Dep. at 24–26).)

1939.1 A fully specified model must take into account many economic factors, including the amount of diversion, margins and costs, and the specification of the type of competition that determines pre- and post-merger prices and investments. Neither Complaint Counsel nor Dr. Scott Morton have offered such a model, relying instead on assumptions, including that there are no merger-specific efficiencies that cannot be achieved by contract and that the Open Offer provides no protection to customers, as well as assumptions about future rivals. Complaint Counsel's and Dr. Scott Morton's assertions that Illumina will have an incentive and ability to harm competition as a result of this transaction are therefore highly speculative. (RX3864 (Carlton Expert Report) ¶ 13); RX6000 (Carlton Trial Dep. at 24–26).)

1940. [redacted]

1941. Complaint Counsel's alleged market for MCED tests is not defined based on any empirical examination of demand for such a product (because Galleri was only introduced in April 2021, and none of the rivals identified by Complaint Counsel or by Dr. Scott Morton (or

any other test developers as far as Dr. Carlton is aware) have a product in their alleged market today), but instead on speculative characteristics of potential future products, some of which are not yet even in development. Neither Dr. Scott Morton (as she acknowledges) nor Complaint Counsel can offer reliable estimates of shares and diversion ratios of sales from GRAIL and its rivals. Without these, it is not possible for Dr. Scott Morton to analyze the overall effect of a vertical merger where there are efficiencies that need to be balanced against any alleged incentive to RRC, and where post-merger constraints exist. (RX3864 (Carlton Expert Report) ¶ 13); [redacted]

1942. Complaint Counsel's first theory of harm is that Illumina will raise GRAIL's rivals' costs by increasing the prices of Illumina-supplied inputs. Because of the Open Offer, Complaint Counsel has not shown that Illumina has the ability to raise costs. Complaint Counsel's theory requires that rivals' costs could be significantly raised by Illumina increasing prices on the inputs it will supply. Such price increases would violate Illumina's contractual commitment not to raise the prices as specified in the Open Offer and to reduce sequencing costs 43 percent by 2025 as specified in the Open Offer. These contractual restrictions indicate that Illumina could not raise rivals' costs, let alone raise them by an amount sufficient to drive up the prices GRAIL's rivals charge for their tests to create meaningful diversions to GRAIL. Moreover, even absent the contractual commitment, Illumina raising input prices to harm GRAIL's competition is unlikely. Current estimates show that Illumina input costs could comprise less than four percent of an equally efficient GRAIL rival's revenues within five years of that rival launching its test. Given this, any attempted price increase would likely have to be very significant to cause substantial harm and could damage Illumina's reputation and dampen investment in the development of other downstream products on the Illumina sequencing platform. These reputational effects should mitigate or eliminate Complaint Counsel's concerns about RRC. Additionally, to the extent that, as Illumina expects, there will be greater upstream competition in the coming years (including following the expiration of its key sequencing patents in 2023), that further constrains Illumina's incentive to raise price. (RX3864 (Carlton Expert Report) ¶ 13); [redacted]

1943. Complaint Counsel's second theory of harm is that Illumina will fail to provide information, access, and assistance to GRAIL's rivals. And, as with RRC, this theory ignores that GRAIL's rivals will be protected from this potential harm by contract through the Open Offer. The contractual protections in the Open Offer provide for GRAIL's rivals to have access to Illumina's future sequencing platforms and support services on the same basis that such access is provided to GRAIL, and that Illumina will continue to offer assistance with downstream rivals' pursuit of cancer screening tests (including IVD Test Kits in the event a rival decides to pursue such a model—though such a model is not anticipated in the U.S. in the foreseeable future), to the extent that the rivals' require that assistance in securing FDA approval for such tests, consistent with Illumina's pre-merger practices. (PX0064 (Illumina) § 4, 6). The inability to write a complete contingent contract that anticipates every possible state of the world where a rival might ask Illumina for help—and where Illumina would have provided such help in the but-for world—does not mean that the contractual protections offered by Illumina are meaningless, which is apparently Complaint Counsel's position and is reflected in Dr. Scott Morton's analysis, which assumes that the Open Offer has no constraining effects on Illumina's actions whatsoever. Why Complaint Counsel believes that the Open Offer's method of handling unforeseen contingencies, via terms that are favorable to customers and subject to arbitration, favors

Illumina is unclear. This method of dispute resolution allows the efficiencies of the transaction to be achieved while eliminating Complaint Counsel's concern of significant harm. In addition, Complaint Counsel's theory ignores that Illumina will be constrained by the prospect that attempts to raise rivals' costs would damage Illumina's reputation and cause downstream firms to reduce investments in new uses for Illumina's sequencing products, as well as lose upstream sales to new entrants and expansion by existing rivals. (RX3864 (Carlton Expert Report) ¶ 13); [redacted]

1944. EDM and other efficiencies projected by Illumina are merger-specific, will be passed through to downstream customers, and are likely to be of significant magnitude. (RX3864 (Carlton Expert Report) ¶ 13); [redacted]

1945. [redacted]

1946. The acquisition will likely result in merger-specific R&D efficiencies. The existence of such efficiencies would not be surprising, as vertical integration is common in industries in which R&D is important. Such vertical integration occurs because the efficiencies that come from combining two companies' complementary R&D efforts often cannot be achieved by contract. Post-merger collaboration between GRAIL and Illumina means there will be a higher probability of breakthrough discoveries. That collaboration does not occur prior to the acquisition because of the well-known difficulty of collaboration by contract when proprietary IP (e.g., GRAIL's data and algorithm), and the inherent reservations about the disclosure of such confidential information, is involved. It is exactly such collaboration in a vertical setting (after Illumina's acquisition of Verinata) that led to discoveries that led to the formation of GRAIL. (RX3864 (Carlton Expert Report) ¶ 13); RX6000 (Carlton Trial Dep. at 61–63).)

2. Richard Cote

a. Background

1947. Dr. Richard J. Cote is the Edward Mallinckrodt Professor and Chair at the Department of Pathology and Immunology, Washington University School of Medicine at St. Louis, Missouri. He is also the Pathologist-in-Chief at Barnes-Jewish Hospital of St. Louis, Missouri. (RX3869 (Cote Expert Report) ¶ 1); Cote Tr. 3717.)

1948. 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. (RX3869 (Cote Expert Report) ¶ 2); Cote Tr. 3717–19.)

1949. Before joining Washington University in 2019, Dr. Cote was the Joseph R. Coulter Jr. Chair of the Department of Pathology, Professor of Biochemistry and Molecular Biology, and Founding Director of the Dr. John T. Macdonald Foundation Biomedical Nanotechnology Institute at the University of Miami Miller School of Medicine at Miami, Florida, since 2009. He was also the Chief of Pathology at the Jackson Memorial Hospital and the Director of the Genitourinary Cancer Program at the University of Miami Sylvester Comprehensive Cancer Center at Miami, Florida. (RX3869 (Cote Expert Report) ¶ 3); Cote Tr. 3717–18.)

1950. Prior to 2009, Dr. Cote was Professor at the Departments of Pathology and Urology at the University of Southern California ("USC") Keck School of Medicine; Director of the Genitourinary Cancer Program and Attending Pathologist at USC Norris Comprehensive Cancer Center; Director of the Laboratory of Immunology and Molecular Pathology in Los Angeles, California; and Director of the USC Biomedical Nanoscience Initiative at the USC Keck School of Medicine. He was also a Clinical Instructor at the Department of Pathology at the Cornell University Medical College in New York City before joining USC in 1990. (RX3869 (Cote Expert Report) ¶ 4); Cote Tr. 3718.)

1951. Dr. Cote received a B.A. in Chemistry and B.S. in Biology, both with honors, at the University of California at Irvine, and an M.D. from the University of Chicago Pritzker School of Medicine in Chicago, Illinois. He completed a surgical internship at the University of Michigan at Ann Arbor, Michigan, and a residency in pathology at the New York Hospital of Cornell University Medical College, a clinical fellowship in pathology and research fellowship in Human Tumor Immunology at Memorial Sloan-Kettering Cancer Center, and a fellowship in Molecular Pathology at the New York University School of Medicine in New York City. (RX3869 (Cote Expert Report) ¶ 5); Cote Tr. 3717–18.)

1952. Dr. Cote's research is focused on the elucidation of cellular and molecular pathways of tumor progression and response to therapy. He has special interests in micro-metastases and circulating tumor cell detection, characterization, and pathology of breast and genitourinary tumors. He has led three of the largest clinical trials in breast, lung and bladder cancer, all based on discoveries from his research. (RX3869 (Cote Expert Report) ¶ 6); Cote Tr. 3719, 3724.)

1953. Dr. Cote is the author of over 300 publications, and he participates on numerous scientific advisory boards for both academic and industry related institutions. He is a frequent lecturer and the co-author of the standard textbooks "Immunomicroscopy: A Diagnostic Tool for the Surgical Pathologist" (now in its third edition) and "Modern Surgical Pathology" (now in its second edition). He also serves as a member and advisor to a large number of national and international study groups, cancer programs and societies, including the National Cancer Institute. (RX3869 (Cote Expert Report) ¶ 7).)

1954. Dr. Cote's laboratory is also focused on technology development, where he and his colleagues have developed immunohistochemical and molecular methods, such as antigen retrieval. With colleagues at the University of Miami, USC, California Institute of Technology (Caltech), and University of California at Berkeley, Dr. Cote has developed nanoscale technologies for cancer diagnostic applications, including bionanosensors for the detection of serum tumor markers, and technologies for the capture, characterization and propagation of circulating tumor cell. Through these efforts, he established the Biomedical Nanoscience Program at USC and the Dr. John T. Macdonald Biomedical Nanotechnology Institute at the University of Miami (BioNIUM) for the development of novel diagnostic platforms and targeted therapeutics. (RX3869 (Cote Expert Report) ¶ 8.)

1955. Dr. Cote also founded several technology companies, including several that focused on cancer testing and cancer analysis. These companies include IMPATH, Clarient, Filtini, Sensitini and Circulogix. IMPATH was one of the first companies to bring esoteric testing for cancer analysis to the market. Dr. Cote founded IMPATH in 1988 to conduct cancer testing and analysis on a contract basis for smaller hospitals that did not perform cancer testing in their own laboratories. It underwent IPO in 1996 and was acquired in 2004 by Genzyme, now a subsidiary of Sanofi. (RX3869 (Cote Expert Report) ¶ 9); Cote Tr. 3724.)

1956. Dr. Cote also helped to start a cellular image analysis company, ChromaVision Medical Systems, Inc. ChromaVision developed an Automated Cellular Imaging System (ACIS®) designed to assist physicians by detecting, counting and classifying cells of clinical interest based on color, size and shape. It underwent IPO in 1997 and Dr. Cote served on ChromaVision's Scientific Advisory Board between 1997 and 2000. In 2003, he helped direct a re-engineering of the company and changed its name to Clarient in 2005. Since 2005, Clarient's revenues had grown at a 68 percent compounded annual growth rate until it was acquired by GE Healthcare in 2010. (RX3869 (Cote Expert Report) ¶ 10.)

1957. Dr. Cote founded Filtini in 2008 to develop membrane microfilters to trapping circulating tumor cells, which help in the detection of recurrence of bladder cancer. He founded Sensitini in 2009 to use monoclonal antibodies to detect tumor-specific antigens and trace amounts of toxin in the blood. He also co-founded Circulogix in 2014 to develop the technology to enrich and capture circulating tumor cells and circulating Cancer Associated Fibroblasts ("cCAF") from body fluid samples (*i.e.*, blood, urine, ascites) for cancer characterization using immunofluorescence, immunochemistry, fluorescence in situ hybridization ("FISH"), RNA in situ hybridization ("RNA ISH"), next-generation sequencing ("NGS"), and tissue culture. (RX3869 (Cote Expert Report) ¶ 11).

1958. Dr. Cote holds numerous patents for cancer related and nanoscale technologies relating to the research conducted in his laboratories and companies. He was recently elected in to the National Academy of Inventors based on the impact of his inventions. (RX3869 (Cote Expert Report) ¶ 12); Cote Tr. 3721.)

b. Summary of Opinions

1959. Market Definition. Dr. Scott Morton's analysis of test developers who are currently pursuing cancer screening tests capable of screening for more than one type of cancer

(which she refers to as the "multi-cancer early detection" market) is flawed. (RX3869 (Cote Expert Report) ¶ 15).

1960. It is undisputed that a purported "multi-cancer screening market" does not exist today. Only one multi-cancer screening test (GRAIL's Galleri test) is currently commercially available and only as a laboratory developed test ("LDT"). Therefore, it is speculative to predict what the cancer screening market will look like in the future, and how cancer screening tests currently in development (and other cancer screening tests that are yet to be developed) will compete with each other, if at all. (RX3869 (Cote Expert Report) ¶15); Cote Tr. 3727.)

1961. [redacted]

1962. [redacted]

1963. Dr. Scott Morton entirely omits consideration of the other features of cancer screening tests in describing the purported product market. But other features of cancer screening tests, such as their ability to detect a cancer signal of origin, are likely to affect which tests are considered substitutable by physicians. [redacted]; RX3869 (Cote Expert Report) ¶ 15); Cote Tr. 3782, [redacted])}

1964. Upstream Market. Dr. Scott Morton omits the fact that currently, there are several viable alternative NGS platforms for those cancer screening tests that are now in development, and as outlined further below, there are several more companies on the horizon, and likely even more once certain Illumina patents expire in 2023. (RX3869 (Cote Expert Report) ¶ 15); Cote Tr. 3739–43.)

1965. It is too speculative and indeed impossible to know at this time to know which provider's platforms will be relied on by cancer screening test developers at the time that such tests are actually commercially available, particularly at wide scale. (RX3869 (Cote Expert Report) ¶ 16.)

1966. [redacted]

1967. Given these long timeframes, all test developers pursuing cancer screening tests will have the option to switch to other clinical diagnostic platforms, including other NGS platforms, without meaningfully affecting timeframes for development and approval. It is common for test developers to need to switch between sequencing instruments offered by the same platform provider (*e.g.*, different Illumina platforms). Test developers are also able to develop a test in parallel on multiple platforms concurrently. Dr. Cote expects that test developers will be able to switch between different platforms under the same timelines as needed to switch between different Illumina instruments, especially as the platforms slated to launch in the United States in the next few years appear to use chemistry that is reasonably similar to Illumina's sequencing chemistry. (RX3869 (Cote Expert Report) ¶ 18); Cote Tr. 3727–28; 3771–74.)

1968. [redacted]

1969. [redacted]

1970. [redacted]

[redacted]

1971. In addition, Dr. Scott Morton's statement that only NGS-based tests may be used for "MCED" is incorrect. As noted, Dr. Scott Morton's contention that all cancer screening tests capable of simultaneously screening for more than one cancer are substitutable for each other is wrong. Further, while a screening test that will identify 50 types of cancer from a single blood sample that can also identify the cancer signal of origin is likely to use NGS technology, a screening test for fewer types of cancer, particularly two or three types of cancer, can use other diagnostic platforms, such as proteomics, PCR or microarray technology. Based on the evidence that he reviewed, Dr. Cote also anticipates that screening tests that detect fewer cancers are likely to complement a test that identifies 50 types of cancers from a single blood sample. For example, a physician may be interested in using a highly sensitive single cancer screening test for individuals with higher risk for that cancer, a view supported by Dr. Richard Abrams. Blood-based single cancer screening tests are also more likely to replace standard of care screening, whereas GRAIL has stated that its Galleri test would be in addition to guideline standard of care screening. (RX3869 (Cote Expert Report) ¶ 22); Cote Tr. 3777–83, 3807–08, **{3829–30.)}**

1972. The adoption of and reimbursement for a diagnostic test is influenced by a number of factors, that first of all rests on evidence-based clinical utility, and a variety of important stakeholders. In addition to public and private payors, any cancer screening test developer must attempt to persuade these stakeholders of the clinical utility of their test to achieve widespread adoption of their test. These stakeholders include health technology assessment ("HTA") and advisory bodies, patient advocacy groups, and medical specialty societies. Each of these stakeholders plays an integral role in shaping the treatment pathway and innovation of oncology, thereby influencing reimbursement coverage in addition to utilization of oncology tests and treatments. Given that development of blood-based cancer screening is in its infancy, and that there are likely to be vastly divergent approaches to cancer screening tests, it is likely to take significant time and resources to educate these groups about novel cancer screening testing technologies, particularly those capable of doing multi-cancer screening, *i.e.*, screening simultaneously for a large number of cancer types, like the Galleri test. (RX3869 (Cote Expert Report) ¶ 23).

1973. [redacted]

3. Patricia Deverka

a. Background

1974. Dr. Deverka is the Deputy Director of the Center for Translational and Policy Research on Personalized Medicine (TRANSPERS) at the University of California at San Francisco (UCSF) and a Senior Researcher in the School of Pharmacy at UCSF. TRANSPERS emphasizes interdisciplinary approaches to gather evidence about how genomic information is being integrated into clinical practice. She is also the Executive Director at Deverka Consulting, LLC with a practice focused on helping biotechnology companies and start-ups develop their evidence strategy to support payer coverage and clinical adoption of innovative technologies. Her most recent projects have focused on breakthrough tests and drugs focused on population genomic screening, cancer, and ultra-rare disorders. (RX3867 (Deverka Expert Report) ¶ 1); RX6001 (Deverka Trial Dep. at 7–8).)

1975. Dr. Deverka holds a Bachelor's degree in Biology from the University of Virginia, a medical degree from the University of Pittsburgh School of Medicine, a master's degree in Preventive Medicine from the University of Maryland and a master's degree in Bioethics from the University of Pennsylvania. Her residency training was in General Preventive Medicine and Public Health and she completed a mid-career policy fellowship at Duke University's Institute for Genome Sciences and Policy in 2007. (RX3867 (Deverka Expert Report) ¶ 2); RX6001 (Deverka Trial Dep. at 8–9).)

1976. During her professional career, Dr. Deverka worked in the fields of health economics and outcomes research in both non-profit and for-profit settings as a researcher, educator, and department head. From 1990–2004, she created and managed departments of outcomes research in both the pharmaceutical and pharmacy benefit management industries. After completing her policy fellowship at Duke, her career transitioned to academia where she spent several years as a Research Associate Professor at the University of North Carolina at Chapel Hill studying the evidence development pathway for the clinical integration of pharmacogenomics as a member of an interdisciplinary team. (RX3867 (Deverka Expert Report) ¶ 3); RX6001 (Deverka Trial Dep. at 10–15).)

1977. While working in academia and several non-profit firms from 2008–2020, Dr. Deverka participated in numerous NIH-funded studies to evaluate policy barriers to clinical integration of new genomic technologies and have published extensively on strategies to promote evidence generation, particularly in the areas of payer coverage for NGS-based tests. She is a member of the National Human Genome Research Institute (NHGRI)'s Genomic Medicine Work Group and serves as a member of NHGRI's Scientific Advisory Council. (RX3867 (Deverka Expert Report) ¶ 4); RX6001 (Deverka Trial Dep. at 15–16).)

1978. Dr. Deverka has published dozens of peer-reviewed articles in medical journals on the topics of payers' evidentiary framework for determining coverage for molecular diagnostics and patient engagement in comparative effectiveness research. She is a referee for a number of medical journals, including Health Affairs, Journal of the National Comprehensive Cancer Network, Journal of Clinical Oncology, Value in Health, Pharmacogenomics, Clinical Pharmacology and Therapeutics, Genetics in Medicine, Personalized Medicine, Journal of

Oncology Practice and the Journal of Comparative Effectiveness Research. She is also a member of the International Society of Pharmacoeconomics and Outcomes Research, a professional organization focused on promoting health economics and outcomes research excellence to improve healthcare decision-making. (RX3867 (Deverka Expert Report) ¶ 5); RX6001 (Deverka Trial Dep. at 22–23).)

b. Summary of Opinions

1979. [redacted]

1980. Developers of MCED tests may find it challenging to receive positive coverage determinations from public and private payors for several reasons. To inform payor decision-making, cancer screening test developers must provide robust evidence of how use of the test affects clinician decision-making and patient outcomes (clinical utility). Clinical utility studies will require large sample sizes due to the low prevalence of individual cancer types in the general population and the need to address concerns regarding the harms of false positives, lead-time bias, and overdiagnosis. These studies will also require sustained patient enrollment over several years to demonstrate significant differences in patient health outcomes for those identified with cancer. These studies must also compare early cancer screening tests to current standard of care cancer screening (including cancers for which the current standard of care (SOC) is no screening). (RX3867 (Deverka Expert Report) ¶ 10); RX6001 (Deverka Trial Dep. at 31–35).)

1981. The specific features of MCED tests that represent a potential paradigm shift for cancer screening also create complexities for demonstrating clinical utility to payors. There is no established evidentiary framework for evaluating a test that is designed to detect multiple cancers simultaneously, given varying benefits and harms by tumor type. While a simple blood draw may facilitate screening accessibility and compliance, the effects of MCED tests on patient and provider behavior and adherence to SOC screening are still unclear, complicating payor interpretation of clinical utility. (RX3867 (Deverka Expert Report) ¶ 11); RX6001 (Deverka Trial Dep. at 61–62).)

1982. Any new cancer screening test targeting all average risk adults ages 50–79 years requires compelling evidence of the risks and benefits resulting from test use. And while the FDA may be focused on evidence that test results accurately identify a patient's clinical status (clinical validity), payors will likely require convincing evidence of clinical utility to cover a new MCED test. This may represent an additional evidence hurdle beyond that set by regulatory authorities. (RX3867 (Deverka Expert Report) ¶ 12); RX6001 (Deverka Trial Dep. at 39–42).)

1983. MCED tests will not be able to receive Medicare coverage through standard coverage processes due to statutory limitations preventing Medicare from covering most preventive services. In order to receive Medicare coverage, manufacturers of these tests will have to either receive a U.S. Preventive Services Task Force (USPSTF) grade of A or B for their test, or wait for the passage of legislation that adds FDA-approved MCED tests as a Medicare benefit category. (RX3867 (Deverka Expert Report) ¶ 13); RX6001 (Deverka Trial Dep. at 48–52.)

1984. In order to receive Medicare reimbursement, MCED test manufacturers will also need to undergo a payment assignment process for a Medicare payment rate to be set for any new code. Time between initial code application and listing of a code's Medicare payment rate on the Clinical Lab Fee Schedule (CLFS) can take 9–23 months, depending on the code type and application cycle. (RX3867 (Deverka Expert Report) ¶ 14); RX6001 (Deverka Trial Dep. at 47–48.)

1985. Obtaining coverage by private payors will also require an assessment of affordability on top of clinical utility requirements. Because it is anticipated that potentially all average risk adults over the age of 50 would be eligible for MCED testing, private payors will face a sizeable budgetary impact if they choose to cover any MCED screening tests in addition to current SOC screening. Because payor assessment of a product's impact on health outcomes typically does not consider impact past one or two years, payors' coverage assessment may not fully consider the long-term clinical and economic benefits that may result from MCED screening (cost-effectiveness data). (RX3867 (Deverka Expert Report) ¶ 15); RX6001 (Deverka Trial Dep. at 36–39).)

1986. In addition, a substantial amount of resources, expertise, and experience (*e.g.*, payor and health system relationships, market access expertise, and investment in long-term prospective studies) will be essential to deliver robust evidence and engagement for payor decision-making. If successfully executed, this evidence would likely accelerate patient access to MCED tests. Over time, providing real-world evidence of the clinical utility of MCED tests could also potentially lower the barriers to market entry for additional MCED tests. (RX3867 (Deverka Expert Report) ¶ 16); RX6001 (Deverka Trial Dep. at 31–32).)

