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

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INTRODUCTION

Illumina, Inc. ("Illumina"), a dominant provider of next-generation DNA sequencing ("NGS") platforms,[1] is seeking to acquire one of its customers, GRAIL, Inc. ("Grail")—a company that recently launched a cancer screening test designed to revolutionize how cancer is detected, diagnosed, and treated—for $7.1 billion (the "Proposed Acquisition").[2] Known as a multi-cancer early detection ("MCED") test, Grail's flagship Galleri test detects early signs of multiple cancers in asymptomatic patients through a simple blood draw. Although Grail launched its test in a limited capacity in April 2021 to select customers who can purchase the test out-of-pocket, its competitors are developing and racing to launch MCED tests to compete head-to-head with Galleri. While Grail's rivals each have different designs for their tests, they have the same goal—to develop the best performing test, save patients' lives, and earn the greatest share of profits possible in a market that is universally expected to be enormous in the coming years. To achieve this goal, however, each of Grail's competitors must rely on Illumina's NGS platforms, which are an essential input into all MCED tests.

Cancer is the second-leading cause of death in the United States, [redacted]. Today, cancer screening exists only for a few types of cancers, while the vast majority of cancers, accounting for approximately 80 percent of cancer deaths, can only be detected after patients have exhibited symptoms when it is often too late to treat effectively. Grail and its competitors seek to change this. Their MCED tests will analyze a patient's blood to determine

[1] Throughout this pre-trial brief, Illumina's NGS platform encompasses Illumina's sequencing instruments and related consumables. The term "instrument" may be used interchangeably with "sequencer," and the term "consumables" may be used interchangeably with "reagents."

[2] Illumina already owns 14.5 percent of Grail and is seeking to purchase all outstanding equity interest. Illumina formed Grail in 2015 but sold the company to outside investors in 2017 given the substantial risk and expenditures involved in running a novel clinical testing company. Since that time, Grail and its rivals have progressed substantially in their test development efforts and are nearing commercialization. With Grail's viability a virtual certainty, Illumina now seeks to acquire Grail again and reap the benefits from its independent efforts.

whether there is any genetic material, known as biomarkers, within the bloodstream that indicates for cancer. Cancer cells shed DNA and other material into the bloodstream even before symptoms appear, making detection of cancer through the blood possible at very early stages and allowing for a diagnosis when more lives can still be saved.

Finding signs of cancer in the blood, however, is akin to finding a needle in a haystack. MCED test developers must run their tests on specialized sequencing technology to accurately and effectively detect cancer and only Illumina's NGS platforms meet their needs. These developers must rely on Illumina for not only NGS equipment and consumables, but also for important services and assistance throughout the development and commercialization process. As one Illumina executive testified, Illumina tries to "enable [its] customers to be successful, and that's more than just, you know, taking an order and fulfilling it and collecting an invoice."[3] Collaboration with Illumina is critical to the success of its customers—Grail's rivals—and Illumina has many levers it can pull to hinder their competitiveness, including increased prices, reduced service and support, delayed access to new technology, or denial of rights for regulatory approval. Thus, it is no surprise that Grail's competitors describe themselves as Illumina's {[redacted]}[4]

Grail and its competitors are engaged in an innovation race to develop the best MCED tests. As Grail itself acknowledges, it continues to "enhance the performance and features of our tests, including seeking ways to improve sensitivity and reduce sequencing costs."[5] Its rivals are doing the same. Such innovation competition is critical because, while Grail has already launched an initial version of Galleri via a limited (pre-FDA approval) release, a superior MCED test being

[3] PX7076 (Berry (Illumina) Depo at 179:19-181:6).
[4] {[redacted]}
[5] PX0043 at 103 (Grail 2020 Form S-1).

developed by one of Grail's many rivals could leapfrog it, taking sales from Galleri and providing American consumers enormous benefits. In fact, {[redacted]}[6] They would switch because a better MCED test would save lives.

Innovation competition will also expand patient choice by facilitating development of MCED tests with different characteristics. But such tests will only reach the market if third parties are allowed to compete on a level playing field with Grail. The more companies competing to win this innovation race, "the greater the chances of new discoveries that lead to more accurate, more effective, and more cost-effective earlier detection tests being developed."[7]

Today, Illumina has the incentive to ensure that its MCED customers—Grail and Grail's rivals—successfully develop and launch their tests to expand sales of its NGS instruments and consumables. The acquisition will change that incentive. In acquiring Grail, Illumina seeks to {[redacted]}[8] As Illumina recognizes, {[redacted]}[9] Given the enormous profits at stake in the U.S. MCED test market, {[redacted]} the combined firm will have a strong incentive to use Galleri to capture as much of the MCED test market as possible. Illumina will be able to do this by pulling one or more of its many levers to prevent

[6] {[redacted]}
[7] PX8400 (Vogelstein (JHU) Decl.) ¶ 10.
[8] {[redacted]}
[9] {[redacted]}.

Grail's rivals from competing effectively and winning lucrative business away from the combined firm.

Respondents try to dismiss the harm from the Proposed Acquisition by characterizing it as "speculative" and too far in the future, ignoring the vibrant innovation competition occurring today. Although the commercial market for MCED tests is nascent, intense innovation competition between Grail and its many rivals is already ongoing. Grail and its rival test developers have already invested hundreds of millions of dollars over the course of years in their race to develop the best MCED test. Grail identifies these other MCED test developers as its competitors in numerous ordinary course analyses, and has for years, and Grail's executives continuously monitor the different approaches each rival is taking to compete in the U.S. MCED test market. Similarly, Grail's rivals view Galleri as their primary competitor and closely track the progress of Galleri's clinical trials, launch, and regulatory efforts.

Illumina's past behavior when it owned Grail, and other downstream clinical tests, shows how it will act when its incentives change post-acquisition. When Illumina owned the majority stake of Grail before selling it to outside investors, {[redacted]} If Illumina is successful in acquiring Grail now, there is no reason to doubt it will do everything possible to thwart, stall, or alter the efforts of any firm that poses a competitive threat to Galleri because it will earn enormous profits from doing so. And as the owner of an essential input with

[10] [redacted]

no substitutes, Illumina will clearly have the ability to prevent rival MCED test developers from competing effectively with Galleri.

In an effort to remedy the substantial harm that will result from its acquisition, Illumina has offered its oncology customers a twelve-year supply agreement (the "Open Offer") that purports to put them on equal footing to Grail. To rival MCED test developers, though, Respondents' attempt at a remedy is {[redacted]} As Respondents' own {[redacted]}[12] and here Illumina has the incentive to secure a dominant position for Grail in the lucrative U.S. MCED test market. Because a supply agreement cannot alter Illumina's incentives, it cannot remedy the competitive harm from the Proposed Acquisition. Moreover, even if Grail's rivals could find a set of terms which, if Illumina abided by them, might be acceptable, MCED test developers do not know how they could detect or monitor Illumina's compliance with such an agreement, especially for immeasurable commitments like service and support. For these and other reasons, {[redacted]} has executed the Open Offer proposed by Respondents. It is Respondents' burden to prove that their proposed remedy would replace the competitive intensity lost as a result of the merger, a burden they cannot come close to meeting. Nor can Respondents meet their burden to show that efficiencies or the elimination of double marginalization would prevent the harm likely to occur from the Proposed Acquisition.

The story of competitive harm in this case is straightforward. Grail currently finds itself leading an innovation race against several rival MCED test developers. The race is spurring these companies to compete to offer the highest-performing, affordable MCED test. Without the acquisition, Illumina—the only supplier of a critical input for any competitive MCED test—has

[11] {[redacted]}
[12] {[redacted]}

an incentive to support the efforts of all test developers. Post-acquisition, however, Illumina has a clear incentive and the undeniable ability to pick the winner of this race—Grail. By cutting the race short, or by making it significantly more difficult for Grail's rivals to compete, Illumina will earn enormous profits, but it will deprive American consumers of the best products that might otherwise have been developed; limit choices of patients, doctors, and insurers; and likely increase the price of accessing these critically important tests.

I. BACKGROUND

A. Cancer Screening and MCED Tests

Cancer is the second-leading cause of death in the United States, trailing only heart disease.[13] Approximately {[redacted]} A primary reason for the high death toll is that most cancers are detected after the cancer has grown or spread when treatment is more difficult.[16] In fact, by some estimates, patients with cancers diagnosed "early," or when it is considered "[l]ocalized," have an 89 percent survival rate, compared to a 21 percent survival rate if diagnosed "late" or after "[d]istant [m]etastases."[17] Accordingly, screening for

[13] *See, e.g.*, Rebecca L. Siegel et al., *Cancer Statistics, 2021*, 71 CA Cancer J. Clin. 7, 7 (2021); {[redacted]}
[14] PX4095 at 005 {[redacted]}
[15] PX8317 at 004 {[redacted]}
[16] *See* NIH Nat'l Cancer Inst., *Cancer Screening Overview (PDQ®)-Patient Version*, https://www.cancer.gov/about-cancer/screening/patient-screening-overview-pdq (last visited Aug. 2, 2021). {[redacted]} Stages of cancer range from Stage 0 to Stage IV. Stage 0 means "[a]bnormal cells are present but have not spread to nearby tissue." NIH Nat'l Cancer Inst., *Cancer Staging*, https://www.cancer.gov/about-cancer/diagnosis-staging/staging (last visited June 30, 2021). From there, "[t]he higher the number, the larger the cancer tumor and the more it has spread into nearby tissues[,]" until Stage IV, which means the "cancer has spread to distant parts of the body." *Id*.
[17] PX5024 at 022 (Illumina, Board of Directors Meeting, Apr. 28, 2020); PX8317 at 020 {[redacted]}

cancer can improve patient survival rates because it increases the chances of detecting certain cancers early, when they might be easier to treat.[18]

Today, cancer screening exists for only a few types of cancer—lung, breast, colorectal, and cervical.[19] While existing screening methods are highly effective at detecting these cancers in patients,[20] the vast majority of cancers have no screening options at all.[21] Several companies, including Grail, seek to change this. These companies are developing MCED tests, designed to detect multiple cancers simultaneously and at early stages, before the cancer has grown or spread in the body. These tests will be offered to asymptomatic patients, potentially as part of a routine physical, through a simple blood draw.[22]

In order to detect cancer in the blood, MCED tests look for certain genetic materials, called biomarkers,[23] within the blood that are consistent with cancer. All cells, including cancer cells, contain deoxyribonucleic acid ("DNA") and ribonucleic acid ("RNA").[24] DNA is typically double stranded and is made up of complementary pairs of nucleotides, known as base pairs.[25] DNA resides in the nucleus of most cells in the form of long (up to hundreds of millions of base pairs)

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[18] PX8398 (Cance (American Cancer Society) Decl.) ¶ 5.
[19] PX5024 at 022 (Illumina, Board of Directors Meeting, Apr. 28, 2020); PX7040 (Getty (Guardant) IH at 26:3-27:22); PX5027 at 018 (Illumina, Board of Directors Meeting, Aug. 3, 2020) (detailing the screening tests recommended by the United States Preventative Services Task Force ("USPSTF"), and noting lung cancer screening is "only recommended for very high-risk smokers"). The USPSTF also recommends that clinicians offer prostate cancer screening, in the form of a prostate-specific antigen (PSA) test, to a limited set of patients. *See* USPSTF, *Final Recommendation Statement – Prostate Cancer: Screening* (May 8, 2018), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prostate-cancer-screening (last visited Aug. 11, 2021).
[20] *See, e.g.*, PX2165 at 011 (Exact, Q3 2020 Earnings Call, Oct. 27, 2020).
[21] PX7040 (Getty (Guardant) IH at 32:4-10); PX2009 at 017 [redacted]
[22] PX0043 at 114 (Grail 2020 Form S-1); PX7051 (Lengauer (Third Rock Ventures) IH at 28:17-29:18); PX7100 (Chudova (Guardant) Depo at 15:15-16:9).
[23] Biomarkers are "biological molecule[s] found in blood, other body fluids, or tissues that [are] sign[s] of a normal or abnormal process, or of a condition or disease." NIH Nat'l Cancer Inst., *NCI Dictionaries*, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/biomarker (last visited Aug. 2, 2021).
[24] PX0043 at 105 (Grail 2020 Form S-1); Nina Parker et al., *Microbiology* 381, 389 (2016). RNA "serves as a photocopy of specific information" from DNA that is used in cellular processes. *Id.* at 390.
[25] PX0043 at 105 (Grail 2020 Form S-1); Nina Parker et al., *Microbiology* 390 (2016).

molecules called chromosomes.[26] When a cell dies, the DNA in the nucleus spills into the bloodstream in small fragments (approximately 150-180 base pairs)[27] and becomes cell-free DNA ("cfDNA"), which is harmless and present in all human bloodstreams.[28] Cancerous cells go through the same process; when cancer cells die, they also produce cfDNA that sheds into the bloodstream.[29] cfDNA from cancerous tumors is called circulating tumor DNA ("ctDNA").[30] ctDNA reflects the genetic makeup of the tumor cells that released it, and it can be different than normal non-cancerous cfDNA in a variety of ways.[31] The levels of ctDNA in a person's blood can vary with the state and size of the person's tumor.[32]

While most MCED tests in development analyze cfDNA in a patient's blood to determine whether there is any ctDNA consistent with cancer,[33] MCED test developers are competing to find the best, most accurate way to do so. Specifically, MCED test developers utilize different

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[26] PX4035 at 010 (PiperJaffray, The 2015 Liquid Biopsy Report, Sept. 2015); PX0043 at 105 (Grail 2020 Form S-1).
[27] PX8313 at 002 (Guardant, Background Information on Liquid Biopsy for NGS Tests); { } PX7041 (Spetzler (Caris) IH at 132:18-133:13).
[28] PX4035 at 010-011 (PiperJaffray, The 2015 Liquid Biopsy Report, Sept. 2015) (noting 50 to 70 million cells die every 24 hours).
[29] { }
[30] { } PX4035 at 011 (PiperJaffray, The 2015 Liquid Biopsy Report, Sept. 2015).
[31] Heidi Schwarzenbach et al., *Cell-free nucleic acids as biomarkers in cancer patients*, 11 Nature Rev. Cancer 426, 426-27 (2011); *see also* Daniel Andersson et al., *Ultrasensitive circulating tumor DNA analysis enables precision medicine*, 21 Expert Rev. Molecular Diagnostics 299, 299 (2021).
[32] *See* Daniel Andersson et al., *Ultrasensitive circulating tumor DNA analysis enables precision medicine*, 21 Expert Rev. Molecular Diagnostics 299, 300 (2021); PX7100 (Chudova (Guardant) Depo at 22:13-23:18).
[33] The basic workflow for all MCED tests is the same, involving four main steps: blood (or other fluid) collection, sample preparation, DNA sequencing, and data analysis. First, a clinician collects a sample from a patient and ships it to a laboratory. PX4035 at 016-017 (PiperJaffray, The 2015 Liquid Biopsy Report, Sept. 2015). The cfDNA (including ctDNA, if any) molecules are then extracted from the sample using chemical reagents and prepared for DNA sequencing in a process called library preparation. Illumina, *Understanding the NGS workflow*, https://www.illumina.com/science/technology/next-generation-sequencing/beginners/ngs-workflow.html (last visited July 1, 2021). The sequencing instrument then identifies the order of the base pairs in each molecule in the library. PX0043 at 105-106 (Grail 2020 Form S-1); Illumina, *Understanding the NGS workflow*, https://www.illumina.com/science/technology/next-generation-sequencing/beginners/ngs-workflow.html (last visited July 1, 2021). Finally, using sophisticated bioinformatics and analytical techniques (including potentially artificial intelligence and machine learning), the sequence data is analyzed to determine whether it indicates that the patient has a particular type of cancer. PX7048 (Klausner (Grail) IH at 118:7-120:6); { }

biomarkers, or a combination of biomarkers (known as "multi-omics"), to examine the cfDNA. These biomarkers may include methylation patterns,[34] mutations,[35] aneuploidy (an abnormal number of chromosomes),[36] or cfDNA fragment size.[37] In addition to cfDNA analyses, some MCED test developers are also looking at other analytes such as proteins.[38] Because most MCED tests are still in development, "[a]t this stage, it is unclear whether analyzing DNA mutations, DNA methylation patterns, chromosomal variations, RNA variations, protein markers, or some other method of detecting cancer in the blood will prove most effective."[39] Although their methods may be different, all MCED tests rely on NGS technology and, specifically, Illumina's NGS platforms.[40] NGS technology can analyze thousands of biomarkers simultaneously,[41] allowing MCED tests to provide detailed information about any specific cancer, its genetic drivers, and its

[34] Each cell type in the body has a unique methylation pattern, known as its "fingerprint," and modifications to such patterns can result in pronounced changes to cellular function. PX0043 at 106 (Grail 2020 Form S-1). Methylation changes can lead to genes becoming over-expressed, under-expressed, or silenced altogether, thus resulting in excessive, reduced, or no protein production (respectively). These deviations from normal cellular function can cause disease. For example, certain methylation modifications can turn off a tumor suppressor gene, leading to tumor growth and cancer. *Id*.

[35] DNA mutations occur when a DNA sequence is altered. While not all mutations result in changes to genetic function, some mutations that do alter function are associated with cancer. Nat'l Cancer Inst., *NCI Dictionary of Cancer Terms*, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/mutation (last visited June 30, 2021).

[36] Aneuploidy is form of large-scale DNA mutation that involves changes in the number of chromosomes in a cell. Such a gain or loss of a significant portion of genetic material can cause genetic instability and, in some cases, cancer. {[redacted]}

[37] Fragments of ctDNA look different than normal cfDNA fragments: they are typically shorter, they can end in particular sequences of bases, and they can have "jagged" ends where only one of the double DNA strands is intact. *See, e.g.*, M.C. Liu et al., *Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA*, 31 Annals Oncology 745, 746 (2020).

[38] DNA and RNA may be translated into amino acid sequences that, in turn, form certain proteins. Proteins are needed for the body to function properly, and they are the basis for body structures, such as skin and hair, and other substances, such as enzymes. Nat'l Cancer Inst., *NCI Dictionary of Cancer Terms*, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/protein (last visited June 30, 2021).

[39] PX8398 (Cance (American Cancer Society) Decl.) ¶ 11.

[40] *See, infra,* § II.C.

[41] PX7042 (Gao (Singlera) IH at 39:2-40:10); {[redacted]}

location in the body.[42] Although other companies sell NGS platforms, only Illumina's have the capabilities required for MCED testing.[43]

B. Regulatory Requirements for MCED Tests

To gain widespread commercialization and reimbursement of an MCED test, developers need Food and Drug Administration ("FDA") approval for their tests.[44] The FDA typically classifies clinical tests like MCED tests as in-vitro diagnostic ("IVD") devices.[45] Under the existing regulatory framework, a laboratory may run in-house clinical tests—known as laboratory-developed tests ("LDTs")—without obtaining FDA approval.[46] LDTs are offered within a single CLIA-approved laboratory,[47] typically either the test developer's lab or another CLIA-approved lab that has validated the LDT.[48] LDTs are prohibited from making certain claims about the efficacy of their tests and cannot make clinical claims regarding the diagnosis of disease.[49] Further, LDTs are unlikely to obtain reimbursement coverage from CMS and commercial insurers.[50]

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[42] PX8313 at 002 (Guardant, Background Information on Liquid Biopsy for NGS Tests).
[43] *See, infra,* § II.C.
[44] PX0043 at 115, 132 (Grail 2020 Form S-1); {[redacted]}
[45] *See* Congressional Research Service, *Regulation of Clinical Tests: In Vitro Diagnostic (IVD) Devices, Laboratory Developed Tests (LDTs), and Genetic Tests* (Apr. 11, 2017) at 4, https://digital.library.unt.edu/ark:/67531/metadc501872/m1/1/high_res_d/R43438_2014Dec17.pdf (last accessed Aug. 12, 2021). IVDs can also be classified as research use only ("RUO"), which cannot be used to inform the clinical treatment of patients. *See id.* at 9-10.
[46] {[redacted]} As Grail noted in its 2020 Form S-1, there is a risk that the FDA could adopt stricter oversight or enforcement policies toward LDTs, although it has not yet done so. PX0043 at 041-043 (Grail 2020 Form S-1).
[47] LDTs must abide by regulations provided by the College of American Pathologists ("CAP") and the Centers for Medicare & Medicaid Services ("CMS") under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"). These regulations regulate the laboratories where an MCED test is performed and the equipment used to perform the test. The regulations also review the analytical validity of the specific LDT. Centers for Medicare & Medicaid Services, *CLIA Overview,* https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/LDT-and-CLIA_FAQs.pdf (last visited Aug. 12, 2021).
[48] *See* PX7049 (Bailey (PGDx) IH at 55:3-18) (explaining how academic labs can validate LDTs and run them in their own labs); Congressional Research Service, *Regulation of Clinical Tests: In Vitro Diagnostic (IVD) Devices, Laboratory Developed Tests (LDTs), and Genetic Tests* (Apr. 11, 2017) at 4, https://digital.library.unt.edu/ark:/67531/metadc501872/m1/1/high_res_d/R43438_2014Dec17.pdf (last accessed Aug. 12, 2021).
[49] PX7056 (Silvis (Tempus) IH at 42:11-19).
[50] *See* {[redacted]}

Accordingly, LDTs typically have lower rates of adoption than FDA-approved tests.[51] Despite the limitations of LDTs, some MCED test developers, {[redacted]} plan to launch their tests initially as LDTs in part to build a customer base and compile more data to help improve their tests.[52]

IVDs that obtain FDA approval can be either single-site IVD tests or distributed, "kitted" IVD tests. A single-site, or centralized, IVD test is approved by the FDA to run in a single approved lab, typically the MCED test developer's own laboratory.[53] Many MCED test developers, {[redacted]} plan to seek a premarket approval ("PMA") from the FDA for the use of their test as a single-site IVD.[54] While similar to an LDT, in that the test is run in a single lab, an FDA-approved single-site IVD test is more likely to receive widespread reimbursement from payors.[55] The PMA approval process for a single-site IVD test includes validating the test developer's laboratory where the developer must run the test.[56] A distributed or

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[redacted]} *See* PX7092 (Ofman (Grail) Depo at 175:17-176:22).

[51] {[redacted]} PX7051 (Lengauer (Thrive) IH at 149:14-22).

[52] *See, e.g.*, {[redacted]} MCED test developers can use the data compiled from the sale of an MCED as an LDT to improve the test's machine learning algorithms and generate additional data used to support a PMA application. *See* {[redacted]}

[53] PX7093 (Young (Illumina) Depo at 43:20-44:6); PX7064 (Goswami (Illumina) IH at 28:22-31:2); PX7040 (Getty (Guardant) IH at 78:6-79:8); *see also* PX7049 (Bailey (PGDx) IH at 25:1-24).

[54] [redacted]

[55] {[redacted]}

[56] [redacted]

"kitted" IVD test is approved by the FDA to be sold as a standalone kit and run in third-party labs.[57] This testing model allows a test to reach the largest market because customers across the country no longer have to send samples to the test developer for results.[58] Distributed IVD tests can also shorten the turnaround time for generating test results and allow the test supplier to scale its test much faster as samples are not being sent across the country for processing.[59] Regardless of which FDA approval path an MCED test developer takes, it must work closely with Illumina to validate its test and convince the FDA that the MCED test is reliable and accurate.[60]

Whether it is a single-site IVD test or a distributed IVD test, FDA-approved IVD tests must go through a similar FDA approval process. The FDA classifies MCED tests as Class III medical devices.[61] A Class III device is considered the riskiest type of medical device because of its intended use and indication for use.[62] The FDA typically requires a developer of a Class III medical device to submit an application for PMA approval in order to determine the safety and efficacy,[63] which requires submitting a lengthy application involving clinical and analytical validation data collected during clinical trials using the device.[64]

Whereas an FDA-approved NGS platform is not required to run an LDT, it likely will be required for obtaining and maintaining FDA approval for a kitted IVD test.[65] Because NGS

[57] PX7065 (Aravanis (Illumina) IH at 139:11-140:22); { } PX7112 (Bailey (PGDx) Depo at 14:2-18); PX7093 (Young (Illumina) Depo at 44:8-14).
[58] *See, e.g.*, PX7040 (Getty (Guardant) IH at 81:14-81:22); PX7041 (Spetzler (Caris) IH at 148:5-149:2).
[59] { } PX7049 (Bailey (PGDx) IH at 25:1-24).
[60] *See, infra*, § II.D.ii.c.
[61] *See, e.g.*, PX7099 (Febbo (Illumina) Depo at 83:25-84:1).
[62] *See* U.S. Food & Drug Admin., *Classify Your Medical Device*, https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device (last visited Aug. 12, 2021).
[63] With respect to MCED tests, some developers anticipate that the clinical and analytical validation data will likely include data demonstrating the precision, accuracy, sensitivity, and specificity of a test relative to current screening technologies on the market. *See* { } U.S. Food & Drug Admin., *Classify Your Medical Device*, https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device (last visited Aug. 12, 2021).
[64] { }
[65] *See* PX7065 (Aravanis (Illumina) IH at 139:11-140:22); PX7099 (Febbo (Illumina) Depo at 83:25-84:9.

instruments, reagents, and other system components are specified as part of the final FDA approval, an approved IVD test is "locked in" to those systems making switching to new technology platforms difficult.[66] Modifying any component of the approved IVD could require conducting an additional clinical trial with the modified component.[67] Accordingly, once an MCED test developer obtains IVD designation for a clinical test using an Illumina platform, it becomes increasingly tethered to Illumina as the regulatory costs of switching the underlying NGS platform increase.

Once an MCED test receives FDA approval, developers may seek reimbursement coverage from third-party payors, including CMS and private insurers[68] to expand the MCED test developer's customer base by providing access to patients who otherwise could not afford to pay the out-of-pocket price of a test.[69] Obtaining widespread payor coverage appears to be the final step in the process of successfully bringing an MCED test completely to market.[70]

C. NGS and Other Technologies

NGS is a method of DNA sequencing, the process of determining the order of nucleotides in DNA molecules. NGS supplanted prior sequencing methods, such as Sanger sequencing, due

[66] PX7045 (Chudova (Guardant) IH at 73:17-74:14); *see also* PX7044 (Stahl (Invitae) IH at 60:13-61:2).
[67] PX7045 (Chudova (Guardant) IH at 73:17-74:14).
[68] {[redacted]}
[69] {[redacted]}
[70] {[redacted]}

to its higher throughput[71] and vastly lower costs.[72] With the advent of NGS, a sequencing project that would have cost billions of dollars and taken over a decade could be done in a single day for under a thousand dollars.[73] The advancements in throughput, accuracy, and cost afforded by NGS "revolutionized the biological sciences, allowing labs to perform a wide variety of applications and study biological systems at a level never before possible."[74]

There are two categories of NGS platforms: short read and long read.[75] The fundamental differences between the two categories are (i) the number of DNA fragments that can be sequenced simultaneously on the instrument, and (ii) the length of those DNA fragments. For short-read NGS, each DNA sample is prepared into a library of short fragments that are typically 350 base pairs or less in length. The fragments are then replicated and sequenced simultaneously, in parallel, on a glass chip known as a "flow cell." A single run of a short-read instrument can read millions, or even billions, of DNA fragments. The benefits of short-read sequencing include high accuracy, high read count, and low cost per read relative to long-read sequencing. By contrast, for long-read

[71] The National Cancer Institute defines "throughput" as "[t]he quantity of information, people, or materials that is put through a process in a specific period of time. In medicine, it can be used to describe the efficiency of laboratory procedures, such as genetic sequencing, or the number of patients seen in a clinic in a certain period of time." NIH Nat'l Cancer Inst., *Dictionary of Genetics Terms*, "Throughput," https://www.cancer.gov/publications/dictionaries/genetics-dictionary/def/throughput (last visited Aug. 11, 2021). NGS is a "high-throughput method used to determine a portion of the nucleotide sequence of an individual's genome. This technique utilizes DNA sequencing technologies that are capable of processing multiple DNA sequences in parallel." NIH Nat'l Cancer Inst., *Dictionary of Genetics Terms*, "Next-Generation Sequencing," https://www.cancer.gov/publications/dictionaries/genetics-dictionary/def/next-generation-sequencing (last visited Aug. 11, 2021).

[72] [redacted]

[73] *See* NIH Nat'l Human Genome Research Inst., *The Cost of Sequencing a Human Genome*, https://www.genome.gov/about-genomics/fact-sheets/Sequencing-Human-Genome-cost (last visited Aug. 11, 2021); *see also* PX0124 at 006-007 (Jon Gertner, *New York Times*, "Genome Sequencing and Covid-19 – How Scientists Are Tracking the Virus," Mar. 25, 2021).

[74] Illumina, *Introduction to NGS*, https://www.illumina.com/science/technology/next-generation-sequencing.html (last visited Aug. 6, 2021).

[75] PX8399 (Henry (PacBio) Decl.) ¶ 3.

NGS, each DNA sample is prepared into a library of long fragments that can range from tens of thousands to millions of base pairs each. In general, long-read sequencers have substantially lower read counts than short-read sequencers.[76] Long-read NGS sequencers can typically read, at most, tens of millions of DNA fragments per run. By contrast, Illumina's NovaSeq 6000 can read up to 20 *billion* DNA fragments per run.[77]

Although other technologies exist to analyze DNA, no other technology can analyze nearly as many DNA fragments as NGS (particularly short-read NGS) or characterize virtually all biomarkers contained within each fragment.[78] For example, polymerase chain reaction ("PCR") techniques alone can identify only a small number of cancer-related biomarkers in a patient's tissue or blood sample and do not have the ability to screen for nearly the number of genetic indicators required for an MCED test.[79] PCR is also limited to interrogating specific regions or points in the genome[80] to identify the presence or absence of pre-determined target sequences, and it is unable to detect novel genetic variants or mutations.[81] Like PCR, microarrays also test DNA fragments for the presence of predefined target sequences,[82] and are typically used to identify only single or

[76] *See* PX8399 (Henry (PacBio) Decl.) ¶ 4; [redacted]
[77] {[redacted]}
[78] *See* PX0120 at 001 (Illumina, "Advantages of next-generation sequencing vs. qPCR") (". . . qPCR can only detect known sequences. In contrast, NGS is a hypothesis-free approach that does not require prior knowledge of sequence information."); *see also* PX7097 (Felton (Thermo Fisher) Depo at 39:10-18) (testifying that PCR is generally not used to detect unknown variants).
[79] PX7097 (Felton (Thermo Fisher) Depo at 37:24-40:21); {[redacted]} PX0120 at 001 (Illumina, "Advantages of next-generation sequencing vs. qPCR") (Although qPCR may be more cost effective than NGS for assays testing for less than 20 targets, qPCR "can only interrogate a limited set of variants" and has "low scalability").
[80] PX7072 (deSouza (Illumina) IH at 240:17-19) ("A PCR test is a type of genomic test where you're looking at very specific regions of the genome.").
[81] PX7097 (Felton (Thermo Fisher) Depo at 39:10-18).
[82] PX7072 (deSouza (Illumina) IH at 55:10-55:25); PX7070 (Felton (Thermo Fisher) IH at 20:20-21:8).

small numbers of variants.[83] Neither of these technologies is appropriate for MCED tests, which require the comprehensive information provided by NGS.[84]

Today, only a few NGS platforms are available in the United States, with Illumina by far the dominant provider:

- ***Illumina.*** Headquartered in San Diego, California, Illumina develops, manufactures, and markets life sciences tools and integrated systems for large-scale analysis of genetic variation and function. Founded in 1998, Illumina's principal product offerings are short-read NGS instruments used for DNA sequencing and associated consumables, analytical software, and ancillary service contracts. Illumina currently sells eleven models of NGS instruments, with its NovaSeq platform as its highest throughput instrument today. [redacted][86] Illumina is the dominant provider of NGS platforms[87] and is the only NGS platform that meets the needs of MCED test developers.[88]

  Illumina also sells a number of clinical tests that run on its NGS instruments. One clinical test that Illumina offers is the TruSight Oncology 500 ("TSO-500") therapy selection test, which is used to help select the appropriate therapy for previously diagnosed cancer patients by analyzing the patient's tissue or blood and profiling the tumor.[89] Another clinical test that Illumina sells is a non-invasive prenatal test ("NIPT"), which is used to screen a pregnant woman's blood sample for a range of fetal chromosomal abnormalities including Down syndrome.[90] [redacted][91] Illumina founded Grail in 2015, but it subsequently

[83] PX7072 (deSouza (Illumina) IH at 55:10-55:25) (One limitation of a microarray is that "[i]t looks typically at only specific sections of the genome rather than the whole genome."); PX7111 (Fesko (Natera) Depo 60:21-61:10).
[84] *See, infra*, § II.C.i.
[85] *See* PX7107 (deSouza (Illumina) Depo at 271:8-22).
[86] [redacted]
[87] PX7070 (Felton (Thermo Fisher) IH at 26:9-28:6).
[88] *See, infra*, § II.C.ii.
[89] *See* PX0118 (Illumina, *TruSight Oncology 500)*, https://www.illumina.com/products/by-type/clinical-research-products/trusight-oncology-500.html (last visited June 30, 2021).
[90] *See* PX0091 at 020 (Illumina Source Book – August 2020) ("VeriSeq NIPT v2 now offers a genome wide screen, which significantly expands the number of chromosomal abnormalities that are screened relative to basic NIPT."); *see also* Illumina, *NIPT: A Breakthrough Genomic Solution*, https://www.illumina.com/clinical/reproductive-genetic-health/nipt.html (last visited Aug. 10, 2021).
[91] [redacted]

sold all but a small minority stake after determining that it could not afford the cost of developing Grail's products.[92]

- ***Thermo Fisher Scientific, Inc.*** Thermo Fisher Scientific, Inc. ("Thermo Fisher"), headquartered in Waltham, Massachusetts, is a global life sciences company[93] that sells short-read NGS platforms in the United States. In addition to NGS platforms, Thermo Fisher is a leading provider of PCR-based technology and Sanger sequencing technology. Thermo Fisher's sequencing platforms have performance limitations compared to Illumina's that make them unsuitable for MCED testing.[94] {[redacted]}

- ***GenapSys, Inc.*** GenapSys, Inc. ("GenapSys"), headquartered in Redwood City, California, is "focused on the advancement of universal access to genomic information by delivering an affordable, scalable, and accurate genomic sequencing ecosystem that empowers both academic and clinical research applications."[96] The Genapsys sequencing platform has significant performance limitations compared to Illumina's that make it unsuitable for MCED testing. For example, the Genapsys platform has a much lower read count than Illumina's platform[97] and potentially lower accuracy.[98]

- ***Long-Read NGS Platforms.*** There are two providers of long-read NGS platforms available in the United States: Pacific Biosciences of California, Inc. ("PacBio"), headquartered in Menlo Park, California, and U.K.-based Oxford Nanopore Technologies Ltd. ("Oxford Nanopore").[99] MCED developers do not view the long-read NGS platforms of PacBio or Oxford Nanopore as viable alternatives to Illumina's short-read NGS platform due to their lower read counts, lower accuracy, and higher costs.[100] {[redacted]}

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[92] PX7057 (Flatley (Illumina) IH at 158:4-160:7); {[redacted]} *see also, infra*, § II.D.iii.b.

[93] Thermo Fisher, *About Thermo Fisher Scientific*, https://corporate.thermofisher.com/us/en/index/about.html (last visited Aug. 10, 2021).

[94] {[redacted]}; PX7097 (Felton (Thermo Fisher) Depo at 29:2-10).

[95] {[redacted]} *see also* PX7044 (Stahl (Invitae) IH at 92:6-93:13).

[96] GenapSys, *About us*, https://www.genapsys.com/about-us/.

[97] The company has one sequencer model and commercially available chip that can read approximately 11.2 million DNA fragments per run. GenapSys, *The Genapsys Sequencer*, https://www.genapsys.com/products/genapsys-sequencer.

[98] GenapSys claims to offer "[e]xceptional accuracy." GenapSys, *The Genapsys Sequencer*, https://www.genapsys.com/products/genapsys-sequencer. But at least one MCED developer disagrees. {[redacted]}

[99] PacBio offers two sequencing platforms: the Sequel II and Sequel IIe. PX8399 (Henry (PacBio) Decl.) ¶ 6. ONT offers several ultra-long read platforms including its portable MinION device, its benchtop GridION, and its largest platform the PromethION. Oxford Nanopore Technologies, *Products*, https://nanoporetech.com/products (last visited July 1, 2021).

[100] *See, infra,* § II.C.ii.

[redacted]

D. Grail and its MCED Rivals

Grail is currently developing an MCED test along with several other firms, including Exact Sciences Corp. ("Exact"), Thrive Earlier Detection Corp. ("Thrive"),[102] {[redacted]} While Grail and its rivals may have differentiated test designs and are at various developmental stages, they all are currently competing to develop an early cancer screening test that can {[redacted]}[104]

- ***Grail.*** Headquartered in Menlo Park, California, Grail is a diagnostics company that develops NGS-based oncology tests,[105] with a focus on early cancer detection. Grail's flagship test is its MCED test, called Galleri, which it claims has the ability to detect over 50 cancers from a single blood draw.[106] Today, most of these cancers have "no existing recommended screening tests."[107] Grail's Galleri test analyzes DNA methylation patterns, or methylation abnormalities, to detect the presence of cancer in the blood.[108] To

[101] PX8399 (Henry (PacBio) Decl.) ¶¶ 5, 9–11.
[102] Thrive is now owned by Exact Sciences. Thrive, *Exact Sciences Completes Acquisition Of Thrive Earlier Detection, Creating a Leader in Blood-Based, Multi-Cancer Screening,* Press Release, Jan. 5, 2021 https://thrivedetect.com/press-release/exact-sciences-completes-acquisition-of-thrive-earlier-detection-creating-a-leader-in-blood-based-multi-cancer-screening (last visited Aug. 11, 2021).
[103] {[redacted]}
[104] {[redacted]}
[105] In addition to its Galleri MCED test, Grail is also developing a diagnostic aid to cancer ("DAC") test, which is {[redacted]} and a minimal residual disease ("MRD") test, which is used to {[redacted]}
[106] Grail, www.grail.com (last visited Aug. 12, 2021); Grail, *The Galleri Test,* https://www.galleri.com/the-galleri-test (last visited Aug. 12, 2021).
[107] PX4082 at 100 (Email attaching Grail 2020 S-1/Amended, Sept. 2020). {[redacted]}
[108] Grail, *The Galleri Test,* https://www.galleri.com/the-galleri-test (last visited Aug. 12, 2021). Grail {[redacted]}

do this, the Galleri test relies on Illumina's NGS instruments and reagents.[109] Grail recently launched Galleri as an LDT in April 2021[110] and {[redacted]}[111] Grail has completed one clinical study and has three ongoing clinical studies related to the Galleri test, one of which produced interim results that Grail has recently released.[112] Grail plans to seek FDA approval for Galleri as early as 2023.[113]

Illumina originally founded Grail {[redacted]}[114] but subsequently sold it to outside investors in 2017 because the amount of investment required to develop Grail's MCED test was "untenable."[115] As of September 2020, Grail had raised {[redacted]}[116] Prior to the Proposed Acquisition, Grail sought to raise additional money through an initial public offering, {[redacted]}[117] Because Illumina and Grail entered into an acquisition agreement on September 20, 2020, Grail never went public.[118] Should the Proposed Acquisition fall through, {[redacted]}[119] Grail, itself, recognizes that it will be {[redacted]}

[redacted]

[109] PX0043 at 011 (Grail 2020 Form S-1); PX7069 (Bishop (Grail) IH at 209:10-210:23.

[110] Grail, *GRAIL Confirms Q2 2021 Introduction of Galleri*, https://grail.com/press-releases/grail-confirms-q2-2021-introduction-of-galleri-first-of-kind-multi-cancer-early-detection-blood-test (last visited Aug. 12, 2021).

[111] {[redacted]}

[112] PX7069 (Bishop (Grail) IH at 79:2-23); PX4082 at 124-27 (Email attaching Grail 2020 S-1/Amended, Sept. 2020); PX0086 (Grail, Press Release: GRAIL Presents Interventional PATHFINDER Study Data at 2021 ASCO Annual Meeting and Introduces Galleri, a Groundbreaking Multi-Cancer Early Detection Blood Test, June 4, 2021).

[113] PX7069 (Bishop (Grail) IH at 193:23-194:16); {[redacted]}

[114] *See* [redacted]

[115] PX7057 (Flatley (Illumina) IH at 157:23-160:7).

[116] PX4082 at 086 (Email attaching Grail 2020 S-1/Amended, Sept. 2020).

[117] {[redacted]}

[118] PX7108 (Freidin (Grail) Depo at 113:1-3). Grail noted in its S-1 filing that as of June 30, 2020 it had $685.6 million in "cash, cash equivalents, and marketable securities" on hand. PX0043 at 245 (Grail 2020 Form S-1).

[119] *See, e.g.,* [redacted]

[120] {[redacted]}

- ***Exact.*** Exact is headquartered in Madison, Wisconsin with locations across the country and in Europe.[121] Exact currently offers a stool-based colorectal screening test called Cologuard that {[122] In October 2020, Exact announced its acquisition of Thrive, {[123] Exact (through Thrive) is developing an MCED test called CancerSEEK, [125] {[131] [132]

- {

[121] PX7058 (Conroy (Exact) IH at 33:22-34:4).
[122] PX7058 (Conroy (Exact) IH at 19:22-20:24; 54:17-55:8).
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[redacted]

E. The Proposed Acquisition

Illumina [redacted][185] In a related presentation, [redacted][187]

179 [redacted]
180 [redacted]
181 [redacted]
182 [redacted]
183 [redacted]
184 [redacted]
185 [redacted]
186 [redacted]
187 [redacted]

Driving its proposed acquisition of Grail was Illumina's recognition that, {[redacted]}[188] As Illumina explained in its {[redacted]}[189] Accordingly, Illumina sought to {[redacted]}[190] An acquisition, {[redacted]}[191]

On September 20, 2020, Illumina entered into an Agreement and Plan of Merger to acquire the approximately 85.5% of Grail voting shares outstanding that it does not already own for cash and stock consideration valued at approximately $7.1 billion.[192]

II. ARGUMENT

"All mergers are within the reach of [Section] 7, and all must be tested by the same standard, whether they are classified as horizontal, vertical, conglomerate or other." *FTC v. Procter & Gamble Co*., 386 U.S. 568, 577 (1967); s*ee also Brown Shoe Co. v. United States*, 370

[188] *See* PX2465 at 006-08 {[redacted]}
[189] {[redacted]}
[190] PX2169 at 045 {[redacted]}
[191] *Id.* at 038.
[192] PX5048 at 002-03 (Grail, Notification and Report Form, Oct. 9, 2020).