1987. Lack of payor coverage of MCED tests will be a barrier to patient access, particularly for vulnerable groups (*e.g.*, those with known disparities in access to cancer screening, treatment, and the resulting health outcomes). To ensure equitable access to MCED tests will require insurance coverage and ongoing evidence generation efforts that can be more rapidly achieved by a larger company with established expertise and the necessary resources. (RX3867 (Deverka Expert Report) ¶ 17); RX6001 (Deverka Trial Dep. at 55–56; 67–68).)

1988. [redacted]

[redacted] relationships with professional societies and advocacy groups that will be essential to ensuring MCED screening is appropriately integrated into screening recommendations and follow-up medical care. Given that the results of MCED tests will require tailored follow-up diagnostic procedures and cancer care referrals across tumor types, MCED test developers will need to engage with specialty medical societies and advocacy groups to properly educate clinicians regarding use and interpretation of MCED tests. (RX3867 (Deverka Expert Report) ¶ 19); RX6001 (Deverka Trial Dep. at 69–71).)

1990. [redacted]

4. **Margaret Guerin-Calvert**

a. Background

1991. Margaret E. 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. She is an industrial organization economist, which is the branch of economics that involves the study of firms, industries, consumer behavior, and pricing. She is also 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, and she continues to serve as Senior Consultant on selected Compass Lexecon matters. (RX3865 (Guerin-Calvert Expert Report) ¶ 1); RX6002 (Guerin-Calvert Trial Dep. at 7–8).)

1992. Guerin-Calvert has worked as an economist in public and private sectors on issues related to competition and competition policy involving a variety of industries since 1979. She served as Assistant Chief of the Economic Regulatory Section of the Antitrust Division, U.S. Department of Justice, where, among other matters, she had primary responsibility for healthcare matters, including market power and regulatory analyses. She also served as Economist at the Federal Reserve Board and as an AdjunFct Lecturer at Duke University Institute of Policy Sciences (now Sanford School of Public Policy). Guerin-Calvert has testified as an economic expert in several healthcare antitrust and class action cases, including matters involving branded

and generic pharmaceuticals and has served as expert for states, federal government, and private sector clients. As an economic expert, Guerin-Calvert testified on matters involving economic analysis of class certification, merits/liability, and damages, among other issues. Some of these matters involved economic analysis of remedies or consent decrees and their efficacy in addressing competitive concerns while permitting the Transaction. (*See*, e.g., *Federal Trade Commission, et al. v. Arch Coal, Inc., et al*. Case No.1:04CV00534 (JDB); Testimony before Pennsylvania Insurance Department regarding proposed affiliation between Highmark, Inc. and the West Penn Allegheny Health System (April 17, 2012); and Report (Economic Analysis Of Highmark's Affiliation with WPAHS and Implementation of an Integrated Healthcare Delivery System), April 2013). Guerin-Calvert's credentials and experience encompass more than three decades of work in antitrust and regulatory policy, including qualification as an expert economist in the U.S., Canada, and New Zealand, and almost 20 years in healthcare antitrust and policy. (RX3865 (Guerin-Calvert Expert Report) ¶ 2, App. A; RX6002 (Guerin-Calvert Trial Dep. at 7–17).)

b. Summary of Opinions

1993. The Open Offer's terms effectively address the concerns asserted by Complaint Counsel and Dr. Scott Morton that Illumina will have the incentive and ability to anticompetitively disadvantage GRAIL's rivals once Illumina re-acquires control of GRAIL. The Open Offer provides Illumina's clinical oncology customers with comprehensive, long-term protections against alleged foreclosure conduct (including raising rivals' costs), specifically, concerns about access, pricing, quality and rights to develop distributable in-vitro diagnostic ("IVD") kits on Illumina's FDA-regulated ("Dx") systems. (RX3865 (Guerin-Calvert Expert Report) ¶ 6); RX6002 (Guerin-Calvert Trial Dep. at 21–22).)

1994. The term "clinical oncology customers" includes any Illumina customer active in the development or commercialization of clinical oncology tests using Illumina's systems who meet the definition of "For-Profit Entity" in the Open Offer, including the entities that Dr. Scott Morton and Complaint Counsel have identified as rivals to GRAIL. (RX3865 (Guerin-Calvert Expert Report) ¶ 6, n. 5); RX6002 (Guerin-Calvert Trial Dep. at 26–27).)

1995. Guerin-Calvert's opinion is based on her independent evaluation of each of the major elements of the Open Offer. Individually and collectively the Open Offer covers the economically necessary set of terms to prevent the alleged competitive harm arising from the proposed Transaction, addresses the specific economic issues and concerns raised by Complaint Counsel and Dr. Scott Morton (primarily by referencing concerns raised by certain Illumina customers), and provides for effective monitoring and enforceability mechanisms. Specifically, the Open Offer covers all relevant aspects of the alleged competition concerns raised in both the short and long term, provides mechanisms to maximize compliance with those terms, and 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) ¶ 7); RX6002 (Guerin-Calvert Trial Dep. at 21–24).)

1996. The Open Offer provides for firewalls to protect from the dissemination of confidential information from Illumina's Next Generation Sequencing ("NGS") customers to GRAIL and misuse of such confidential information. Illumina commits to both structural

separations and policies that ensure against such information exchanges. These types of firewalls and protections have been implemented by the FTC (and other antitrust agencies or regulatory agencies) in vertical transactions with success, and these provisions can be effectively implemented. This supports the conclusion that the firewall provided for in the Open Offer also can be effective here in addressing concerns with anticompetitive information sharing. (RX3865 (Guerin-Calvert Expert Report) ¶ 8); RX6002 (Guerin-Calvert Trial Dep. at 79–85).)

1997. The Open Offer makes use of the same principles that have been implemented in practice with regard to enforcement mechanisms (e.g., incentives or mechanisms to enforce compliance or address issues). The audit and arbitration terms of the Open Offer provide Illumina's clinical oncology customers with effective oversight and enforcement mechanisms to ensure compliance with the Open Offer terms and to effectuate its purpose, i.e., ensuring the proposed Transaction will not harm innovation or result in higher prices as compared to the but-for world where Illumina does not re-acquire control of GRAIL. The very public aspect of the Open Offer can also bolster compliance. (RX3865 (Guerin-Calvert Expert Report) ¶ 9); RX6002 (Guerin-Calvert Trial Dep. at 86–92).)

1998. The firewall and audit terms in the Open Offer are not novel or unusual provisions. Regulatory agencies, including the FTC, and private parties use these types of compliance or reporting audits regularly in transactions and consent decrees concerning challenged transactions. Illumina has already worked to operationalize the procedures necessary to comply with and audit the Open Offer terms. (RX3865 (Guerin-Calvert Expert Report) ¶ 10); RX6002 (Guerin-Calvert Trial Dep. at 79–85).)

1999. Illumina also presented the FTC with a set of unilateral behavior commitments in the form of consent principles on February 26, 2021 ("Consent Principles"), which would grant the FTC oversight, monitoring, and access authority post-acquisition—all features commonly used by the FTC in remedial consent decrees. Specifically, the Consent Principles would (i) permit the FTC to appoint a monitor trustee, (ii) provide for submission of an annual verified written report to the FTC regarding Illumina's compliance with the Consent Principles, and (iii) grant FTC access to Illumina books, records, officers, directors and employees to determine or secure compliance with the Consent Principles. The Consent Principles provide additional evidence of Illumina's commitments to openness and compliance, which comport with the FTC's commonly accepted practice of putting in place such consent decrees. (RX3865 (Guerin-Calvert Expert Report) ¶ 11); RX6002 (Guerin-Calvert Trial Dep. at 95–98).)

2000. In addition to effectively codifying the pre-merger status quo, the Open Offer represents an improvement over the status quo for customers, based on the current provisions governing relationships, pricing, and access for customers (focusing in particular on those customers discussed in Dr. Scott Morton's report) compared to those in the Open Offer. (RX3865 (Guerin-Calvert Expert Report) ¶ 12); RX6002 (Guerin-Calvert Trial Dep. at 29–75).)

2001. The Open Offer terms provide commitments that did not exist prior to Illumina's announcement of the Transaction and which benefit Illumina's clinical oncology customers. For example, customers under the Open Offer are assured equivalent access to Supplied Products, access which will not favor GRAIL over other customers, including in times of scarce supply. The Open Offer also offers clinical oncology customers access to standard pricing, which for

many customers will be more favorable than current pricing terms. The Open Offer provides for customers to have the option to keep their pricing terms that are in effect as of the GRAIL Transaction ("Transaction") closing. These are relevant improvements. (RX3865 (Guerin-Calvert Expert Report) ¶ 13); RX6002 (Guerin-Calvert Trial Dep. at 34–48).)

> 2001.1 Supplied Products is defined in the Open Offer as Illumina's NextSeq, NextSeqDx and NovaSeq instruments, and any future sequencing instruments launched by Illumina or its Affiliates, or Sequencing Consumables, which are consumables intended by Illumina to be used to perform a sequencing process on any of these instruments. (RX3865 (Guerin-Calvert Expert Report) ¶ 13, n. 6).

2002. [redacted]

2003. [redacted]

Dr. Scott Morton also fails to evaluate the commitments in the Consent Principles, which provides monitoring and reporting commitments similar to many of the FTC's consent decrees in other matters. Dr. Scott Morton reaches her opinions based on an incorrect but-for world and post-Transaction world with the Open Offer that misstates the changes in incentives and ability of Illumina from the but-for world. She conducts no independent analysis of the specific terms or enforceability of the Open Offer and instead relies on selected testimony of third parties. These include testimony about potential unknown circumstances or the ability of contracts to cover all possible theoretical states of the world and contingencies, as well as speculation about theoretical ways Illumina could circumvent the Open Offer that she has not demonstrated are plausible or not addressed by the audit and arbitration mechanisms in the Open Offer. The Scott Morton report also provides inconsistent economic analyses of Illumina's supposed ability to reach complex contractual agreements with customers governing longer and shorter term risks and uncertainties, while asserting that the detailed provisions of the Open Offer governing multiple aspects of contracts are incomplete, inadequate, and unable to address customer issues. (RX3865 (Guerin-Calvert Expert Report) ¶ 15); RX6002 (Guerin-Calvert Trial Dep. at 103–105).)

2004. Complaint Counsel also asserts that the Open Offer is deficient in that it is not enforceable with regard to firewalls or compliance (audits), although Complaint Counsel and Dr. Scott Morton do not address the specific provisions of the Open Offer, provide evidence of non-enforceability or insufficiency of the terms, or distinguish use of firewalls in the multiple other matters in which the FTC (or other agencies) have used them. These are largely generalized concerns and statements of potential concerns and not detailed analysis of the

specifics of the Open Offer and how it might (and does) address them. Nor is Dr. Scott Morton consistent in the weight she places on third-party testimony. [redacted]

2005. The Open Offer provides for the Transaction's benefits to occur, which are lost if the Transaction is stopped. The Transaction occurs in a developing marketplace where there are no *a priori* assurances or guarantees about commercial outcomes or the identity or number of successful innovators. These factors are highly relevant to Illumina's incentives post-Transaction to continue to work with GRAIL's rivals and the protections afforded to them and to the assessment of the competitive effects of the Transaction with the Open Offer. They also are relevant to the standard principles applied in crafting remedies in vertical transactions or in private arrangements between vertically-aligned companies with multiple downstream companies, including in developing markets or ones with potentially many different outcomes—namely, of achieving the benefits of the Transaction while effectively addressing the competitive concerns. (RX3865 (Guerin-Calvert Expert Report) ¶ 17.)

5. **Robert Willig**

a. Background

2006. Robert Willig is a Professor of Economics and Public Affairs Emeritus at Princeton University, where he held a joint appointment in the Economics Department and at the Woodrow Wilson School of Public and International Affairs from 1978 to 2016, and continued to teach the graduate course "Legal and Regulatory Policy Toward Markets". His teaching and research have specialized in the fields of industrial organization (the field that includes antitrust), government-business relations, and social welfare theory. He served as Deputy Assistant Attorney General for Economics in the Antitrust Division of the U.S. Department of Justice from 1989 to 1991, and in that capacity served as the Division's Chief Economist. (RX3871 (Willig Expert Report) ¶ 1.)

2007. Mr. Willig authored some 80 articles in the economics literature and is the author of "Welfare Analysis of Policies Affecting Prices and Products" and "Contestable Markets and the Theory of Industry Structure" (with W. Baumol and J. Panzar). He is also a co- editor of "The Handbook of Industrial Organization", which summarizes the state of economic thinking on the structure of industries and the nature of competition among firms, and has served on the editorial boards of the American Economic Review, the Journal of Industrial Economics, and the MIT Press Series on Regulation. He is an elected Fellow of the Econometric Society and was an associate of The Center for International Studies. (RX3871 (Willig Expert Report) ¶ 2.)

2008. Mr. Willig appeared as an expert witness before Congress, federal and state courts, federal administrative agencies, and state public utility commissions on subjects involving competition, regulation, intellectual property rights, and antitrust. He also served as a consultant to the Federal Trade Commission, the U.S. Department of Justice, OECD, the World Bank, the Inter-American Development Bank and many leading corporations on antitrust,

regulation, and economic policy issues arising in a wide variety of industries in the United States and around the world. (RX3871 (Willig Expert Report) ¶ 3.)

b. Summary of Opinions

2009. Alleged Relevant Market. Prof. Scott Morton has failed to define the relevant product market reliably. (RX3871 (Willig Expert Report) ¶ 6.)

2010. Prof. Scott Morton's methodology is speculative because it is based on projections about the highly uncertain characteristics of products that are years away from being commercialized and on projections about the identities of competitors whose products are uncertain. (RX3871 (Willig Expert Report) ¶ 6).

2011. [redacted]

2012. Prof. Scott Morton ignores the conduct and influence of payors when defining the relevant product market. Including them in the analysis shows that Prof. Scott Morton has failed to establish that existing cancer screening methods should be excluded from the relevant product market. (RX3871 (Willig Expert Report) ¶ 6.)

2013. Timing is a key dimension of the putative MCED test product market because the claimed "related product", namely Illumina's NGS platform, is part of a highly dynamic market subject to its own important changes over time. The timing of the putative MCED test products is highly uncertain and Prof. Scott Morton has not established that their purported market will come into existence with all or most of the products and rivals of GRAIL identified by Prof. Scott Morton at a time when there may be no viable alternative to the related product supplied by Illumina. (RX3871 (Willig Expert Report) ¶ 6.)

2014. Alleged Anticompetitive Effects. Complaint Counsel's theories of anticompetitive effects are belied by the actions of firms in the marketplace. (RX3871 (Willig Expert Report) ¶ 7.)

2015. Complaint Counsel's theory undergirding the proposed merger's purported anticompetitive effects presupposes that there will be no viable substitutes to Illumina's NGS platforms to which GRAIL's potential competitors in the purported MCED test relevant market could readily switch in response to Illumina increasing its prices or engaging in foreclosure. (RX3871 (Willig Expert Report) ¶ 7.)

2016. Complaint Counsel's presupposition is inherently speculative. Multiple companies are developing NGS platforms that they expect will effectively compete with Illumina's NGS platform within the next several years. This is relevant because many of the companies that Complaint Counsel has identified as GRAIL's potential MCED test rivals do not

expect to finish developing and commercializing their MCED tests for at least several years. (RX3871 (Willig Expert Report) ¶ 7.)

2017. [redacted]

2018. Illumina's willingness to pay $8.3 billion for the outstanding shares of GRAIL also would not make economic sense if Illumina expected that it would be able to extract most of the returns from GRAIL's sales of NGS-based cancer screening tests, including Galleri, by then increasing the prices of the essential NGS platforms that it would sell to GRAIL. Thus, Illumina's willingness to pay such a large sum for GRAIL strongly suggests that Illumina expects its ability to raise prices substantially in the future will be constrained. This conclusion is further supported by the underlying assumptions driving Illumina's valuation of GRAIL, which have GRAIL earning a much larger share of the total profits from sales of its MCED tests than Illumina throughout the period analyzed in the valuation model (which ends in 2035). (RX3871 (Willig Expert Report) ¶ 7.)

2019. Bargaining. Prof. Scott Morton's analysis of the impact of the proposed acquisition through the economic theory of bargaining or negotiation is flawed and fails to establish that the proposed transaction would substantially lessen competition. (RX3871 (Willig Expert Report) ¶ 8.)

2020. Prof. Scott Morton's bargaining example is based on a model that is unrelated to the key characteristics of the market that she and Complaint Counsel otherwise assume. (RX3871 (Willig Expert Report) ¶ 8.)

2021. Even more striking is the fact that Prof. Scott Morton's conclusions within her own analytic frame are completely reversed with the addition of only one additional element—namely the availability of either an alternative upstream source or an ex ante supply agreement offer. (RX3871 (Willig Expert Report) ¶ 8.)

6. Robert Rock

a. Background

2022. Robert Rock is a Managing Director at AlixPartners, LLP ("AlixPartners"). He has been with AlixPartners for approximately 27 years. Prior to joining AlixPartners, he was with Price Waterhouse for 18 years. During his last seven years at Price Waterhouse, he was a partner. (RX3870 (Rock Expert Report) ¶ 1; RX6003 (Rock Trial Dep. at 9).)

2023. Mr. Rock has a bachelor's degree in business administration with a concentration in accounting and an MBA from the University of Michigan. He has been a Certified Public Accountant since 1978. (RX3870 (Rock Expert Report) ¶ 2; RX6003 (Rock Trial Dep. at 8–9).)

2024. While he was at Price Waterhouse, he directed audit engagements of public and private companies and provided professional business consulting services to companies in a variety of industries. (RX3870 (Rock Expert Report) ¶ 3.);

2025. His current practice areas at AlixPartners include investigative/forensic accounting, business consulting, and litigation consulting in commercial matters. He has testified as an expert witness in many cases. (RX3870 (Rock Expert Report) ¶ 4; RX6003 (Rock Trial Dep. at 10–11).)

2026. Mr. Rock has been engaged by the U.S. Department of Justice and the Securities and Exchange Commission as a litigation consultant or expert witness on numerous matters. In addition, he has been appointed as a Receiver, Arbitrator, Special Master or Funds Custodian by federal judges in seven different matters. (RX3870 (Rock Expert Report) ¶ 5; RX6003 (Rock Trial Dep. at 10–11).)

b. Summary of Opinions

2027. An independent auditor or consultant can be effective in examining an entity's compliance with various terms of contracts, performing agreed-upon procedures related to an entity's compliance with specified terms, and performing agreed-upon procedures related to an entity's internal controls over compliance with specified terms. (RX3870 (Rock Expert Report) ¶ 11; RX6003 (Rock Trial Dep. at 29–30).)

7. Richard Abrams

a. Background

2028. Dr. Richard S. Abrams is a primary care physician and founder of Colorado Preventative Medicine, where he has practiced Internal Medicine. He is also affiliated with the Rose Medical Center. He also serves on the clinical faculty at the University of Colorado School of Medicine. Dr. Abrams holds a Bachelor's Degree from Northwestern University and a Doctorate of Medicine from the University of Missouri School of Medicine (Columbia). In addition, he currently serves on GRAIL, Inc.'s ("GRAIL") clinical advisory board, where he has served as a thought partner. (PX6097 (Abrams Expert Report) ¶ 1; Abrams Tr. 3601–02.)

2029. Dr. Abrams has been a primary care physician at Colorado Preventative Medicine since 2006, when the health organization was first founded. Before founding Colorado Preventative Medicine, he practiced as an internist focusing on preventive medicine. (PX6097 (Abrams Expert Report) ¶ 2; Abrams Tr. 3605–06.)

2030. Dr. Abrams has written and edited several books and numerous articles on medical problems during pregnancy, including *Will It Hurt the Baby*, which was featured on the NBC Today Show, ABC Good Morning America, and CBS This Morning. He is board certified in Internal Medicine. (PX6097 (Abrams Expert Report) ¶ 3.)

2031. 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) ¶ 4; Abrams Tr. 3602; 3605–06.)

b. Summary of Opinions

2032. In summary, Dr. Abrams concluded that primary care physicians play a key role in cancer screening today and will be primarily responsible for recommending MCED tests as they become commercially available and reimbursable in the future. (PX6097 (Abrams Expert Report) ¶ 10; Abrams Tr. 3613–15.)

2033. Primary care physicians will consider a variety of factors when recommending or ordering a cancer screening test, including the patient's risk factors for a particular cancer, the cancers that the test will be able to detect, the test specificity and sensitivity and other capabilities of the test, the cost of the test to the patient, the health risks associated with the test (*e.g.*, the invasiveness of the test, exposure to radiation, and other considerations), as well as published research studies that support the validity of the test. Primary care physicians will consider these factors when recommending or prescribing a multi-cancer screening test and will also need to decide whether any given multi-cancer screening test can be used as a substitute for or complement to other screening options. (PX6097 (Abrams Expert Report) ¶ 10; Abrams Tr. 3614–15.)

2034. Although the technology is still in the early stages of development, the most important attributes of an MCED test for primary care physicians will be a test's ability to detect the presence of a cancer and site of origin, the number of cancers detected, and the opportunity to treat early-stage cancer. Primary care physicians will also likely consider the cost to patients of prescribing a given multi-cancer screening test as compared to other multi-cancer and single-cancer options. The attributes that weigh most heavily will vary based on a patient's particular risk factors and may in some cases support the use of complementary screening tests. For example, it may be appropriate for a patient at a higher risk of lung cancer to be screened with a test that has demonstrated high sensitivity and specificity for lung cancer in conjunction with a multi-cancer screening test that is appropriate for asymptomatic individuals. (PX6097 (Abrams Expert Report) ¶ 10; Abrams Tr. 3623–28.)

2035. [redacted]

2036. [redacted]

2037. [redacted]

2038. [redacted]

2039. It is difficult to predict what options there will be for early cancer screening in the future. Dr. Abrams can evaluate what factors will likely be relevant to him as a primary care physician in selecting and using a screening test, but he cannot evaluate whether any particular test will be a viable option several years from now or what new tests may be developed. (PX6097 (Abrams Expert Report) ¶ 10; Abrams Tr. 3639–40.)

8. **Michael L. Katz**

a. Background

2040. Michael L. Katz is the Sarin Chair Emeritus in Strategy and Leadership at the University of California at Berkeley. He holds a joint emeritus appointment in the Haas School of Business Administration and in the Department of Economics. He also served on the faculties of the Department of Economics at Princeton University and the Stern School of Business at New York University. Dr. Katz received his A.B. from Harvard University *summa cum laude* and a doctorate from Oxford University. Both degrees are in Economics. (PX6105 (Katz Expert Report) ¶ 2; RX6004 (Katz Trial Dep. at 8–9).)

2041. Dr. Katz specializes in the economics of industrial organization, which includes the study of antitrust and regulatory policies. He is the co-author of a microeconomics textbook, and has published numerous articles in academic journals and books. He has written academic articles on issues regarding the economics of network industries, intellectual property, and antitrust policy enforcement, including the antitrust economics of healthcare. He is also a co-editor of the Journal of Economics and Management Strategy and serves on the editorial board of Information Economics and Policy. (PX6105 (Katz Expert Report) ¶ 3; RX6004 (Katz Trial Dep. at 10–11).)

2042. In addition to his academic experience, Dr. Katz has held several positions in government. From January 1994 through January 1996, he served as the Chief Economist of the Federal Communications Commission. From September 2001 through January 2003, he served as the Deputy Assistant Attorney General for Economic Analysis at the U.S. Department of Justice. His title as Deputy Assistant Attorney General notwithstanding, he is not an attorney. Dr. Katz is currently a Senior Fellow in the Office of Healthcare Transformation in the Ministry of Health of Singapore. (PX6105 (Katz Expert Report) ¶ 4; RX6004 (Katz Trial Dep. at 11–12).)

2043. Dr. Katz has consulted on the application of economic analysis to issues of antitrust and regulatory policy for both private and governmental clients. He has served as a consultant to the U.S. Department of Justice, U.S. Federal Trade Commission (including the review of three mergers regarding healthcare products and care providers), and U.S. Federal Communications Commission on competition issues, and he has served as an expert witness before state and federal courts. He has also provided expert testimony before state regulatory commissions and the U.S. Congress. (PX6105 (Katz Expert Report) ¶ 5; RX6004 (Katz Trial Dep. at 11–13).)

b. Summary of Opinions

2044. Alleged Relevant Market. Prof. Scott Morton has failed to define the relevant product market reliably. (RX3871 (Willig Expert Report) ¶ 6); PX6105 (Katz Expert Report) ¶ 9; RX6004 (Katz Trial Dep. at 15).)

2045. Prof. Scott Morton's methodology is speculative because it is based on projections about the highly uncertain characteristics of products that are years away from being commercialized and on projections about the identities of competitors whose products are uncertain. (RX3871 (Willig Expert Report) ¶ 6; RX6004 (Katz Trial Dep. at 17–26).)

2046. [redacted]

2047. Prof. Scott Morton ignores the conduct and influence of payors when defining the relevant product market. Including them in the analysis shows that Prof. Scott Morton has failed to establish that existing cancer screening methods should be excluded from the relevant product market. (RX3871 (Willig Expert Report) ¶ 6; RX6004 (Katz Trial Dep. at 31–34).)

2048. Timing is a key dimension of the putative MCED test product market because the claimed "related product", namely Illumina's NGS platform, is part of a highly dynamic market subject to its own important changes over time. The timing of the putative MCED test products is highly uncertain and Prof. Scott Morton has not established that their purported market will come into existence with all or most of the products and rivals of GRAIL identified by Prof. Scott Morton at a time when there may be no viable alternative to the related product supplied by Illumina. (RX3871 (Willig Expert Report) ¶ 6; [redacted]

2049. Alleged Anticompetitive Effects. The Complaint Counsel's theories of anticompetitive effects are belied by the actions of firms in the marketplace. (RX3871 (Willig Expert Report) ¶ 7; RX6004 (Katz Trial Dep. at 36; [redacted]

2050. Complaint Counsel's theory undergirding the proposed merger's purported anticompetitive effects presupposes that there will be no viable substitutes to Illumina's NGS platforms to which GRAIL's potential competitors in the purported MCED test relevant market could readily switch in response to Illumina increasing its prices or engaging in foreclosure. (RX3871 (Willig Expert Report) ¶ 7; RX6004 (Katz Trial Dep. at 42–48).)

2051. Complaint Counsel's presupposition is inherently speculative. Multiple companies are developing NGS platforms that they expect will effectively compete with Illumina's NGS platform within the next several years. This is relevant because many of the companies that Complaint Counsel has identified as GRAIL's potential MCED test rivals do not expect to finish developing and commercializing their purported MCED tests for at least several years. (RX3871 (Willig Expert Report) ¶ 7; PX6105 (Katz Expert Report) ¶ 9.)

2052. [redacted]

2053. [redacted]

2054. Bargaining. Prof. Scott Morton's analysis of the impact of the proposed acquisition through the economic theory of bargaining or negotiation is flawed and fails to establish that the proposed transaction would substantially lessen competition. (RX3871 (Willig Expert Report) ¶ 8; RX6004 (Katz Trial Dep. at 53–58).)

2055. Prof. Scott Morton's bargaining example is based on a model that is unrelated to the key characteristics of the market that she and Complaint Counsel otherwise assume. (RX3871 (Willig Expert Report) ¶ 8; RX6004 (Katz Trial Dep at 54–56).)

2056. Even more striking is the fact that Prof. Scott Morton's conclusions within her own analytic frame are completely reversed with the addition of only one additional element—namely the availability of either an alternative upstream source or an ex ante supply agreement offer. (RX3871 (Willig Expert Report) ¶ 8; RX6004 (Katz Trial Dep at 56–58).)

E. Complaint Counsel's Experts

1. Fiona Scott Morton

a. Background

2057. Dr. Fiona 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.)

2058. [redacted]

2059. [redacted]

2060. [redacted]

2061. [redacted]

2062. [redacted]

2063. [redacted]

a. Opinions

2064. [redacted]

2065. [redacted]

2065.1 [redacted]

2065.2 [redacted]

2065.3 [redacted]

2065.4 [redacted]

2065.5 [redacted]

2066. [redacted]

2066.1 [redacted]

2066.2 [redacted]

2066.3 [redacted]

2066.4 [redacted]

2066.5 [redacted]

2066.6 [redacted]

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2068.1 [redacted]

2068.2 [redacted]

[redacted]

2069. [redacted]

2069.1 [redacted]

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2083.1 [redacted]

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2099. [redacted]

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2099.6 [redacted]

2099.7 [redacted]

2099.8 [redacted]

2099.9 [redacted]

2100. [redacted]

2101. [redacted]

2101.1 [redacted]

2101.2 [redacted]

2101.3 [redacted]

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[redacted]

2102.1 [redacted]

2102.2 [redacted]

2103. [redacted]

2104. [redacted]

2105. [redacted]

2106. [redacted]

2106.1 [redacted]

2106.2 [redacted]

2106.3 [redacted]

2106.4 [redacted]

2107. [redacted]

2108. [redacted]

2109. [redacted]

2110. [redacted]

2111. [redacted]

2111.1 [redacted]

2112. [redacted]

2113. [redacted]

2114. [redacted]

2115. [redacted]

2116. [redacted]

[redacted]

2117. [redacted]

2118. [redacted]

2119. [redacted]

2120. [redacted]

2120.1 [redacted]

2120.2 [redacted]

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2127.1 [redacted]

2127.2 [redacted]

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2132. [redacted]

2132.1 [redacted]

2132.2 [redacted]

2132.3 [redacted]

2132.4 [redacted]

2132.5 [redacted]

2132.6 [redacted]

2132.7 [redacted]

2132.8 [redacted]

2132.9 [redacted]

2132.10 [redacted]

2133. [redacted]

2134. [redacted]

2135. [redacted]

2136. [redacted]

2136.1 Dr. Scott Morton repeatedly weighs the evidence in the course of offering her opinions here. (RX3852 (Scott Morton Dep. at 193, 212).) [redacted] She also takes at face value the FTC's arguments and disregards efficiencies sworn to by Illumina fact witnesses. (RX3852 (Scott Morton, Dep. at 242) ("Q. . . . No one has shared with you any deposition testimony concerning supply chain and operational efficiencies expected because of the transaction; correct? A. I asked for everything important. Therefore, there isn't anything of importance for my report that falls in the category you are talking about, or I would've seen it.").)

2. **Amol Navathe**

a. Background

2137. [redacted]

2138. Dr. Navathe's research focuses on health economics. (PX7139 (Navathe Trial Dep. at 9.)

b. Opinions

2139. Acceleration of Reimbursement. [redacted]

2140. Dr. Navathe is not an expert on FDA evaluation of MCED tests, including Galleri. (PX7139 (Navathe Trial Dep. at 97–99.)

2141. Dr. Navathe lacks expertise on subjects relevant to concluding that the transaction will not accelerate payer reimbursement and approval of Galleri. (PX7139 (Navathe Trial Dep. at 98–102.)

2142. Dr. Navathe does not have any experience in obtaining FDA approval for any product, including building and supervising a team seeking FDA approval or analyzing a company's capability to get FDA approval. (PX7139 (Navathe Trial Dep. at 101.)

2143. Dr. Navathe does not have any experience in seeking premarket authorization from the FDA for any product. (PX7139 (Navathe Trial Dep. at 101.)

2144. Dr. Navathe has never built a team to seek payor coverage for a medical diagnostic. (PX7139 (Navathe Trial Dep. at 106.)

2145. Dr. Navathe has never supervised a team working on seeking payor coverage for a medical diagnostic. (PX7139 (Navathe Trial Dep. at 106.)

2146. Dr. Navathe has never helped a manufacturer of a medical diagnostic test generate evidence to obtain payor coverage. (PX7139 (Navathe Trial Dep. at 106.)

2147. Dr. Navathe has never analyzed a company's capability to get payor coverage for a medical diagnostic test. (PX7139 (Navathe Trial Dep. at 106–07.)

2148. Dr. Navathe does not have any experience with coverage decisions for medical diagnostics, including MCED tests. (PX7139 (Navathe Trial Dep. at 107)

2149. [redacted]

2150. Dr. Navathe agrees that to commercialize Galleri at scale so that it becomes widely available to large numbers of Americans, Galleri will need to achieve FDA approval, Medicare coverage and private payer coverage. (PX7139 (Navathe Trial Dep. at 118.)

2151. Dr. Navathe admits facts establishing that GRAIL will have difficulty obtaining payer coverage and approval without the benefit of Illumina's payer experience.

2152. [redacted]

2153. [redacted]

2154. [redacted]

2155. [redacted]

2156. [redacted]

2157. [redacted]

2158. [redacted]

2159. [redacted]

2160. [redacted]

2161. [redacted]

2162. Dr. Navathe testified to facts showing that, absent the transaction, there is no guarantee that GRAIL will obtain payer coverage of Galleri at the same time or earlier than it would with completion of the transaction.

2163. [redacted]

2164. [redacted]

2165. [redacted]

2166. [redacted]

2167. [redacted]

2168. [redacted]

2169. [redacted]

2170. Dr. Navathe did not reach independent conclusions about whether the transaction will accelerate approval of Galleri.

2171. [redacted]

2172. [redacted]

2173. [redacted]

2174. [redacted]

2175. [redacted]

2176. [redacted]

2176.1 [redacted]

2177. [redacted]

[redacted]

2178. Value of Lives Saved. Dr. Navathe asserts that Dr. Carlton's analysis of the value of lives saved from the purported acceleration of Galleri is flawed and unreliable.

2179. [redacted] holding all other factors constant, if more Galleri tests are conducted, more cancers will be found at earlier stages, (PX7139 (Navathe Trial Dep. at 136); if FDA approval for Galleri, Medicare reimbursement for Galleri and private payer coverage for Galleri were accelerated such that the use of Galleri at scale in the United States were accelerated, more patients would have access to Galleri than if those things didn't occur. (PX7139 (Navathe Trial Dep. at 136.)

2180. [redacted]

2181. Dr. Navathe claims that Dr. Carlton's use of the VSL methodology is not used as a professional standard in health economics, but Dr. Navathe admits that the Department of Health and Human Services Guidelines for Regulatory Impact Analysis approach for valuing mortality risk reductions includes the use of value per statistical life. (PX7139 (Navathe Trial Dep. at 143.)

2182. Dr. Navathe lacks key information concerning scholarly usage of the VSL methodology.

2183. Dr. Navathe was not aware of the Department of Health and Human Services guideline on the use of value per statistical life for valuing mortality risk reductions at the time he drafted his report. (PX7139 (Navathe Trial Dep. at 145.)

2184. Dr. Navathe was not aware of the Food and Drug Administration's Mammography Quality Standards Act: Amendments to Part 900 Regulations that used the value per statistical life approach to value reduced mortality as well as breast cancer treatment costs at the time that he drafted his report. (PX7139 (Navathe Trial Dep. at 146–49.)

2185. [redacted]

3. Dov Rothman

a. Background

2186. Dr. Dov Rothman is the Managing Principal of Analysis Group, Inc., and has previously provided expert testimony on matters involving commercial health insurers, hospital, physicians and pharmaceuticals. (PX7140 (Rothman Trial Dep. at 7, 9.)

2187. Dr. Rothman is not an expert in FDA approval, (PX7140 (Rothman Trial Dep. at 42–43); payer reimbursement, (PX7140 (Rothman Trial Dep. at 45); medical technology risk-sharing agreements, (PX7140 (Rothman Trial Dep. at 45–46); medical device collaborations, (PX7140 (Rothman Trial Dep. at 46); [redacted]

2188. Dr. Rothman does not have any prior experience analyzing the efficiencies of vertical mergers. (PX7140 (Rothman Trial Dep. at 42.)

b. Opinions

2189. Efficiencies. Dr. Rothman asserts that Respondents' experts have not adequately substantiated that the transaction will accelerate FDA and payer approval of Galleri or create research and development and supply chain and operational efficiencies.

2190. Dr. Rothman opines that efficiencies must be able to be verified by reasonable means and relied only on the FTC's and DOJ's Horizontal Merger Guidelines and Vertical Merger Guidelines as support, (PX7140 (Rothman Trial Dep. at 54–57), but Dr. Rothman acknowledges issues attendant to his asserted efficiencies verification standard.

2190.1 Dr. Rothman admits that neither the Vertical Merger Guidelines or the Horizontal Merger Guidelines use the phrase "reasonable means". (PX7140 (Rothman Trial Dep. at 58–59, 64).

2190.2 Dr. Rothman concedes that the FTC withdrew the Vertical Merger Guidelines after Dr. Rothman's report was submitted. (PX7140 (Rothman Trial Dep. at 60.)

2190.3 Dr. Rothman agrees that the Vertical Merger Guidelines do not dictate to a court how to assess the efficiencies of a vertical merger. (PX7140 (Rothman Trial Dep. at 62.)

2190.4 Dr. Rothman admits that verification of an efficiency by reasonable means does not mean defining the specific dollar amount of the efficiency. (PX7140 (Rothman Trial Dep. at 67.)

2190.5 Dr. Rothman concedes that the Vertical Merger Guidelines and the Horizontal Merger Guidelines do not require that costs to achieve an efficiency have to be specified by a specific dollar amount. (PX7140 (Rothman Trial Dep. at 67.)

2190.6 Dr. Rothman agrees that the Vertical Merger Guidelines and the Horizontal Merger Guidelines do not provide a precise timeline for when parties need to establish an efficiency in order for the efficiency to be cognizable. (PX7140 (Rothman Trial Dep. at 67.)

2190.7 [redacted]

2191. Dr. Rothman is not offering an opinion as to whether Respondents' support for the asserted efficiencies satisfies the relevant legal burden of proof. (PX7140 (Rothman Trial Dep. at 62–63); [redacted]

2192. [redacted]

2193. Acceleration of Galleri. Dr. Rothman asserts that Respondents' experts have not adequately substantiated that the transaction will accelerate FDA and payer approval of the Galleri test.

2194. Dr. Rothman lacks expertise on subjects relevant to determining whether the transaction will accelerate FDA and payer approval of Galleri.

2194.1 Dr. Rothman is not an expert in FDA approval. (PX7140 (Rothman Trial Dep. at 42–43.)

2194.2 Dr. Rothman is not an expert in payer reimbursement. (PX7140 (Rothman Trial Dep. at 45.)

2194.3 Dr. Rothman is not an expert in medical technology risk-sharing agreements. (Rothman, Tr. 45–46.)

2194.4 Dr. Rothman is not an expert in medical device evidence generating collaborations. (Rothman, Tr. 46.)

2194.5 [redacted]

2194.6 [redacted]

2194.7 Dr. Rothman lacks experience with medical device evidence generation and medical technology risk-sharing agreements. (PX7140 (Rothman Trial Dep. at 46.)

2195. [redacted]

[redacted]

2196. [redacted]

2197. [redacted]

2198. [redacted]

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2199.1 [redacted]

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2203. [redacted]

2204. [redacted]

[redacted]

2205. [redacted]

2206. [redacted]

RESPONDENTS' PROPOSED CONCLUSIONS OF LAW

I. LEGAL STANDARD AND BURDEN OF PROOF

1. Complaint Counsel seeks an injunction unwinding the reunion of Illumina and GRAIL under Section 7 of the Clayton Act. (Compl. at 28.)

2. Complaint Counsel bears "the burden on every element of their Section 7 challenge." *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 116 (D.D.C. 2004).

3. Complaint Counsel's "failure of proof in any respect will mean the transaction should not be enjoined." *Arch Coal*, 329 F. Supp. 2d at 116.

4. To prove a violation of the Clayton Act, Complaint Counsel must show that, "notwithstanding the merger's [] procompetitive effects, [it] has met its burden of proof of establishing" that the merger of Illumina and GRAIL, "at this time and in this remarkably dynamic industry, is likely to substantially lessen competition in the manner it predicts." *U.S. v. AT&T* (*AT&T I*), 310 F. Supp. 3d 161, 194 (D.D.C. 2018).

5. Although Section 7 requires "making a prediction about the future", and deals with probabilities, *id.* at 189–91, it does not permit blocking a merger based on speculative "possibilities", *id.*, or "guesswork", and it does not permit ignoring the actual facts. *FTC v. AG-Stiftung*, 436 F. Supp. 3d 278, 311 (D.D.C. 2020) ("[A]ntitrust theory and speculation cannot trump facts, and even Section 13(b) cases must be resolved on the basis of the record evidence relating to the market and its probable future." (quoting *FTC v. Arch Coal*, 329 F. Supp. 2d 109, 116–17 (D.D.C. 2004))).

6. Complaint Counsel must therefore prove that "the challenged acquisition [is] *likely* substantially to lessen competition." *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 115 (D.D.C. 2004) (emphasis added); *see United States v. Marine Bancorp.*, 418 U.S. 602, 623 n.22 (1974) (alleged future harm to competition must be "sufficiently probable and imminent" to warrant relief); *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1109 (N.D. Cal. 2004) (rejecting merger challenge because government failed to prove the "merger will *likely* lead to a substantial lessening of competition") (emphasis added); *In re Altria Grp., Inc.*, FTC No. 9393, at 110 (Feb. 15, 2022) (citing *Mercantile Tex. Corp. v. Bd. of Governors of Fed. Rsrv. Sys.*, 638 F.2d 1255, 1272 (5th Cir. 1981) ("The competitive conditions of a market five years in the future cannot reliably be predicted."); *see also FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1051 (8th Cir. 1999) ("Section 7 deals in probabilities not ephemeral possibilities.").

7. Because the Transaction is purely vertical, Complaint Counsel "cannot use a short cut to establish a presumption of anticompetitive effect"; rather, it must make a "fact-specific" showing that the Transaction is anticompetitive. *United States v. AT&T, Inc.*, 916 F.3d 1029, 1032 (D.C. Cir. 2019); *see also Republic Tobacco Co. v. North Atl. Trading Co.*, 381 F.3d 717, 737 (7th Cir. 2004) ("As horizontal agreements are generally more suspect than vertical agreements, we must be cautious about importing relaxed standards of proof from horizontal agreement cases into vertical agreement cases. To do so might harm competition and frustrate the very goals that antitrust law seeks to achieve.").

8. Complaint Counsel cannot prove that the merger is likely to substantially lessen competition absent a showing that it would likely result in anticompetitive harm that substantially outweighs the efficiencies reasonably likely to result from the Transaction.

9. Complaint Counsel cannot sustain its burden merely by showing that the Transaction may disadvantage some of GRAIL's putative rivals vis-à-vis GRAIL—for example, as a result of GRAIL becoming a more efficient competitor through vertical integration—because "[t]he antitrust laws . . . were enacted for the protection of competition not competitors." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977). Rather, Complaint Counsel must demonstrate that GRAIL rivals would be foreclosed "in a substantial share" of a well-defined relevant product market, enabling Illumina to suppress innovation and output, and raise prices. *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 595 (1957); *see also Fruehauf Corp. v. FTC,* 603 F.2d 345, 352 n.9 (2d Cir. 1979); *McWane Inc. v. FTC*, 783 F.3d 814, 838–39 (11th Cir. 2015).

II. COMPLAINT COUNSEL FAILED TO PROVE THE REQUISITE ANTITRUST MARKETS

A. Complaint Counsel Failed To Prove Its Alleged Relevant Market

10. Defining the relevant market is a "necessary predicate" to finding a Clayton Act violation because the statute proscribes only mergers that "will substantially lessen competition within the area of effective competition." *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 593 (internal quotations omitted); *see United States v. Baker Hughes Inc.*, 908 F.2d 981, 982 (D.C. Cir. 1990) (government must show "that a transaction will lead to undue concentration in the market for a particular product"). Defining a relevant market is necessary because the scope of the relevant market dictates the analysis of market power and a merger's potential anticompetitive effects. *See United States v. Sungard Data Sys., Inc.*, 172 F. Supp. 2d 172, 181 (D.D.C. 2001).

11. Complaint Counsel "bears the burden of proof and persuasion in defining the relevant market." *Arch Coal*, 329 F. Supp. 2d at 118. If it is unable to carry that burden, then the its case fails. *FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 291 (D.D.C. 2020) ("Defining the relevant market is a necessary predicate to finding a Clayton Act violation because the proposed merger must be one which will substantially lessen competition within the area of effective competition.") (citations and quotations omitted); *see also Determined Prods. v. R. Dakin Co.*, 514 F. Supp. 645, 648 (N.D. Cal. 1979), *aff'd*, 649 F.2d 866 (9th Cir. 1981) ("Plaintiff must [] come forward with evidence of the relevant market. Failure to do so entitles defendant to judgment.").

12. Here, Complaint Counsel's alleged market fails for five, independent reasons: (1) it is impermissibly speculative and simultaneously over- and under-inclusive; (2) it disregards "reasonable interchangeability and cross-elasticity of demand"; (3) it runs counter to the Supreme Court's *Brown Shoe* factors; (4) it flunks the Hypothetical Monopolist Test; and (5) it depends on the agency's subjective and changing policy assessments, rather than established law and objective evidence.

1. The Alleged Relevant Market Is Impermissibly Speculative and Simultaneously Over- and Under-Inclusive

13. To meet its burden, Complaint Counsel was required to adduce admissible evidence proving its alleged relevant market, not mere speculation. *See Reifert v. S. Cent. Wisconsin MLS Corp.*, 450 F.3d 312, 318 (7th Cir. 2006) ("a conclusory assumption of competition where products or services appear to be similar is insufficient" to prove a relevant product market); *Arch Coal*, 329 F. Supp. 2d at 117 (D.D.C. 2004) ("[A]ntitrust theory and speculation cannot trump facts"). It was also required to draw a market that was neither over- nor under-inclusive. *See Arch Coal*, 329 F. Supp. 2d at 120 (holding that the relevant product market was "no broader and no narrower than the SPRB coal" based on the "narrowest market" principle); *United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 58–60 (D.D.C. 2011) ("[T]he relevant product market should ordinarily be defined as the smallest product market that will satisfy the hypothetical monopolist test"). Complaint Counsel fell far short: (a) its proposed market is impermissibly speculative because other than Galleri, it consists entirely of products that are still in development, some in very early stages, and (b) its proposed market is simultaneously over- and under-inclusive, as it includes putative MCED tests that, if and when launched, will not be viewed by physicians or patients as substitutes for Galleri, and it excludes screening tests that use non-NGS technology.

14. While courts have interpreted the language in Section 7 to infer that Congress's "concern was with probabilities, not certainties", that language was "intended to allow courts to appreciate immediately the potential consequences that a particular acquisition might have upon an *existing line of commerce*." *SCM Corp. v Xerox Corp.*, 645 F.2d 1195, 1211 (2d. Cir. 1981) (emphasis added) (citing *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962)). Thus, it is "[t]he existing market [which] provides the framework in which the probability and extent of an adverse impact upon competition may be measured." *SCM Corp.*, 645 F.2d at 1211. Complaint Counsel may not—as it does here—rely exclusively on speculation about future markets to support its alleged antitrust market. *Arch Coal*, 329 F. Supp. 2d at 116–17.