U.S. 294, 323-334 (1962) (applying Section 7 analysis to the vertical aspects of a proposed merger); *Ford Motor Co. v. United States*, 405 U.S. 562, 568-71 (1972) (same). As the Supreme Court has explained, "[e]conomic arrangements between companies standing in a supplier-customer relationship are characterized as 'vertical.'" *Brown Shoe*, 370 U.S. at 323. As Illumina supplies its customer, Grail, with the critical input for Grail's MCED test, the Proposed Acquisition is considered a "vertical merger" and Section 7 applies. Antitrust agencies routinely take law enforcement actions against vertical mergers where they could lead to downstream foreclosure or other anticompetitive effects.[193]

Section 7 of the Clayton Act bars mergers "the effect of [which] may be substantially to lessen competition, or to tend to create a monopoly" in "any line of commerce or in any activity affecting commerce in any section of the country[.]" 15 U.S.C. § 18 (2012). "Congress used the words '*may be* substantially to lessen competition' to indicate that its concern was with probabilities, not certainties[.]" *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 337 (3d Cir. 2016) (quoting *Brown Shoe*, 370 U.S. at 323) (emphasis in original); *see also In re Tronox Ltd.*, 2018 FTC LEXIS 190 at *16 (F.T.C. Dec. 14, 2018) ("[I]t is not necessary to demonstrate certainty that a proposed merger will produce anticompetitive effects, or even that such effects are highly probable, 'but only that the loss of competition is a "sufficiently probable and imminent" result of the merger or acquisition.'"). Section 7 of the Clayton Act was specifically enacted to "arrest anticompetitive tendencies in their 'incipiency.'" *Polypore Int'l, Inc. v. FTC*, 686 F.3d 1208, 1213-14 (11th Cir. 2012) (quoting *United States v. Phila. Nat'l Bank*, 374 U.S. 321, 362 (1963)); *see also FTC v. Proctor & Gamble Co.*, 386 U.S. 568, 577 (1967). Thus, "the ultimate issue under

[193] *See* U.S. Dep't of Justice & Federal Trade Commission, Vertical Merger Guidelines §§ 4-5 [hereinafter *Vertical Merger Guidelines*]; Steven Salop & Daniel Culley, *Vertical Merger Enforcement Actions: 1994-April 2020*, https://scholarship.law.georgetown.edu/facpub/1529/ (last visited Aug. 5, 2021) (summarizing 66 vertical merger enforcement actions since 1994).

Section 7 is whether anticompetitive effects are reasonably probable in the future, not whether such effects have occurred as of the time of trial." *In re Polypore Int'l, Inc.,* 2010 WL 9549988, at *8 (F.T.C. Nov. 5, 2010) (*citing United States v. General Dynamics Corp.*, 415 U.S. 486, 505-06 (1974)); *see also Brunswick Corp. v. Pueblo Bowl-o-Mat*, 429 U.S. 477, 485 (1977) (Section 7 is, "as [the Supreme Court has] observed many times, a prophylactic measure, intended 'primarily to arrest apprehended consequences of intercorporate relationships before those relationships could work their evil'" (quoting *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 597 (1957)). "[T]he 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 1, 79 (D.D.C. 2017) (quoting *Brown Shoe*, 370 U.S. at 321-22).

"Courts and the Commission have traditionally analyzed Section 7 claims under a burden-shifting framework," *In re Otto Bock HealthCare N. Am., Inc.*, 2019 FTC LEXIS 79, at *29 (Nov. 1, 2019); *Polypore Int'l*, 2010 WL 9549988 at *9, and the same burden-shifting framework applies to vertical mergers. *See United States v. AT&T Inc.*, 310 F. Supp. 3d 161, 191 n.15 (D.D.C. 2018) (rejecting, "as a matter of law and logic," defendants' assertion that the Section 7 burden-shifting framework is inapplicable to vertical merger cases such that the government must "account for all defendants' proffered efficiencies as part of making its prima facie case"). Under this framework, "[f]irst, the government must establish a prima facie case that an acquisition is unlawful." *Polypore Int'l*, 2010 WL 9549988 at *9; *see also United States v. Baker Hughes, Inc.*, 908 F.2d 981, 982 (D.C. Cir. 1990). In the context of vertical mergers, the government's *prima facie* case requires a "fact-specific" inquiry to determine if a vertical merger poses a reasonable probability of

anticompetitive harm in a relevant market.[194] *See United States v. AT&T, Inc.*, 916 F.3d 1029, 1032 (D.C. Cir. 2019). One way a vertical merger may result in anticompetitive harm is by "foreclosing competitors of the purchasing firm in the merger from access to a potential source of supply, or from access on competitive terms." *Yankee Entm't & Sports Network, LLC v. Cablevision Sys. Corp.*, 224 F. Supp. 2d 657, 673 (S.D.N.Y. 2002); *see also Vertical Merger Guidelines* § 4 ("A vertical merger may diminish competition by allowing the merged firm to profitably use its control of the related product to weaken or remove the competitive constraint from one or more of its actual or potential rivals in the relevant market."). As the Supreme Court explained, such foreclosure "may act as a 'clog on competition,' which 'deprive[s] . . . rivals of a fair opportunity to compete.'" *Brown Shoe*, 370 U.S. at 324 (quoting *Standard Oil Co. of Cal. v. United States*, 337 U.S. 293, 314 (1949)). Consistent with the *Vertical Merger Guidelines*, a fact-specific showing that a merger poses a reasonable probability of competitive harm can be established by showing that the merged firm has the ability and incentive to foreclose, or offer inferior terms to, rivals in the relevant market. *See Vertical Merger Guidelines* § 4; *United States v. AT&T Inc.*, 310 F. Supp. 3d 161, 252 (D.D.C. 2018) (holding that the government failed to show that AT&T has "either the 'incentive' or the 'ability' to withhold" certain promotional rights from its customers). Non-price competitive harms—such as the harm to ongoing innovation in the nascent commercial MCED market resulting from the Proposed Acquisition—are sufficient to establish a *prima facie* case under Section 7. *See AT&T, Inc.*, 916 F.3d at 1045.

Respondents can then rebut the *prima facie* case "by producing evidence to cast doubt on the accuracy of the Government's evidence as predictive of future anti-competitive effects." *Otto*

[194] Respondents endorse this approach, noting in their Answer that the FTC "must make a 'fact-specific' showing that the proposed merger is anticompetitive." *See* Answer and Defenses of Respondents Illumina, Inc. and GRAIL, Inc., *In the Matter of Illumina, Inc., and GRAIL, Inc.,* Docket No. 9401 at 5 (Apr. 13, 2021) [hereinafter "Answer"].

Bock, 2019 FTC LEXIS 79, at *31 (quoting *Chi. Bridge & Iron Co. N.V. v. FTC*, 534 F.3d 410, 423 (5th Cir. 2008)); *Polypore Int'l*, 2010 WL 9549988, at *9; *Baker Hughes*, 908 F.2d at 982. The stronger the *prima facie* case, however, "the greater [Respondents'] burden of production on rebuttal." *Polypore Int'l*, 2010 WL 9549988 at *9; *see also FTC v. H.J. Heinz Co.*, 246 F.3d 708, 725 (D.C. Cir. 2001); *Baker Hughes*, 908 F.2d at 991. Particularly in the vertical merger context, cognizable efficiencies and elimination of double marginalization ("EDM")—{[redacted]}—may, in certain cases, produce procompetitive effects to be balanced against any competitive harm. It is Respondents' burden to establish that these countervailing factors eliminate the anticompetitive harm set out in the government's *prima facie* case as Respondents are best positioned to have evidence relating to such factors. *See Smith v. United States*, 568 U.S. 106, 112 (2013) ("'[W]here the facts with regard to an issue lie peculiarly in the knowledge of a party,' that party is best situated to bear the burden of proof." (quoting *Dixon v. United States*, 548 U.S. 1, 9 (2006)); *see also Otto Bock*, 2019 FTC LEXIS 79 at *168-170 (citing *United States v. H&R Block, Inc.*, 833 F. Supp. 3d 36, 89 (D.D.C. 2011)); U.S. Dep't of Justice & Federal Trade Commission, Horizontal Merger Guidelines (2010) § 10 [hereinafter *Horizontal Merger Guidelines*] (explaining that "much of the information relating to efficiencies is uniquely in the possession of the merging firms").

Similarly, Respondents also "bear the burden of showing that any proposed remedy would negate any anticompetitive effects of the merger[.]" *Otto Bock,* 2019 FTC LEXIS 79, at *132 (quoting *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016)). Respondents assert that Illumina's Open Offer will remedy the Proposed Acquisition's potential for anticompetitive harm.[196] Respondents bear the burden of showing the Open Offer would "replace the competitive

[195] {[redacted]}
[196] Answer at 3-4.

intensity lost as a result of the merger." *Aetna*, 240 F. Supp. 3d at 60 (internal quotation marks omitted) (emphasis in original). If Respondents successfully rebut the *prima facie* case, the burden shifts again to the government, which has the ultimate burden of persuasion at all times. *FTC v. ProMedica*, 2011 WL 1219281, at *53 (N.D. Ohio Mar. 29, 2011); *Chi. Bridge*, 534 F.3d at 423; *Baker Hughes*, 908 F.2d at 983.

A. MCED Tests Form a Relevant Product Market

As this Court has explained, "[t]he first step in evaluating whether an acquisition may substantially lessen competition" is to "determine the relevant product market and the relevant geographic market." *In re Otto Bock HealthCare N. Am., Inc.*, 2019 FTC LEXIS 33, *33 (F.T.C. May 6, 2019) (quoting *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1110 (N.D. Cal 2004)). Even when the acquisition is vertical, the same analysis applies. *See Brown Shoe*, 370 U.S. at 324-28 (applying the same relative product market analysis to the vertical aspects of the merger). The relevant product market is the "line of commerce" affected by a proposed merger. *Brown Shoe*, 370 U.S. at 324. A product market's "outer boundaries" are determined by the "reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *FTC v. Tronox Ltd.*, 332 F. Supp. 3d 187, 198 (D.D.C. 2018) (quoting *Brown Shoe*, 370 U.S. at 325). Rather than a formulaic calculation, "the boundaries of the relevant market must be drawn with sufficient breadth to . . . recognize competition where, in fact, competition exists," *Brown Shoe*, 370 U.S. at 326. To make this determination, courts generally look to two types of evidence: "the 'practical indicia' set forth by the Supreme Court in *Brown Shoe*, and testimony from experts in the field of economics."[197] *FTC v. Sysco Corp.*, 113 F. Supp.

[197] Courts regularly use the hypothetical monopolist test set forth in the *Horizontal Merger Guidelines* as one means to define a relevant market. *FTC v. Penn State Hershey Med. Center*, 838 F.3d 327, 338 (3d Cir. 2016); *Sysco*, 113 F. Supp. 3d at 33; *H&R Block,* 833 F. Supp. 3d at 51-52. This test defines a relevant market in economic terms, by asking whether a hypothetical monopolist of a particular group of substitute products could profitably impose a

3d 1, 27 (D.D.C. 2015). Here, both types of evidence support the conclusion that MCED tests constitute an appropriate relevant antitrust market.

While the commercial MCED market is nascent, Section 7 of the Clayton Act was specifically enacted to "arrest anticompetitive tendencies in their 'incipiency.'" *Polypore Int'l, Inc. v. FTC*, 686 F.3d 1208, 1213-14 (11th Cir. 2012) (quoting *United States v. Phila. Nat'l Bank*, 374 U.S. 321, 362 (1963)); *see also FTC v. Proctor & Gamble Co.*, 386 U.S. 578, 577 (1967). In fact, courts have long applied antitrust laws to firms that have not yet entered or do not yet have sales in the relevant markets. *See, e.g.*, *Polypore Int'l, Inc. v. FTC*, 686 F.3d 1208, 1214 (11th Cir. 2012) (explaining that although a company had not sold products in the market, it is still a competitor as Section 7 of the Clayton Act is "concerned with probabilities, not certainties"); *FTC v. Procter & Gamble Co.*, 386 U.S. 568, 578, 580 (1967) (finding that the acquisition "eliminates the potential competition of the acquiring firm"); *United States v. General Dynamics Corp.*, 415 U.S. 486, 501 (1974) ("Evidence of past production does not, as a matter of logic, necessarily give a proper picture of a company's future ability to compete."); *see also Horizontal Merger Guidelines* § 5.3 ("A merger between an incumbent and a potential entrant can raise significant competitive concerns.") and § 5.1 ("Firms not currently earning revenues in the relevant market, but that have committed to entering the market in the near future, are also considered market participants."); *United States v. Aetna Inc.*, 240 F. Supp. 3d 1, 76 (D.D.C. 2017) ("Antitrust law is concerned with a company's future ability to compete, and deals in probabilities, not certainties.") (internal cites and quotations omitted).[198] Here, although most MCED tests are still in

"small but significant non-transitory increase in price" ("SSNIP") over those products, or whether customers switching to alternative products would make such a price increase unprofitable. *Horizontal Merger Guidelines* § 4.1.1; *see also In re Otto Bock HealthCare N. Am., Inc.*, 2019 FTC LEXIS 33, *37 (May 6, 2019).

[198] Courts similarly apply antitrust principles of competition to firms *perceived* to be competitors when it "would be reasonable to consider [them] as . . . potential entrant[s] into a market." *See United States v. Falstaff Brewing Co.*, 410 U.S. 526, 533 (1973).

development, {[redacted]}[199] Instead, these extensive development efforts reveal the active and vigorous innovation competition taking place today.[200]

i. *Brown Shoe* Practical Indicia Show MCED Tests Constitute a Relevant Product Market

In *Brown Shoe,* the Supreme Court identified a series of "practical indicia" courts should consider in determining the relevant product market. The indicia include "industry or public recognition of the [market] as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." *Brown Shoe*, 370 U.S. at 325; *see also Sysco* 113 F. Supp. 3d at 27; *Aetna*, 240 F. Supp. 3d at 21; *H&R Block*, 833 F. Supp. 2d at 51. At least five of the practical indicia discussed in *Brown Shoe* establish MCED tests as a relevant product market. Together, these practical indicia establish MCED tests as a separate relevant product market for purposes of assessing the Proposed Acquisition's impact on competition.[201]

[199] {[redacted]}

[200] *See, e.g.*, [redacted]

[201] MCED test" is a commonly used term across the industry to describe early cancer screening tests that detect multiple cancers simultaneously. {[redacted]}

Peculiar Characteristics and Uses. Because of their novel role in cancer detection, MCED tests have unique characteristics that set them apart from other oncology tests. Considered the "holy grail" of liquid biopsies, MCED tests can detect multiple types of early-stage cancer in asymptomatic individuals by examining the presence of ctDNA in the bloodstream.[202] MCED tests are positioned to fundamentally change the standard of care across oncology testing[203] by detecting cancer much earlier than traditional methods.[204]

First, MCED tests have different intended uses and different characteristics than other non-early detection oncology tests, including other NGS-based oncology tests like DAC, MRD, and therapy selection tests. MCED test developers expect that their tests will be used to detect multiple cancers simultaneously in otherwise healthy individuals.[205] In contrast, DAC tests, like the one in development from Grail, are {[redacted]}[206] Therapy selection tests are intended for patients with "advanced cancer" and assist the physician with determining "the course of therapy they will pursue" to treat the cancer.[207] And MRD tests are

[redacted]

[202] {[redacted]}

[203] The goal of these tests is to screen for multiple cancers simultaneously using only a single blood sample, which will "improve compliance [with cancer screening protocols] and reduce cancer-related mortality." PX5027 at 005 (Illumina, Board of Directors Meeting, Aug. 3, 2020).

[204] *See* PX0037 at 002-006 (Grail, Investor Call Script, Jan. 10, 2016).

[205] {[redacted]} PX7100 (Chudova (Guardant) Depo at 15:15-16:9); {[redacted]}

[207] PX7040 (Getty (Guardant) IH at 44:21-45:22) (describing Guardant360, a 74-gene therapy selection assay).

{[redacted]}[208]

Second, MCED tests are designed to be complementary to, not a replacement for, existing cancer screening methods. Today, USPSTF, an independent group of experts which "set[s] the standards" for cancer screening, recommends cancer screening tests for only four types of cancer—lung, breast, colorectal, and cervical.[209] And, the vast majority of cancers have no screening options at all.[210] Market participants, including the parties, recognize that MCED tests will "complement [existing USPSTF] tests rather than replace them."[211] For instance, Grail has publicly represented on the front page of its website for its Galleri test that Galleri "is intended to be used in addition to and not replace other cancer screening tests."[212] Likewise Illumina, in its {[redacted]}[213] Even one of {[redacted]}[214] Industry participants have testified that MCED tests will be used in conjunction with existing

[208] {[redacted]} As Respondents admit in their Answer, "[a] monitoring test personalized for an individual's tumor is nothing like a generalized 50+ cancer test for population-scale screening of asymptomatic individuals who are not known for cancer and certainly have never been treated for cancer." Answer at 9.
[209] PX7040 (Getty (Guardant) IH at 26:3-27:22); {[redacted]}
[210] {[redacted]}
[211] PX7101 (Vogelstein (JHU) Depo at 51:16-52:13); {[redacted]}; PX7082 (Ofman (Grail) Depo at 92:5-15) (stating that "Grail's multi-cancer early detection test is a complement to, not a replacement for, the standard of care single-cancer screening tests").
[212] Grail, *Galleri*, www.galleri.com (last visited Aug. 9, 2021); *see also* PX7083 (Bishop (Grail) Depo at 24:1-25); {[redacted]}
[213] {[redacted]}
[214] {[redacted]}

screening technologies, either to detect cancers for which there are no current screens, or to serve as a "noninvasive test up front" before proceeding to USPSTF recommended screenings.[215]

NGS-based single cancer screening tests are also not close substitutes for MCED tests. As Grail recognizes, MCED tests [redacted]}[216] Illumina agrees, explaining in an ordinary course document that [redacted]}[217] Illumina acknowledges that, unlike single cancer screening tests, MCED tests identify more tumors, improve patient compliance, and enable [redacted]}[218] For these reasons, other market participants also do not view NGS-based single cancer early detection tests as directly competitive with MCED tests.[219] As Guardant's VP of Commercial, Cancer Screening Core, William Getty testified, "if we can offer a physician a test that covers colorectal, breast, lung, pancreatic, you know, so on and so forth, with the check of a pen . . . that would have significant value to the patient to be screened for multiple

[215] PX7040 (Getty (Guardant) IH at 154:5-155:8); {[redacted]} *see also* PX7083 (Bishop (Grail) Depo at 24:1-25).
[216] {[redacted]}
[217] {[redacted]}
[218] {[redacted]}
[219] *See* PX7105 (Getty (Guardant) Depo at 25:19-27:9) (testifying that "a multi-cancer test provides distinct value over a single cancer test"); PX7042 (Gao (Singlera) IH at 120:7-24).

cancers at one particular time and also value for the physician who could do so in an efficient fashion."[220]

Although some MCED test developers first plan to seek regulatory approval for a single cancer indication, it does not change the fact that these companies have and are continuing to develop MCED tests to rival Grail's Galleri test. As one market participant explains, {[redacted]}[223] {[redacted]}[226] {[redacted]}

[220] PX7105 (Getty (Guardant) Depo at 23:9-24); [redacted]

[221] {[redacted]}

[222] {[redacted]}

[223] {[redacted]}

[224] {[redacted]}

[225] {[redacted]}

[226] {[redacted]}

[redacted]}[227] In fact, Grail itself publicly pivoted from single cancer to multi-cancer detection as recently as 2018.[228]

Distinct Customers. MCED tests are designed to screen asymptomatic patients at their annual routine appointments.[229] Because these tests are targeted towards patients who do not have symptoms of, and have not been treated for, cancer, {[redacted]}[230] This contrasts with other oncology tests, including the DAC and MRD tests in development from Grail and the therapy selection tests offered by Illumina, which target oncologists and other cancer specialists. Because DAC tests are intended for [redacted]}[232] who would see the patients experiencing symptoms.[233] As the patient is undergoing treatment for cancer, these same oncologists would use therapy selection tests to help inform the treatment.[234] Finally, once a patient has been treated for cancer, oncologists who have

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[redacted]

[227] {[redacted]}

[228] Grail, *Galleri Development Timeline*, https://grail.com/wp-content/uploads/2021/06/GRAIL_-_Galleri_Development_Timeline_FINAL.pdf (last visited Aug. 12, 2021) (stating that in April 2018 "Grail announced pivot from single cancer to multi-cancer detection").

[229] PX7040 (Getty (Guardant) IH at 31:21-32:3); *see also* {[redacted]} PX7051 (Lengauer (Third Rock Ventures) IH at 28:17-29:18); PX7100 (Chudova (Guardant) Depo at 15:15-16:9); PX7094 (Nolan (Freenome) Depo at 252:18-253:17).

[230] {[redacted]}

[231] {[redacted]}

[232] {[redacted]}

[233] {[redacted]}

[234] PX7040 (Getty (Guardant) IH at 68:25-69:20); {[redacted]} Pharmaceutical companies may also use therapy selection tests as a companion to their drugs and therapies. *See* {[redacted]}

engaged in the patients' treatment will use MRD tests to monitor their patients for cancer recurrence.[235]

Distinct Prices. MCED test developers plan to set prices for their MCED tests distinctly from other oncology tests. Because many other oncology tests are targeted towards more discrete patient populations, such as patients suspected to have or already diagnosed with cancer, insurance will cover the higher prices of these tests.[236] In contrast, MCED tests are expected to cover a more general population, with the goal of screening a large portion of asymptomatic adults in the United States.[237] Accordingly, these tests must be priced low enough to become widely adopted in the marketplace.[238] As Illumina's CEO Francis deSouza testified, {[redacted]}[239] Guardant's Senior VP of Product, Nitin Sood, {[redacted]} testifying that "screening, to be widely accepted, must be economical because it addresses such a large population. Whereas . . . tests that may address niches of people, you know, patient population, small groups of patient populations, can be more expensive."[240] Grail internally performed its own analysis of {[redacted]}

[235] {[redacted]}
[236] *See* [redacted]
[237] {[redacted]}
[238] {[redacted]}
[239] {[redacted]}
[240] PX7090 (Sood (Guardant) Depo at 110:9-111:11).

[redacted]}[241] Moreover, Grail monitoring the pricing of its {[redacted]}[242]

Specialized Vendors. To develop MCED tests successfully, MCED test developers require specialized equipment to run their tests and large-scale clinical trials to verify and validate their tests. Because finding traces of cancer in the blood of an otherwise healthy patient is akin to finding a "needle in a haystack,"[243] MCED tests require NGS technology. Unlike other testing technologies, NGS is able to screen for thousands or tens of thousands of potential biomarkers (such as mutations or methylation patterns) consistent with cancer in asymptomatic individuals, and can provide detailed information about the specific cancer, its genetic drivers, and its location in the body.[244] Further, in order to commercialize MCED tests, test developers must engage in multi-year, large-scale clinical studies to ensure that the test works. As Respondents explain in their Answer, "[g]iven the low prevalence of cancer in asymptomatic average-risk individuals, such multi-year studies are essential to safely launch such a test."[245] Accordingly, Grail and its competitors have initiated or conducted these studies in pursuit of launching their tests.[246] The need for these large-scale trials, however, necessarily limits the number of developers able to compete in the U.S. MCED test market. As Grail explained in its S-1 filing, many companies do

[241] {[redacted]}
[242] {[redacted]}
[243] {[redacted]} PX7040 (Getty (Guardant) IH at 38:24-39:17) ("you truly are finding a needle in a haystack"); PX7042 (Gao (Singlera) IH at 39:12-40:7) (explaining that "the cancer signal [in the blood is] very subtle"); PX7045 (Chudova (Guardant) IH at 30:3-31-2).
[244] PX7042 (Gao (Singlera) IH at 39:2-40:7).
[245] Answer at 9.
[246] *See* Answer at 9 ("In developing Galleri, GRAIL has conducted multiple multi-year large-scale clinical studies, costing several hundred million dollars[.]"); {[redacted]}

not have "the financial resources to invest in population-scale clinical trials and rigorous analytics to compete with our products."[247]

Industry Recognition of MCED Tests as a Separate Market. "When determining the relevant product market, courts often pay close attention to the defendants' ordinary course of business documents." *Sysco*, 113 F. Supp. 3d at 41 (quoting *H&R Block*, 833 F. Supp. 2d at 52). Here, Respondents' own documents, as well as those of other market participants, unambiguously reveal that MCED tests constitute a relevant product market and that MCED tests will likely be close substitutes for one another. Throughout its ordinary course documents, Grail identifies itself as {[redacted]}[248] Grail also considers other MCED test developers as its {[redacted]}[249] and they view Grail as the same.[250] To further classify MCED tests as a separate market, Grail {[redacted]}

[247] PX0043 at 119-120 (Grail 2020 Form S-1).

[248] {[redacted]} This is consistent with testimony from Grail's executives. *See* {[redacted]} PX7083 (Bishop (Grail) Depo at 23:12-24:25); PX7103 (Jamshidi (Grail) Depo at 38:13-39:9).

[249] *See, e.g.*, {[redacted]}

[250] {[redacted]}

[251] {[redacted]}

[redacted]}[254] Illumina and Grail's views are consistent with those of other MCED test developers.[255]

In addition, the U.S. House of Representatives and Senate introduced the Medicare Multi-Cancer Early Detection Screening Coverage Act of 2020, which states that MCED tests "can complement the covered early detection tests," rather than replace them. This bill would authorize CMS to cover MCED tests once approved by the FDA, leap-frogging the USPSTF's review process.[256]

ii. Differentiation in MCED Tests Does Not Change the Relevant Product Market

[252] {[redacted]}

[253] MCED Consortium, Press Release: Multi-Cancer Early Detection (MCED) Consortium to Chart Path Forward for Use of New Technologies to Improve Early Cancer Detection, Apr. 22, 2021, https://www.prnewswire.com/news-releases/multi-cancer-early-detection-mced-consortium-to-chart-path-forward-for-use-of-new-technologies-to-improve-early-cancer-detection-301274579.html (last accessed Aug. 12, 2021).

[254] {[redacted]}

[255] *See* [redacted]}

[256] *See* H.R. 8845 (116th Congress, 2d Session), Sec. 2(a)(7); *see* Press Release, Reps. Sewell, Arrington, Ruiz, and Hudson Introduce Bipartisan Legislation to Remove Barriers to Innovative Multi-Cancer Screening Technology for Medicare Beneficiaries (Dec. 3, 2020), https://sewell.house.gov/media-center/press-releases/reps-sewell-arrington-ruiz-and-hudson-introduce-bipartisan-legislation (stating "these new tools will complement, not replace, existing screenings").

Respondents point out technical differences between Grail's Galleri test and other MCED tests, arguing that rival tests "are likely to be differentiated from Galleri in several ways," including "the number and types of cancers detected," "the level of sensitivity and specificity for different cancers," and "the ability or inability to detect cancer signal of origin[.]"[257] But products need not be identical to fall within the same product market. *See United States v. Energy Sols., Inc.*, 265 F. Supp. 3d 415, 436 (D. Del. 2017) (products comprising a relevant market "need not be identical, only reasonable substitutes"); *see also Hicks v. PGA Tour Inc.,* 897 F.3d 1109, 1122 (9th Cir. 2018) (holding that "claims of increased effectiveness" of certain products does not "place" those products "in a distinct market"); *Humana Inc. v. Mallinckrodt Ard LLC*, 2020 U.S. Dist. LEXIS 101378 at *12, FN2 (C.D. Cal 2020) (explaining "it is wrong" to suggest that because two products "are not identical" they are not in the same relevant product market). Instead, the number of cancers that MCED tests detect, the level of specificity and sensitivity that they achieve, and their ability to detect the tissue of origin of a cancer signal are all *points of competition* rather than *the absence of competition*.[258]

[257] Answer at 10. Respondents' [redacted]

[258] For example, { [redacted] *Id.*

MCED tests that look to different types of biomarkers than Grail or focus on different sets of cancers do not create entirely separate product markets, but instead represent different approaches to solving the difficult problem of early cancer screening. In order to detect cancer in the blood, MCED tests look for certain biomarkers or analytes that are indicative of cancer.[259] In developing their tests, MCED test developers are analyzing different biomarkers, or different combinations of biomarkers, in the pursuit of developing the best performing test. For example, {[redacted]}[261] As Dr. Cance explained, "I don't believe we will have one test be 100 percent accurate and zero percent inaccurate. So, therefore, multiple companies and institutions developing and improving this technology is very important."[262] Similarly, MCED tests that measure several, but fewer than 50, cancers are also not excluded from the market. {[redacted]}[263] Further, for some cancers, if the sensitivity level, meaning the ability to detect cancer in a patient that actually has cancer, is

[259] {[redacted]}
[260] {[redacted]}
[261] {[redacted]}
[262] PX7086 (Cance (American Cancer Society) Depo at 100:15-101:10).
[263] *See, e.g.*, {[redacted]}

too low, it diminishes the value of detecting those cancers.[264] {[redacted]}[265]

Even the CEOs of both Illumina and Grail recognize that the benefits of having multiple approaches to the development of MCED tests. Grail's CEO, Hans Bishop, testified that patients benefit from having multiple MCED tests in development. As he explained: "difficult problems are, by definition, hard to solve, and having a multitude of different approaches is a good thing."[266] He went on to emphasize that "one of the exciting things about the horizon scanning we do and the field in general is the number of different approaches different companies are taking."[267] Whereas Grail has chosen to focus on cfDNA methylation, he explained that other companies have chosen to focus on protein analysis and others on multi-omics that "combin[e] those different modalities."[268] These approaches, Bishop emphasized, all intend to reach the same goal—"to get to the highest-performing technology."[269] In addition, after Illumina spun off Grail into an independent entity, Illumina's CEO, Francis deSouza, explained at a conference:

> There are 70-plus players now in the liquid biopsy space. We want to encourage them to look at all different avenues because this is important and the outcome's terrific for mankind. There are different points of view. There are companies that believe it's going to be a combination of ultra-deep screening of the blood samples plus tissue, whole transcriptome analysis to identify tissue of origin. And to be honest, I think people are approaching it slightly differently and the market will sort of determine where the biology is and what the right answer is.[270]

[264] *See* PX7105 (Getty (Guardant) Depo at 48:13-50:3); {[redacted]}
[265] {[redacted]}
[266] PX7069 (Bishop (Grail) IH at 154:22-156:2).
[267] *Id.*
[268] *Id.*
[269] *Id.*
[270] Illumina Inc. at Goldman Sachs Global Healthcare Conference, FD (Fair Disclosure) Wire, Conference Call Transcript, June 13, 2017.

Rather than delineating entirely new product markets, differences among MCED tests, such as differences in performance, will simply be factors that a physician weighs in choosing between MCED tests.[271]

As the Supreme Court explained in *Brown Shoe*, "the boundaries of the relevant market must be drawn with sufficient breadth . . . to recognize competition where, in fact, competition exists." *Brown Shoe*, 370 U.S. at 326. This is because the relevant product market is meant to reflect actual "business reality" of where the competitive concerns may arise. *FTC v. Cardinal Health,* 12 F. Supp. 2d 34, 46 (D.D.C. 1998) (quoting *FTC v. Coca-Cola Co.*, 641 F. Supp. 1128, 1132 (D.D.C. 1986), *vacated as moot*, 829 F.2d 191 (D.C. Cir. 1987)). Respondents seek to avert the purpose of the relevant product market definition and instead narrow it so much so that *no one* competes against Grail;[272] this belies actual market realities. Instead, MCED test developers are currently investing hundreds of millions of dollars to innovate and compete against Grail and other MCED developers to develop and commercialize MCED tests.[273] {

[271] *See* PX7105 (Getty (Guardant) Depo at 199:24-200:10 (testifying that "the value proposition presented to a physician and the choice that a physician will make will be based on a multitude of factors, and one of those is performance"); {

[272] {

[273] {

}

[redacted][274]

Grail, through its competitive intelligence team, recognizes and vigorously tracks the same MCED test developers with whom Respondents now claim Grail will not compete, including [redacted][275] In its competitive analyses, [redacted][276] Moreover, every MCED test developer similarly views Grail as their primary competitor.[277] Indeed, Grail is not a market of one, but a participant in a market with several strong competitors nipping at its heels.

iii. The Hypothetical Monopolist Test Confirms MCED Tests Are a Relevant Product Market

Along with the practical indicia set out in *Brown Shoe*, courts also commonly use the hypothetical monopolist test to assess the relevant product market. *See FTC v. Advocate Health Care Network*, 841 F.3d 460, 468-69 (7th Cir. 2016) (applying the hypothetical monopolist test to define a relevant geographic market); *In re ProMedica Health Sys., Inc.*, 2012 WL 1155392, at *14 (F.T.C. Mar. 28, 2012) (citations omitted); *see also Sysco*, 113 F. Supp. 3d at 33; *Horizontal Merger Guidelines* § 4. Under the hypothetical monopolist test, a candidate market constitutes a

[redacted]

relevant antitrust market if a hypothetical monopolist could profitably impose a "small but significant and non-transitory increase in price" ("SSNIP") on at least one product of the merging parties in the candidate market. Here, the applicable question is whether a hypothetical monopolist owning Grail's Galleri test and all other third-party MCED tests currently in development could profitably impose a SSNIP, or a reduction in test quality, on one of the products, because if it could, MCED tests would constitute a relevant product market.

[redacted][278]

[redacted][281]

B. The United States is the Relevant Geographic Market

[redacted]

278 [redacted]
279 [redacted]
280 [redacted] *see also Horizontal Merger Guidelines* § 4.1.3 ("Even when the evidence necessary to perform the hypothetical monopolist test quantitatively is not available, the conceptual framework of the test provides a useful methodological tool for gathering and analyzing evidence pertinent to customer substitution and to market definition. The Agencies follow the hypothetical monopolist test to the extent possible given the available evidence, bearing in mind that the ultimate goal of market definition is to help determine whether the merger may substantially lessen competition.").
281 [redacted]

The relevant market in which to assess the anticompetitive harms of the Proposed Acquisition necessarily includes the relevant geographic market, or the area of competition affected by the merger. *See Sysco*, 113 F. Supp. 3d at 48 ("[t]he proper question to be asked . . . [is] where, within the area of competitive overlap, the effect of the merger on competition will be direct and immediate.'" (quoting *Phila. Nat'l Bank*, 374 U.S. at 357)); *see also Horizontal Merger Guidelines* § 4.2. Here, the United States is the relevant geographic market in which to analyze the effects of the Proposed Acquisition. MCED tests are carefully regulated in the United States by the FDA and CMS (via the CLIA).[282] {[redacted]}[283] and because of the unique payor system in the United States, {[redacted]}[284] Furthermore, turnaround time for these tests is important to ensure that cancer is identified and treated quickly,[285] so end customers are unlikely to turn to a foreign-based firm which may increase the time to receive results.[286] {[redacted]}

[282] *See, supra,* § I.B.
[283] *See* {[redacted]}
[284] {[redacted]}
[285] PX7040 (Getty (Guardant) IH at 51:7-54:1); *see also* PX0043 at 032-33 (Grail 2020 Form S-1).
[286] MCED test developers also have raised concerns about other countries having access to data from American citizens. *See, e.g.*, {[redacted]} These concerns extend beyond mere speculation. Recent news reports reveal that BGI provided pregnant mothers' genetic data to the Chinese military to "improve 'population quality.'" Reuters, *China's gene giant harvests data from millions of women*, https:// https://www.reuters.com/investigates/special-report/health-china-bgi-dna/ (last visited Aug. 11, 2021).

[redacted]}[287]

C. Illumina's NGS Instruments and Consumables are Related Products to MCED Tests

While merger analysis typically defines a "relevant market in which the merger may substantially lessen competition," vertical mergers typically involve one or more *related* products that are "positioned vertically or [are] complementary to the products and services in the relevant market."[288] Although the government is not required to prove a related product market to prevail in a vertical merger case, *see Brown Shoe*, 370 U.S. at 325 (finding a Section 7 violation when only a relevant product market was shown); *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 593-95 (1957) (same); *see also Vertical Merger Guidelines* § 3, a vertical merger may raise competitive concerns if the merged firm can "profitably use its control of the related product to weaken or remove the competitive constraint from one or more of its actual or potential rivals in the relevant market."[289] *Id*. at § 4(a).

Here, Illumina's NGS instruments and consumables are related products to MCED tests, serving as critical inputs necessary to their development and commercialization. As Illumina's Senior VP of Corporate Development and Strategic Planning explained, "NGS is a great solution" for applications like cancer screening because "cancer is by definition a disease that manifests due to changes in DNA" and "NGS helps customers assess the . . . changes in DNA . . . very, very quickly and comprehensively."[290] While there are a limited number of NGS systems available for use in the United States, none of them (aside from Illumina) meet the requirements of MCED test

[287] {[redacted]}
[288] *Vertical Merger Guidelines* § 3.
[289] *See also* Steven C. Salop, *Invigorating Vertical Merger Enforcement*, 127 Yale L.J. 1962, 1975 (2018).
[290] PX7087 (Goswami (Illumina) Depo at 100:10-101:3).

developers regarding accuracy and throughput.[291] Instead, MCED test developers must depend on Illumina's NGS instruments and reagents to develop and run their tests because no other technology—NGS or otherwise—is capable of meeting the MCED test developers' requirements of high accuracy, high throughput (specifically high read count), and low cost. It is no surprise, then, that every MCED test developer relies on Illumina today.[292]

i. MCED Test Developers Require Highly Accurate, High-Throughput NGS Instruments

MCED test developers must solve the difficult problem of finding cancer signals in the blood of otherwise healthy patients.[293] {[redacted]}[295] As Grail illustrated in an external presentation, {[redacted]}

[291] *See, infra*, § II.C.ii.

[292] Complaint Counsel is not aware of any MCED test developer using a non-NGS instrument or non-NGS technology to develop its MCED test. [redacted]

[293] PX7042 (Gao (Singlera) IH at 39:12-40:7) (explaining that "the cancer signal [in the blood is] very subtle"); PX7045 (Chudova (Guardant) IH at 28:19-31:20) ("What you're looking for is a mutation that originate in the tumor, so you have to test all thousand molecules to find that single one that potentially has the mutation. And so, in addition to covering large number of mutations, you have to sequence each locus deeply to find that needle in the haystack that potentially contains the mutation that you're looking for, so it's a combination of testing multiple sites and testing them deeply for any one individual patient to give them a comprehensive answer.").

[294] {[redacted]} PX7040 (Getty (Guardant) IH at 38:24-39:17).

[295] {[redacted]}

[296] {[redacted]}

[redacted]}

Accordingly, MCED tests require highly accurate, high-throughput NGS instruments and consumables.[297]

Because inaccurate MCED screening results can significantly harm patients,[298] MCED tests must deliver a high level of accuracy, which includes (1) specificity, and (2) sensitivity. First, an MCED test must have high specificity, meaning the test does not indicate that a patient *has* cancer when, in fact, the patient does not.[299] A false-positive test result is a "potentially damaging, worrisome thing" that could lead to unnecessary follow-up screening, if not more invasive interventions.[300] Second, an MCED test must have high sensitivity, meaning that the test actually indicates for cancer when a patient does, in fact, have cancer.[301] A false-negative result could

[297] {[redacted]}.
[298] PX7042 (Gao (Singlera) IH at 32:5-16); PX7041 (Spetzler (Caris) IH at 131:18-132:13).
[299] PX7042 (Gao (Singlera) IH at 31:8-13); PX7041 (Spetzler (Caris) IH at 33:13-34:5).
[300] PX7042 (Gao (Singlera) IH at 31:14-25); *see also* PX7040 (Getty (Guardant) IH at 36:10-37:19); PX7045 (Chudova (Guardant) IH at 64:6-25); {[redacted]}
[301] PX7042 (Gao (Singlera) IH at 32:1-4); PX7041 (Spetzler (Caris) IH at 33:13-34:5).

leave a patient with life-threatening cancer undiagnosed.[302] To deliver sufficiently accurate results, MCED test developers must use sequencing technology with low error rates.[303]

In addition to accuracy, successful development and commercialization of MCED tests requires high-throughput sequencing. Throughput refers to the amount of DNA that a sequencer can read in a single run of the instrument or in a given period of time. Throughput may be expressed as the total sequencing output (i.e., number of gigabases of DNA read) per run or as the number of DNA fragments sequenced (i.e., read count) per run.[304] For the MCED test application, read count per run is the critical measure of throughput, as that determines the number of cfDNA molecules that can be analyzed[305] and, in turn, the number of patient samples that an NGS platform can process in a given period of time.[306] Moreover, as MCED testing approaches population-scale asymptomatic screening, having a sequencer able to process a high number of patient samples per run becomes increasingly important.[307] {[redacted]}

[redacted]

[redacted]

[redacted]

[302] PX7042 (Gao (Singlera) IH at 32:5-33:2).

[303] {[redacted]} PX7075 (Stahl (Invitae) Depo at 71:6-74:16) (describing how some NGS platform's error rates are prohibitively high for Invitae's applications).

[304] *See, e.g.*, Illumina, *NovaSeq™ 6000 Sequencing System* ("The NovaSeq 6000 System offers output up to 6 Tb and 20B reads in <2 days."), https://www.illumina.com/content/dam/illumina/gcs/assembled-assets/marketing-literature/novaseq-6000-spec-sheet-770-2016-025/novaseq-6000-spec-sheet-770-2016-025.pdf (last visited Aug. 11, 2021).

[305] {[redacted]} PX7054 (Rabinowitz (Natera) IH at 47:3-19) (explaining that "throughput refers to the number of reads").

[306] *See, e.g.*, {[redacted]} PX7047 (Cooper (Progenity) IH at 54:11-55:1).

[307] {[redacted]} PX7070 (Felton (Thermo Fisher) IH at 52:2-53:19).

[redacted]}[308] Finally, high-throughput NGS sequencing also reduces the cost of sequencing for MCED tests. The more patient samples an NGS platform can process per sequencing run, the lower the costs to MCED test developers of running each patient sample.[309] Because MCED test developers seek to ultimately test most of the adult population in the United States, low costs are critical to the success of an MCED test.[310]

ii. Illumina is the Only NGS Platform to Meet the Requirements of MCED Tests

Illumina is the only NGS platform capable of meeting the technological demands required by MCED test developers. Illumina's NGS platforms offer lower error rates than other NGS sequencers available in the United States and, thus, are uniquely capable of meeting MCED accuracy requirements.[311] For instance, {[redacted]}[312] Illumina's NGS platform is also the only platform with sufficient throughput (read count per run) to accommodate MCED testing.[313] {[redacted]}[314]

308 {[redacted]}
309 {[redacted]}
310 *See, supra,* § II.A.i.
311 {[redacted]}
312 {[redacted]}
313 {[redacted]}
314 {[redacted]}

[redacted][315] And related to its high-throughput capability, Illumina's NGS platform is also the only cost-effective technology for these tests.[316] [redacted][317]

MCED test developers, including Grail, recognize their reliance on Illumina as the only option for the development and commercialization of their tests.[318] [redacted][321] Even Grail detailed in the "Risk Factors" in its Form S-1 to investors, "[w]e rely on Illumina, Inc. as a sole supplier for our next-generation sequencers and associated reagents[.]"[322] In an internal document, Grail also [redacted][323]

Other NGS instruments and consumables available for use in the United States are not options for MCED test developers. [redacted]

315 [redacted]
316 PX7042 (Gao (Singlera) IH at 43:8-13 ("Illumina has the highest throughput and also low cost per base. . . ."); [redacted]
317 *See* [redacted]
318 *See, e.g.*, [redacted]
319 [redacted]
320 [redacted]
321 [redacted]
322 PX0043 at 011 (Grail 2020 Form S-1).
323 [redacted]

[redacted]}[324] Thermo Fisher, the only other company offering a short-read NGS platform in the United States, is not an adequate alternative to Illumina for MCED tests. In fact, MCED test developers expressed a full-throated rejection of its technology. Not only is Thermo Fisher's platform difficult to use,[325] its throughput is too low for MCED screening.[326] Likewise, MCED test developers have testified that Thermo Fisher's error rate is far too high to be used for a commercially viable test.[327] Even Thermo Fisher's Vice President of Product Management, Andrew Felton, admits Thermo Fisher's NGS platforms are not used for MCED tests because "the implementation of such a test is likely favored to a very high throughput system in a centralized facility, and our systems are generally suited to . . . smaller amounts of patient samples."[328]

Long-read NGS platforms are not alternatives to Illumina's NGS platform for MCED tests.[329] The main benefit of long-read sequencing over short-read sequencing, like Illumina's, is the ability to sequence contiguous strands of DNA that are typically tens of thousands of base pairs long or more.[330] This capability, however, provides zero benefit for sequencing cfDNA, as required for MCED tests, because cfDNA strands are typically fewer than 200 base pairs long.[331]

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[324] {[redacted]}

[325] PX7042 (Gao (Singlera) IH at 42:18-43:7) (testifying that Thermo Fisher's platforms are "not cost-effective" and "not an easy workflow," and that "[t]hey are not basically a viable alternative to Illumina['s] platform.").