15. The fact that the hypothesized MCED market proposed by Complaint Counsel does not, in fact, exist is significant because courts have held that where a market does not exist, there can be no anticompetitive effects. *Kenney v. Am. Bd. of Internal Med.*, 412 F. Supp. 3d 530, 547 (E.D. Pa. 2019), *aff'd*, 847 F. App'x 137 (3d Cir. 2021) (holding that Defendant "cannot have a monopoly in a market that does not exist."); *Collins v. Associated Pathologists, Ltd.*, 844 F.2d 473, 480 (7th Cir. 1988) ("It is impossible to monopolize a market that does not exist."); *Siva v. Am. Bd. of Radiology*, 418 F. Supp. 3d 264, 277 (N.D. Ill. 2019) (holding that a defendant cannot have or exploit a "monopoly in a market that does not exist."); *In re Altria Grp., Inc.*, No. 9393, at 110 (Feb. 15, 2022) (citing *Mercantile Tex. Corp. v. Bd. of Governors of Fed. Rsrv. Sys.*, 638 F.2d 1255, 1272 (5th Cir. 1981) ("The competitive conditions of a market five years in the future cannot reliably be predicted.").

16. Courts have repeatedly rejected alleged markets defined to include products that are not yet in existence and whose features are highly uncertain, and have rejected the inclusion of undefined future products in a relevant market. *See SCM Corp.*, 645 F.2d at 1211 (overturning jury verdict in plaintiffs' favor and holding that patent acquisitions did not violate

Section 7 as a matter of law because the relevant product market did not exist at the time of the acquisitions and for another eight years following the acquisitions); *Fraser v. Major League Soccer, L.L.C.*, 97 F. Supp. 2d 130, 140 (D. Mass. 2000), *aff'd*, 284 F.3d 47 (1st Cir. 2002) ("The relevant test under § 7 looks to whether competition in *existing* markets has been reduced. Where there is no existing market, there can be no reduction in the level of competition. . . . Competition that does not exist cannot be decreased."); *Epic Games, Inc. v. Apple Inc.*, 2021 WL 4128925 at *56 (N.D. Cal. 2021) (excluding the offerings of certain gaming companies from the relevant product submarket because the record was limited as to those companies, and they were "too new for a determination of whether they should or should not be included in the relevant product market"); *Apartment Source of Pa., L.P. v. Phila. Newspapers, Inc.*, No. CIV. A. 98–5472, 1999 WL 349938, at *22–24 (E.D. Pa. May 21, 1999) (finding in defendants' favor because plaintiffs' alleged market was at most an "emerging market" within an apparent broader market and was not a well-defined separate market); *Crucible, Inc. v. Stora Kopparbergs Bergslags AB*, 701 F. Supp 1157, 1161 (W.D. Pa. 1988) ("Regarding the 1966 acquisition of the Battelle patents, a finding of no relevant market in PM high speed steel products is mandated by the fact that commercial production and marketing of PM high speed steel products in the United States did not begin until 1971, four years after the patent acquisitions".).

17. Where plaintiffs have tried to define a market based on speculative future products, courts have instead opted to define the market based on existing products. *Apartment Source*, 1999 WL 349938, at *1.

18. The fact that "courts have long applied antitrust laws to firms that have not yet entered or do not yet have sales in the relevant markets" (CC Pretrial Br. at 31) is no help to Complaint Counsel here. In those cases, courts blocked acquisitions between an incumbent firm and a potential competitor that demonstrated concrete plans to enter a mature, well-defined and—perhaps most critically—undisputed product market; none holds that products in early stage development should be considered part of the same relevant product market as a commercial product. For example, the court in *Polypore Int'l, Inc. v. FTC*, 686 F.3d 1208 (11th Cir. 2012) held that the acquired firm, Microporous, was an actual, rather than potential, competitor to Polypore in the SLI separator market based on its conduct and preparations to enter that market. 686 F.3d at 1214-15. There was no dispute as to the definition and contours of the SLI separator market. *Id*. Similarly, in *FTC v. Procter & Gamble Co.*, the Supreme Court held that a merger between Procter & Gamble and Clorox would eliminate potential competition of Procter & Gamble in the agreed-upon market for household liquid bleach. 386 U.S. 568, 571, 580 (1967). Complaint Counsel also cited *United States v. General Dynamics Corp.*, 415 U.S. 486, 501 (1974) for the proposition that "[e]vidence of past production does not, as a matter of logic, necessarily give a proper picture of a company's future ability to compete." (CC Pretrial Br. at 31.) The case plainly does not support Complaint Counsel's theory (and it is not apparent why Complaint Counsel believes it does): *General Dynamics* held that the vagaries of the coal production market are such that evidence of past market share is not as relevant a predictor of future strength as it would be in most markets. *Id.* Nothing in the decision supports including undefined products which are years from existence in a relevant product market.

19. By defining the market to include tests that cannot be shown to be substitutes for Galleri or each other, Complaint Counsel's proposed market violates the narrowest market rule.

See FTC v. Arch Coal, Inc., 329 F. Supp. 2d 109, 120 (D.D.C. 2004) ("Relevant market analysis is based on the 'narrowest market' principle, the analysis of which requires "examining the most narrowly-defined product or group of products sold . . . [that] constitutes a relevant market"); (*see also* PPF ¶ 690.1 (Dr. Scott Morton "did not attempt to define the narrowest relevant market, you know, that would -- the narrowest market that would pass the hypothetical [monopolist] test, and I believe this is a fact, that she did not explain or offer a justification for why that would be appropriate. And that's not something that's relying on testimony by other people. It's a failure of the logic and the form of analysis that she's applied.").)

20. Complaint Counsel's proposed market is also under-inclusive, because it excludes MCED tests that are not based on NGS technology. (PFF ¶ 690.) Complaint Counsel offers no basis for excluding these tests, which are currently on the market, from its proposed relevant market. *See Sungard Data Sys*, 172 F. Supp. 2d 193 ("[T]he Court cannot accept the government's overly narrow and static definition of the product market."); *State of N.Y. v. Kraft Gen. Foods, Inc.*, 926 F. Supp. 321, 361 (S.D.N.Y. 1995) (rejecting plaintiff's more narrowly defined "adult cereal" market, finding "no principled basis for defining the relevant product market more narrowly than all [ready-to-eat] cereals.").

21. These non-NGS tests are too early in the development timeline to be included in the relevant market with Galleri. (PFF ¶ 693.1.) But if there were any merit to Complaint Counsel's approach to market definition (which sweeps in numerous tests that are in the early stages of development), then there is no reason to exclude them. What customers care about is whether a test works and for which indications, not how exactly it works. (PFF ¶ 696); *see, e.g.*, *Apartment Source*, 1999 WL 349938, at *23 (E.D. Pa. May 21, 1999) ("Even though the means used by these apartment communities to secure renters may not be identical substitutes for one another, they serve the same function and are used interchangeably"); *Telerate Systems, Inc. v. Caro*, 689 F. Supp. 221, 237–38 (S.D.N.Y. 1988) ("The first issue [of reasonable interchangeability] is "functional interchangeability"—the degree to which various products are able to perform the same *functions*") (emphasis added).

2. The Alleged Market Includes Products in Development That Are Not Reasonably Interchangeable

22. The government's relevant market is also flawed because it fails to satisfy the test of reasonable interchangeability. A relevant product market consists of "products that have reasonable interchangeability for the purposes for which they are produced—price, use and qualities considered." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 404 (1956). "The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *Brown Shoe*, 370 U.S. at 325; *see du Pont*, 351 U.S. at 395. The test of reasonable interchangeability requires that courts "consider only substitutes that constrain pricing in the reasonably foreseeable future, and only products that can enter the market in a relatively short time can perform this function." *U.S. v. Microsoft Corp.*, 253 F.3d 34, 53–54 (D.C. Cir. 2001); *see also Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 218 (D.C. Cir. 1986) (citation omitted) (only substitutes that can enter the market "promptly" should be considered).

23. "Interchangeability of use and cross-elasticity of demand look to the availability of products that are similar in character or use to the product in question and the degree to which buyers are willing to substitute those similar products for the product." *FTC v. Swedish Match*, 131 F. Supp. 2d 151, 157 (D.D.C. 2000). "The first principle of market definition is substitutability: a relevant product market must 'identify a set of products that are reasonably interchangeable[.]'". *ProMedica Health Sys. v. FTC*, 749 F.3d 559, 565 (6th Cir. 2014) (quoting Horizontal Merger Guidelines § 4.1). "Chevrolets and Fords might be interchangeable in this sense, but Chevrolets and Lamborghinis are probably not." *Id.* (citing 2B Phillip E. Areeda, Herbert Hovenkamp & John L. Solow, Antitrust Law ¶ 533e at 259 (3d ed. 2007)). "The general question is whether two products can be used for the same purpose, and if so, whether and to what extent purchasers are willing to substitute one for the other." *Arch Coal, Inc.*, 329 F. Supp. 2d at 119 (quotations omitted).

24. At present, there is no product in existence that is reasonably interchangeable with GRAIL's Galleri test. (PFF ¶ 697; *see, e.g., U.S. v. Microsoft Corp.*, 253 F.3d 34, 53–4 (D.C. Cir. 2001) (excluding middleware from the relevant market because "[w]hatever middleware's ultimate potential . . . consumers could not *now* abandon their operating systems and switch to middleware"); *Golden Gate Pharmacy Servs., Inc. v. Pfizer, Inc*, 433 F. App'x 598, 599 (9th Cir. 2011) ("The failure to allege a product market consisting of reasonably interchangeable goods renders the complaint 'facially unsustainable'").)

25. Even if the tests in development were on the market, or could be expected to launch in the near term, Complaint Counsel failed to prove that any of these tests will be reasonably interchangeable with Galleri if and when they are launched. (PFF ¶ 708.) The purchasers of any MCED test will be patients, health care providers and/or insurers. (PFF ¶ 708.1.) Complaint Counsel did not call even a single medical expert, patient, health care provider or insurer to testify that he/she would substitute one of the tests in development (were it ever to be sold) for Galleri. (PFF ¶ 708.2.) Nor did Complaint Counsel conduct any surveys of such groups (PFF ¶ 708.3 (Complaint Counsel's expert "didn't attempt to fill those information gaps in by, say, doing some sort of survey of, you know, clinicians or payers to understand what they would think about, you know, various alternatives and how close they would view those to be substitutes and then try to infer from that what that would mean for their switching behavior.")—although such surveys are routinely done in healthcare markets. *See, e.g.*, *United States v. Mercy Health Servs.*, 902 F. Supp. 968, 982–83 (N.D. Iowa 1995) (agreeing with defendants' relevant market based on survey results of patient preferences). Complaint Counsel also did not attempt to show the likely price of these tests. (PFF ¶¶ 750.1–750.4.) These are fatal flaws, especially where Complaint Counsel had ample power and authority to produce such a witness if there were any favorable to its case. *See Boardman v. Nat'l Med. Enterprises*, 106 F.3d 840, 844 (8th Cir. 1997) ("Drawing an adverse inference from the failure of a party to put on key witnesses relevant to some issue is most reasonable when it is the party with the burden of proof on that issue who fails to do so"); *Streber v. Comm'r*, 138 F.3d 216, 221–22 (5th Cir. 1998) ("In general, a court may draw a negative inference from a party's failure to produce a witness "whose testimony would elucidate the transaction") (citation and quotations omitted); *United States v. Lowe*, 234 F.2d 919, 923 (3d Cir. 1956) ("The rule is well known that as a general proposition when one fails to call a witness who might have something relevant to say about his case an unfavorable inference can be urged against the one who fails to call him.").

26. While Complaint Counsel points to instances where the test developers are termed "competitors", "the mere fact that a firm may be termed a competitor in the overall marketplace does not necessarily require that it be included in the relevant product market for antitrust purposes"; rather, market definition hinges on whether *consumers* view the products as reasonable substitutes. *FTC v. Sysco Corp*., 113 F. Supp. 3d 1, 26 (D.D.C. 2015) (emphasis added) (citations omitted); *Ky. Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc.*, 588 F.3d 908, 919 (6th Cir. 2009) (holding that lay testimony and internal marketing documents "do[] not provide a sound economic basis for assessing the market . . . the way that a proper interchangeability test would."); *FTC v. Lundbeck, Inc.*, No. CIV. 08-6379 JNE/JJG, 2010 WL 3810015, at *20 (D. Minn. Aug. 31, 2010), *aff'd,* 650 F.3d 1236 (8th Cir. 2011) (rejecting FTC's proposed market definition consisting of both NeoProfen and Indocin IV despite internal company documents that refer to a market that consists of NeoProfen and Indocin IV); *Geneva Pharms. Tech. Corp. v. Barr Lab'ys Inc.*, 386 F.3d 485, 498 (2d Cir. 2004) (finding that generic warfarin sodium alone constituted the relevant market even though "the industry undoubtedly acknowledges that Coumadin competes to some extent with generics").

3. Complaint Counsel's Alleged Market Runs Counter to the Supreme Court's *Brown Shoe* Factors

27. In addition to interchangeability of use and cross-elasticity of demand, courts look to the "practical indicia" set forth in *Brown Shoe* as guides for defining the relevant market. *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962) (examining "such practical indicia as industry or public recognition of the submarket 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").

28. The *Brown Shoe* factors "are not to be used in a 'talismanic fashion' whereby their presence or absence are regarded as mechanically dispositive of the issue." *Kaplan v. Burroughs Corp.*, 611 F.2d 286, 292 (9th Cir. 1979) (citation omitted). Rather, they must be applied "pragmatically" to determine the existence of the "economically significant" product market. *Id.* (citations omitted).

29. To the extent there is sufficient evidence to properly apply the *Brown Shoe* indicia, they point to a relevant product market consisting only of Galleri, not Galleri and a number of uncertain and unfinished potential tests in development that lack, and cannot plausibly develop in the foreseeable future, the distinctive features of Galleri. *See Microsoft*, 253 F.3d at 53–54 (stating that the test of reasonable interchangeability requires that courts "consider only substitutes that constrain pricing in the reasonably foreseeable future, and only products that can enter the market in a relatively short time can perform this function"); *Epic Games, Inc. v. Apple Inc.*, No. 4:20–CV-05640–YGR, 2021 WL 4128925, at *56 (N.D. Cal. Sept. 10, 2021) (excluding Nintendo and other gaming services from the market because they were "too new" to determine "whether consume[r]s will or do consider these products reasonably interchangeable").

a. No industry or public recognition of the alleged market as a separate economic entity

30. The "industry or public recognition" factor is one that concerns "observations about what one ordinarily observes when a market is distinct" and "matters because we assume that economic actors usually have accurate perceptions of economic realities." *Rothery*, 792 F.2d at 218 n.4.

31. Neither the industry nor the public recognizes an MCED market *as defined by Complaint Counsel*. Courts have declined to recognize a proposed market as a separate economic entity even where there was greater industry or public recognition than there is here. *See, e.g., Se. Mo. Hosp. v. C.R. Bard, Inc.*, 642 F.3d 608, 616 (8th Cir. 2011) (declining to recognize the hospital's proposed market despite evidence of industry recognition from hospital documents, statements by other industry executives and contracts); *Ky. Speedway*, 588 F.3d at 919 (holding that lay testimony and internal marketing documents "do[] not provide a sound economic basis for assessing the market . . . the way that a proper interchangeability test would."); *Geneva Pharms. Tech.*, 386 F.3d at 496 (refusing to recognize a market of generic warfarin sodium and Coumadin although "the industry undoubtedly acknowledges that Coumadin competes to some extent with generics"); *Lundbeck*, No. CIV. 08-6379 JNE/JJG, 2010 WL 3810015, at *20 (rejecting FTC's proposed market definition consisting of both NeoProfen and Indocin IV despite internal company documents that refer to a market that consists of NeoProfen and Indocin IV).

b. The products' peculiar characteristics and uses

32. "The 'product's peculiar characteristics' refers to the general truth that substitutes in a market often have a strong physical and functional relationship". *Rothery Storage*, 792 F.2d at 218 n.4. A product or group of products constitutes a distinct market when it has "(sufficient) peculiar characteristics and uses which make it distinguishable from all other products". *United States v. Brown Shoe Co.*, 179 F. Supp. 721, 729 (E.D. Mo. 1959), *aff'd*, 370 U.S. 294 (1962) (quotations omitted). The peculiar characteristics and uses of Galleri and the MCED tests in development place them in different relevant markets.

33. Products have been placed in separate antitrust markets based on differences in characteristics and uses that are less pronounced than the differences between the characteristics and uses of Galleri and other MCED tests in development. *See, e.g.*, *FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 302 n.15 (D.D.C. 2020) (separating hydrogen peroxide into distinct markets based on their end uses because "end uses within standard grade, by their definition, have 'peculiar characteristics and uses'"); *United States v. Aetna Inc.*, 240 F. Supp. 3d 1, 23 (D.D.C. 2017) (placing Medicare Advantage and Original Medicare into distinct markets due to distinct characteristics of Medicare Advantage, such as limited out-of-pocket expenses and supplemental benefits).

c. Unique production facilities

34. "The cross-elasticity of production facilities may also be an important factor in defining a product market." *Brown Shoe*, 370 U.S. at 325, n.42. "If a product requires unique

production facilities, and the producer raises the price above the competitive level, the ability of other producers to shift resources to make the product would be limited, and the market definition should be likewise limited." *Rothery Storage*, 792 F.2d at 219 n.4; *see also IGT v. All. Gaming Corp.*, 702 F.3d 1338, 1347 (Fed. Cir. 2012) ("[T]here are no unique production facilities or specialized vendors for wheel games versus ordinary gaming machines; one can just as easily produce a gaming machine with a square bonus as one with a circular bonus."). Courts are more likely to find that two products are in separate antitrust markets under this factor if they have a need for specialized technology. *See Epic Games*, 2021 WL 4128925, at *42 (excluding non-game apps from the market of game apps as "game developers often use specialized technology to create their apps" and "tend to specialize in the development of game apps and related gaming software").

35. GRAIL's use of "specialized technology" distinct from the other putative MCED test developers demonstrates that Galleri and these putative tests in development do not belong in the same market. *See Epic Games*, 2021 WL 4128925, at *42. In any event, Complaint Counsel has not shown there to be cross-elasticity of production facilities between Galleri and the putative MCED tests in development to merit including them in the same market. *See Brown Shoe*, 370 U.S. at 325, n.42; *Rothery Storage*, 792 F.2d at 219 n.4.

d. Distinct customers

36. A finding that a product has distinct customers "may indicate unique product attributes, which refers again to the fact that products with distinct physical and functional attributes tend to be priced differently." *Rothery Storage*, 792 F.2d at 218 n.4. "[W]hen one or a few firms differentiate themselves by offering a particular package of goods or services, it is quite possible for there to be a central group of customers for whom only [that package] will do." *United States v. Grinnell Corp.*, 384 U.S. 563, 574 (1966). A core group of distinct customers may constitute a distinct market "because they find a particular product uniquely attractive". *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 112 (1984).

e. Distinct prices

37. Products with distinct prices "suggest[] that cross-elasticity of demand is low", *Rothery Storage*, 792 F.2d at 218 n.4, and should be placed in different antitrust markets. *Reynolds Metals Co. v. FTC,* 309 F.2d 223, 229 (D.C. Cir. 1962). The "distinct prices" inquiry is quantitative, as it "goes directly to the economic criteria that make one market distinct from another." *In re Live Concert Antitrust Litig.*, 863 F. Supp. 2d 966, 985–86 (C.D. Cal. 2012).

f. Sensitivity to price changes

38. ""If a slight decrease in the price of product A causes a considerable number of customers of product B to switch to A, that would indicate that a cross-elasticity of demand exists between A and B and that they compete in the same product market." *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 120 (D.D.C. 2004). Therefore, courts should "exclude any other product to which, within reasonable variations in price, only a limited number of buyers will turn." *Id.* (quoting *Times–Picayune Publ'g Co. v. United States,* 345 U.S. 594, 612 n. 31 (1953)).

39. Where, as here, a plaintiff cannot show price sensitivity based on an appropriate economic analysis, courts regularly find that a plaintiff cannot meet its burden to prove a relevant market, even in instances where the plaintiff has presented more than Complaint Counsel here--for example, survey evidence. *See, e.g.*, *Se. Mo. Hosp.*, 642 F.3d at 616 (finding that the plaintiff failed to prove a relevant market because the expert asserted that customers were not sensitive to price changes but offered "no market studies to support this claim, making the assertion without analytic or even anecdotal evidence"); *Menasha Corp. v. News Am. Mktg. In-Store, Inc.*, 354 F.3d 661, 664 (7th Cir. 2004) (finding that the plaintiff failed to prove that at-shelf dispensers were a relevant market because he "introduced no econometric evidence of any kind" and instead "offered a potpourri of survey research and armchair economics"); *Thurman Indus., Inc. v. Pay 'N' Pak Stores, Inc.*, 875 F.2d 1369, 1376 (9th Cir. 1989) (rejecting the plaintiff's proposed market because mere assertions of consumer preferences were "wholly inadequate to allow a finding" of a lack of price sensitivity); *U.S. Anchor Mfg., Inc. v. Rule Indus., Inc*., 7 F.3d 986, 997 (11th Cir. 1993) (rejecting the plaintiff's proposed market for providing "no basis other than guesswork" for concluding that consumers would be sensitive to price changes); *Vollrath Co. v. Sammi Corp.*, 9 F.3d 1455, 1462 (9th Cir. 1993) (rejecting market definition where expert's opinion based on "limited anecdotal evidence" and "[t]here was no detailed examination of market data or analysis of cost, comparable usage, or comparative features of other competing products").

g. Specialized vendors

40. Finally, specialized vendors "may indicate unique product attributes, which refers again to the fact that products with distinct physical and functional attributes tend to be priced differently." *Rothery Storage*, 792 F.2d at 219 n.4. A product has specialized vendors when it has "avenues for distribution . . . which differ[] in both kind and degree". *Epic Games*, 2021 WL 4128925, at *42.

41. Products are routinely held to fall in different markets where they are sold by specialized vendors or distributed differently. *Epic Games,* , 2021 WL 4128925, at *42 (separating game apps from the non-game apps market because "game apps have multiple avenues for distribution," which "differ[] in both kind and degree from those available to non-gaming apps" and are "specifically designed for such games—and not non-gaming apps").

42. The *Brown Shoe* factors point decidedly against the FTC's alleged market. *See, e.g.*, *FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 302 n.15 (D.D.C. 2020) (rejecting the FTC's proposed market of standard grade hydrogen peroxide because the Brown Shoe factors pointed to a narrower market based on the "peculiar characteristics and uses" of hydrogen , the customers that "tend to be different" but still overlap, and the distinct prices); *U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.*, 7 F.3d 986, 996 (11th Cir. 1993) (rejecting the plaintiff's proposed market because of insufficient evidence of price sensitivity and countervailing evidence of a different market due to its distinct customers).

4. The Alleged Market Fails the Hypothetical Monopolist Test

43. In addition to the *Brown Shoe* practical indicia, courts (and the Commission) sometimes rely on the approach set forth in the Merger Guidelines to define the relevant product

market–the hypothetical monopolist test. *See, e.g., Staples*, 190 F. Supp. 3d at 121–22; *Sysco*, 113 F. Supp. 3d at 33–34; *ProMedica*, 2012 FTC LEXIS 293, at *40–41 (citations omitted); *Polypore*, 2010 WL 9549988 at *11, *15. That test asks whether a hypothetical monopolist of a particular group of substitute products could profitably impose a "small but significant and non-transitory increase in price" ("SSNIP"), typically five percent, on at least one of the products in the candidate market, including at least one product sold by one of the merging firms. Merger Guidelines §§ 4.1.1–4.1.3. "If enough consumers are able to substitute away from the hypothetical monopolist's product to another product and thereby make a price increase unprofitable, then the relevant market cannot include only the monopolist's product and must also include the substitute goods. On the other hand, if the hypothetical monopolist could profitably raise price by a small amount, even with the loss of some customers, then economists consider the monopolist's product to constitute the relevant market." *Sysco*, 113 F. Supp. 3d at 33. The hypothetical monopolist test is typically based on prices that would "likely prevail absent the merger" or, if prices are likely to change absent the merger, the test may use "anticipated future prices". Merger Guidelines § 4.1.2.