[326] {[redacted]}

[327] {[redacted]}

[328] PX7070 (Felton (Thermo Fisher) IH at 52:2-53:19).

[329] For a discussion of the differences between long-read and short-read sequencing, *see, supra,* § I.C.

[330] PX8399 (Henry (PacBio) Decl.) ¶ 3. "Longer reads are particularly beneficial for applications such as human whole-genome sequencing because it is easier to determine the entire genomic sequence by assembling fewer longer sequence fragments than by assembling many short ones." *Id.*

[331] PX8313 at 002 (Guardant, Background Information on Liquid Biopsy for NGS Tests) ("cfDNA is composed of small DNA fragments mostly in the range of 140-190 base pairs[.]"); [redacted]

Illumina's short-read NGS platform is capable of sequencing entire strands of cfDNA, rendering long-read sequencing technology unnecessary.[332] Long-read sequencing platforms also have higher error rates, much lower throughput (on the critical metric of read count per run), and higher cost per patient sample than short-read sequencing platforms. For these reasons, MCED developers dismissed long-read NGS platforms for MCED tests.[333] {[redacted]}[334]

NGS platform providers also recognize long-read sequencing as a poor fit for MCED tests, where high throughput and accuracy are paramount. Illumina's Senior Vice President and Chief Technology Officer, Alex Aravanis, described Illumina as "superior in a meaningful way . . . around data accuracy, so the accuracy of the Oxford Nanopore reads is not as good as the Illumina reads."[335] {[redacted]}

[332] PX8399 (Henry (PacBio) Decl.) ¶ 5; PX2544 at 026-027 (Email from Tyco Peterson, JP Morgan, attaching "JP Morgan Life Sciences CEO Conference Call Series Transcript," Sept. 5, 2019) (Francis deSouza, Illumina's CEO, noting that in looking at circulating tumor DNA fragments, "the ability to do very long-read doesn't offer any incremental value and certainly isn't worth paying a significant premium in terms of the cost per base.").

[333] {[redacted]}

[334] {[redacted]}

[335] PX7065 (Aravanis (Illumina) IH at 157:22-159:7) (noting that MCED tests other than Grail are even more sensitive to NGS accuracy).

[redacted]}[336] Even Francis deSouza, Illumina's CEO, told investors that short-read NGS platforms are much more suitable for detecting ctDNA fragments.[337] He explained:

> The way we see it is that there are applications that are very well suited for long-read technology, that frankly short-read technology don't address and vice versa it's true as well. But there are markets, our core markets where short-read technologies work exceptionally well and long-read don't offer any additional values. So let me give you some specifics. If you look at some of our core markets, for example, in NIPT the fragments we're looking at are 150-ish base pairs. So somewhere between 130 base pairs and maybe up to 200 base pairs long. And so the ability to sequence fragments that are a million base pairs long or a hundred thousand base pairs long is frankly irrelevant, because the fragments are nowhere near that long. And so what customers are looking for is a high-volume sequencer that's able to cost effectively and accurately read those short fragments. That's true in circulating tumor DNA fragments in the oncology space as well. And so if you look at the number of our core markets, the ability to do very long-read doesn't offer any incremental value and certainly isn't worth paying a significant premium in terms of the cost per base.[338]

iii. Non-NGS Technologies Are Unsuitable for MCED Tests

Non-NGS technologies are also not alternatives to Illumina's NGS instruments and consumables for MCED test developers. Although Respondents state in their Answer that other technologies, like PCR, microarray, and proteomics, "are expected to be used for cancer screening tests in the future,"[339] there is no evidence to support their claims. First, PCR-based detection technology is only capable of identifying a small number of known mutations or biomarkers.[340] PCR-based detection technology is poorly suited for MCED tests because it lacks the ability to

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[336] {[redacted]}

[337] PX2544 at 026-027 (Email from Tyco Peterson, JP Morgan, attaching JP Morgan Life Sciences CEO Conference Call Series Transcript, Sept. 5, 2019).

[338] *Id.*

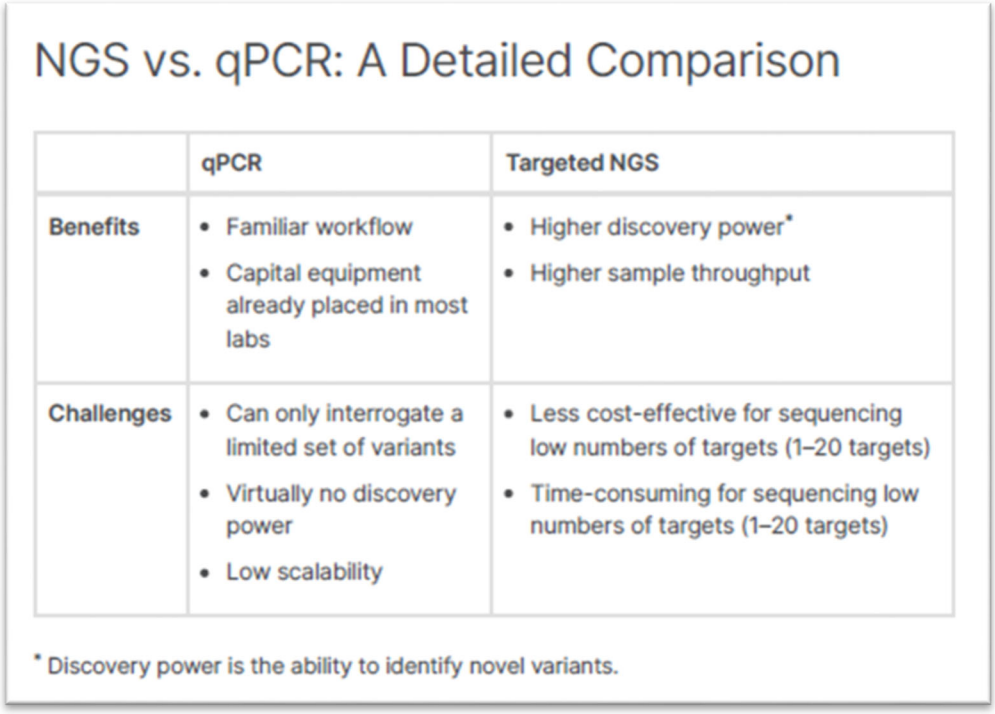
[339] Answer at 6.

[340] PX7042 (Gao (Singlera) IH at 38:13-40:10); {[redacted]} An example of an application for which PCR-based technology is suitable is the detection of genetic material associated with SARS-CoV-2 for COVID-19 testing. *See* U.S. Food & Drug Admin., *A Closer Look at COVID-19 Diagnostic Testing*, https://www.fda.gov/health-professionals/closer-look-covid-19-diagnostic-testing (last visited Aug. 11, 2021).

analyze the number of biomarkers required to test for several cancers simultaneously.[341] {[redacted]}[342] {[redacted]}[343] Even Andrew Felton, Vice President of Product Development at Thermo Fisher, a leading PCR-based technology provider, acknowledged PCR's inability to handle MCED screening. He testified that PCR-based technology is "entirely unlikely to be scalable or have enough data points generated in a reasonable amount of time [for MCED testing], and therefore, the economics and the scalability of the answer is likely highly unsuited for that environment."[344] He also noted that it would "almost certainly" cost more to run MCED tests on PCR, and likely "orders of magnitude" more.[345] Consistent with this testimony, Illumina's own marketing materials highlight the drawbacks of PCR-based detection technology relative to NGS, noting that "[w]hile qPCR is effective for low target numbers, the workflow can be cumbersome for multiple targets. NGS is preferable for studies with many targets or samples. A single NGS experiment can identify variants across thousands of target regions with single-base resolution."[346] The following chart from Illumina's published marketing materials shows that PCR-based detection

[341] {[redacted]} PX7090 (Sood (Guardant) Depo at 89:16-90:18); {[redacted]} PX7041 (Spetzler (Caris) IH at 134:18-135:3).
[342] {[redacted]}
[343] {[redacted]}
[344] PX7070 (Felton (Thermo Fisher) IH at 67:7-15).
[345] PX7070 (Felton (Thermo Fisher) IH at 67:15-19).
[346] PX0120 at 001 (Illumina, Advantages of next-generation sequencing vs. qPCR).

technology is limited by its "scalability" and ability to analyze more than "a limited set of variants":[347]



NGS vs. qPCR: A Detailed Comparison

	qPCR	Targeted NGS
Benefits	• Familiar workflow • Capital equipment already placed in most labs	• Higher discovery power* • Higher sample throughput
Challenges	• Can only interrogate a limited set of variants • Virtually no discovery power • Low scalability	• Less cost-effective for sequencing low numbers of targets (1–20 targets) • Time-consuming for sequencing low numbers of targets (1–20 targets)

* Discovery power is the ability to identify novel variants.

Similar to PCR-based technologies, other non-NGS technologies such as microarrays and proteomics are not options for MCED testing.[348] Microarrays determine whether specific sequences are present within a sample.[349] Nitin Sood, Guardant's Senior VP of Product, testified that microarrays are "very difficult" and "will not work because [MCED testing requires] very deep sequencing. . . . And microarrays just wouldn't have the sensitivity to analyze the small

[347] PX0120 at 001 (Illumina, Advantages of next-generation sequencing vs. qPCR).
[348] Although Respondents do not appear to have raised this alternative in their Answer, Sanger sequencing, which preceded NGS as a sequencing technology, is also unsuitable for MCED tests. Andrew Felton of Thermo Fisher, a leading provider of Sanger sequencers, similarly explained that Sanger sequencing "would take too much time, cost too much, and would not be scalable enough to deal with the very large number of samples that you would be trying to interrogate." PX7070 (Felton (Thermo Fisher) IH at 66:15-20); *see also* PX7041 (Spetzler (Caris) IH at 134:4-17) (testifying that it would take 2.5 million Sanger sequencing runs per patient to analyze all the biomarkers that its current NGS-based liquid biopsy test analyzes).
[349] PX7070 (Felton (Thermo Fisher) IH at 20:20-21:8).

number of DNA molecules present[.]"[350] One company, [redacted] }[352] Proteomics also is not a standalone alternative to Illumina's NGS platforms for MCED tests. Proteomics analyzes protein levels as a biomarker for cancer.[353] MCED test developers that use proteomics do so *in addition* to NGS, rather than in replacement of NGS, because proteomics would result in poor performance on its own.[354] Furthermore, no existing technology can look at the number of proteins in the body that would be necessary to screen for multiple cancers, so using proteomics in place of NGS would require developing a new platform capable of doing so.[355]

D. The Proposed Acquisition Will Substantially Lessen Competition in the U.S. MCED Test Market

A vertical merger may substantially lessen competition by "foreclosing competitors of the purchasing firm in the merger from access to a potential source of supply, or from access on competitive terms." *Yankee Entm't & Sports Network, LLC*, 224 F. Supp. 2d at 673; *see also Vertical Merger Guidelines* § 4 ("A vertical merger may diminish competition by allowing the merged firm to profitably use its control of the related product to weaken or remove the competitive constraint from one or more of its actual or potential rivals in the relevant market."). As the

[350] PX7090 (Sood (Guardant) Depo at 93:9-94:9). Sood also acknowledged that microarrays cannot look for the thousands of markers for its MCED test "at the sensitivity required for detection[.]" *Id.* at 94:2-9.

[351] [redacted]

[352] [redacted]

[353] [redacted]

[354] [redacted]

[355] PX7090 (Sood (Guardant) Depo at 92:5-93:7).

Supreme Court has held, such foreclosure "may act as a 'clog on competition,' which 'deprive[s] . . . rivals of a fair opportunity to compete.'" *Brown Shoe Co*., 370 U.S. at 324 (internal quotations omitted). To determine whether there is a probability of such foreclosure, the typical vertical merger analysis involves assessing whether the merged firm will have the ability and incentive to harm rivals in the relevant market.[356] *See Vertical Merger Guidelines* § 4; *AT&T Inc.*, 310 F. Supp. 3d at 252 (holding that the government failed to show that AT&T has "either the 'incentive' or the 'ability' to withhold" certain promotional rights from its customers).

Here, Grail and its rivals are racing to develop and commercially launch MCED tests that can revolutionize how cancer is detected and treated in the United States. These firms are currently engaged in intense innovation competition to develop tests that will compete across a number of dimensions, including test design, performance, price, and service.[357] While Grail's competitors have made substantial progress in bringing their products close to launch through years of research and development and hundreds of millions of dollars in investment, their success or failure depends heavily on Illumina, which provides a critical input (with no substitutes) for their tests. As MCED test developers explain, they are {[redacted]} to Illumina.[358] Given the immense profits Illumina stands to gain from Grail's sales in the U.S. MCED test market compared

[356] *See also* Steven C. Salop, *Invigorating Vertical Merger Enforcement*, 127 Yale L.J. 1962, 1967 (2018) (explaining that "a rational vertical merger policy would analyze the likely ability and incentives of the merging firms to engage in various types of foreclosure conduct").

[357] For example, throughout the development process, MCED test developers are striving to offer the best balance of sensitivity and specificity. {[redacted]}

[358] *See* {[redacted]}

to its own sales of instruments and consumables, Illumina has an extremely strong incentive to act in ways that ensure Grail—rather than other MCED test developers—captures as much of the market as possible. The evidence shows that Illumina has both the ability and incentive to impair Grail's rivals should the acquisition occur.[359]

i. Grail and its MCED Rivals Are in an Innovation Race

Anticompetitive harm under Section 7 is not limited to price effects, but includes harm to innovation. *See Otto Bock*, 2019 FTC LEXIS 79 at *3 (finding that the acquisition "is likely to cause future anticompetitive effects in the form of higher prices and less innovation"); *In re Polypore Int'l, Inc.*, 2010 WL 943806, at *211 (F.T.C. Mar. 1, 2010) (finding that in one market "innovation competition has been eliminated post-acquisition"); *In re R.R. Donnelley & Sons*, 1995 FTC LEXIS 215, at *31-32 (F.T.C. July 21, 1995) (competitive harm under Section 7 may "include a prediction of adverse effects in competitive dimensions other than price—reductions in output, product quality, or innovation"); *see also Horizontal Merger Guidelines* § 6.4 (explaining that harm to innovation can be an anticompetitive effect of a merger). In fact, in *United States v. AT&T, Inc.*, the D.C. Circuit explained that it "does not hold that quantitative evidence of price increase is required in order to prevail on a Section 7 challenge. Vertical mergers can create harms beyond higher prices for consumers, including decreased product quality and reduced innovation."

[359] As Respondent Illumina's counsel acknowledges, it is important to examine the views of the actual customers that may be impacted by the Proposed Acquisition. Respondent Illumina's counsel has said that "[c]oncerns of vertical foreclosure and raising rivals' costs obviously become more credible the more often such views are convincingly repeated by industry participants." Christine A. Varney, *Vertical Merger Enforcement Challenges at the FTC*, July 17, 1995, https://www.ftc.gov/public-statements/1995/07/vertical-merger-enforcement-challenges-ftc (last visited Aug. 11, 2021). As discussed in this section, every Illumina MCED customer has raised substantial concerns about the Proposed Acquisition and its impact on innovation and competition in the market.

916 F.3d 1029, 1045-46 (D.C. Cir. 2019).[360] {[redacted]}[361]

While the commercial market for MCED tests is nascent, MCED test developers are actively and aggressively competing to develop and innovate their products today. While most MCED tests are still in development, it is undisputed that MCED test developers have already invested hundreds of millions of dollars and years of development on their MCED tests.[362] Specifically, MCED test developers have spent incredible efforts to improve test performance, add test features, enhance the patient experience, and reduce costs in order to better compete against rivals.[363] Although there is a significant advantage to being the first mover in the market,[364] a better quality test could allow a competitor to leapfrog existing competition and take market share from rivals.[365] In fact, test performance will be a critical factor in how physicians ultimately

[360] The court continued, "[i]ndeed, the Supreme Court upheld the Federal Trade Commission's Section 7 challenge to Ford Motor Company's proposed vertical merger with a major spark plug manufacturer without quantitative evidence of price increases." *AT&T, Inc.*, 916 F.3d at 1045-46 (citing *Ford Motor Co. v. United States*, 405 U.S. 562 (1972)).

[361] {[redacted]}

[362] {[redacted]}

[363] {[redacted]}

[364] {[redacted]}

[365] {[redacted]}

choose between MCED tests.[366] {[redacted]}[367] As such, {[redacted]}[368] Moreover, even if an MCED test developer does not leapfrog Grail, patients will benefit by having options of MCED tests with various features and relative benefits.[369] And as the U.S. MCED test market matures, competition among MCED suppliers would likely result in lower prices and spur improvements in test quality and innovation of next-generation products.[370]

Grail, along with its MCED rivals, already has been spurred to innovate due to competitive pressures from other MCED test developers. {[redacted]}

[redacted]}

[366] *See* {[redacted]}

[367] {[redacted]}

[368] {[redacted]}

[369] PX8398 (Cance (American Cancer Society) Decl.) ¶ 11 (explaining that "[h]aving multiple approaches to compare against one another can ultimately lead to better clinical outcomes for patients and more cost-effective approaches to cancer detection for the benefit of patients"); {[redacted]}

[371] {[redacted]}

[372] {[redacted]}

[redacted]}[374] Likewise, Grail's primary competitors expect to compete against Grail on innovation.[375] {[redacted]}[376] Grail's CEO, Hans Bishop, also testified, "having a multitude of different approaches is a good thing" as everyone works to reach the same goal—"to get to the highest-performing technology."[377]

Innovation competition will ultimately inure to the benefit of patients. Continually improving the performance of an MCED test will "catch more early stage disease" before it becomes aggressive and spreads, as well as "save [patients] the mental anguish of telling them

373 {[redacted]}
374 {[redacted]}
375 {[redacted]}
376 {[redacted]}
377 PX7069 (Bishop (Grail) IH at 154:22-156:2); *see also* {[redacted]}

they have a disease" when they do not.[378] As Dr. Vogelstein explained, "[t]he greater the number of teams of researchers working with [NGS] sequencing technologies such as Illumina's to identify cancer-specific differences in nucleic acids in the blood, the greater the chances of new discoveries that lead to more accurate, more effective, and more cost-effective earlier detection tests being developed."[379] {[redacted]}[380]

While Respondents attempt to claim that there can be no competitive harm because MCED tests are still in development,[381] this ignores the realities and benefits of the innovation competition happening today.[382] If the Court were to accept Respondents' claim and dismiss the elimination of ongoing innovation competition as insufficient to violate the U.S. antitrust laws, it would provide dominant companies like Respondents free reign to extinguish competition that is vital to American consumers so long as it was taking place in a new and innovative market. Fortunately, this is not the case. Instead, "the proper timeframe for evaluating the effects of the merger on future competition must be 'functionally viewed, in the context of its particular industry.'" *Aetna, Inc.,* 240 F. Supp. 3d 79 (internal citation omitted). MCED test developers are competing aggressively to innovate and develop their tests. Although most of these tests have not yet launched commercially given the complicated problem they are trying to solve, the negative impact the Proposed Acquisition would have on innovation today, or at any point during

[378] PX7105 (Getty (Guardant) Depo at 29:5-30:2).
[379] PX8400 (Vogelstein (JHU) Decl.) ¶ 10. Similarly, Dr. William Cance, Chief Medical and Scientific Officer of the American Cancer Society, testified that "multiple companies and institutions developing and improving this technology is very important." PX7086 (Cance (ACS) Depo at 100:15-101:10).
[380] {[redacted]}
[381] Answer at 5-6.
[382] *See* §§ II.A.ii; II.D.i.

development and commercialization, will diminish quality and choice for patients tomorrow, and thus violates Section 7 of the Clayton Act.

ii. Illumina Has the Ability to Harm Grail's Rivals

To assess whether a vertical merger may diminish competition, the first step is to determine whether the merged firm will have the *ability* to harm its downstream rivals.[383] Here, Illumina's NGS technology serves as a critical input to MCED tests, and there are no alternatives to it. Illumina's MCED customers do not simply rely on Illumina for their purchases of NGS instruments and consumables, they also depend on Illumina for service and support, access to new technology, and rights to seek certain regulatory approvals. This expansive reliance gives Illumina unique insight into its customers' activities and allows Illumina to specifically target those companies that pose a threat to Grail and its success. Illumina can, at any point, pull one of its many levers to maintain Grail's spot as the market leader, insulating Grail from innovative threats and stifling competition to the detriment of American patients. Although Respondents seek to dismiss any potential anticompetitive actions as "speculative," many of the tools that Illumina can use to impair Grail's rivals are tools Illumina has used in the past when it has been vertically integrated in a market and faced significant competition from downstream rivals that relied on Illumina's upstream NGS products and services.

a. *MCED Test Developers Have No Alternatives to Illumina*

As discussed *supra*, MCED test developers have no alternatives to Illumina.[384] And, even if there were alternatives, switching to another platform would be expensive and delay the

[383] *AT&T Inc.*, 310 F. Supp. 3d at 252 (holding that the government failed to show that AT&T has "either the 'incentive' or the 'ability' to withhold" certain promotional rights from its customers); *Vertical Merger Guidelines* § 4 (explaining that "ability" to foreclose means "[b]y altering the terms by which it provides a related product to one or more of its rivals, the merged firm would likely be able to cause those rivals (a) to lose significant sales in the relevant market . . . or (b) to otherwise compete less aggressively for customers' business.").
[384] *See, supra,* § II.C.ii.

commercialization of their tests.[385] As such, { } have testified that they are beholden to Illumina. {

} Illumina is "in a position where they could take significant advantage by kneecapping our ability to run our lab, which would of course flow through to our inability to compete."[388]

Given its monopolist position as the sole supplier of NGS instruments and reagents to MCED test developers, Illumina can dictate the terms of its customer agreements. {

}[391] As a result, whatever terms Illumina wants to impose, its customers must accept.