44. As described in the Findings of Fact, Complaint Counsel's expert did not conduct a SSNIP analysis based on quantitative purchase data, did not examine data describing past purchase patterns of consumers and their responses to price changes, did not consider any normal course of business documents describing how Galleri customers responded to a price increase, and did not consider any normal course business documents describing how any MCED test customer would respond to a price increase. *See In re Live Concert Antitrust Litig.*, 863 F. Supp. 2d at 985; *see also Se. Mo. Hosp.*, 642 F.3d at 616 (rejecting expert conclusion that a SSNIP in the relevant market would not cause customers to switch when there were "no market studies to support [the] claim" and the "assertion [was] without analytic or even anecdotal evidence."); *Vollrath*, 9 F.3d at 1462 (rejecting market definition where expert's opinion based on "limited anecdotal evidence" and "[t]here was no detailed examination of market data or analysis of cost, comparable usage, or comparative features of other competing products."); *Reifert*, 450 F.3d at 318, 320 (requiring that "a plaintiff prove that products are good substitutes *using economic evidence*; a conclusory assumption of competition where products or services appear to be similar is insufficient.") (emphasis added).

45. Complaint Counsel's expert purports to have conducted a SSNIP test using qualitative data but this analysis consists of nothing more than a thought exercise in which she weighed the evidence shown to her by her staff and Complaint Counsel, and pronounced that the hypothetical monopolist test is satisfied. That is not permissible expert testimony. *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("Expert testimony is useful as a guide to interpreting market facts, but it is not a substitute for them."); *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1435–36 (9th Cir. 1995) ("In the context of antitrust law, if there are undisputed facts about the structure of the market that render the inference economically unreasonable, the expert opinion is insufficient to support [a finding of fact].").

46. In any case, courts will typically reject an expert's "proposed product market definition [based] entirely upon his qualitative assessment of the market, without any supporting quantitative economic analysis." *In re Live Concert Antitrust Litig.*, 863 F. Supp. 2d at 985; *see also Se. Mo. Hosp.*, 642 F.3d at 616 (rejecting expert conclusion that a SSNIP in the relevant market would not cause customers to switch when there were "no market studies to support [the]

claim" and the "assertion [was] without analytic or even anecdotal evidence."); *Reifert*, 450 F.3d at 318, 320 ("While the 'practical indicia' named in *Brown Shoe* . . . are important considerations in defining a market, they were never intended to exclude economic analysis altogether"); *ABS Glob., Inc. v. Inguran, LLC*, No. 14–CV-503–WMC, 2016 WL 3963246, at *14 (W.D. Wis. July 21, 2016) ("[This] Circuit has repeatedly emphasized the need for both a quantitative and qualitative economic analysis in arriving at a market definition"); *Vollrath*, 9 F.3d at 1462 (rejecting market definition where "[t]here was no detailed examination of market data or analysis of cost, comparable usage, or comparative features of other competing products."); *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1145–49 (N.D. Cal. 2004) (expert included significant, specific, and extensive analysis of the factors thought to be relevant to making a hypothetical claim based on an SSNIP). Imagining a scenario in which the SSNIP test might be satisfied is not the same thing as proving it, especially where, as here, Dr. Scott Morton did not attempt to fill the information gaps using surveys or other means, did not attempt to analyze substitution from the perspective of payors and did not attempt to use the limited available information about the possible characteristics of the tests to assess whether switching is likely within her defined market. (PFF ¶ 767.) Using "qualitative evidence" is no different than doing a market definition analysis using the *Brown Shoe* factors—which the alleged market does not satisfy for the reasons discussed above.

47. Complaint Counsel's expert opinion does not "incorporate all aspects of the economic reality" of the relevant market, amounts to "mere speculation", and therefore should not be admitted. *Concord Boat*, 207 F.3d at 1057.

48. Defining a relevant product market generally requires a detailed examination of "market data, figures or other relevant material adequately describing the nature, cost, usage or other features of competing products." *Grason Elec. Co. v. Sacramento Mun. Util. Dist.*, 571 F. Supp. 1504, 1521 (E.D. Cal. 1983) (quoting *Morton Bldgs. of Neb. Inc. v. Morton Bldgs., Inc.,* 531 F.2d 910, 919 (8th Cir. 1976). "Expert testimony that is speculative is not competent proof and contributes nothing to a legally sufficient evidentiary basis." *Concord Boat*, 207 F.3d at 1057. (internal citations and quotations omitted). Thus, Dr. Scott Morton's market definition opinions should be disregarded.

5. Complaint Counsel's Proposed Relevant Market Depends on Subjective and Changing Policy Assessments, Rather Than Established Law and Objective Evidence

49. Complaint Counsel seeks to dismiss the shortcomings in its proof by asserting that the relevant market is nascent and that there is limited economic evidence . (PFF ¶ 771.) It suggests that the law is specially written to protect nascent markets and that such markets are not inoculated from application of the antitrust laws. (PFF ¶ 771.)

50. While it is true that Galleri is a nascent product, that other MCED tests in development do not even yet exist, and that that there is limited economic evidence, none of this relieves Complaint Counsel of its burden to prove the relevant market. The law does not set a different standard for establishing a nascent market. *See, e.g., Apartment Source*, 1999 WL 349938, at *1 (rejecting the plaintiffs' proposed market because "[a]n emerging submarket that has not yet developed into a distinct and identifiable market by definition is not well-defined, and

therefore does not constitute a relevant product market under Section 2 of the Sherman Act."); *Epic Games, Inc. v. Apple Inc.*, No. 4:20–CV-05640–YGR, 2021 WL 4128925, at *56 (N.D. Cal. Sept. 10, 2021) (requiring all products in the mobile game apps market to be reasonably interchangeable and thus excluding certain gaming services from the product for being "too new" for the court to determine "whether consumes [*sic*] will or do consider these products reasonably interchangeable").

51. Complaint Counsel's lax approach would not only relieve it of its burden of proof and substitute the agency's subjective and changing policy assessments for established law and objective evidence. No case supports the FTC's approach to market definition, which relies on platitudes about innovation instead of analysis grounded in the law and fact (CC Pretrial Br. At 2, 5 (noting that "Grail and its [alleged] competitors are engaged in an innovation race")). *See OrthoAccel Techs., Inc. v. Propel Orthodontics, LLC*, No. 4:16–CV-00350–ALM, 2017 WL 1213629, at *3 (E.D. Tex. Apr. 3, 2017) (requiring plaintiff to "plead a relevant product market in precise economic terms" despite it being "difficult to assess cross-elasticity of demand for nascent products in a relatively new market"); *Golden Gate Pharmacy Servs., Inc. v. Pfizer, Inc.*, No. C-09–3854 MMC, 2010 WL 1541257, at *3 (N.D. Cal. Apr. 16, 2010), aff'd, 433 F. App'x 598 (9th Cir. 2011) (rejecting the plaintiffs' alleged product market because they failed to sufficiently allege interchangeability "both in the pharmaceutical product markets and in the innovation market for pharmaceutical products"). "Innovation is intangible, uncertain, unmeasurable, and often even unobservable, except in retrospect." Richard T. Rapp, *The Misapplication of the Innovation Market Approach to Merger Analysis*, 64 Antitrust L.J. 19, 27 (1995). Relying on truisms about innovation instead of rigorous analysis greatly increases the likelihood of false positives—a finding that a merger will substantially lessen competition in a relevant innovation market when, in fact, it would not. *See* Richard T. Rapp, Should Antitrust Enforcers Rely on Potential Competition Analysis or the Concept of Innovation Markets?, Written Testimony Before the Federal Trade Commission Hearings on Global and Innovation-Based Competition (Oct. 25, 1995). The potential harm from these false positives is especially great here where there is unrefuted evidence that the Transaction will save lives.

52. Complaint Counsel's reliance on innovation principles to compensate for the infirmity of its case relies on a theory of harm that is not based on the ability of the merged entity to exercise market power but rather on the effects of the merger on abstract notions of competition. This approach is flawed, because, as a former Director of the Antitrust Division's Economic Policy Office explained: "[T]he research and development that is described as being of concern is not happening in a market . . . There are no arm's length transactions between suppliers and customers. There are no prices, there are no readily recognized indicia of market power. . . . [T]he concern has to be the consequences for output markets somewhere somehow." Federal Trade Commission Hearings on Global and Innovation-Based Competition (1995) (testimony of Lawrence White). Even if an innovation market approach were acceptable, Complaint Counsel cannot rely on it here because Dr. Scott Morton has not performed the necessary analysis. For an innovation market, the relevant definitional questions are: (i) "[D]id a hypothetical monopolist that controlled some set of assets to innovation . . . find it profitable to cut back on innovation?"; and (ii) to find the boundaries of the market, what are the firm's "capabilities to do innovation?" (PFF ¶ 772.) Dr. Scott Morton did no such analysis. (PFF ¶ 772 (RX6004 (Katz Trial Dep. at 26) ("I think it's clear that Professor Scott Morton when she

applies her hypothetical monopolist test is applying it to defining a product market, not an innovation market.").)

B. Complaint Counsel Also Failed To Prove Its Alleged Related Product Market

53. In challenging a vertical merger, Complaint Counsel must demonstrate that "by altering the terms on which it provides a related product to one or more of its rivals, [the merged firm] would likely be able to cause those rivals to lose significant sales in the relevant market or otherwise compete less aggressively for customers." *Commentary on Vertical Merger Enforcement* (Dec. 2020) (withdrawn Sept. 2021) at 9. Defining a cognizable related product market is a necessary element of making this showing, since "[v]ertical restraints often pose no risk to competition unless the entity imposing them has market power, which cannot be evaluated unless the Court first defines the relevant market." *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2285, n.7 (2018); *see also Auburn News Co. v. Providence Journal Co*., 659 F.2d 273, 278 (1st Cir. 1981) ("Where substantial market power is absent at any one product or distribution level, vertical integration will not have an anticompetitive effect."); *Fruehauf Corp. v. FTC* 603 F.2d 345, 353 (2d Cir. 1979)..

54. The requirement to prove a related product market can also be inferred from prior decisions on vertical mergers, even though courts may not have expressly considered the question. *Fruehauf Corp. v. FTC* concerned a government challenge of the merger between Fruehauf, the nation's largest manufacturer of truck trailers, and Kelsey, a manufacturer of various components to truck trailers, including heavy duty wheels ("HDWs") and antiskid braking devices ("ASBDs"). 603 F.2d 345, 347 (2d Cir. 1979). The FTC alleged that the acquisition would harm competition in the truck trailer market by enabling Kelsey to divert to Fruehauf HDWs that would otherwise go to Fruehauf's competitors. *Id.* at 354. The court rejected this contention, as it was based on the assumption that "Kelsey is a significant and substantial supplier of HDWs to Fruehauf's competitors", which had "no appreciable evidentiary support." *Id.* Critically, the *Fruehauf* court held that in assessing the anticompetitive effect of a vertical merger, it must measure "the degree of market power that would be possessed by the merged enterprise and *the number and strength of competing suppliers and purchasers*". *Id.* at 353 (emphasis added). Defining the relevant markets at all levels of the distribution chain is necessary to conduct such an analysis and the *Fruehauf* court did so: it defined the truck trailer market, the HDW market and the ASBD market, with reference to total sales volume and Fruehauf's and Kelsey's respective market shares in each one. *Id.* at 349–51.

55. Further, commentary on the Vertical Merger Guidelines supports the necessity of defining a related product market, especially in input foreclosure cases such as this one. In such cases, "it will be necessary to understand what inputs are included in the 'related product' category when there is actual input substitution." Jonathan B. Baker, Nancy L. Rose, Steven C. Salop & Fiona Scott Morton, *Recommendations and Comments on the Draft Vertical Merger Guidelines* (Feb. 24, 2020) at 6–7. In addition, it is necessary to understand (i) "whether price increases by the merging firm that produces the 'related product' will lead to accommodating price increases by its competitors that could exacerbate the anticompetitive potential of a price increase by the upstream merging firm" and (ii) "measure the share of output accounted for by the related product." *Id.*

56. In its pre-trial brief, Complaint Counsel cited both *Brown Shoe* and *du Pont* to support its theory that it does not bear the burden to show a related product market. (CC Pretrial Br. at 49 (citing *Brown Shoe*, 370 U.S. at 325; *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 593–95 (1957).) The burden to prove a related product market was not at issue in either case, and therefore cannot be fairly read to support Complaint Counsel's desired conclusion. In *Brown Shoe*, the Supreme Court held that the "relevant line[s] of commerce" were the markets for men's, women's and children's shoes, rather than the narrower proposed markets that Brown Shoe suggested. 370 U.S. at 326 (noting that Brown argued the district court's market definitions "fail to recognize sufficiently 'price/quality' and 'age/sex' distinctions in shoes"). While the Court did not consider the issue of a plaintiff's burden to define both a related and relevant product market, it explicitly discussed both Brown Shoe's and Kinney's market power in the *manufacture* and *retail* of men's, women's and children's shoes, respectively, as it related to the vertical harm that would arise from the merger. Brown was the fourth largest manufacturer and Kinney owned the largest chain of retail stores in the country. *Id.* at 332–33. Because of Kinney's market power in the related market, Brown would use its ownership of Kinney to force Brown shoes into Kinney stores, thereby foreclosing Brown's manufacturer competitors from access to Kinney's retail channel. *Id.* at 333. Kinney's market power in the related retail stores market was critical to such a finding.

57. Complaint Counsel also cites to the (now withdrawn) Vertical Merger Guidelines to support its claim that it need not define a related product market. However, nowhere did the Guidelines suggest that defining a related product market is unnecessary. In order to assess "the merged firm's rivals' ability to switch to alternatives to the related product", the Guidelines suggested reviewing "the types of evidence the Agencies use to evaluate customer switching when implementing the hypothetical monopolist test." Vertical Merger Guidelines § 4(a)). Invoking a hallmark principle of market definition to assess alternatives to the related product is inconsistent with a claim that the Guidelines did not require defining a related product market.

58. In concluding that Illumina's NGS instruments and consumables comprise the related product market, Complaint Counsel did not conduct any detailed examination of "market data, figures or other relevant material adequately describing the nature, cost, usage or other features of competing products." *Grason Elec. Co.*, 571 F. Supp. at 1521 (citation omitted). Complaint Counsel did not undertake any effort to conduct a SSNIP test to determine whether the boundaries of the related product market were limited to Illumina's NGS systems, other NGS systems, or non-NGS systems. *See Sysco*, 113 F. Supp. 3d at 33. Rather, it simply asserted that the related product market consisted of Illumina's NGS instruments and consumables, and nothing else.

59. Complaint Counsel's failure to properly define a related product market is fatal to its case, as proof of a related product market is an element of Complaint Counsel's case on which it bears the burden of proof. *See Arch Coal, Inc.*, 329 F. Supp. 2d at 116. As discussed *infra*, because the dynamics in the upstream market are critical to Complaint Counsel's theory of harm of foreclosure and raising rivals' costs, without properly defining the related product market, it cannot show that the merger is likely to "substantially lessen competition in the manner it predicts." *AT&T I*, 310 F. Supp. 3d at 194.

III. COMPLAINT COUNSEL FAILED TO PROVE THE TRANSACTION IS LIKELY TO SUBSTANTIALLY LESSEN COMPETITION

60. Complaint Counsel's failure to prove its relevant and related product market allegations is not the only reason its challenge to the Transaction is untenable. Assuming, *arguendo*, the relevant and related markets were as Complaint Counsel imagines, its case lacks merit because it is based on impermissible speculation. *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 116–17 (D.D.C. 2004) ("[A]ntitrust theory and speculation cannot trump facts, and even Section 13(b) cases must be resolved on the basis of the record evidence relating to the market and its probable future."). Such speculation cannot be the basis for the claim that the Transaction is likely to substantially lessen competition, as is required to establish a claim under Section 7 of the Clayton Act. *AT&T I*, 310 F. Supp. 3d at 194 (to prove a violation of the Clayton Act, the Government must show that "notwithstanding the merger's [] procompetitive effects, [it] has met its burden of proof of establishing" that the merger, "at this time and in this remarkably dynamic industry, is likely to substantially lessen competition in the manner it predicts.").

61. Complaint Counsel's challenge to this vertical merger cannot rely on any presumptions of harm that may be available in a horizontal case. As the Court of Appeals in *AT&T II* recognized, "unlike horizontal mergers, the government cannot use a short cut to establish a presumption of anticompetitive effect through statistics about the change in market concentration, because vertical mergers produce no immediate change in the relevant market share." *AT&T II*, 916 F.3d at 1032. Further much more is required than "testimony from third-party competitors" that is "speculative, based on unproven assumptions, or unsupported." *Id.* at 1038 (quoting *AT&T I*, 310 F. Supp. at 214). Rather, Complaint Counsel was required to bring forward substantial evidence that the Transaction likely will result in competitive harm that outweighs the Transaction's procompetitive benefits. As discussed below, Complaint Counsel failed to carry its burden of proving likely competitive harm by a wide margin.

62. More specifically, Complaint Counsel's case falls short because it (1) is based on assumptions unsupported by a reliable economic model and out of step with economic reality; (2) fails to account for the fact that foreclosing GRAIL's rivals would hurt Illumina's NGS sales and reputation; (3) disregards the fact that NGS costs will be a very small part of MCED test revenues and margins going forward; (4) offers no basis to predict any material diversion to Galleri from the alleged foreclosure strategy; (5) overlooks viable alternatives to Illumina's NGS products for MCED development; (6) misunderstands Illumina's prior vertical integrations and (7) ignores the Open Offer (see Section IV *infra*).

63. While the burden shifting framework announced in *U.S. v. Baker Hughes Inc.*, 908 F.2d 981, 990 (D.C. Cir. 1990) may apply, it operates differently for vertical mergers than it does for horizontal mergers. In particular, a challenge to a vertical merger must be assessed in the light of the widespread recognition that, unlike horizontal mergers, "most vertical mergers are procompetitive." 4A Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law § 10A-1 (5th ed. 2021); *see also Republic Tobacco Co. v. North Atl. Trading Co.*, 381 F.3d 717, 737 (7th Cir. 2004) ("As horizontal agreements are generally more suspect than vertical agreements, we must be cautious about importing relaxed standards of proof from horizontal agreement cases into vertical agreement cases. To do so might harm competition and frustrate the very goals that antitrust law seeks to achieve.").

64. Complaint Counsel thus bears the burden to demonstrate that a vertical merger is anticompetitive when any resulting harm is balanced against any resulting efficiencies. The District Court of the District of Columbia applied this approach in *AT&T I*, the only vertical merger challenged by the DOJ in over four decades. 310 F. Supp. 3d 161. In rejecting the DOJ's challenge to the vertical merger at issue, the court in *AT&T I* observed that there is "recognition among academics, courts, and antitrust enforcement authorities alike that many vertical mergers create vertical integration efficiencies between purchasers and sellers." *Id.* at 193. The court described the government's burden under the *Baker Hughes* framework, explaining: "I will discuss the conceded consumer benefits associated with the proposed merger. Mindful of those conceded benefits, and the need to balance them against the Government's allegations of consumer harm, I will then evaluate whether the Government has carried its burden to show a likelihood that the challenged merger will result in a substantial lessening of competition." *Id*. at 195.

A. Complaint Counsel Offered No Reliable Model

65. To meet its burden here, Complaint Counsel was required to present a model showing any anticompetitive effects of the Transaction outweighed its efficiencies. *See, e.g., AT&T I*, 310 F. Supp. 3d at 237 (rejecting the government's challenge to the vertical merger for failure to meet "the Government's burden to adequately support its proffered [vertical theory of] harm"); *Fruehauf Corp.*, 603 F.2d at 355, 360 (rejecting the government's challenge to a vertical merger because its theories were based on "speculation rather than fact" with respect to one market and "too ephemeral" with respect to another market to prove that some degree of foreclosure would be sufficient to "significantly lessen" competition); *United States v. Hammermill Paper Co.*, 429 F. Supp. 1271, 1293–94 (W.D. Pa. 1977) (finding that "the United States has not carried its burden of proof that the effect of the [vertical] acquisition . . . may be substantially to lessen competition in the manufacture and sale of printing and fine paper in the United States" because "the possibility of foreclosure of access by manufacturers is barred by" a multitude of factors).

66. As Respondents' economics expert Dr. Carlton explained, "vertical merger analysis requires a complete model . . . that you quantitatively can use to balance all the various economic factors that arise in an industry", including efficiencies, profit margins at both stages of production, reputational and contractual constraints on the merged firm, demand curves, substitution patterns, diversion ratios and upstream competition. (PFF ¶¶ 802-03). Ultimately, if the model does not "take account of the efficiencies, or more broadly the incentive to lower price, you risk preventing a merger that would bring large benefits to society because you've failed to balance the benefits against the possible harms." (PFF ¶ 803.1.) The model must also take account of the "timing and magnitude of potential harm versus likely benefit" because "if the harms are far off in the future, but the benefits are closer in", that critical balance of potential harms versus benefits would be skewed and a procompetitive vertical merger could, as a result, be disallowed, depriving consumers of enormous benefits. (PFF ¶ 805.)

67. As a leading antitrust treatise explains, "there is no comparable theoretical basis for dealing with vertical mergers" as with horizontal mergers. 4A Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 1000a (5th ed. 2021). "[W]hether vertical mergers are likely to harm competition, and under what circumstances, are ultimately empirical questions." Gregory

S. Crawford, et al, *AT&T/Time Warner and Antitrust Policy Toward Vertical Mergers*, CPI Antitrust Chron, 2, 3 (July 2019).

68. Complaint Counsel and its expert, Dr. Scott Morton, did not offer any quantitative model that balances all the economic factors that arise. (PFF ¶ 808.) Rather they simply assumed—contrary to the undisputed evidence—that there are no efficiencies and pinned their case on a thought exercise on what might happen under a series of unproven assumptions. That is not enough to stop a life-saving Transaction. The undisputed evidence showed that the Transaction will generate huge efficiencies, accelerating patient access to Galleri, at lower prices, resulting in thousands of lives saved with monetary benefits exceeding $35 billion. (PFF ¶ 1123.)

69. At bottom, Dr. Scott Morton's "model" amounts to hand-waving; neither she nor Complaint Counsel conducted a serious analysis of the factors required to reliably model the effects of a vertical merger. (PFF ¶ 808–814.) Their failure to put forward a full model of the effects of the Transaction is fatal to Complaint Counsel's challenge of the Transaction.

70. Furthermore, to demonstrate "the probable anticompetitive effect of the merger" Complaint Counsel must show that Illumina's likely incentives absent the transaction would be different, or else there could be no merger-specific "effect". *AT&T I*, 310 F. Supp. 3d at 190 (internal quotations omitted). In other words, Complaint Counsel must prove that the Transaction will change the *status quo* to a large enough extent to substantially lessen competition. Complaint Counsel's showing fails here as well.

71. By electing not to conduct a proper analysis of Illumina's incentives absent the merger, Complaint Counsel failed to prove a "probable anticompetitive *effect of the merger*". *AT&T I*, 310 F. Supp. 3d at 190 (emphasis added).

72. Complaint Counsel effectively asks the Court to adopt a presumption against vertical mergers, though "no body of empirical evidence" supports such a presumption (based on structure or any other grounds)", Kobayashi & Muris, at 2, and the law is clear that Complaint Counsel bears the burden to prove the Transaction unlawful, *AT&T I*, 310 F. Supp. 3d at 194; *FTC v. Rag-Stiftung*, 436 F. Supp. 3d 278, 311 (D.D.C. 2020).

B. Complaint Counsel's Approach Is Out of Step With Economic Reality

73. Evaluating the effect of any merger requires consideration of the transaction's effect on the marketplace, which necessarily entails consideration of the economic reality. *See, e.g.*, *AT&T II*, 916 F.3d at 1038 (holding that "the government had not met its first-level burden of proof" as "[n]either the model nor Professor Shapiro's opinion accounted for the effect of the irrevocably-offered arbitration agreements, which the district court stated would have 'real world effects' on negotiations"); *FTC v. Libbey*, 211 F. Supp. 34, 46 (D.D.C. 2002) (criticizing the FTC for predicating its request for an injunction on the terms of an original merger agreement rather than the amended agreement). Yet here, neither Complaint Counsel nor its expert took account of the Open Offer in balancing the alleged harms of the Transaction against its demonstrated efficiencies. They simply dismissed the Open Offer as a conduct remedy that they view as insufficient by itself to alleviate their concerns about the Transaction.

74. While Complaint Counsel and its expert erred in dismissing the Open Offer as a viable "remedy" (as is discussed in Section IV below), that is a different matter from its impact on the likely real-world effects of the merger as mandated by the Clayton Act. Complaint Counsel failed altogether to factor the Open Offer into the assessment of the merger's real-world effects, instead taking the position that the Open Offer can be analyzed merely as a remedy to a proven anticompetitive merger. However, the Open Offer is a binding contractual commitment, just as Illumina's customer supply agreements are binding commitments and, therefore, a real-world fact that impacts Illumina's incentives and constrains its conduct. As such, Complaint Counsel must account for the effects of the Open Offer, just as it is required to account for all relevant economic facts in its attempt to demonstrate foreclosure effects as part of its prima facie case. *See Arch Coal*, 329 F. Supp. 2d at 159 (citing defendants' post-merger transaction commitment in rejecting claim of harm). As the Court of Appeals in *AT&T II* observed, the government has previously recognized that, "especially in vertical mergers, conduct remedies . . . can be a very useful tool to address the competitive problems while preserving competition and allowing efficiencies that may result from the transaction." *AT&T II,* 916 F.3d at 1041 (internal quotations omitted). And where an irrevocable offer to customers guaranteeing fair treatment is made by the merging firm, the government's speculative claims of changed incentives, without taking that offer into account, become "largely irrelevant". *See id.* at 1046–47 (noting that "the government failed to meet its burden of proof" because DOJ's expert had not considered the effect of offers of arbitration agreements). Thus, Complaint Counsel's challenge to the Transaction fails for yet another reason: it is divorced from economic realities and evidence.

C. Complaint Counsel's Foreclosure Theory Fails, Because There Is No Basis To Predict Any Material Diversion to Galleri from the Alleged Foreclosure Strategy

75. Having failed to prove that the MCED tests in development will be close substitutes to Galleri, Complaint Counsel failed to prove material diversion. *See HTI Health Servs*, 960 F. Supp. at 1136 (rejecting the 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"); *Crouse-Hinds Co. v. InterNorth, Inc.*, 518 F. Supp. 416 (N.D.N.Y. 1980) (rejecting the plaintiff's foreclosure claim because of the "limited evidence adduced by the plaintiff . . . to even give a rough estimate of the degree of foreclosure" and "the statistics that . . . [did] not indicate a substantial foreclosure").

76. Complaint Counsel and Dr. Scott Morton speculate that current differentiation does not matter because they say the tests in development can easily and swiftly jump from single- or few-cancer tests to 50-cancer tests. But attorney argument and an economist's speculation cannot outweigh the uncontested evidence to the contrary. *Arch Coal, Inc.*, 329 F. Supp. 2d at 117 ("[A]ntitrust theory and speculation cannot trump facts")

D. Complaint Counsel Failed to Account for the Impact Any Attempted Foreclosure would have on Illumina's NGS Sales and Reputation

77. Further undermining its case is the fact that Complaint Counsel's foreclosure theory does not account for the impact of an attempted foreclosure strategy on Illumina's upstream sales and reputation. *See, e.g.*, *AT&T I*, 310 F. Supp. 3d 161, 243–44 (2018) (rejecting

the government's vertical foreclosure theory because "it would be 'profitable' for the merged entity to continue to license [upstream] Time Warner content to [downstream competitors] virtual MVPDs" and to "maximize distribution of Turner content"); *Fruehauf Corp. v. FTC*, 603 F.2d 345, 354 (2d Cir. 1979) (rejecting the Commission's assumptions of vertical foreclosure and diversion because upstream supplier, Kelsey, "would risk [customers'] retaliating by shifting to competing suppliers not only their purchases of [Heavy Duty Wheels] HDWs but of other products presently bought from Kelsey, which could cause it greater economic harm"); *HTI Health Servs. Inc. v. Quorum Health Grp., Inc.*, 960 F. Supp. 1104, 1137 (S.D. Miss. 1997) (rejecting the plaintiff's vertical foreclosure theory because "any financial incentive or alleged ability on the part of the [upstream] Vicksburg Clinic physicians to shift patients to [downstream] ParkView is negated by" "a countervailing economic incentive . . . to maintain a cooperative association with [ParkView's competitors]").

78. Complaint Counsel's foreclosure argument as to what might happen 10 or more years from now is mere conjecture, and "speculation cannot trump facts". *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 116 (D.D.C. 2004).

79. In view of the impact foreclosure would have on Illumina's sales and reputation, the only way Illumina could have an incentive to foreclose GRAIL's rivals—whether by attempting to cut off their supply of Illumina NGS products, rasising their costs, withholding services, or otherwise—is if foreclosure diverted enough sales from GRAIL's rivals to recoup all the losses resulting from the damage foreclosure would cause to Illumina's upstream sales and reputation. *See, e.g.*, *AT&T*, 310 F. Supp. 3d at 251; *HTI Health Servs.*, 960 F. Supp. 1136–37 (S.D. Miss. 1997); *Fruehauf*, 603 F.2d at 359.

80. Complaint Counsel failed altogether to show that the revenue and reputation losses that Illumina would incur by foreclosing GRAIL's rivals would be offset by any additional profits it would make from rival sales diverted to Galleri. Thus, Complaint Counsel failed to meet its burden, which cannot be satisfied with speculation. *AT&T*, 310 F. Supp. 3d at 251 (rejecting the government's vertical foreclosure theory because the government offered insufficient evidence to show "that HBO promotions [the upstream products] were so valuable that withholding or restricting them would drive customers to AT&T [the downstream firm]") (emphasis added); *HTI Health Servs., Inc.*, 960 F. Supp. at 1136 (finding no foreclosure because there was "no credible evidence that postmerger financial incentives [would] cause the Vicksburg Clinic physicians [upstream suppliers] to shift their hospital patient admissions to ParkView [downstream firm]" away from ParkView's competitors); *Fruehauf Corp.*, 603 F.2d at 359 (rejecting the FTC's vertical foreclosure theory in part because the Commission erroneously assumed that the "corporation being acquired [the upstream supplier of Heavy Duty Wheels and other products] . . . would divert to [the downstream] acquiring corporation sales that would otherwise be made to other customers").

E. Complaint Counsel Disregards the Fact that NGS Costs Will be a Very Small Part of MCED Test Revenues Going Forward

81. Where, as here, the cost of the upstream input only represents price represents only a small percentage of the downstream product price, vertical foreclosure is not a concern. *See* George Raitt, The Metaphysics of Market Power: The Zero-sum Competition and Market

Manipulation Approach 180 (2020) ("If the input is a relatively small part of the total costs of producing the downstream product, foreclosure would have little effect on downstream competition"); William P. Rogerson, *Modelling and Predicting the Competitive Effects of Vertical Mergers: The Bargaining Leverage over Rivals (BLR) Effect* 13, (February 28, 2020) ("[W]here the price charged by any particular upstream firm is small relative to the price of the downstream product that incorporates the input . . . even a relatively large percentage change in the price of an upstream good will result in a relatively small percentage change in the price of the downstream product, even if the entire upstream price increase is passed through to the downstream price. . . . [A] model which assumes that firms ignore these effects may still be relatively accurate even if firms do take account of these effects"); *cf. Fruehauf*, 603 F.2d at 354 (reversing Commission's order for divestiture in part because "neither the [upstream antiskid braking devices] ASBD market nor Fruehauf's [downstream] purchases in that market are likely to be significant")

F. Complaint Counsel's Theory Ignores Intensifying Upstream Competition

82. A necessary condition for a vertical merger to harm competition in the relevant market is a limited ability by the merged firm's rivals to switch their purchases of the related product to sufficiently close substitutes. (PFF ¶ 916.) Thus, Complaint Counsel was required to establish that Illumina will control NGS platforms, and that there will be no viable substitutes (from the standpoint of MCED test developers that could potentially compete with Galleri) for Illumina's NGS platforms during the relevant time period. (PFF ¶ 916.1.) Complaint Counsel failed to make that showing.

83. In horizontal merger challenges, "by putting forward statistics to show that the proposed 'merger would produce a firm controlling an undue percentage share of the relevant market, and would result in a significant increase in the concentration of firms in that market,' the Government triggers a 'presumption' that the merger will substantially lessen competition." *AT&T I*, 310 F. Supp. 3d at 192. That presumption can then be defeated by the merging parties by showing that there is likely entry that prevents the presumption of harm based on the structural features of the horizontal market at issue. In vertical cases, no such presumption exists, and, therefore, the "timely, likely and sufficient" framework that Complaint Counsel seeks to import here does not apply. Instead, "[w]ith no presumption of harm in play, the Government . . . must make a 'fact-specific' showing that the effect of the proposed merger 'is likely to be anticompetitive.'" *Id*. Such a showing requires proving that competition will not prevent the combined firm from having an incentive and ability to foreclose rivals. As Complaint Counsel acknowledges, "the proper timeframe for evaluating the effects of the merger on future competition must be 'functionally viewed, in the context of its particular industry.'" *United States v. Aetna, Inc.,* 240 F. Supp. 3d 79 (D.D.C. 2017) (internal citation omitted). Thus, it was Complaint Counsel's burden to demonstrate that Illumina has the ability and incentive to foreclose during the relevant timeframe—when any MCED test in development emerges as a likely rival to GRAIL, which is, at best, far in the future—and it failed to meet that burden, including because its theory cannot account for the surge of NGS investment and impending entry

IV. COMPLAINT COUNSEL ERRS IN DISMISSING THE OPEN OFFER

84. Assuming, *arguendo*, that the Transaction would give Illumina an incentive and ability to foreclose GRAIL's putative rivals in the absence of any contractual commitments not to do so, the Open Offer prevents any possible anticompetitive harms.

85. Courts adjudicating merger challenges frequently find proposed remedies like the Open Offer sufficient to address the alleged anticompetitive harms. *See, e.g., United States v. AT&T, Inc.* (*AT&T II*), 916 F.3d 1029, 1042–43 (D.C. Cir. 2019) (holding, in a vertical merger case, that "Turner Broadcasting's irrevocable offers of no-blackout arbitration agreements" made the merger "unlikely to afford Turner Broadcasting increased bargaining leverage", the government's primary theory of harm); *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, 1298 (W.D. Mich. 1996) (holding that merging hospitals had successfully rebutted FTC's *prima facie* case and evidence in light of the hospitals' proposed "Community Commitment", which served as an "additional assurance that the merged entity would not exercise its market power to raise prices or otherwise injure the community"); *see also FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 304 (D.D.C. 2020) (holding that "any anticompetitive effects of the merger in the proposed Pacific Northwest geographic market are resolved by PeroxyChem's proposed divestiture of its Prince George plant"); *New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 223, 225, 233 (S.D.N.Y. 2020) (holding that Defendants successfully rebutted Plaintiff States' *prima facie* case because the proposed remedies and conditions to the transaction "significantly reduce the concerns and persuasive force of Plaintiff States' market share statistics"); *FTC v. Atlantic Richfield Co.*, 549 F.2d 289, 299 (4th Cir. 1977) (holding that the FTC's claim that the merger would substantially lessen competition was rendered "moot" by subsequent post-merger agreement to divest certain assets).

86. The audit and arbitration provisions have also been recognized in other cases. Together, these enforcement provisions help guarantee that the Open Offer "will have real world effects" and put Illumina's "'money where [its] mouth is' in showing that the proposed merger, far from being aimed at 'doing any of the things that the government alleges,' is instead a 'vision deal' being pursued to achieve 'lower prices, improved quality, enhanced service, and new products.'" *United States v. AT&T Inc.*, 310 F. Supp. 3d 161, 241 n.51 (D.D.C. 2018), *aff'd*, 916 F.3d 1029 (D.C. Cir. 2019).

87. The Second Circuit confronted a similar situation in *Fruehauf Corp. v. FTC*. 603 F.2d 345 (1979). There, a manufacturer of truck trailers, Fruehauf Corporation ("Fruehauf"), acquired Kelsey-Hayes Company ("Kelsey"), one of Fruehauf's suppliers of heavy-duty wheels ("HDWs"). *Id.* at 347. After the acquisition, Fruehauf promised that Kelsey would continue its historic practice of allocating supply shortages pro rata among all of its customers. *Id.* at 355. The Court explained that while "[o]ne might reasonably question the weight to be given to [Fruehauf's] self-serving assurances that Kelsey would allocate [p]ro rata if the need arose", Fruehauf's promises "need not rest upon some philosophical commitment to egalitarianism since it could also make sound business sense. If Kelsey deprived its regular customers of a proportionate share of HDWs in times of shortage it would risk their retaliating by shifting to competing suppliers not only their purchases of HDWs but of other products presently bought from Kelsey, which could cause it greater economic harm." *Id.* at 355. In part based on this reasoning, the Court held that the merger was not substantially likely to lessen competition. *Id.*

Similarly here, the promises Illumina has made in the Open Offer "need not rest upon some philosophical commitment to egalitarianism" because they "make sound business sense" given that customers could retaliate against any breach of the Open Offer by "shifting to competing suppliers".

88. Now that Illumina has made the Open Offer available to its customers, it cannot revoke it. The Open Offer clearly states that "[t]his irrevocable offer is binding on Illumina." (PFF ¶ 994.1.) Under New York contract law, which governs the Open Offer (PFF ¶ 994.1), Illumina is "firmly bound to hold [the Open Offer] open for the agreed time" of six years from the close of the Transaction. *Silverstein v. United Cerebral Palsy Ass'n of Westchester Cnty.*, 232 N.Y.S.2d 968, 968 (N.Y. App. Div. 1st Dep't 1962). If Illumina attempted to revoke the Open Offer prior to the end of the six-year term, customers could also sue Illumina under the promissory estoppel doctrine because the Open Offer is a clear and unambiguous promise, *see Ripple's of Clearview, Inc. v. Le Havre Assocs.*, 452 N.Y.S.2d 447, 449 (N.Y. App. Div. 2d Dep't 1982), and it is reasonably foreseeable that current or prospective customers of Illumina would rely on the commitments set forth in the Open Offer, *see Villnave Constr. Servs., Inc. v. Crossgates Mall Gen. Co. Newco, LLC*, 1612 N.Y.S.3d 480, 486 (N.Y. App. Div. 3d Dep't 2022). Illumina executives have made several public commitments to the Open Offer, including under oath at this trial, thus giving reasons even beyond New York contract law for Illumina to adhere to the Open Offer. (PFF ¶ 994.2.) Accordingly, Illumina is bound to hold the Open Offer open for six years after the close of the Transaction.

89. The Open Offer's provisions are consistent with consent decrees adopted by the FTC in the past. (PFF ¶¶ 1000.3, 1103.3); *see, e.g.*, *Broadcom Inc.*, FTC Docket No. C-4622 (Aug. 17, 2017); *Evanston Northwestern Healthcare Corp.*, FTC Docket No. 9315 (Apr. 24, 2008); *Northrop Grumman Corp.*, FTC Docket No. C-4652 (June 5, 2018); *PepsiCo, Inc.*, FTC Docket No. C-4301 (Sept. 27, 2010); *Sycamore Partners II*, FTC Docket No. C-4667 (Jan. 25, 2019). Complaint Counsel has provided no compelling reason why Illumina's Proposed Consent Order's terms differ from those of past consent decrees in a way that suggests the Proposed Consent Order would be less effective.

90. Even aside from the Open Offer's formal provisions, extrinsic aspects of the Open Offer help ensure that Illumina will abide by its terms. (PFF ¶ 998.) Accordingly, it would be a mistake "to conclude that [Illumina] would (much less could) retreat from the commitment [of the Open Offer] in light of the apparent reputational costs of doing so—costs that would imperil future negotiations in a marketplace with repeat players." *AT&T I*, 310 F. Supp. 3d at 241 n.51.

[redacted]

91. Consent decrees are effective measures for resolving antitrust disputes and have been used by the FTC and other regulatory agencies for many years. (PFF ¶ 1072.1.) The Open Offer's provisions are consistent with consent decrees adopted by the FTC in the past. (PFF ¶¶ 1000.3, 1103.3); *see, e.g.*, *Broadcom Inc.*, FTC Docket No. C-4622 (Aug. 17, 2017); *Evanston Northwestern Healthcare Corp.*, FTC Docket No. 9315 (Apr. 24, 2008); *Northrop Grumman Corp.*, FTC Docket No. C-4652 (June 5, 2018); *PepsiCo, Inc.*, FTC Docket No. C-4301 (Sept. 27, 2010); *Sycamore Partners II*, FTC Docket No. C-4667 (Jan. 25, 2019).

92. Consent orders or judgments subject to certain conditions are especially appropriate when, as here, defendants are willing to be legally bound by such orders or conditions. *See, e.g.*, *Butterworth*, 946 F. Supp. at 1298 (denying plaintiff's motion for injunction when "[d]efendants [were] willing to enter into a consent decree making the Community Commitment legally binding") (consent decree signed by court one month later); *United States v. Comcast Corp.*, 808 F. Supp. 2d. 145 (D.D.C. 2011) (approving merger where "defendants agreed to abide by the provisions of a proposed Final Judgment that would allow the merger to go forward, while also putting into place certain remedies for what the Government alleged was anti-competitive behavior") (final judgment entered on same day); *Anaconda Co. v. Crane Co.*, 411 F. Supp. 1210, 1218 (S.D.N.Y. 1975) (denying plaintiff's request for preliminary injunction in light of defendant's consent order that the Court determined was "sufficiently broad to prohibit any unilateral actions by Crane . . . which may have the effect of lessening competition with Anaconda"); *AT&T II*, 916 F.3d at 1041 (affirming the district court's approval of merger given defendant's voluntary offer of arbitration and no-blackout agreements that were "irrevocable" and "legally enforceable"); *United States v. Metro Denver Concrete Ass'n*, No. C-2478, 1972 WL 520 (D. Colo. Feb. 28, 1972) (final judgment entered pursuant to a consent decree executed by the defendants).

V. THE BENEFITS OF THE TRANSACTION MORE THAN OFFSET THE ALLEGED HARM

93. Complaint Counsel cannot prove that the merger is likely to substantially lessen competition absent a showing that it would likely result in anticompetitive harm that substantially outweighs the efficiencies reasonably likely to result from the Transaction. The Transaction will lead to a number of significant efficiencies.

A. The Reunion of Illumina and GRAIL Will Save Lives

94. For all the parties' disagreements, it is undisputed that accelerating consumer access to Galleri will save lives. (PFF ¶ 1117.) Respondents offered overwhelming evidence the Transaction will save lives and Complaint Counsel offered no credible evidence to the contrary.

95. Courts have rejected challenges to mergers generating much less substantial healthcare benefits. *See*, *e.g.*, *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, 1032 (W.D. Mich. 1996) (concluding that "defendants have persuasively rebutted not only the FTC's prima facie case, but also the FTC's additional evidence of anticompetitive effect" as "[i]n the real world, hospitals are in the business of saving lives . . . Permitting defendant hospitals to achieve the efficiencies of scale that would clearly result from the proposed merger would enable the board of directors of the combined entity to continue the quest for establishment of world-class health facilities"); *United States v. Long Island Jewish Med. Ctr.*, 983 F. Supp. 121, 149 (E.D.N.Y. 1997) (holding that "the Government failed to prove that the merger of these hospitals will substantially lessen competition" after finding that the cost savings from the merger may be used "to fulfill [the defendants'] mission to provide high quality health care to economically disadvantaged and elderly members of the community"); *United States v. Carilion Health Sys.*, 717 F. Supp. 840, 846 (W.D. Va. 1989) (rejecting the government's Sherman Act merger challenge after finding that "the planned merger would probably improve the quality of health care in western Virginia").

B. The Reunion of Illumina and GRAIL Will Accelerate Market Access to a Life Saving Test

96. The evidence showed the reunion of Illumina and GRAIL will substantially accelerate market access for Galleri. Complaint Counsel offered no persuasive evidence to the contrary.

97. Dr. Navathe and Dr. Rothman argue that Illumina does not have the incentive to accelerate Galleri. (PFF ¶ 1134.7.) However, they are, of course, unqualified to speak to Illumina's state of mind. *Kruszka v. Novartis Pharm. Corp.*, 28 F. Supp. 3d 920, 937 (D. Minn. 2014) ("Expert testimony on 'the intent, motives, or state of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise.'"); *Deutsch v. Novartis Pharm. Corp.*, 768 F. Supp. 2d 420, 442 (E.D.N.Y. 2011) ("to the extent [an expert] seeks to opine on the 'intent, motive, or state of mind, or evidence by which such state of mind may be inferred,' such testimony is inadmissible").

98. Increasing consumer access to a product has been found to outweigh purported anticompetitive harms in other cases—and in those cases, the product was not a test that saves lives. *See*, *e.g.*, *United States v. Crocker-Anglo Nat'l Bank*, 277 F. Supp. 133, 191 (N.D. Ca. 1967) ("[E]ven had a substantial lessening of competition occurred as a result of the merger of defendant banks, such anticompetitive effects were clearly outweighed in the public interest" in part because the merger "caused an immediate increase in the number of statewide banks competing within the state"); *New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 208–09 (S.D.N.Y. 2020*)* (denying the government's request for an injunction to block the merger after considering that the proposed merger would allow "New T-Mobile to support additional subscribers at reduced marginal costs by creating "an 'inordinate amount' of new supply in the market"); *FTC v. Great Lakes Chem. Corp.*, 528 F. Supp. 84, 98 (N.D. Ill. 1981) (denying the FTC's request for injunction in part because the acquiring company, "an aggressive marketer of flame retardants internationally", would help the international market gain access to the acquired company's products).

C. Reuniting Illumina and GRAIL Will Lead to R&D Efficiencies

99. In addition to accelerating market access, the Transaction will lead to significant R&D efficiencies, through the combination of GRAIL's expertise in methylation, data science and software development and Illumina's complementary expertise in sequencing and bioinformatics. (PFF ¶ 1136.) Respondents presented extensive fact testimony in support of this efficiency, whereas Complaint Counsel presented no fact witness to refute it. (PFF ¶ 1137.)

100. Courts have rejected merger challenges based on the presence of R&D efficiencies. *See, e.g., Deutsche Telekom*, 439 F. Supp. 3d at 209 (finding that the proposed merger's efficiencies outweighed the anticompetitive harms in part because the merger would "reduce the cost and delay that T-Mobile would otherwise incur from building new towers for future network development", "accelerate mobile wireless carriers' provision of 5G" and "catalyze the earlier creation of new applications and services not currently possible in the 4G/LTE environment"); *AT&T I*, 310 F. Supp. 3d at 182–83, 191 n.17 (where the Court was "confident that defendants will achieve considerable efficiencies beyond those conceded by the

Government" such as the "gains in innovation—particularly by way of a new programmatic advertising platform" before holding that the government failed to establish that the proposed merger violated Section 7 of the Clayton Act); *Great Lakes Chem. Corp.*, 528 F. Supp. at 94, 98 (finding that the procompetitive effects demonstrated the "absence of any lessening of competition", in part because "the acquisition will enhance critically needed research and development in the industry [as the acquiring company] is an acknowledged leader in research and development.").