[385] *See, infra,* § II.E.i.b.
[386] { }
[387]
[388] PX7105 (Getty (Guardant) Depo at 68:3-69:19).
[389] { }
[390] { }
[391] { }

b. *Illumina Can Identify and Target Grail's Rivals*

As Illumina's Vice President and General Manager, Americas, Nicole Berry, explained, today, pre-acquisition, Illumina considers its customers to be its partners, meaning Illumina "enable[s its] customers to be successful."[392] Because of this, Illumina and its customers share information with each other in pursuit of the mutual goal of developing the best products. These partnerships give Illumina insight into how its customers are using its products,[393] and Illumina can use that knowledge to target those that become threats to Grail's market position. First, Illumina can learn its customers' end uses from their purchase history.[394] This is because certain Illumina consumables are better suited for certain applications.[395] {[redacted]}[396] And, many times, customers will provide Illumina with details on their tests so that Illumina can recommend which of its consumables the customers should purchase.[397] Second, Illumina learns its customers' applications through one-on-one negotiations. For example, during supply agreement negotiations with {[redacted]}[398] And, finally, Illumina gathers information on its customers'

[392] PX7076 (Berry (Illumina) Depo at 179:19-181:6).
[393] PX7076 (Berry (Illumina) Depo at 54:19-55:9; 56:16-57:2) (explaining that Illumina classifies customers based on segments such as reproductive health, genetic disease testing, and oncology on the clinical side, and cell and molecular biology research, genetic disease research, cancer research, and microbiology on the research side).
[394] PX7076 (Berry (Illumina) Depo at 54:19-55:9).
[395] PX7063 (Berry (Illumina) IH at 220:19-221:7).
[396] {[redacted]}
[397] *See* PX7076 (Berry (Illumina) Depo at 62:14-23). For example, customers may inform Illumina's sales team of their read length they are looking for, what analytes they are detecting, and what platform they are using, among other things, to get input on which Illumina consumables would best service their requirements. *Id.* at 63:14-64:8.
[398] PX7076 (Berry (Illumina) Depo at 258:22-266:22); {[redacted]}

end uses through its sales and servicing of customer equipment. As Berry testified, customers may seek Illumina's assistance when they get abnormal results from their sequencing runs. In order for Illumina to provide effective service, customers may share with Illumina certain attributes of their tests or provide information on the expected outcomes of their test, so that Illumina can determine the underlying cause.[399]

Given the broad exchange of information between Illumina and its customers, Illumina has the ability to identify which MCED test developers pose a threat to Grail's competitive position and can take action at that point to frustrate their development and commercialization efforts. Already, Illumina knows which of its customers compete against Grail. For example, after the announcement of the Proposed Acquisition, {

[399] PX7076 (Berry (Illumina) Depo at 32:18-33:15). Customers also may choose to turn on Proactive, a data sharing software embedded in Illumina's instruments, in order to receive discounts and improved service from Illumina. This provides Illumina with information on the number of runs its customers perform on each instrument, whether machines are turned off or on, and what errors customers receive from their runs. *See* PX7076 (Berry (Illumina) Depo at 38:6-39:17); {

[400] {}

[401] {}

[redacted]}[403]

Illumina can and has used its knowledge of customer applications to offer different terms to certain customers and applications in the past.[404] {[redacted]}[406] In addition, Illumina has created pricing grids and strategies based on specific applications.[407] To do this, Illumina sometimes imposes "field of use" clauses in its clinical agreements to ensure that certain discounts that Illumina offers are only used for certain applications. {[redacted]

[402] {[redacted]}
[403] *See* PX7076 (Berry (Illumina) Depo at 24:15-21) (explaining that a customer's volumes may increase when it is running a clinical trial); {[redacted]}
[404] *See, e.g.*, PX7081 (George (Invitae) Depo at 82:24-85:17) (testifying that Illumina charges "different pricing or price tiers or price volume tiers, depending on what we're doing with it"); PX7082 (Cooper (Progenity) Depo at 124:17-125:5) ("So we have to buy the fancy reagents in a different-colored box to run an NIPT versus cheap reagents for research use in doing discovery purposes."). For information on how Illumina sets its prices, *see, infra*, § II.D.ii.c.
[405] PX7076 (Berry (Illumina) Depo at 260:13-261:24).
[406] {[redacted]}
[407] PX7076 (Berry (Illumina) Depo at 177:9-22) (explaining Illumina created a pricing grid for oncology customers specifically); {[redacted]

[redacted]}[408] For example, Illumina has invoked a field of use clause when it was {[redacted]}[409] {[redacted]}[410]

c. ***Illumina Has Many Tools to Disadvantage Grail's Rivals***

As the supplier of a vital, and technologically complex, input to its customers' MCED tests, Illumina plays a critical role throughout the development and commercialization of its customers' products.[411] As Illumina's Berry, testified, Illumina tries to "enable [its] customers to be successful, and that's more than just, you know, taking an order and fulfilling it and collecting an invoice."[412] This is echoed by Illumina's {[redacted]}[413] Guardant's Senior VP of Products, Nitin Sood, testified that "throughout the

[408] {[redacted]}
[409] {[redacted]}
[410] {[redacted]}
[411] {[redacted]}
[412] PX7076 (Berry (Illumina) Depo at 179:19-181:6).
[413] {[redacted]}

life cycle from the product to development to regulatory approval to product production you need active responsiveness and cooperation of the platform provider."[414] Because Illumina controls the pricing and supply of its critical NGS inputs, and because Grail's rivals rely on Illumina throughout the development process, Illumina has the ability to impact MCED test developers' innovation race in multiple ways.

Illumina can increase prices. Because there are no viable alternatives to Illumina, Illumina can increase the prices it charges to Grail's rivals. As discussed *supra*, MCED tests require a lower price than other NGS-based oncology tests because they are designed for a large, asymptomatic patient population.[415] Given that Illumina's NGS inputs represent a large portion, if not the majority, of an MCED test's costs,[416] Illumina can raise its prices and directly impact the profitability and competitiveness of rival tests. As Guardant's Sood testified, "the cost structure of these tests . . . are a very big component of them being widely available."[417]

Illumina uses a multi-part pricing strategy for its products, pricing separately for its instruments, consumables, and service and support. {[redacted]}

[414] PX7090 (Sood (Guardant) Depo at 119:25-121:5).
[415] *See, supra,* § II.A.i.
[416] {[redacted]} *see also* PX7047 (Cooper (Progenity) IH at 54:4-10) (testifying that NGS platform costs are "one of the main drivers of cost of goods sold or COGS, and, you know, plays a role in the profitability of your products").
[417] PX7090 (Sood (Guardant) Depo at 110:9-111:11).
[418] {[redacted]}
[419] {[redacted]}

[redacted] Accordingly, Illumina's pricing scheme gives it the ability to increase prices anywhere along the value chain—from the sale of instruments and consumables to the provision of services—and target specific applications or customers by altering the discounts it offers.

Any increase in prices by Illumina will squeeze the profitability of Grail's rivals and, ultimately, diminish innovation in the market.[426] As Chief Medical and Scientific Officer for the American Cancer Society, Dr. William Cance, stated, "[i]f development costs increase, companies that would otherwise have worked towards developing these tests may struggle to carry their ideas

[420] [redacted]

[421] Although Respondents claim their Open Offer eliminates Illumina's ability to raise prices to Grail's rivals, the Open Offer only equalizes the volume-based discounts that MCED test developers may receive for certain levels of sales. *See infra,* § II.F. The Open Offer does nothing to account for the [redacted]

[423] [redacted]

[424] [redacted]

[425] [redacted]

[426] PX7105 (Getty (Guardant) Depo at 74:12-76:25) (testifying that Illumina has the ability to act so that "the profitability is squeezed for other manufacturers such that over time, those manufacturers are rendered nonexistent. And ultimately, then innovation slows down because there's no advantage for Illumina to advance their technology" and "patients will be negatively impacted").

forward to where they can become a reality for doctors and patients."[427] Illumina's MCED customers agree.[428] For example, {[redacted]}[429]

{[redacted]}[430]

Illumina can impact supply. Because Illumina is their sole-source supplier for a critical input, {[redacted]} depend on Illumina to provide consistent and quality instruments and reagents in a timely manner. As Natera wrote in its annual report to its investors, "Illumina is currently the sole supplier of our sequencers and related reagents for [our tests]. . . . Without sequencers and the related reagents, we would be unable to run our tests and commercialize our products."[431] According to Guardant's VP of Commercial, Cancer Screening Core, William Getty, if Illumina stopped supplying Guardant with its products, or failed to supply them in a timely manner, Guardant's business "would be nonexistent."[432]

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[427] PX8398 (Cance (American Cancer Society) Decl.) ¶ 12.

[428] *See* {[redacted]}

[430] {[redacted]} Illumina has used its upstream position to assert control over its customers pricing structure when it has been vertically integrated. For example, {[redacted]}

[431] PX0155 at 039 (Natera 10-K, Feb. 25, 2021). Natera also acknowledged that the Proposed Acquisition may add to that risk. *Id.* at 40.

[432] PX7105 (Getty (Guardant) Depo at 58:9-25). Like Natera, Guardant also identified Illumina in its annual report as its "sole supplier of sequencers and as the sole provider of maintenance and repair services for these sequencers."

Due to its customers' reliance on its products, Illumina has the ability to control the supply of its products, or the quality and timeliness of that supply, at any point, directly impeding the ability of its customers to operate. Today, when there is an issue with a customer's purchase or supply, Illumina claims to "do our best to resolve customer issues quickly."[433] One way Illumina does this is by making sure that products get to its customers when they want them.[434] For example, when {[redacted]}[435] Issues with supply, however, can and do arise, particularly where Illumina is vertically integrated. {[redacted]}

PX0153 at 047 (Guardant, 2020 Form 10-K, Feb. 25, 2021). According to Guardant, "[a]ny disruption in operations of Illumina . . . could materially and adversely impact our supply chain and laboratory operations of our precision oncology platform and thus our ability to conduct our business and generate revenue." *Id.* Grail even admits in its S-1 filing with the SEC that "[a]ny disruption in Illumina's operations or breach of our supply-related agreements would impact our supply chain and laboratory operations as well as our ability to develop and commercialize our products, including Galleri and DAC." PX5049 (Grail, Form S-1, Sept. 9, 2020).

[433] PX7076 (Berry (Illumina) Depo at 83:25-84:15).

[434] PX7076 (Berry (Illumina) Depo at 85:20-86:9).

[435] {[redacted]}

[436] {[redacted]}

[437] {[redacted]}

[438] {[redacted]}

[439] {[redacted]}

[redacted] } While supply issues may be a normal part of business, Illumina's MCED customers are concerned that Illumina may create, or resolve, these issues in a way that disadvantages them relative to Grail.[443]

Illumina can diminish service and support. Illumina's MCED customers regularly rely on Illumina for the assistance, service, and support of their NGS products.[444] Because Illumina's NGS products are highly technical, Illumina's service team offers unique expertise to fix any issues that may arise.[445] {[redacted]

[redacted]

440 {[redacted]}
441 {[redacted]}
442 {[redacted]}
443 *See, e.g.,* {[redacted]} Because supply issues do happen in the ordinary course of business, this makes Illumina's proposed remedy even harder to monitor. *See, supra,* § II.D.ii.c.. It would be nearly impossible for a monitor, or an independent auditor, to know whether Illumina's supply issues resulted from normal business afflictions or from purposeful conduct.
444 *See* {[redacted]
445 *See* [redacted] }

[redacted]}[446] And, when problems do arise, customers need Illumina to fix the issue quickly.[447] Many MCED test developers have testified that they rely on Illumina's service and support almost daily to operate their businesses,[448] and some even have a full-time Illumina service person onsite.[449]

Customers have expressed concerns that any corrosion of this service and support would harm their MCED test development.[450] For instance, if a customer's equipment goes down and Illumina does not resolve the issue in a timely manner, {[redacted]}[452]

Illumina can delay or deny access to new technology. Illumina also has the ability to delay or deny access to its new, improved technology to Grail's rivals**.** {[redacted]}[453] {[redacted]

446 {[redacted]}
447 {[redacted]
448 {[redacted]}
449 {[redacted]}
450 *See* {[redacted]}
451 {[redacted]}
452 {[redacted]}
453 {[redacted]

[redacted]}[454] {[redacted]

[redacted]}[455] Thus, having access to Illumina's newest technology at the same time, or before, competitors can significantly advantage a customer's test.[456] As Guardant's Getty testified, without access to Illumina's latest technology, Guardant will not be able to offer patients the best performing or the lowest cost test.[457]

In addition to providing access to new technology, Illumina also assists its customers in switching to its upgraded products. Today, when customers seek to upgrade their NGS instruments, Illumina will send a technician to get the new instruments "up and running and to assist in troubleshooting matters."[458] As Illumina's Berry testified, Illumina "work[s] with a customer to confirm that the instrument is performing to spec and the general purpose reagents, the sequencing kits that they buy from us to sequence samples using their assay, are performing to our specifications."[459] Further, Illumina often provides the customer with {[redacted]

[redacted]

[454] {[redacted]}

[455] {[redacted] PX7067 (Blanchett (Illumina) IH at 194:23-195:13); {[redacted]}

[456] {[redacted]

[457] PX7105 (Getty (Guardant) Depo at 74:12-75:25); *see also* PX7041 (Spetzler (Caris) IH at 154:18-155:7).}

[458] PX7082 (Cooper (Progenity) Depo at 87:11-18).

[459] PX7076 (Berry (Illumina) Depo at 151:17-152:10).

[redacted][460] [redacted]

[redacted][461]

Grail's rivals have raised concerns that post-acquisition, Illumina could impede their access to technology upgrades.[462] [redacted][463]

And, it is not just access to the instruments and reagents after they are released that matters, but even if Illumina gives Grail advanced *knowledge* of its product upgrades, it could put Grail's rivals at a significant disadvantage.[464] As Dr. Bert Vogelstein explained, advanced knowledge of "future product developments and refinements" from Illumina "could substantially alter research and development in the field and the nature of the test products that are eventually produced."[465] These concerns are not merely hypothetical. [redacted]

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[460] [redacted]

[461] [redacted] *see also* PX7076 (Berry (Illumina) Depo at 146:19-147:4) (explaining that it typically costs customers $50,000 to upgrade the NextSeq500 to the NextSeq550).

[462] *See, e.g.,* [redacted]

[463] [redacted]

[464] *See* [redacted]

[465] PX8400 (Vogelstein (JHU) Decl.) ¶ 9.

[redacted]}[467]

Illumina can deny access to critical information and agreements for FDA approvals. Illumina could also disrupt the efforts of Grail's rivals to obtain FDA approval for a distributed, or "kitted," IVD version of their MCED tests.[468] A distributed IVD test is a test that has received regulatory approval to be sold and used by third-party labs, such as a hospital lab or large reference lab, like LabCorp or Quest.[469] Once MCED tests become more widely accepted and used, it will likely be important for MCED test developers to offer distributed IVD tests to customers.[470] Because they allow samples to be processed locally, distributed IVD tests improve turnaround time for test results and alleviate capacity constraints at developers' centralized labs, which will likely be critical for test developers as MCED tests become routinely used in the market.[471]

[466] PX2541 at 008 {[redacted]}
[467] {[redacted]}
[468] A test developer may seek FDA approval of its test as either a single-site IVD, meaning it can only be run at a single approved lab, or as a distributed IVD, meaning it can be run at any third-party lab. *See* PX7065 (Aravanis (Illumina) IH at 139:11-140:22); {[redacted]} PX7112 (Bailey (PGDx) Depo at 14:2-18); PX7093 (Young (Illumina) Depo at 43:20-44:14).
[469] PX7111 (Fesko (Natera) Depo at 82:5-10); *see also* PX7049 (Bailey (PGDx) IH at 68:19-29:25).
[470] *See* {[redacted]}
[471] {[redacted]} PX7042 (Gao (Singlera) IH at 110:13-24; 111:9-13); PX7049 (Baily (PGDx) IH at 68:4-10).

FDA approval for a distributed IVD test requires cooperation from Illumina,[472] typically in the form of an IVD partnership agreement (or "IVD rights").[473] {[redacted]}[474] This means that a company "could develop a product under IVD use, get all the way to submitting it to the FDA, and then the FDA says 'Where's your agreement with Illumina and access to their technical file?' And if you do not have that, they deny your submission."[475] Because Illumina decides with whom it will enter into IVD agreements, Illumina dictates which tests can obtain approval as a distributed IVD. Thus, post-acquisition, Illumina can restrict Grail's rivals from offering distributed tests by denying them IVD rights or charging excessive fees.[476]

In the past, a vertically integrated Illumina has denied IVD rights or charged substantial fees to certain customers in order to protect its own competitive position downstream. {[redacted]

[472] *See* {[redacted]}
[473] While it may be technically feasible to offer a distributed test without an IVD partnership agreement with Illumina, it is not commercially viable. When PGDx first approached Illumina to enter into an IVD partnership agreement to offer its therapy selection test as a distributed product, Illumina denied PGDx's request because Illumina's own therapy selection test competed with PGDx's. *See* PX7049 (Bailey (PGDX) IH at 96:25-97:15); {[redacted]} PGDx's pharmaceutical customers said that "they would not consider a companion diagnostic program with us without an IVD co-development agreement," and prospective investors told PGDx "that they would not make an investment without us having the IVD co-development agreement with Illumina." PX7049 (Bailey (PGDX) IH at 111:12-112:14). {[redacted]}
[474] {[redacted]}
[475] PX7075 (Stahl (Invitae) Depo at 69:15-70:2).
[476] While Illumina's Open Offer provides standardized IVD partnership agreements, {[redacted]} Specifically, the standardized IVD partnership agreement in the Open Offer requires, for IVD rights to all platforms, a tech access fee of $25 million, development milestone payments of $1 million to $5 million per IVD test kit, and a revenue sharing royalty of 6 percent. PX0087 (Illumina) at 021, 041 (Illumina IVD Test Kit Agreement – All Platforms, dated Mar. 30, 2021).

[redacted][479] {

[redacted]}

Illumina's strategy to disadvantage customers who compete with it is evident in its negotiations with {[redacted]}[480] {

477 {[redacted]}
478 {[redacted]}
479 {[redacted]}
480 {[redacted]

[redacted]}

{[redacted]

481 {[redacted]}

482 {[redacted]}

483 {[redacted]

484 {[redacted]

[redacted]}[485]

Restriction from IVD rights can impact innovation. {[redacted]}[486] And, when PGDx had to go to market without IVD rights from Illumina, PGDx's pharmaceutical customers said that "they would not consider a companion diagnostic program with us without an IVD co-development agreement," and prospective investors told PGDx "that they would not make an investment without us having the IVD co-development agreement with Illumina."[487] Reduced investment decreased PGDx's ability to fund its research and development projects.[488]

iii. Illumina Has a Strong Incentive to Harm Grail's Rivals

The second step in analyzing the competitive effects of a vertical merger is to determine whether the merged firm has the *incentive* to harm its downstream rivals.[489] An incentive to

[redacted]}

[485] {[redacted]

[486] {[redacted]

[487] PX7049 (Bailey (PGDX) IH at 111:12-112:14).
[488] PX7112 (Baily (PGDx) Depo at 195:15-23).
[489] *United States v. AT&T Inc.*, 310 F. Supp. 3d 161, 250-51 (D.D.C. 2018) (holding that the government "failed to show that the merged entity would have *any* incentive to foreclose" its rivals); *Vertical Merger Guidelines* § 4.a.(2).

foreclose Grail's competitors would arise if, as a result of the Proposed Acquisition, Illumina "would likely find it profitable to foreclose rivals or offer inferior terms for the related product, because it benefits significantly in the relevant market when rivals lose sales or alter their behavior in response to the foreclosure or to the inferior terms."[490] Here, the incentives are clear. Through its acquisition of Grail, {[redacted]}[491] Once Illumina makes this shift and becomes a competitor to its own MCED test developer customers, Illumina will have a strong incentive to do whatever it can to capture as much of the market as possible and entrench Grail as the market leader, even to the detriment of its rivals.

a. ***The Expected Profits of Winning the Innovation Race Far Outweigh Illumina's Continued NGS Sales***

In its internal documents, Illumina recognizes that {[redacted]}[492] To capture this substantial opportunity, Illumina sought to {[redacted]}

[490] *Vertical Merger Guidelines* § 4.a.(2).

[491] {[redacted]}

[492] {[redacted]} *see also* {[redacted]}

[redacted][493] [redacted][494] Illumina noted that it would [redacted] but that it planned to [redacted][495] [redacted][497]

Illumina's own ordinary course documents detail its shifting incentives post-acquisition. [redacted]

493 [redacted]
494 *See* [redacted]
495 [redacted]
496 [redacted]
497 [redacted]
498 [redacted]
499 [redacted]

[redacted]}[500] As Illumina explained to its Board, [redacted]}[501]

{[redacted]}[502] {

[redacted]}

[500] {[redacted] Other industry participants also estimate similar sized MCED test markets. For example, Guardant's SVP of Commercial, Bill Getty, projects that, on the low end, the MCED test market will reach $50 billion. PX7105 (Getty (Guardant) Depo at 50:24-51:16); *see also* [redacted] PX8515 at 004 (Singlera, Singlera Genomics) (estimating that the global market for cancer screening will exceed $100 billion by 2023). As Guardant's Getty explained, "[t]he sequencing business is a much, much smaller slice . . . relative to that 60-billion-dollar opportunity. So as an organization, [Illumina's] acquisition of Grail is ostensibly geared to moving into this much bigger opportunity and maximizing that opportunity." PX7105 (Getty (Guardant) Depo at 68:3-69:19).

[501] {[redacted]}

[502] {[redacted]}

[redacted]

Thus, Illumina's own analyses show that it can earn [redacted][503] [redacted][504] As Grail is already in the lead as the first commercialized MCED test, Illumina has a strong incentive to protect Galleri's leading position in this lucrative emerging market.