D. The Reunion of Illumina and GRAIL Has Already Reduced GRAIL's Royalty Burden, Which Is a Benefit to Consumers

101. The Transaction will also lead to significant efficiencies by reducing royalties that GRAIL was required to pay Illumina before the Transaction. (PFF ¶ 1146.) Complaint Counsel presented no contrary evidence. (PFF ¶ 1148.5.)

102. Nothing in Dr. Scott Morton's reports or in the reports of Complaint Counsel's other experts changes the fact that cost savings are a well-recognized justification for a merger. *See, e.g.*, *Long Island Jewish Med. Ctr.*, 983 F. Supp. at 148–49 (finding that the Government failed to prove that the merger would substantially lessen competition because the cost savings of "approximately 25 to 30 million dollars per year" due to the merger "will ultimately result in benefits to the consumers"); *Advocacy Org. for Patients & Providers v. Mercy Health Servs*., 987 F. Supp. 967, 975 (E.D. Mich. 1997) (denying plaintiff's request to block a merger because "an injunction would delay or foreclose the realization of cost savings [resulting from the merger] in the amount of $15 million annually to the people of Michigan"); *Carilion Health Sys.*, 717 F. Supp. at 846 (holding that the government failed to meet its burden to block a merger after finding that "Defendants' board of directors could be expected to help insure that savings realized from the affiliation will be passed on to consumers"); *AT&T I*, 310 F. Supp. 3d 161, 164, 173 (D.D.C. 2018) (where the government conceded that the "vertical merger would result in hundreds of millions of dollars in annual cost savings to AT&T's customers" and "reduce the 'bargaining friction' inherent in the arm's-length affiliate negotiations . . . between traditional programmers and distributors" before the Court approved the merger).

E. The Reunification of Illumina and GRAIL Will Result in Elimination of Double Marginalization

103. Respondents offered overwhelming evidence that the Transaction will lead to the elimination of double marginalization. Complaint Counsel does not present any factual testimony or other evidence suggesting that there were not two margins prior to the Transaction or that the elimination of double marginalization will not be achieved. (PFF ¶ 1155.1.)

104. Contrary to Complaint Counsel's present view, the elimination of double marginalization is a well-accepted efficiency of vertical integrations, as numerous courts have recognized. *See*, *e.g.*, *Viamedia, Inc. v. Comcast Corp.*, 951 F.3d 429, 465 (7th Cir. 2020) (interpreting *Port Dock & Stone Corp. v. Oldcastle Northeast, Inc.*, 507 F.3d 117 (2d Cir. 2007)—which affirmed the district court's dismissal of the plaintiff's complaint against a vertical integration—as an illustration of elimination of double marginalization); *Alberta Gas Chems Ltd. v. E.I. Du Pont de Nemours & Co.*, 826 F.2d 1235, 1247 (3d Cir. 1987) ("Because of post-

merger efficiencies allowing [a firm] to purchase the acquiring company's output at a better price than in the marketplace, the acquired company's purchasing costs would fall—a procompetitive benefit capable of being passed on via lower prices for its products. Thus, in this scenario, post-merger self-dealing could result in efficiencies reflected in lower prices to the ultimate consumer") (holding that the plaintiff failed to present evidence of antitrust injury); *U.S. v. AT&T Inc.*, 310 F. Supp. 3d 161, 193, 197 (2018) ("[T]he Government concedes that this case implicates one 'standard benefit' associated with vertical mergers: the elimination of double marginalization ('EDM')") (finding that the Government failed to prove that the merger would substantially lessen competition).

F. The Reunion of Illumina and GRAIL Will Lead to Additional Efficiencies

105. The reunion of Illumina and GRAIL will also (1) lead to supply chain and operational efficiencies and (2) accelerate the international expansion of Galleri. (PFF ¶ 1156.)

106. Courts have found cost savings arising from similar supply chain and operational efficiencies supporting the legality of mergers. *See*, *e.g.*, *United States v. Long Island Jewish Medical Center*, 983 F. Supp. 121, 147 (E.D.N.Y. 1997) (approving the merger because "[a]mong these merger-related savings are: a reduction in personnel in various departments of both hospitals . . .; some reduction in the cost of clinical laboratory services and medical supplies; claims recovery costs and utilities; laundry costs; in-house consulting services; and computer and information services."); *FTC v. Lab'y Corp. of Am.*, No. SACV 10-1873 AG MLGX, 2011 WL 3100372, at *10-11 (C.D. Ca. 2011) (denying the FTC's request for a preliminary injunction enjoining the merger) ("LabCorp presented evidence that the transaction will result in over $22 million annually in merger-specific efficiencies resulting from consolidating redundant facilities and employees and taking advantage of LabCorp's lower supply costs"); *FTC v. Butterworth*, 946 F. Supp. 1285, 1301 (W.D. Mich. 1996) (hospitals successfully rebutted the government's prima facie case because of evidence that "the proposed merger would result in significant efficiencies, in the form of capital expenditure avoidance and operating efficiencies, totaling in excess of $100 million" which "is, by any account, a substantial amount"); *New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 209 (S.D.N.Y. 2020) (finding that the proposed merger's efficiencies outweighed the anticompetitive harms as the proposed merger would "save $4.2 billion in operating costs per year" and create savings "from streamlined advertising, the closing of 3,000 redundant retail stores, and reducing the costs of billing and other professional 'back office' services").

107. Courts have found acceleration of international expansion as supporting the legality of a merger. *FTC v. Great Lakes Chem. Corp.*, 528 F. Supp. 84, 98 (N.D. Ill. 1981) (denying the FTC's request for injunction against the proposed acquisition in part because "the acquisition will serve the national interest by promoting foreign trade. . . . Because Great Lakes plans to increase bromine-related sales abroad, the proposed transaction will result in increased exports and will benefit the nation's balance of payments and the economy as a whole. In this regard, courts have recognized that the "stimulation of additional international . . . activity is procompetitive and beneficial.'") (citations omitted). This Court should come to a similar conclusion.

G. The Benefits of the Transaction Are Merger Specific

108. Each of the efficiencies arising from the Transaction is merger specific because each was not, and could not have been, achieved but for the Transaction.

H. The Contentions of Complaint Counsel's Experts Do Not Rebut the Efficiencies

109. Complaint Counsel's only real response to the overwhelming and undisputed evidence that the Transaction will generate sizeable efficiencies is to fall back on its experts' assertions that the efficiencies are unsubstantiated. (PFF ¶ 1178.) That is no answer for multiple reasons.

110. *First*, whether an efficiency is substantiated is a question for the Court; it is not an appropriate subject of expert testimony. *FTC v. Simple Health Plans LLC*, No. 18-CV-62593-, at *21–22 (S.D. Fla. Mar. 3, 2021) (excluding the expert's testimony because the expert was "opining about the sufficiency of [Plaintiff's] evidence" and thus impermissibly instructed the factfinder "about how to weigh the evidence") (quotations omitted); *In re Initial Pub. Offering Sec. Litig.*, 174 F. Supp. 2d 61, 64 (S.D.N.Y. 2001) ("[E]very circuit has explicitly held that experts may not invade the court's province by testifying on issues of law."); *Goodman v. Harris County*, 571 F.3d 388, 399 (5th Cir. 2009) ("[A]n expert may never render conclusions of law.") (citations omitted); *United States v. Thanh Quoc Hoang*, 891 F. Supp. 2d 1355, 1361-62 (M.D. Ga. 2012) ("[An expert] cannot offer testimony about the legal implications of evidence.").

111. *Second*, the efficiencies are supported by fact testimony that Complaint Counsel's experts, for the most part, did not even consider. Their opinions amount to a critique of the opinions of Respondents' experts, whose opinions represent only a portion of Respondents' case.

112. *Third*, Complaint Counsel's experts arrive at their conclusions by weighing the evidence, crediting the testimony that fit Complaint Counsel's thesis and dismissing the evidence that did not—again usurping the role of the Court. *United States v. Adams*, 271 F.3d 1236, 1245 (10th Cir. 2001) ("The credibility of witnesses is generally not an appropriate subject for expert testimony."); *Ellis v. Hobbs Police Dept.*, 472 F. Supp. 3d 1087, 1096 (D.N.M. 2020) (same); PFF ¶ 1178.1 (Scott Morton stating that she "weighed [witness statements] according to the information they had, the role they play in the company and the type of competition in which they are engaged.")).

113. In sum, the Transaction will generate numerous efficiencies, including accelerating the adoption of Galleri, streamlining the supply chain, streamlining operations, accelerating international expansion, generating R&D efficiencies and, most importantly, saving lives. This evidence justifies allowing the Transaction, easily offsetting any alleged harm.

VI. COMPLAINT COUNSEL'S CHALLENGE TO THE TRANSACTION VIOLATES THE U.S. CONSTITUTION

114. Complaint Counsel's challenge to the Transaction should be rejected because it violates Article II and the Due Process and Equal Protection Clauses of the U.S. Constitution. The FTC's case violates Article II, because FTC ALJs are afforded dual-layer protection from presidential review. It violates the Due Process Clause, because the FTC is acting simultaneously as prosecutor, judge, and jury. And it violates the Equal Protection Clause, because it irrationally deprives Respondents of the structural and procedural protections they would possess in a challenge brought by the U.S. Department of Justice's Antitrust Division ("DOJ").

A. The FTC Violates Article II

115. In their challenge to Illumina's reunion with GRAIL, Complaint Counsel and the Commission have impinged upon the executive power vested in the President of the United States in violation of Article II of the U.S. Constitution.

116. Article II of the U.S. Constitution vests "[t]he executive Power . . . in a President of the United States of America", who must "take care that the laws be faithfully executed". U.S. Const. art II, § 1, cl. 1, § 3. In light of "[t]he impossibility that one man should be able to perform all the great business of the State", the Constitution provides for executive officers to "assist the supreme Magistrate in discharging the duties of his trust." 30 Writings of George Washington 334 (John C. Fitzpatrick ed., 1939).

117. Since 1789, the Constitution has been understood to empower the President to keep these officers accountable by removing them from office if necessary. *See generally Myers v. United States*, 272 U.S. 52 (1926). The Supreme Court has recognized only two exceptions to the President's unrestricted removal power. In *Humphrey's Executor v. United States*, 295 U.S. 602 (1935), the Court held that Congress can, under certain circumstances, create independent agencies run by principal officers, whom the President may not remove at will but only for good cause. Likewise, in *United States v. Perkins*, 116 U.S. 483 (1886), and *Morrison v. Olson*, 487 U.S. 654 (1988), the Court sustained similar restrictions on the power of principal executive officers—themselves responsible to the President—to remove their own inferiors.

118. In *Free Enterprise Fund v. Public. Co. Accounting. Oversight Board.*, the Court considered "whether these separate layers of protection may be combined"—that is, whether the President may "be restricted in his ability to remove a principal officer, who is in turn restricted in his ability to remove an inferior officer, even though that inferior officer determines the policy and enforces the laws of the United States". 561 U.S. 477, 483–84 (2010). The Court held that "such multilevel protection from removal is contrary to Article II's vesting of the executive power in the President". *Id.* at 484. The President cannot "take Care that the Laws be faithfully executed" if he cannot oversee the faithfulness of the officers who execute them. *Id.*

119. Here, Complaint Counsel's challenge runs afoul of Article II, because it seeks to undo the Transaction in a proceeding in which the President cannot "take Care that the Laws be faithfully executed", as he cannot adequately oversee the faithfulness of the officers who execute

them. There is no question that FTC ALJs enjoy two layers of protection from the President. *See In re Otto Bock HealthCare N. Am., Inc.*, No. 9378, 2019 WL 5957363, at *49 (FTC Nov. 1, 2019) (acknowledging that FTC ALJs enjoy dual-layer protection from presidential review) (PFF ¶ 1181.) Like the Public Company Accounting Oversight Board ("PCAOB") members that the Court considered in *Free Enterprise Fund*, FTC ALJs may be removed only "for good cause established and determined by" someone other than the President, namely the Merit Systems Protection Board ("MSPB"). 5 U.S.C. § 7521(a). And like the SEC Commissioners who wielded limited removal power in *Free Enterprise Fund*, MSPB members may be removed by the President only for "inefficiency, neglect of duty, or malfeasance in office." 15 U.S.C. § 41.. "Neither the President, nor anyone directly responsible to him, nor even an officer whose conduct he may review only for good cause, has full control over" FTC ALJs. *Free Enter. Fund*, 561 U.S. at 496. These removal procedures are therefore "contrary to Article II's vesting of the executive power in the President." *Id.*

120. In prior challenges under Article II, the FTC has argued that the dual-level of protection afforded to FTC ALJs is of no constitutional moment because they are not "Officers of the United States". *See In re LabMD, Inc.*, No. 9357, Compl. Counsel's Opp'n to Resp't's Mot. to Amend Affirmative Defenses and to Dismiss this Proceeding 2-3 n.2-3 (Jul. 24, 2015). Following the Supreme Court's decision in *Lucia v. SEC*, 138 S. Ct. 2044 (2018), however, that argument is untenable. In *Lucia*, the Court held that SEC ALJs are "Officers of the United States". 138 S. Ct. at 2053–54. And there is no constitutionally significant difference between FTC ALJs and the SEC ALJs held to be "Officers of the United States" in *Lucia*. *Id.* Both may be "appoint[ed]" by their respective Commissions. 5 U.S.C. § 3105. Both "exercis[e] significant authority pursuant to the laws of the United States" by exercising the authority needed to ensure fair and orderly adversarial hearings. *Freytag v. Comm'r of Internal Rev.*, 501 U.S. 868, 881 (1991) (quoting *Buckley v. Valeo,* 424 U.S. 1, 126 (1976)). Both "take testimony", "conduct trials", "administer oaths, rule on motions, and generally 'regulat[e] the course of' a hearing, as well as the conduct of parties and counsel". *Lucia*, 138 S. Ct. at 2053 (quoting 17 C.F.R. §§ 201.111(c)) (SEC ALJs); *see* 16 C.F.R. § 3.42(c) (empowering FTC ALJs to, among other things, "receive evidence", "conduct . . . hearings", "administer oaths", "rule upon . . . motions", and "regulate the course of the hearings and the conduct of the parties and their counsel"). Both are empowered to "make and file initial decisions", which may then be appealed to the respective full Commission. 16 C.F.R. §§ 3.42(c)(9), 3.52(a)(1) (FTC ALJs); *see* 17 C.F.R. § 201.360(a)(1) (SEC ALJs). And both "have all powers necessary" to "dispos[e] of" the proceedings over which they preside. 16 C.F.R. § 3.42(c) (FTC ALJs); *see* 17 C.F.R. §§ 201.111, 200.14(a) (SEC ALJs).

121. The Commission has relied on a footnote in *Free Enterprise Fund* to argue that its ALJs can be afforded dual-layer protection without violating Article II because FTC ALJs "perform adjudicative rather than enforcement or policymaking functions" and "possess purely recommendatory powers." *Free Enter. Fund*, 501 U.S. at 507 n.10; *see, e.g.*, *In re Axon Enter., Inc.*, No. 9389, Order Denying Resp't's Mot. to Disqualify the Administrative Law Judge 3-6 (Sept. 3, 2020). However, *Free Enterprise Fund* did not reach the question of whether ALJs are covered by its holding. The *Lucia* Court later made clear that they are. *See* 138 S. Ct. at 2049. And whether FTC ALJs perform adjudicative rather than enforcement or policymaking functions and possess recommendatory powers is not determinative after *Lucia.* *See id.* at 2060 (Breyer, J., concurring in part) (noting that if ALJs are "Officers", they may present a constitutional removal

problem, since Congress has also provided ALJs with dual-layer removal protection—"just what *Free Enterprise Fund* interpreted the Constitution to forbid in the case of the Board members").

122. In any case, FTC ALJs have both adjudicative and policymaking functions (like members of the PCAOB addressed in *Free Enterprise Fund*). *See* 501 U.S. at 507 n.10; *id.* at 3148 (citing 15 U.S.C. §§ 7213-7215 (2006)); *see also* Kevin M. Stack, *Agency Independence After PCAOB*, 32 Cardozo L. Rev. 2391, 2409-10 (2011). In addition to their adjudicative functions, FTC ALJs engage in some policymaking by conducting rulemaking proceedings and ensuring that the rulemaking proceeds in an orderly fashion. *See* 16 C.F.R. §1.13. The Supreme Court has recognized that all "judges do engage in policymaking at some level", by exercising discretion concerning issues of public importance. *Chisom v. Roemer*, 501 U.S. 380, 399 n.27 (1991) (citation omitted). Any claim that FTC ALJs possess "purely recommendatory powers" is incorrect. *Free Enter. Fund*, 501 U.S. at 507 n.10. While the Commission may review an ALJ's decision, the Commission may also decide not to review an ALJ decision at all, in which case the ALJ's decision becomes final. 16 C.F.R. § 3.52(a)(1).

122.1 The Commission in *In re Axon* suggested that the Commission's ability to modify or set aside an ALJ decision means that the Commission, rather than the ALJ, is responsible for final agency decisions. *In re Axon Enter., Inc.*, No. 9389, Order Denying Resp't's Mot. to Disqualify the Administrative Judge 5 (Sept. 3, 2020). However, *Free Enterprise Fund* presumes that PCAOB members do not possess "purely recommendatory powers". Since PCAOB members' issuance of rules and impositions of sanctions are subject to the SEC's approval and alteration, FTC ALJs also cannot possess "purely recommendatory powers" simply because the Commission may review an ALJ's decision. 15 U.S.C. §§ 7217(b)-(c); *Free Enter. Fund*, 501 U.S. at 486.

123. And in the past 26 years, the FTC has *never* reversed a decision in which an FTC ALJ found liability. Joshua D. Wright, Comm'r, FTC, Remarks at the Symposium on Section 5 of the Federal Trade Commission Act, *Section 5 Revisited: Time for the FTC to Define the Scope of Its Unfair Methods of Competition Authority* 6 (Feb. 26, 2015).

124. As the Supreme Court explained in *Seila L. LLC v. Consumer Financial Protection Bureau*, "[t]he Framers' constitutional strategy [wa]s straightforward: divide power everywhere except for the Presidency, and render the President directly accountable to the people through regular elections." 140 S. Ct. 2183, 2187 (2020). In that scheme, individual executive officials will still wield significant authority, but that authority will remain subject to the ongoing supervision and control of the elected President. Through the President's oversight, "the chain of dependence [is] preserved", so that "the lowest officers, the middle grade, and the highest" all "depend, as they ought, on the President, and the President on the community". 1 Annals of Cong. 499 (1789) (J. Madison). The FTC's dual-protection structure for ALJs contravenes this carefully balanced system by vesting significant governmental power in the hands of a single individual who is neither elected by the people nor meaningfully controlled (through the threat of removal) by someone who is.

125. In addition, the single-layer constraint on the President's removal of the FTC Commissioners violates Article II. 15 U.S.C. § 41. The Solicitor General recently agreed in *Seila L. LLC*, that "[t]he reasoning for *Humphrey's Executor* [*v. United States*, 295 U.S. 602

(1935)]," which held that a single layer of good-cause protection is permissible under limited circumstances, "does not withstand careful analysis." *See* Br. for Resp't Supporting Vacatur, No. 19-7, 2019 WL 6727094, at *31, 45 (U.S. Dec. 9, 2019). Should the Court be inclined to revisit *Humphrey's Executor*, this case presents an appropriate opportunity to do so.

B. The FTC's Internal Administrative Process Violates the Due Process Clause

126. In addition to violating Article II, Complaint Counsel's challenge to the Transaction runs afoul of the Due Process Clause of the Fifth Amendment of the U.S. Constitution. "A fair trial in a fair tribunal is a basic requirement of due process". *Kaley v. United States*, 571 U.S. 320, 345 (2014) (quoting *In re Murchison*, 349 U.S. 133, 136 (1955)). This requirement applies to any adjudicative body, whether it be an administrative tribunal or a court. *Gibson v. Berryhill*, 411 U.S. 564, 579 n.17 (1973). Not only is a biased decision maker constitutionally unacceptable but our system of law has also "always endeavored to prevent even the probability of unfairness." *Republican Party of Minn. v. White*, 536 U.S. 765, 815 (2002) (quoting *In re Murchison*, 349 U.S. at 136). In *Withrow v. Larkin*, the Supreme Court held that the combination of investigative and adjudicative functions does not necessarily constitute a due process violation. 421 U.S. 35, 58 (1975). However, the Court also made clear that there are circumstances in which the combination of investigative and adjudicative functions can constitute a due process violation, as there are situations "in which experience teaches that the probability of actual bias on the part of the judge or decision-maker is too high to be constitutionally tolerable". *Id.* at 47. In *Williams v. Pennsylvania*, the Supreme Court held that "an unconstitutional potential for bias exists when the same person serves as both accuser and adjudicator in a case". 579 U.S. 1, 1905 (2016).

127. Some lower court cases before *Williams* can be read to authorize an agency to combine investigatory and adjudicatory functions, but they are clearly limited in the wake of *Williams*. *See, e.g.*, *Kennecott Copper Corp. v. FTC*, 467 F.2d 67 (10th Cir. 1972); *FTC v. Cinderella Career & Finishing Schs.*, 404 F.2d 1308 (D.C. Cir. 1968).

128. As in *Williams*, the FTC's challenge to the Transaction here creates an unconstitutional potential bias because the same people who voted out the complaint against Respondents—and have prosecuted the case against them—will adjudicate it.

129. An accuser lacks the necessary neutrality to determine the merits of its own allegations. (PFF ¶ 1197.)

130. As a former FTC Commissioner has acknowledged, once the Commission votes out a complaint, it finds in favor of itself 100% of the time. Joshua D. Wright, Comm'r, FTC, Remarks at the Symposium on Section 5 of the Federal Trade Commission Act, *Section 5 Revisited: Time for the FTC to Define the Scope of Its Unfair Methods of Competition Authority* 6 (Feb. 26, 2015).

C. The FTC's Structure and Procedural Rules Violate the Equal Protection Clause

131. The constitutional infirmity of Complaint Counsel's case is not limited to the fact that it violates Article II and the Due Process Clause. Complaint Counsel's challenge to the

Transaction should also be rejected, because it violates the Equal Protection Clause of the U.S. Constitution.

132. The Equal Protection Clause of the Fifth Amendment commands that the government shall not "deny to any person within its jurisdiction the equal protection of the laws". U.S. Const. amend. XIV, § 1; *U.S. v. Windsor,* 570 U.S. 744, 774 (2013) ("The liberty protected by the Fifth Amendment's Due Process Clause contains within it the prohibition against denying to any person the equal protection of the laws.") (citing *Bolling v. Sharpe*, 347 U.S. 497, 499–50 (1954)). "The guaranty of 'equal protection of the laws is a pledge of the protection of equal laws'". *Romer v. Evans*, 517 U.S. 620, 633-34 (1996) (quoting *Skinner v. Oklahoma ex rel. Williamson*, 316 U.S. 535, 541 (1942)). Thus, the Equal Protection Clause protects against "arbitrary and irrational discrimination" by the Government, *Bankers Life & Cas. Co. v. Crenshaw*, 486 U.S. 71, 83 (1988), and demands that "all persons similarly situated should be treated alike", *Tennessee v. Lane*, 541 U.S. 509, 522 (2004) (quoting *Cleburne v. Cleburne Living Center, Inc.*, 473 U.S. 432, 439 (1985)). Any difference in treatment "run[s] afoul of the Equal Protection Clause" when there is no "rational relationship between the disparity of treatment and some legitimate governmental purpose". *Montgomery v. Louisiana*, 577 U.S. 190, 231 (2016).

133. No one can seriously dispute that the parties to a merger challenged by the FTC are treated very differently from the parties to a merger challenged by DOJ.

134. There is no rational basis for these differences, which can be outcome determinative. Treating parties differently based on whether their merger is reviewed by the FTC instead of DOJ is unrelated to any legitimate governmental purpose.

VII. COMPLAINT COUNSEL'S CASE RUNS COUNTER TO THE OVERWHELMING PROOF AND RESTS ON "EVIDENCE" THAT IS INADMISSIBLE AND/OR DESERVING OF NO WEIGHT

A. Complaint Counsel's Alleged Experts

1. Dr. Fiona Scott Morton

135. Dr. Scott Morton's opinions on MCED technology, the viability of alternative NGS platforms, regulatory approval, and reimbursement should be disregarded because she lacks the scientific expertise to opine on these matters. It is black letter law that experts must be qualified to offer the opinions that they seek to express. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 588 (1993); *Nat'l Comm'ns. Ass'n v. AT&T*, 1998 WL 118174, at *42–49 (S.D.N.Y. Mar. 16, 1998) (excluding an economic expert's testimony because he conceded he was not an expert in the technical area where he was offering an opinion).

136. Dr. Scott Morton lacks any 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. (PX7138 (Scott Morton, Trial Dep. at 111–12, 177).) *See In re Whirlpool Corp. Front-Loading Washer Prods. Liab. Litig.*, 45 F. Supp. 3d 724, 758 (N.D. Ohio 2014) ("The Court will not permit Bresnahan (or any other economist/damages expert) to offer any opinion

suggesting a washer does not have a design defect or has a 'superior design' or is 'innovative.' Bresnahan is not an engineer and has no expertise to render such a conclusion."); *Nat'l Communs. Ass'n*, 1998 WL 118174, at *42–49 (excluding an economic expert's testimony because he conceded he was not an expert in the technical area where he was offering an opinion).

137. Dr. Scott Morton did not attempt to fill the information gaps using surveys or other means, including information about the preferences and switching behavior of clinicians, patients, and payors related to the products she includes and excludes from her proposed MCED market, and, most importantly, she did not attempt to analyze substitution from the perspective of payors, despite acknowledging that payor choices will drive adoption of different screening tests. These are fatal omissions. *See Teradata Corp. v. SAP SE*, 2021 WL 5178828, at *18 (N.D. Cal. Nov. 8, 2021) ("Asker's methodology in defining the tying market is unreliable. Contrary to Teradata's assertion, he does not measure the cross-elasticity of demand or the substitutability of products based on reliable quantitative and qualitative analyses. Because his methodology for defining the relevant tying market is unreliable, his conclusions that SAP has market power in his proposed market should also be excluded."); *Lantec, Inc. v. Novell, Inc.*, 2001 U.S. Dist. LEXIS 24816, at *14–16 (D. Utah Feb. 13, 2001) ("This is simply insufficient foundation for, or evidence of, the consumer behavior or preferences helpful in defining a relevant market for antitrust purposes. . . . Dr. Beyer's evidence amounts to nothing but anecdotal information from his own experience, that of two IT managers similarly situated, and the experience of one supplier (Lantec) which Dr. Beyer is extrapolating into 'expert evidence.' Lantec has defined the market as 'worldwide,' and the anecdotal evidence cited is statistically insignificant in terms of number and geographic sampling. . . . His conclusions as to the switching costs and therefore the assumed 'lock-in' phenomenon are based on basically the same, and therefore similarly insufficient, foundation.") (citations omitted).

138. Dr. Scott Morton ignored or discounted the evidence of investment, development, and market entry of these companies as well as other companies that are developing non-NGS platforms. *See, e.g.*, *Abarca v. Franklin Cnty. Water Dist.*, 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Ca. 2011) ("A scientist might well pick data from many different sources to serve as circumstantial evidence for a particular hypothesis, but a reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted."); *Rimbert v. Eli Lilly & Co.*, 2009 WL 2208570, at *14 n.19 (D.N.M. July 21, 2009); *aff'd*, 647 F.3d 1247 (10th Cir. 2011) ("[A]n expert who chooses to completely ignore significant contrary epidemiological evidence in favor of focusing solely on non-epidemiological studies that support her conclusion engages in a methodology that courts find unreliable.").s

139. Dr. Scott Morton's conclusion that Illumina allegedly will foreclose competition in the alleged MCED market by raising rivals' costs is based entirely on speculation. Dr. Scott Morton did not analyze the degree to which Illumina would have to raise the prices to GRAIL's putative rivals to effectively foreclose them. (Scott Morton, Tr. 224.) Dr. Scott Morton's "model" does not account for any efficiencies, ignoring the statement in the Vertical Guidelines that vertical mergers have the capacity to generate cognizable efficiencies. (Vertical Merger Guidelines, at 11). And Dr. Scott Morton does not perform a diversion analysis and disregards the testimony of Respondents' two experts who are practicing physicians, Drs. Cote and Abrams,

who have testified that number of cancers detected and signal of origin are key differentiating features that will affect physician and patient choice. (Abrams, Tr. 3624; **Cote Tr. 3817-18.)** Given these flaws, Dr. Scott Morton's foreclosure analysis is unreliable. *See Teradata Corp.*, 2021 WL 5178828, at *18.

140. Dr. Scott Morton's opinions are inadmissible and unreliable to the extent that she impermissibly usurps the role of the fact finder by opining on the credibility of witness testimony or weighing the evidence. "The credibility of witness testimony is a matter left to the [fact finder] and generally is not an appropriate subject for expert testimony." *Wilson v. Muckala*, 303 F.3d 1207, 1218 (10th Cir. 2002); *see also United States v. Adams*, 271 F.3d 1236, 1246 (10th Cir. 2001) ("The offered testimony does little more than vouch for the credibility of another witness and thereby encroaches upon the [fact finder's] vital and exclusive function to make credibility determinations." (internal quotations omitted)).

2. **Dr. Amol Navathe**

141. Courts routinely disregard expert opinions regarding FDA regulations where the expert's only connection to the FDA is through his experience as a physician. *See, e.g.*, *Hall v. Boston Scientific Corp.*, 2015 WL 868907, at *24 (S.D.W.V. Feb. 27, 2015) (finding that expert's "distinguished career as a urogynecologist cannot uphold his opinions on product warnings and FDA compliance.")

142. Allowing "experts" to testify as to purely subjective views in the guise of expert opinions would "border on the absurd." *In re Rezulin Products Liability Litig.*, 309 F. Supp. 2d 531, 544 (S.D.N.Y. 2004).

143. Having merely reviewed selected documents provided to him by Complaint Counsel, Dr. Navathe cannot properly testify regarding acceleration. *See Mid-State Fertilizer Co. v. Exch. Nat'l Bank*, 877 F.2d 1333, 1340 (7th Cir. 1989) (excluding economist who merely "examined materials produced in discovery and drew inferences from the record" instead of "draw[ing] on the skills of an economist").

144. Dr. Navathe's critique usurps the role of the Court insofar as he purports to opine on whether Respondents made a sufficient showing of an efficiency. *See Mid-State Fertilizer Co.*, 877 F.2d at 1340 (excluding economist who merely "examined materials produced in discovery and drew inferences from the record" instead of "draw[ing] on the skills of an economist"); *SEC v. Tourre*, 950 F. Supp. 2d 666, 675, 678, 681-82 (S.D.N.Y. 2013) ("Acting simply as a narrator of the facts does not convey opinions based on an expert's knowledge and expertise; nor is such a narration traceable to a reliable methodology.").

145. Even if Dr. Navathe could appropriately offer such an opinion, he could not do so here because he failed even to assess the entirety of the proof put forward by Respondents. *See, e.g.*, *Abarca*, 761 F. Supp. 2d at 1066 n.60 ("A scientist might well pick data from many different sources to serve as circumstantial evidence for a particular hypothesis, but a reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted.").

3. Dr. Dov Rothman

146. Like Dr. Navathe's critique of Dr. Carlton, these opinions should be given no weight because they invade the Court's province and constitute improper legal opinion. *See In re Initial Pub. Offering Sec. Litig.*, 174 F. Supp. 2d at 64 ("[E]very circuit has explicitly held that experts may not invade the court's province by testifying on issues of law.").

147. To the extent that Dr. Rothman intends his interpretations of the Guidelines to guide the ALJ's assessment of what may constitute a cognizable efficiency, his opinions improperly invade the Court's province. *See In re Initial Pub. Offering Sec. Litig.*, 174 F. Supp. 2d at 64.

148. Dr. Rothman's artificially limited inquiry to only materials he characterizes as specifically "offered as substantiation," makes his opinions irrelevant and unreliable. *See In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d at 425, 437-38 (excluding experts that "ignored a large amount of information").

B. IH Transcripts and Other Documents

149. The IH testimony of third parties was wasteful and cumulative in light of the fact that the court also admitted deposition testimony and trial testimony, and vastly expanded Complaint Counsel's effective trial time. *See In re McWane*, No. 9351, 2012 WL 3597376 (FTC Aug. 15, 2012).

150. Furthermore, IH testimony constitutes inadmissible hearsay because: (1) it is not necessary to "aid in the determination of the matter" as Complaint Counsel could and did take deposition testimony from most of the nonparties represented in the IHTs; and (2) the IHTs are not "reliable" or "fair", as they are replete with improper leading questions, speculation and inadmissible lay opinion. *See In re Resort Car Rental Sys., Inc.*, 83 FTC 234, 1973 WL 165056, at *33 (July 31, 1973) ("Complaint counsel made a request . . . to introduce into evidence excerpts of testimony attained at an investigational hearing, for the truth of the matters contained therein. The administrative law judge rejected this evidence . . . .").

VIII. COMPLAINT COUNSEL IS NOT ENTITLED TO THE REMEDY IT SEEKS

151. Complaint Counsel's request for a divestiture is overbroad, against the public interest and inequitable. Accordingly, it should be denied.

152. A divestiture remedy would be overbroad and unnecessarily punitive. The purpose of an antitrust remedy is to "restore competition". *United States* v. *E. I. du Pont de Nemours & Co.*, 366 U.S. 316, 326 (1961). "Courts are not authorized in civil proceedings to punish . . . and relief must not be punitive." *Id.* The idea is to "attempt to craft a remedy that will create a competitive environment that would have existed in the absence of the violations." *In re Evanston Nw. Healthcare Corp.*, No. 9315, 2007 WL 2286195, at *77 (F.T.C. Aug. 6, 2007). "Absent some measure of confidence that there has been an actual loss to competition that needs to be restored, wisdom counsels against adopting radical structural relief.'" *New York* v. *Deutsche Telekom AG*, 439 F. Supp. 3d 179, 230 n.23 (S.D.N.Y. 2020) (quoting *United States* v. *Microsoft Corp.*, 253 F.3d 34, 80 (D.C. Cir. 2001)).

153. A divestiture order would be unnecessarily punitive, eliminating the life-saving benefits of the Transaction in order to address concerns that are entirely eliminated by the Open Offer. Illumina's Open Offer eliminates all of the alleged concerns raised by Complaint Counsel. Illumina has committed to formalize these binding contractual commitments in a consent order. A Commission consent order requiring Illumina to abide by the terms of the Open Offer would be a more appropriate and effective remedy than divestiture. A consent order would allow the combined company to continue pursuing its plan to save more lives, more quickly. *See AT&T,* 916 F.3d at 1041 (noting that the government has recognized, "especially in vertical mergers, that conduct remedies . . . can be a very useful tool to address the competitive problems while preserving competition and allowing efficiencies that may result from the transaction").

154. A divestiture of GRAIL would result in harm to "the interest of the general public." *United States* v. *Am. Tobacco Co*., 221 U.S. 106, 185 (1911). Where divestiture will result in the elimination of benefits that have been created by a merger, an alternative remedy is appropriate. In *Evanston*, Complaint Counsel sought the divestiture of respondent's acquisition of Highland Park Hospital and Chief Administrative Law Judge McGuire agreed. The Commission reversed Judge McGuire's divestiture order and instead entered an injunctive remedy. *In the Matter of Evanston Nw. Healthcare Corp.,* No. 9315, 2007 WL 2286195 (F.T.C. Aug. 6, 2007) (requiring respondent to provide a non-divestiture proposal to the Commission for relief that would remedy the alleged harm). In reaching its decision, the Commission noted that respondent had "made improvements at Highland Park since the merger." *In re Evanston*, 2007 WL 2286195, at *78. The improvements were "relevant to determining whether divestiture is appropriate because divestiture may reduce or eliminate the resulting benefits for a material period of time." *Id.*

155. If the Transaction is allowed to proceed, it will result in significant efficiencies, including the saving of thousands of lives, the acceleration of Galleri, significant cost savings and R&D efficiencies. A divestiture would eliminate all of these efficiencies at great loss to the public interest

156. But even assuming these efficiencies are discounted, a divestiture will remove the undisputed financial security that the Transaction has brought to GRAIL. Despite its tremendous progress to date, GRAIL faces many challenges which will require significant funding. For example, it is undisputed that continuing the population-scale clinical trials that GRAIL and now Illumina have undertaken to date will cost millions, if not hundreds of millions of dollars. (PFF ¶ 2129 (PX7138 (Scott Morton Trial Dep. at 319).)) Similarly, as Respondents have described above, Illumina will need to spend millions of dollars to accelerate Galleri's FDA approval and achieve widespread payor reimbursement for Galleri. The Transaction has provided GRAIL with critical funding that it needs in order to achieve these goals. (*See, e.g.*, PFF ¶ 1629.1.)

157. Under the unique circumstances of this case, divestiture would be fundamentally inequitable to Respondents. Divestiture is an equitable remedy, *E. I. du Pont de Nemours & Co.*, 366 U.S. at 326, and "the current situation is always relevant to the question of equitable relief," Areeda & Hovenkamp, *Antitrust Law* ¶ 1205a. "Economic hardship" to Respondents is appropriately considered when choosing among "effective remedies", and the Supreme Court has long held that a remedy must take "proper regard for the vast interests of private property which

may have become vested in [for example, stockholders] as a result of the acquisition . . . without any guilty knowledge or intent." *du Pont*, 366 U.S. at 327–28.

158. Here, it is undisputed that a divestiture would affect private property interests. Indeed, attempting to reverse this billion dollar Transaction would be a significant undertaking. More important, allowing the Commission to order a divestiture after it withdrew its complaint seeking a preliminary injunction in federal court would be inequitable. At the outset of this case, Respondents agreed not to close the Transaction while the Commission's preliminary injunction complaint was adjudicated by a federal court. The Commission later withdrew its preliminary injunction and allowed the Transaction to close under U.S. law. It would be fundamentally unfair for the Commission to order a divestiture of a Transaction it affirmatively decided not to prevent. This is especially the case where, as here, there are narrower and less costly remedies available.

CONCLUSION

159. For these reasons, Complaint Counsel's attempt to unwind the reunion of Illumina and GRAIL is rejected and judgment is entered in favor of Respondents.

Dated: April 15, 2022

Respectfully submitted,

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RESPONDENTS' EXHIBIT INDEX

CONFIDENTIAL - REDACTED IN ENTIRETY

In the Matter of Illumina, Inc. and GRAIL, Inc.
FTC Docket No. 9401

RESPONDENTS' WITNESS INDEX

NAME	TITLE	COMPANY	TRANSCRIPT CITE **TOTAL**	TRANSCRIPT CITE **IN CAMERA **	DATE	VOLUME
Christoph Lengauer	Partner	Third Rock Ventures	155:7 - 275:10	175:1- 241:5 266:1 - 274:14	8/24/2021	Volume 1
Matthew Rabinowitz	Executive Chairman	Natera	284:1 - 452:3	314:1 - 449:23	8/25/2021	Volume 2
Christopher Della Porta	Director of Growth Strategy	GRAIL	453:7 - 564:10 571:3 - 589:3	473:1 - 563:9	8/25/2021 8/26/2021	Volume 2 Volume 3
William Cance	Chief Medical and Scientific Officer	The American Cancer Society	590:19 - 640:14	N/A	8/26/2021	Volume 3
Nicole Berry	Senior Vice President and General Manager of the Americas Commercial team	Illumina	641:10 - 727:17 734:3 - 988:19	736:1 - 802:15 936:1 - 989:2	8/26/2021 8/27/2021	Volume 3 Volume 4
Kenneth Chahine	Board Advisor	Helio Health	997:19 - 1133:9	1048:1 - 1123:25	8/30/2021	Volume 5
Darya Chudova	Senior Vice President of Technology	Guardant Health	1134:10 - 1261:20 1268:3 - 1314:8	1191:1 - 1260:5 1270:1 - 1313:19	8/30/2021 8/31/2021	Volume 5 Volume 6
Hans Bishop	Former Chief Executive Officer	GRAIL	1315:7 - 1516:6	1435:1 - 1515:15	8/31/2021	Volume 6
Kevin Conroy	Chairman and CEO	Exact Sciences	1525:16 - 1761:6	1556:1 - 1696:20 1750:1 - 1760:21	9/2/2021	Volume 7
Alex Aravanis	Chief Technology Officer	Illumina	1769:8 - 1977:9	1794:1 - 1808:15	9/3/2021	Volume 8
Andrew Felton	Vice President, Product Management	Thermo Fisher Scientific	1977:20 - 2048:18 2056:3 - 2070:10	2005:1 - 2048:18 2058:1 - 2069:9	9/3/2021 9/9/2021	Volume 8 Volume 9
John Leite	Former Vice President, Clinical Business Development	Illumina	2070:24 – 2189:20	2091:1 – 2049:7	9/9/2021	Volume 9

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Francis deSouza	Chief Executive Officer	Illumina	2190:4 - 2361:10 2368:3 - 2479:20	2242:1 - 2305:14	9/9/2021 9/10/2021	Volume 9 Volume 10
William Getty	Senior Vice President of Commercial for the Screening Division	Guardant Health	2480:10 - 2652:16 2660:3 - 2693:03	2528:1 - 2632:16	9/10/2021 9/13/2021	Volume 10 Volume 11
Michael Nolan	CEO	Freenome	2693:18 - 2857:7	2746:1 - 2856:21	9/13/2021	Volume 11
Gary Gao	Co-Founder and Scientific Advisor	Singlera Genomics	2859:18 - 2953:9	N/A	9/13/2021	Volume 11
Aaron Freidin	Senior Vice President of Finance	GRAIL	2964:1 - 3173:7	3029:1 - 3134:16 3171:1 - 3172:12	9/14/2021	Volume 12
Joydeep Goswami	Chief Strategy and Corporate Development Officer	Illumina	3180:15 - 3273:23	3238:1 - 3260:16	9/15/2021	Volume 13
Joshua Ofman	Chief Medical Officer and Head of External Affairs	GRAIL	3276:1 - 3459:8	3323:1 - 3429:4	9/15/2021	Volume 13
Fiona Scott Morton	Complaint Counsel's Expert	Yale University Charles River Associates	6:15 - 360:15	21:7-360:15	9/16/2021	Trial Deposition
Matthew Strom	Managing Director	Morgan Stanley	3473:3 - 3600:5	3495:1 - 3581:24	9/17/2021	Volume 14
Richard Abrams	Respondents' Expert	Expert	3601:7 - 3709:9	3693:1 - 3705:12	9/17/2021	Volume 14
Richard Cote	Respondents' Expert	Washington University School of Medicine	3716:13 - 3929:12 3940:7 - 4012:7	3817:1 - 3929:16 3940:1 - 3958:21	9/20/2021 9/21/2021	Volume 15 Volume 16
Arash Jamshidi	Senior Vice President of Data Sciences	GRAIL	4012:21 - 4072:18	4027:1 - 4070:12	9/21/2021	Volume 16

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Jay Flatley	Former CEO and Chairman of the Board	Illumina	4073:5 - 4097:11	N/A	9/21/2021	Volume 16
Ammar Qadan	Vice President and Global Head of Market Access	Illumina	4098:12 - 4218:20 4228:4 - 4300:17	4180:1 - 4218:22 4228:1 - 4248:14	9/21/2021 9/23/2021	Volume 16 Volume 17
Dov Rothman	Complaint Counsel's Expert	Analysis Group	6:10 - 100:23	19:10-40:22; 47:24-50:18; 69:08-72:01; 73:23-77:04; 77:15-83:16; 86:07-100:14	9/22/2021	Trial Deposition
Phil Febbo	Chief Medical Officer	Illumina	4301:1 - 4453:19	4381:1 - 4443:25	9/23/2021	Volume 17
Konstantin Fiedler	Chief Operating Officer	Foundation Medicine Incorporated	4463:7 - 4508:5	4476:1 - 4505:21	9/24/2021	Volume 18
Jorge Velarde	Senior Vice President of Corporate Development and Strategy	Singular Genomics	4510:24 - 4572:7	4536:1 - 4570:16	9/24/2021	Volume 18
Robert Rock	Respondents' Expert	Alix Partners, LLP	6:11 - 104:11	N/A	9/28/2021	Trial Deposition
Patricia Deverka	Respondents' Expert	Center for Translational and Policy Research in Personalized Medicine	6:10 - 197:21	24:13-23; 68:07-69:04; 85:18-20; 86:18-25; 100:16-102:03; 104:03-16; 106:03-110:11; 119:05-120:05; 128:14-129:08; 143:12-19; 145:14-146:13; 150:10-12	9/29/2021	Trial Deposition

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Margaret Guerin-Calvert	Respondents' Expert	FTI Consulting - Center for Healthcare Economics and Policy	6:2-163:25	20:08-10; 39:20-40:12; 40: 19-41:24; 63:22-64:10; 72:04; 89:16-17; 103:05-09; 136:21-137:10; 143:20-144:01; 150:25-151:01; 157:13-14· 157:21	9/30/2021	Trial Deposition
Dennis Carlton	Respondents' Expert	University of Chicago Compass Lexecon	4:25 - 204:4	30:10-31:07; 32:06-33:02; 37:01-03:41:20-42:04; 50:17-22; 51:02-03; 53:04-25; 66:23-67:06; 67:10-14; 70: 10-14; 81:21-23; 86:14-87:12; 87:17-23; 91:24-92:08; 100:15-101:11; 102:10-103:20; 104:11- 106:21; 109:09-24; 115:05-23; 116:12-19; 117:19- 118:07; 123:13-124:21; 126:05-22; 156:05-08; 162:14-20; 170:05-15; 180:9-18; 181:04-21; 181:24-25; 182:02-15;	10/1/2021	Trial Deposition

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				193:04-194:08; 199:12-24; 203:05-09		
Amol Navathe	Complaint Counsel's Expert	University of Pennsylvania School of Medicine	6:9 - 173:15	21:15-25:11; 26:08-19; 27:04-30:16; 34:13-35:14; 36:10-42:24; 44:01-50:19; 52:10-16; 54:07-55:04; 62:04-64:02; 64:18-67:20; 70:06-85:04; 119:01-123:23; 125:05-15; 126:19-25; 128:03-135:09; 137:09-139:12; 156:19-157:10; 158:03-159:18; 160:09-162:21; 163:18-164:08; 170:09-172:11	10/1/2021	Trial Deposition
Michael Katz	Respondents' Expert	Self-Employed	6:5 - 175:10	33:05-13; 37:20-22; 41:04-14; 49:23-52:09; 62:25-64:07; 65:14-71:05; 74:10-75:01; 82:09-84:06; 85:05-07; 104:14-106:19; 107:10-15; 111:09-112:21; 129:17-22; 131:17-	11/1/2021	Trial Deposition

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				132:23; 133:09-24; 150:22-151:11		

CERTIFICATE OF SERVICE

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

April Tabor
Acting Secretary Federal Trade Commission 600
Pennsylvania Ave., NW, Rm. H-113 Washington,
DC 20580
ElectronicFilings@ftc.gov

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

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

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U.S. Federal Trade Commission
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April 22, 2022

/s/ Sharonmoyee Goswami
Sharonmoyee Goswami