Illumina would have an incentive to harm Grail's rivals if the merged firm would likely find doing so profitable because it would benefit from the rivals' lost sales or diminished

[503] [redacted] PX6090 at ¶ 194 (Scott Morton Report).

[504] [redacted]

performance.[505] Here, MCED test developers consider Grail to be their primary competitor[506]

}[512] Thus, post-acquisition, to protect the combined firm's downstream MCED test

[505] *Vertical Merger Guidelines* § 4.a.(2).
[506] *See*
}
[507]
}
[508]
}
[509] *See, e.g.*,
}
[510] *See, e.g.*,
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[512]
}

business, Illumina will use its ability to identify competitive threats to Galleri and employ its available tools, at whatever point the threat occurs, to ensure Grail's rivals do not develop closely competing MCED tests as quickly as they would have absent the merger, and possibly not at all.[513]

Grail's MCED rivals recognize that Illumina's incentives will shift post-acquisition, given the lucrative market opportunity in cancer screening tests. {[redacted]}[514]

{[redacted]}[515]

[513] *See, supra,* § II.D.ii.
[514] {[redacted]}
[515] {[redacted]}

[redacted][518]

b. ***Illumina's Prior Behavior Illustrates its Post-Acquisition Incentives***

When Illumina has become vertically integrated in the past, it has reevaluated its supply relationships with downstream competitors in ways consistent with the change in incentives that will result from Illumina's acquisition of Grail. Perhaps the most relevant example is when Illumina wholly owned Grail, before spinning it off to outside investors in 2017. [redacted]

516 [redacted]
517 [redacted]
518 [redacted]
519 [redacted]
520 [redacted]
521 [redacted]

[redacted] } Ultimately, though, in 2016, Illumina realized that it had significantly underestimated the time and expense necessary to develop an MCED test and elected to give up its majority stake in Grail.[526] [redacted]

[522] [redacted]
[523] [redacted]
[524] [redacted]
[525] [redacted]
[526] PX7057 (Flatley (Illumina) IH at 158:4-160:7).
[527] [redacted]
[528] [redacted]
[529] [redacted]

[redacted]}[530]

{[redacted]

[530] {[redacted]

[531] *See, supra,* § II.D.ii.c.; *see also* [redacted]} *see generally* {[redacted]}

[532] {[redacted]}

[533] {[redacted]}

[redacted]

Although Respondents claim that Illumina's "long-standing and core strategy is to catalyze development and expansion of sequencing,"[535] when Illumina is vertically integrated, as it would become through this Proposed Acquisition, this objective is weighed against the impact on Illumina's own downstream sales when it determines its strategy. By doing this, Illumina is simply acting as any standalone profit-maximizing firm would; it is only that Illumina is spurred to do this *through* acquisition that runs afoul of the law.[536]

E. Respondents Cannot Rebut Complaint Counsel's *Prima Facie* Case Showing the Proposed Acquisition Would Result in Competitive Harm

i. Respondents Cannot Demonstrate Entry is Timely, Likely, or Sufficient to Prevent Harm from the Proposed Acquisition

[534] [redacted]
[535] Answer at 7.
[536] *See, e.g.*, *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 768-69 (1984) (explaining, in a non-merger antitrust case, that when "two or more entities that previously pursued their own interests separately are combining to act as one for their common benefit" it "deprives the marketplace of the independent centers of decisionmaking that competition assumes and demands").

"Courts have held that likely entry or expansion by other competitors can counteract anticompetitive effects that would otherwise be expected." *H&R Block*, 833 F. Supp. 2d at 73. But "[t]he mere existence of potential entrants does not by itself rebut the anticompetitive nature of an acquisition." *Chi. Bridge & Iron Co.*, 534 F.3d at 436. Entry or expansion must be "'timely, likely, and sufficient in its magnitude, character, and scope' to counteract a merger's anticompetitive effects." *United States v. Anthem, Inc.*, 236 F. Supp. 3d 171, 222 (D.D.C. 2017) (citations omitted). Respondents bear the burden of providing evidence that "ease of entry" rebuts Complaint Counsel's *prima facie* case. *Otto Bock*, 2019 FTC Lexis 79 at *31 (citing *Heinz*, 246 F.3d at 984); *see also H&R Block*, 833 F. Supp. 2d at 73 (noting that respondents "carry the burden to show" that entry or expansion is sufficient "to fill the competitive void" that would result from the merger). Here, not only do MCED test developers have no alternative available to Illumina's NGS platform today, there is little evidence to suggest that new entry of NGS platform providers is likely for several years or that any prospective entrants could provide meaningful competition to Illumina for MCED business. The technological, patent, and commercial barriers to creating an NGS platform capable of handling MCED screening are substantial. Moreover, even if new NGS platforms became available, switching to these platforms due to any foreclosure by Illumina would still cause harm, delaying commercialization and reducing quality of MCED tests.

a. ***Barriers to Developing and Commercializing an NGS Platform Suitable for NGS Tests are Substantial***

The barriers to developing, commercializing, and gaining regulatory approval for an NGS platform are substantial, making new entry not timely or likely to counter the competitive harm from the Proposed Acquisition. Today, Illumina dominates sales of NGS instruments and reagents in the United States,[537] and it has been difficult for potential entrants to chip away at Illumina's

[537] *See* {[redacted]}

dominance. NGS platforms involve complex, highly technical instruments and consumables and developing these products requires substantial investments of time and money, with no guarantee of commercial success. {[redacted]}[543] In addition to time and effort, the monetary investment required to create and commercialize an NGS platform is significant. {[redacted]}

538 {[redacted]}
539 {[redacted]}
540 A research use only version means that the platform cannot be used for clinical purposes, meaning it cannot be used for MCED tests.
541 {[redacted]}
542 {[redacted]}
543 {[redacted]}
544 {[redacted]}

[redacted]}[545]

In addition to investing considerable resources in NGS platform development, a prospective NGS entrant must navigate a broad and dense intellectual property landscape. Illumina holds numerous NGS-related patents, which it has used to initiate patent infringement litigation against several potential competitors. For example, soon after potential-entrant Qiagen launched its NGS platform, Illumina sued Qiagen for patent infringement and won an injunction that prevented Qiagen from selling its NGS product in the United States.[546] Qiagen subsequently exited the market altogether.[547] Illumina also won a preliminary injunction against BGI for patent infringement, preventing BGI from selling its sequencers in the United States.[548] At least one MCED test developer doubts that any new NGS entrant could navigate the NGS IP landscape successfully and maintain freedom to operate.[549]

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[545] *See* {[redacted]}

[546] *Illumina, Inc. v. Qiagen N.V.*, 207 F. Supp. 3d 1081 (N.D. Cal. 2016) (enjoining Qiagen from selling its GeneReader NGS platform and related products in the United States); *see also* Stipulated Consent Judgment, *Illumina, Inc. v. Qiagen N.V.*, Case No. 3:16-cv-02788-WHA (N.D. Cal. July 21, 2017) (approving settlement preventing Qiagen from selling necessary chemistries for its GeneReader sequencing platform in the United States).

[547] Qiagen, *QIAGEN reports preliminary Q3 2019 results and announces measure to prioritize resource allocation*, https://corporate.qiagen.com/newsroom/press-releases/press-release-details/2019/QIAGEN-reports-preliminary-Q3-2019-results-and-announces-measures-to-prioritize-resource-allocation/default.aspx (last visited Aug. 11, 2021) ("QIAGEN intends to continue supporting customers of the GeneReader NGS System, which is a complete Sample to Insight system for the processing of smaller targeted gene panels, but has now decided to suspend ongoing NGS-related instrument development activities.").

[548] PX0119 (Illumina, *Illumina Inc. Announces that U.S. Federal Court Issues Preliminary Injunction Against BGI Companies)*, https://www.illumina.com/company/news-center/press-releases/2020/0be08dbc-b1a0-4db8-86a7-32d9bb661420.html (last visited Aug. 11, 2021). In a separate litigation, Illumina filed a counterclaim against BGI alleging infringement of additional patents that expire in 2026 and 2027. Answer and Counterclaim, *Complete Genomics, Inc. v. Illumina, Inc.*, Case 1:19-cv-00970-MN (D. Del.) (July 25, 2019); {[redacted]} In addition to Qiagen and BGI, Illumina also sued Oxford Nanopore over certain nanopore-based patents. Illumina, *Illumina Sues Oxford Nanopore for Patent Infringement*, https://emea.illumina.com/company/news-center/press-releases/2016/2142351.html (last visited Aug. 11, 2021). Even after Oxford Nanopore launched a new technology that circumvented Illumina's patent claims, it was then sued by PacBio. *Pacific Biosciences of California, Inc. v. Oxford Nanopore Technologies, Inc.*, Case: 20-2155 (Fed. Cir. May 11, 2021).

[549] *See* {[redacted]}

Although there are significant barriers to develop and launch a successful NGS platform, it is even more difficult for an NGS platform to launch with the capabilities necessary for MCED tests.[550] Clinical testing, including MCED screening, requires high-throughput, highly accurate NGS platforms.[551] {[redacted]}[552] Not only are potential NGS technologies unproven on these key performance metrics, prospective NGS entrants are all years away from commercializing a platform—even for non-clinical use—in the United States:[553]

- **BGI:** Due to a lawsuit by Illumina, BGI is currently enjoined from providing NGS instruments and consumables in the United States,[554] and therefore is not an option for MCED test developers.[555] Even if it became available, however, MCED test developers have serious reservations about using BGI for their tests.[556] First,

[550] And even if a hypothetical NGS platform had similar characteristics to Illumina, MCED test developers would not necessarily use the new platform due to high switching costs. PX7042 (Gao (Singlera) IH at 60:13-24) ("[U]nless you show superiority over Illumina, why [would] we want to throw away what we have done to go with you, so we never go with any other company.").
[551] *See, supra*, § II.C.i.
[552] {[redacted]}
[553] Importantly, by the time any of the potential NGS technologies may theoretically become available, {[redacted]}
[554] PX0119 (Illumina, *Illumina Inc. Announces that U.S. Federal Court Issues Preliminary Injunction Against BGI Companies)*, https://www.illumina.com/company/news-center/press-releases/2020/0be08dbc-b1a0-4db8-86a7-32d9bb661420.html (last visited Aug. 11, 2021). Although the patents in the injunction are set to expire in 2023, Illumina has filed additional patent infringement claims against BGI for patents expiring in 2026 and 2027. Answer and Counterclaim, *Complete Genomics, Inc. v. Illumina, Inc.*, Case 1:19-cv-00970-MN (D. Del.) (July 25, 2019); {[redacted]}
[555] *See, e.g.*, {[redacted]} PX7042 (Gao (Singlera) IH at 63:3-23).
[556] Among other reasons, some MCED developers have questioned whether BGI's technical capabilities are sufficient for MCED testing. *See, e.g.*, {[redacted]}

MCED test developers recognize that BGI could be at risk of additional patent infringement lawsuits, which would pose a substantial business risk to customers.[557] Second, test developers have raised concerns[558] about BGI's long-standing ties to the Chinese government.[559] This concern is exacerbated by recent news reports alleging that BGI provided pregnant mothers' prenatal testing genetic data to the Chinese military to "improve 'population quality.'"[560] Moreover, the U.S. Department of Commerce added certain BGI subsidiaries to an economic blacklist banning their exports because it found that they are "conducting genetic analysis used to further the repression of Muslim minority groups" in Xinjiang, China.[561]

- {

[557] *See, e.g.*,

[558] *See, e.g.*, { } *see also* PX7075 (Stahl (Invitae) Depo at 99:16-22); PX7065 (Aravanis (Illumina) IH at 156:5-20) ("[T]here have been some concerned raised about the privacy and data integrity of data produced on the BGI system and whether or not that data would be protected . . . for its customers. . . . [such as] data from the instruments, you know, being sent to China, perhaps without customers' knowledge.").

[559] BGI was founded with Chinese government support, received a $1.5 billion loan from a Chinese state development bank, and maintains China's national gene bank. Axios, *Chinese coronavirus test maker agreed to build a Xinjiang gene bank*, https://www.axios.com/chinese-coronavirus-test-maker-agreed-to-build-a-xinjiang-gene-bank-f82b6918-d6c5-45f9-90b8-dad3341d6a6e.html (last visited Aug. 11, 2021).

[560] *See* Reuters, *China's gene giant harvests data from millions of women*, https:// https://www.reuters.com/investigates/special-report/health-china-bgi-dna/ (last visited Aug. 11, 2021); *see also*

[561] Addition of Certain Entities to the Entity List; Revision of Existing Entries on the Entity List, 85 Fed. Reg. 44,159 (July 22, 2020) (to be codified as 15 C.F.R. pt. 744). Illumina's Senior Director of Corporate Strategy circulated a }

[562] {

[563] {

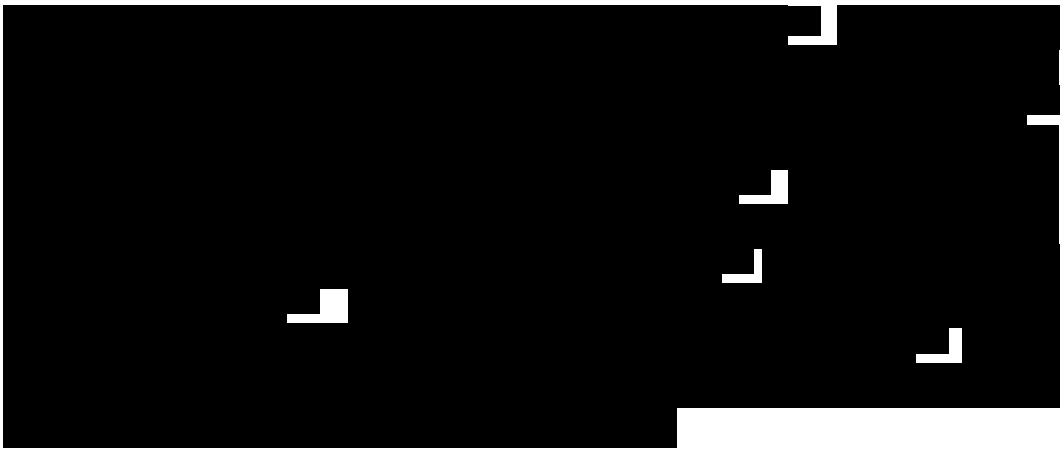
[564] {

[565] {

[redacted]

- **Other NGS technologies:** Other firms that Respondents allege are potential entrants, such as [redacted] are also unlikely to introduce alternative NGS platforms in a timely and sufficient manner to counteract any competitive harm from the Proposed Acquisition. [redacted]

566 [redacted]
567 [redacted]
568 [redacted]
569 *See* [redacted]
570 [redacted] PacBio recently agreed to acquire Omniome, there is no evidence that [redacted] *See* PacBio, *Pacific Biosciences Signs Definitive Agreement to Acquire Omniome*, https://www.pacb.com/press_releases/pacific-biosciences-signs-definitive-agreement-to-acquire-omniome/ (last visited Aug. 11, 2021). [redacted]
571 *See* [redacted]
572 [redacted]
573 *See* [redacted] PX0085 at 001, 003 (Illumina NovaSeq 6000 System Specifications).
574 [redacted]



Furthermore, using a new and unproven platform would create substantial business risks for companies developing—and obtaining regulatory approval for—MCED tests. Guardant's Senior VP of Technology, Darya Chudova, emphasized that "[t]here is a very significant business risk to switching to a new technology" including the risk that Guardant would not receive consistent quality or supply of products.[582] According to Chudova, "I would be extremely concerned about launching any clinical testing on the new platforms that haven't [gone through a] development cycle."[583] {

}[584]

[575] {
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[576] {
} PX0085 at 001 (Illumina NovaSeq 6000 System Specifications); {
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[578] {
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[579] {
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[580] {
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[581] {
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[582] PX7045 (Chudova (Guardant) IH at 115:10-116:17).
[583] PX7045 (Chudova (Guardant) IH at 115:10-116:17).
[584] {
}

b. *Even if an Alternative to Illumina's NGS Platform Ever Became Available, Switching Costs Would be Extremely High*

Although entry is unlikely to take place for several years (if at all), even if a viable NGS alternative became available, it would not be sufficient to counteract the harms of the Proposed Acquisition. Switching an MCED test away from Illumina is extremely costly and time-consuming. MCED test developers are entrenched in Illumina's NGS technology, having invested significant time and money to develop their MCED tests on its platforms. According to {[redacted]}[586] The costs of switching could exceed {[redacted]}[587] which some MCED test developers describe as {[redacted]}[588] As {[redacted]}[589]

To switch to a new platform, an MCED test developer must redesign its test to be compatible with the new NGS instrument, which although "theoretically possible" involves a "significant amount of development work."[590] Furthermore, as MCED test developers continue

585 {[redacted]}
586 {[redacted]}
587 {[redacted]}
588 {[redacted]}
589 {[redacted]}
590 PX7045 (Chudova (Guardant) IH at 53:2-56:5); *see also* {[redacted]}

developing their tests, {[redacted]}[591] Switching to a new NGS platform would {[redacted]}[592] Even after redesigning the MCED test, a test developer would need to revalidate its test on the new platform and, at a minimum, perform "a smaller scale clinical sample analysis."[593] Switching may also require redoing entire clinical trials or obtaining new regulatory approvals.[594] As the Co-Founder and Scientific Advisor of Singlera testified, the test developer might need to "replicate . . . every study [it has] done on Illumina to [the new platform] to convince [itself] this is comparable."[595]

The time to switch an MCED test to a new NGS platform would likely take at least {[redacted]}[596] Given the significant time and cost, switching to a new NGS platform would derail funds from existing research and development efforts and delay commercialization of MCED tests in a market where {[redacted]}[597] {[redacted]}[598] As Guardant's Senior

[redacted]} PX7042 (Gao (Singlera) IH at 55:16-56:14); {[redacted]}

[591] {[redacted]}

[592] {[redacted]}

[593] PX7100 (Chudova (Guardant) Depo at 82:2-13); *see also* [redacted]}

[594] *See* {[redacted]} PX7042 (Gao (Singlera) IH at 55:16-56:14).

[595] PX7042 (Gao (Singlera) IH at 55:16-56:14).

[596] {[redacted]}

[597] {[redacted]}

[598] {[redacted]} PX7045 (Chudova (Guardant) IH at 118:12-119:21) (testifying that switching to a new platform "will delay and potentially annihilate existence of such test on the market because the cost of development and implementation would start being prohibitive from a business standpoint to continue on that path, so again I think it would lead from the path to 2023 launch to infinite path to launch").

VP of Technology, Darya Chudova, explained, switching to a new platform "will delay and potentially annihilate existence of such test on the market because the cost of development and implementation would start being prohibitive from a business standpoint[.]"[599] The delay or diversion of R&D resources to redesigning and revalidating an MCED test on an NGS platform without any technological benefit is, itself, a significant harm to the U.S. MCED test market where innovation is the current competitive battleground.

ii. Respondents Cannot Demonstrate that their Proposed Efficiencies Outweigh Competitive Harm

Respondents claim several efficiencies will result from the Proposed Acquisition, including: (i) {[redacted]}[600] Respondents bear the burden of demonstrating that claimed efficiencies are cognizable and outweigh the Proposed Acquisition's anticompetitive effects. *See Otto Bock*, 2019 FTC LEXIS 33 at *168-170. Cognizable efficiencies are "merger specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *Id.* (citing *H&R Block*, 833 F. Supp. 2d at 89).[601] To be merger specific, Respondents must "represent a type of cost saving that could not be achieved without the merger[.]" *FTC v. Wilh. Wilhelmsen Holding ASA,* 341 F. Supp. 3d 27, 72 (D.D.C. 2018); *see also*

[599] PX7045 (Chudova (Guardant) IH at 118:12-119:21).

[600] {[redacted]} Respondents list several additional efficiencies in their Answer but have not quantified these claims or provided sufficient evidence to test their merger specificity or otherwise verify them by reasonable means. These include "speed to scale" and "accelerating international expansion." Answer at 12-13. Similarly, Respondents' {[redacted]}

[601] The *Vertical Merger Guidelines* recommend, "evaluat[ing] efficiency claims by the parties using the approach set forth in Section 10 of the Horizontal Merger Guidelines." *Vertical Merger Guidelines* § 6.

Horizontal Merger Guidelines § 10 (defining merger-specific efficiencies as "those efficiencies likely to be accomplished with the proposed merger and unlikely to be accomplished in the absence of either the proposed merger or another means having comparable anticompetitive effects."). And to be verifiable, Respondents must provide "clear evidence showing that the merger will result in efficiencies that will offset the anticompetitive effects and ultimately benefit consumers." *Otto Bock*, 2019 FTC LEXIS 33, at *169 (citing *Penn State Hersey Med. Ctr.*, 838 F.3d at 350). More specifically, "'it is incumbent upon the merging firms to substantiate efficiency claims' so that it is possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency, how and when each would be achieved (and any costs of doing so), how each would enhance the merged firm's ability and incentive to compete, and why each would be merger specific.'" *Id.* (citing *H&R Block*, 833 F. Supp. 2d at 89). Lastly, projections of efficiencies generated outside of the usual business planning process "may be viewed with skepticism." *Horizontal Merger Guidelines* § 10.

a. Respondents' Claimed Acceleration Efficiency is neither Verifiable nor Merger Specific

Respondents and their experts claim the Proposed Acquisition will accelerate FDA approval, Medicare reimbursement, and private insurance reimbursement of Grail's MCED test.[602] With respect to FDA approval, Respondents fail to establish that the claimed acceleration efficiency is merger specific because they provide no evidence that acceleration is "likely to be accomplished" with the Proposed Acquisition and "unlikely to be accomplished in the absence of either the proposed merger or another means having comparable anticompetitive effects." *Horizontal Merger Guidelines* § 10. For example, Grail could likely accomplish this result by

[602] Answer at 12; *see also* {[redacted]}

other means such as the hiring of employees with relevant expertise or the retention of third-party consultants.[603] Respondents also fail to explain adequately why Grail could not gain this expertise through partnership with a company other than Illumina, or through an agreement with Illumina outside of the Proposed Acquisition.[604] Similarly, with respect to payor acceleration, Respondents and {[redacted]}[605] But Illumina has entered into {[redacted]}[606] Respondents' {[redacted]}[607]

Similarly, Respondents do not provide evidence sufficient to verify this FDA acceleration claim. For example, Respondents claim that Illumina's {[redacted]}[608] But only {[redacted]}[609] and there are {[redacted]}

[603] {[redacted]}
[604] {[redacted]}
[605] {[redacted]}
[606] {[redacted]}
[607] {[redacted]}
[608] {[redacted]} *see also* Answer at 12. Respondents admit that the FDA has not provided guidance regarding the MCED approval process, and so it is also unclear how Illumina's limited experience could be beneficial when the FDA's requirements are unknown. PX6069 at 006-008 (Respondent Illumina, Inc.'s Responses and Objections to Complaint Counsel's Requests for Admissions to Illumina, Inc., June 21, 2021); *see also* {[redacted]}
[609] Respondents fail to address how {[redacted]}

[redacted]}[610] In fact, even in its own {[redacted]}[612]

Respondents also fail to substantiate their claim that Illumina **could** {[redacted]}[613] Respondents' deal documents do not identify {[redacted]} as a benefit or rationale for the Proposed Acquisition.[614] And none of {[redacted]}[615] Additionally, Respondents make no mention of the cost to achieve these efficiencies, despite the indication by {[redacted]}[616]

b. Respondents' R&D Efficiency Claim is neither Verifiable nor Merger Specific

610 {[redacted]}
611 {[redacted]}
612 {[redacted]}
613 {[redacted]}
614 In ordinary course documents, Illumina anticipated {[redacted]} *See id.*
615 {[redacted]}
616 {[redacted]}

Respondents also claim the Proposed Acquisition "will help accelerate new breakthroughs in oncology and other fields."[617] According to {[redacted]}[618] But Respondents provide no evidence whatsoever to verify this R&D efficiency claim, relying instead on the hunch that such efficiencies will {[redacted]} appear. Respondents do not identify which specific products could be developed as a result of the Proposed Acquisition, when they will be developed, or why they are merger specific. Similarly, Respondents {[redacted]}[619]

c. Respondents' Claimed Supply Chain and Laboratory Operational Efficiencies are not Verifiable

Lastly, Respondents claim that the Proposed Acquisition will result in {[redacted]}[620] {[redacted]}

[617] Answer at 13.
[618] {[redacted]}
[619] {[redacted]}
[620] {[redacted]} This efficiency is not claimed in Respondents' Answer. *See generally* Answer at 11-14.
[621] {[redacted]}
[622] {[redacted]}

[redacted]}[623] During his investigational hearing, {[redacted]

[redacted]}[624] Moreover, Respondents have failed to provide sufficient information to verify this claim, assess the costs associated with achieving it, or explain how the claimed efficiency is merger-specific.[625]

iii. Respondents Cannot Demonstrate that Elimination of Double Marginalization Outweighs Competitive Harm

Respondents identify EDM as one of several efficiencies that they claim outweigh any competitive harm resulting from the Proposed Acquisition.[626] Because Respondents are best positioned to present evidence relating to EDM, it is Respondents' burden to show that EDM eliminates the anticompetitive harm set out in the government's *prima facie* case. *See Smith v. United States*, 568 U.S. 106, 112 (2013) ("[W]here the facts with regard to an issue lie peculiarly in the knowledge of a party,' that party is best situated to bear the burden of proof."); *Horizontal Merger Guidelines* § 10 (explaining that "much of the information relating to efficiencies is uniquely in the possession of the merging firms"); *Vertical Merger Guidelines* § 6 (observing that "it is incumbent on the merging firms to provide substantiation for claims that they will benefit from the elimination of double marginalization"). {[redacted]

[redacted]} Nor can Respondents demonstrate that EDM will be merger specific.

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[623] *See generally* {[redacted]}

[624] {[redacted]}

[625] For example, {[redacted]

[626] {[redacted]}

Respondents cannot quantify EDM or determine the amount of cost savings from EDM that will be passed through to customers. {[redacted]}[629]

Even if Respondents' claimed EDM effect were quantifiable, it is not merger specific because, {[redacted]} Unlike contractual relationships between buyers and sellers that rely on standard linear pricing, Illumina and Grail include {[redacted]} Illumina's use of complex, multi-part pricing allows it to set a profit-maximizing price for itself and Grail via contract. Thus,

627 {[redacted]}
628 {[redacted]}
629 {[redacted]}

{[redacted]}[630] A merger of Illumina and Grail is therefore not necessary to {[redacted]}[631]

Finally, even if Respondents could demonstrate merger-specific EDM, {[redacted]}[632]

F. Respondents' Proposed Remedy Fails to Replace the Competitive Intensity Lost from the Proposed Acquisition

In rebuttal, Respondents may introduce evidence that a proposed remedy will "effectively preserve competition in the relevant market." *Otto Bock*, 2019 FTC LEXIS 33 at *161 (quoting *Aetna*, 240 F. Supp. 3d at 60). In other words, the remedy must "replac[e] the competitive intensity lost as a result of the merger." *Id*. (quoting *Sysco*, 113 F. Supp. 3d at 72). Whereas here Complaint Counsel has shown that the Proposed Acquisition clearly runs afoul of antitrust laws, "all doubts as to remedy are to be resolved in its favor." *Otto Bock*, 2019 FTC LEXIS 33 at *181 (quoting *United States v. E.I. du Pont de Nemours & Co.*, 366 U.S. 316, 334 (1961)); *see also Ford Motor Co.*, 405 U.S. at 575. In an apparent effort to meet this burden, Respondents have made a series of attempts to enter into long-term supply agreements with MCED test developers. These attempts, which have culminated in a publicly available twelve-year Open Offer posted on

630 {[redacted]}
631 {[redacted]}
632 {[redacted]}

Illumina's website in March,[633] fail to "replace the competitive intensity" lost from the Proposed Acquisition. Due to the clear inadequacies of the Open Offer, along with the outstanding concerns of those actually subject to the terms of the Open Offer, Respondents' proposed remedy falls well short of meeting their burden.

First, the Open Offer does nothing to change Illumina's post-acquisition incentives to harm Grail's MCED rivals. As explained in the Department of Justice's 2020 Merger Remedies Manual, when a remedy requires that a supplier help its customers compete against itself, "it is unlikely to exert much effort to ensure the products or inputs it supplies are of high quality, arrive as scheduled, match the order specifications, and satisfy other conditions that are necessary to preserve competition."[634] Here, given Illumina's multibillion-dollar incentive to ensure that Grail captures the bulk of the U.S. MCED test market, Illumina will possess an extremely strong incentive to delay supply, impede product quality, restrict access to new technology, and otherwise fail to uphold its stated promise to "maximize customer success and satisfaction."[635] As the former FTC Bureau Director, Bruce Hoffman, said in a speech, "conduct remedies that only address the ability to engage in anticompetitive behavior post-acquisition may not be sufficient to prevent competitive harm because people are smart—they will still have the incentive to engage in that behavior and they may find other ways to act on that incentive."[636]

Because Illumina will have a strong incentive to prevent MCED test developers from competing significantly with Galleri, the Open Offer, which Illumina has unilaterally proposed as a contractual framework to govern its future relationships with MCED test developers, would need

[633] *See* PX0064 (Illumina Open Offer agreement, dated Mar. 29, 2021).
[634] U.S. Dep't of Justice, Merger Remedies Manual (2020) § III.B.1.
[635] PX7076 (Berry (Illumina) Depo at 105:21-106:25).
[636] D. Bruce Hoffman, *Vertical Merger Enforcement at the FTC*, Jan. 10, 2018, https://www.ftc.gov/public-statements/1995/07/vertical-merger-enforcement-challenges-ftc (last visited Aug. 13, 2021).

to contemplate and address all possible contingencies that might arise over a period of more than a decade in order to remedy the competitive harm.[637] But evidence shows creating such a contract under these conditions is impossible.[638] {[redacted]}[639] There is no way to create a contract that would replicate the cooperation Illumina would have been incentivized to provide third-party MCED test developers absent the Proposed Acquisition (which is the source of Illumina's changed incentives).[640]

As discussed above, *see supra*,[641] MCED test developers rely on Illumina for more than just the purchase and supply of instruments and consumables. And, their dependency on Illumina will only increase as MCED test developers pursue regulatory approvals and commercialization.[642] Accordingly, it is difficult, if not impossible, today for either Illumina or MCED test developers to draft sufficient contractual terms to protect against competitive harms over the next twelve years. {[redacted]}

[637] {[redacted]}
[638] {[redacted]}
[639] {[redacted]}
[640] {[redacted]} The DOJ's Merger Remedies Guidelines also warn that one key issues with remedying mergers through long-term supply agreements is that "[c]ontractual terms are difficult to define and specify with the requisite foresight and precision." U.S. Dep't of Justice, Merger Remedies Manual (2020) § III.B.1.
[641] *See, supra*, § II.D.ii.c.
[642] *See, e.g.*, {[redacted]}
[643] {[redacted]}

[redacted]}[645]

Examination of specific provisions of the Open Offer reveals the difficulty in drafting contractual protections to cover the provision of goods and services over more than a decade. For example, the Open Offer states that a customer shall have "access to the same product services and support services for purchase" as Grail.[646] The Open Offer does not define "product services" or "support services," however, nor does it attempt to explain how such services could be measured to ensure consistency in treatment between Grail and its rivals. {[redacted]

[644] {[redacted]}

[645] PX2385 {[redacted]

[646] PX0064 § 4.a. (Illumina Open Offer agreement, dated Mar. 29, 2021).

[647] {[redacted]}

[redacted]}[650]

Even if one could draft contractual terms that could address the plethora of post-acquisition harms, such a contract would not prevent Illumina from acting on its incentive to disadvantage Grail's rivals unless violations of the contract could be detected and enforced quickly. Illumina's compliance with the terms of the Open Offer, however, will be difficult (if not impossible) to monitor. For example, although the Open Offer purports to provide customers with the same access to products, services, and prices as Grail, MCED test developers have no way of knowing what products Grail has access to (or when), what services Grail received from Illumina (and the quality of such service), or even what prices Grail pays Illumina.[651] {[redacted]}[652]

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648 {[redacted]}

649 *See, e.g.,* [redacted]}

650 {[redacted]

651 PX7076 (Berry (Illumina) Depo at 291:25-24) (testifying that customers will not know in real time the pricing, products, or services that Illumina provides to Grail); {[redacted]}

652 {[redacted]}

While the Open Offer provides for "an annual audit by an independent third-party auditor selected by Illumina,"[653] this once-a-year review of Illumina's adherence to its own contractual terms falls flat. First, like Illumina's customers, it is unclear how an auditor could gauge accurately compliance with certain non-quantitative terms of the Open Offer, such as service and access to new technology. For example, if one customer's service is delayed one week, an auditor would have to understand the cause of the delay, the intent behind the delay, and the impact of the delay.[654] As Guardant's Getty testified, "the individual that was chosen to go to Guardant Health could simply have had a vacation scheduled so that seems like normal course of business. But the person who didn't have a vacation scheduled ended up at GRAIL. . . . So even a third party auditor would be – it would be very difficult to gauge like for like in terms of services."[655] {[redacted]}[656] Second, because the Open Offer only provides for an audit once per year,[657] the audit, and subsequent remedial measures, may not take place until

[653] PX0064 § 12.a. (Illumina Open Offer agreement, dated Mar. 29, 2021).

[654] {[redacted]}

[655] PX7105 (Getty (Guardant) Depo at 85:12-86:19).

[656] {[redacted]}

[657] While the Open Offer also provides 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," *see* PX0064 § 12.a.(Illumina Open Offer agreement, dated Mar. 29, 2021), it is unclear what constitutes a "good faith basis" and how a customer could obtain such a basis. [redacted]

well after the breach of the contractual terms, after substantial harm has already taken place.[658] {[redacted]}[659] In the meantime, customers must primarily rely on Illumina's own assurances that it is adhering to its commitments,[660] {[redacted]}[661] Even if, as Respondents have suggested in their submissions to the Court[662] and in deposition questioning,[663] the FTC appointed a monitor trustee to "continually monitor" Illumina's compliance with the Open Offer, the amount of oversight required would create substantial

[redacted] Although Illumina's Berry testified that she is "quite confident" that "we will be generous with our definitions of good faith," Berry could not point to any language that explains the good faith standard. PX7076 (Berry (Illumina) Depo at 296:10-297:13).

[658] *See, e.g.*, [redacted] PX7105 (Getty (Guardant) Depo at 90:5-91:3) (testifying that if "over that [year-long] period of time Illumina was able to take that breach and turn it into a significant competitive advantage for GRAIL by advancing their technology ahead of Guardant's" then "that would be extremely, extremely problematic").

[659] {[redacted]}

[660] {[redacted]}

[661] {[redacted]}

[662] *See* Motion for Conference to Facilitate Settlement, *In the Matter of Illumina, Inc., and GRAIL, Inc.,* Docket No. 9401 (July 13, 2021) at 4.

[663] {[redacted]}

government entanglement in an industry thriving on innovation.[664] It is for this reason that courts have generally warned that conduct remedies are "disfavored because they 'risk excessive government entanglement in the market.'"[665]

MCED test developers have also raised concerns that the firewall provisions in the Open Offer are insufficient to prevent Grail from having access to their competitively sensitive information. The Open Offer provides that "Illumina shall establish a firewall designed to prevent any GRAIL personnel . . . from accessing any Confidential Information obtained by or made available to Illumina relating to Customer or its business or products."[666] This undefined "firewall," however, is insufficient. {[redacted]}[667] Guardant's Getty also testified that the upper level individuals at both Illumina and Grail "would be shareholders in a combined company" and so they will all "have a financial and perhaps even other incentives to share information and create

[664] *See* U.S. Dep't of Justice, Merger Remedies Manual (2020) at 4 (noting that remedies should not create ongoing government regulation of the market); U.S. Dep't. of Justice, Antitrust Div., *Assistant Attorney General Makan Delrahim Delivers Keynote Address at American Bar Association's Antitrust Fall Forum*, https://www.justice.gov/opa/speech/assistant-attorney-general-makan-delrahim-delivers-keynote-address-american-bar (Nov. 16, 2017) ("[A]t times antitrust enforcers have experimented with allowing illegal mergers to proceed subject to certain behavioral commitments. That approach is fundamentally regulatory, imposing ongoing government oversight on what should preferably be a free market."); *id.* ("Instead of protecting the competition that might be lost in an unlawful merger, a behavioral remedy supplants competition with regulation; it replaces disaggregated decision making with central planning.").

[665] *Steve & Sons, Inc. v. Jeld-Wen, Inc.*, 988 F.3d 690, 720 (4th Cir. 2021) (quoting *St. Alphonsus Med. Ctr. – Nampa, Inc. v. St. Luke's Health Sys.*, 778 F.3d 775, 793 (9th Cir. 2015)); *see also* U.S. Dep't of Justice, Merger Remedies Manual (2020) at 4.

[666] PX0064 at § 10.b. (Illumina Open Offer agreement, dated March 29, 2021).

[667] {[redacted]}

the most competitive Grail that can possibly exist in order to win the 60-billion-dollar market."[668] Moreover, a firewall also may not be practical as people switch between Illumina and Grail. {[redacted]}[669]

A conduct remedy, like the Open Offer, cannot change Respondents' strong incentive to harm Grail's rivals post-acquisition. Even attempting to do so would require such substantial monitoring and regulation of the highly innovative U.S. MCED test market that it would "substitute central decision making for the free market," stifling the flourishing the competition that exists today.[670] Accordingly, Respondents fall well short of meeting their burden to show that their proposed remedy would replace the competitive intensity lost as a result of the Proposed Acquisition.

CONCLUSION

For the foregoing reasons, the evidence presented at trial and admitted to the record will establish that the Proposed Acquisition violates Section 7 of the Clayton Act and Section 5 of the FTC Act, as alleged in the Complaint, and will justify entry of an Order by the Court granting the relief sought therein.

[668] PX7105 (Getty (Guardant) Depo at 100:8-101:21).
[669] {[redacted]}
[670] U.S. Dep't of Justice, Merger Remedies Manual (2020) § II.

Dated: August 20, 2021

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CERTIFICATE OF SERVICE

I hereby certify that on August 20, 2021, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

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PUBLIC

EXHIBITS CITED TO IN COMPLAINT COUNSEL'S PRE-TRIAL BRIEF

(All Exhibits Served via FTP Transfer - Aggregate File Size Over the Limit to E-File)

Illumina at Goldman Sachs Global Healthcare Conference (2017)	PX0037	PX0043
PX0064	PX0085	PX0086
PX0087	PX0091	PX0118
PX0119	PX0120	PX0124
PX0153	PX0155	PX2005 -- Partially REDACTED
PX2006	PX2009 -- REDACTED	PX2010 -- REDACTED
PX2013 -- REDACTED	PX2023 -- REDACTED	PX2035 -- REDACTED
PX2043	PX2069 -- REDACTED	PX2077 -- REDACTED
PX2089 -- REDACTED	PX2095 -- REDACTED	PX2102 -- REDACTED
PX2121 -- REDACTED	PX2122 -- REDACTED	PX2151 -- REDACTED
PX2152 -- REDACTED	PX2158 -- REDACTED	PX2165
PX2167 -- REDACTED	PX2169 -- REDACTED	PX2170 -- REDACTED
PX2199 -- REDACTED	PX2203 -- REDACTED	PX2265 -- REDACTED
PX2290 -- REDACTED	PX2301 -- REDACTED	PX2302 -- REDACTED
PX2314 -- REDACTED	PX2316 -- REDACTED	PX2346 -- Partially REDACTED
PX2377 -- REDACTED	PX2378 -- REDACTED	PX2379 -- REDACTED
PX2385 -- REDACTED	PX2386 -- REDACTED	PX2387 -- REDACTED
PX2391 -- REDACTED	PX2399 -- REDACTED	PX2406 -- REDACTED
PX2465 -- REDACTED	PX2488 -- REDACTED	PX2507 -- REDACTED
PX2541 -- REDACTED	PX2544	PX2553 -- REDACTED
PX2557 -- Partially REDACTED	PX2558 -- REDACTED	PX2560 -- REDACTED
PX2581 -- REDACTED	PX2588 -- REDACTED	PX2597
PX2598 -- REDACTED	PX2599 -- REDACTED	PX2601 -- REDACTED
PX2603 -- REDACTED	PX2613 -- REDACTED	PX2617 -- REDACTED
PX2620 -- REDACTED	PX2624 -- REDACTED	PX2625 -- REDACTED
PX2631 -- REDACTED	PX2688 -- REDACTED	PX2764 -- REDACTED
PX2822	PX4004 -- REDACTED	PX4006 -- REDACTED
PX4012 -- REDACTED	PX4016 -- REDACTED	PX4029 -- REDACTED
PX4032 -- REDACTED	PX4035	PX4037 -- REDACTED
PX4048 -- REDACTED	PX4054 -- REDACTED	PX4055 -- REDACTED
PX4075 -- REDACTED	PX4079 -- REDACTED	PX4082
PX4085 -- REDACTED	PX4095 -- REDACTED	PX4112 -- REDACTED
PX4116 -- REDACTED	PX4120 -- REDACTED	PX4137 -- REDACTED
PX4140 -- REDACTED	PX4170 -- REDACTED	PX4209 -- REDACTED
PX4250 -- REDACTED	PX4267 -- REDACTED	PX4284 -- REDACTED
PX4323 -- REDACTED	PX4381 -- REDACTED	PX4467 -- Partially REDACTED
PX4468 -- REDACTED	PX4574 -- REDACTED	PX5023
PX5024	PX5025	PX5027
PX5030	PX5048	PX5049

PX6050	PX6061 -- Partially REDACTED	PX6069
PX6090 -- REDACTED	PX6091 -- REDACTED	PX6092 -- REDACTED
PX6093 -- REDACTED	PX6097 -- REDACTED	PX7040 -- REDACTED
PX7041 -- REDACTED	PX7042 -- REDACTED	PX7043 -- REDACTED
PX7044 -- REDACTED	PX7045 -- REDACTED	PX7047 -- REDACTED
PX7048 -- REDACTED	PX7049 -- REDACTED	PX7050 -- REDACTED
PX7051 -- REDACTED	PX7052 -- REDACTED	PX7053 -- REDACTED
PX7054 -- REDACTED	PX7055 -- REDACTED	PX7056 -- REDACTED
PX7057 -- REDACTED	PX7058 -- REDACTED	PX7060 -- REDACTED
PX7063 -- REDACTED	PX7064 -- REDACTED	PX7065 -- REDACTED
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PX7094 -- REDACTED	PX7097 -- REDACTED	PX7099 -- REDACTED
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PX7107 -- REDACTED	PX7108 -- REDACTED	PX7109 -- REDACTED
PX7110 -- REDACTED	PX7111 -- REDACTED	PX7112 -- REDACTED
PX7113 -- REDACTED	PX7114 -- REDACTED	PX7117 -- REDACTED
PX7118 -- REDACTED	PX7119 -- REDACTED	PX7121 -- REDACTED
PX7123 -- REDACTED	PX7124 -- REDACTED	PX7130 -- REDACTED
PX7132 -- REDACTED	PX7133 -- REDACTED	PX7134 -- REDACTED
PX7137 -- REDACTED	PX8305 -- REDACTED	PX8313 -- Partially REDACTED
PX8314 -- REDACTED	PX8317 -- REDACTED	PX8324 -- REDACTED
PX8392 -- REDACTED	PX8398	PX8399 -- Partially REDACTED
PX8400	PX8402 -- REDACTED	PX8474 -- REDACTED
PX8515	PX8530	PX8532 -- REDACTED
PX8540 -- REDACTED	PX8612 -- REDACTED	PX8654
RX3864 -- REDACTED	RX3866 -- REDACTED	RX3867 -- REDACTED
RX3871 -- Partially REDACTED		