PUBLIC

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

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

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Dated: April 22, 2022

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INTRODUCTION

MCED tests are poised to turn the tide in the war on cancer. Through a simple blood draw, these tests detect multiple cancers at early stages, leading to improved outcomes and saving lives. The companies currently competing head-to-head in the research, development and commercialization of MCED tests ("MCED Tests" or the "MCED Test Market")—including Grail, Exact Sciences ("Exact"),[1] [redacted] Guardant Health ("Guardant"), Freenome, Singlera, Helio Health ("Helio"), and {[redacted]}— all rely on Illumina's NGS platforms.[2] Now, through its acquisition of Grail, Illumina can use its power over a critical input to suppress Grail's competitors, and reap the rewards of, what Illumina calls, "the single biggest market segment that we can imagine." (CCFF ¶ 476). Illumina is a profit maximizing firm that owes a duty to its shareholders to generate revenue. As such, Illumina will follow its incentives and utilize every lever at its disposal to capture that market and generate revenue for its shareholders, just as it has done previously. Illumina executives internally explained their vision for Illumina in pursuing that goal—"May God have mercy on my enemies, because I will not!" (CCFF ¶ 3080).

The potential harm from Illumina's acquisition of Grail (the "Acquisition") is best understood in the context of the important role MCED tests, and MCED test developers, play in the war on cancer. Cancer is the second-leading cause of death in the United States, killing approximately 630,000 Americans each year. Today, cancer screening exists only for a few types of cancers, while the vast majority of cancers, accounting for approximately 80 percent of cancer

[1] Exact acquired Thrive in January 2021. (CCFF ¶ 1917).
[2] The term "NGS platform" as used herein 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."

deaths, can only be detected after patients have exhibited symptoms when it is often too late to treat effectively. MCED test developers seek to change this dynamic. Their MCED tests, known as the "holy grail" of cancer detection, will analyze a patient's blood to determine whether there is any genetic material, known as biomarkers, within the bloodstream that indicates the presence of 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. Developing technology that can find traces of cancer in the blood has the potential to revolutionize how cancer is detected and treated in the United States. As one MCED test developer testified, "[w]e always dreamt that it would be great to detect cancer early, because early cancer detection saves lives. Even with the current treatments that we have, if you use the same treatment and you were tested back for cancer earlier, most individuals not only live longer but actually get cured." (CCFF ¶ 268).

To achieve the "holy grail" in cancer detection and save lives of the many Americans who are living with or may be diagnosed with cancer, competition must be allowed to flourish. According to Dr. William Cance, Chief Medical and Scientific Officer of the American Cancer Society, "multiple companies and institutions developing and improving [MCED test] technology is very important." (CCFF ¶ 3574). Today, Grail and its rivals are competing head-to-head on multiple dimensions to develop the best quality MCED test and gain widespread adoption among customers. While Grail is the first developer to launch its test, commercializing an initial version of its Galleri MCED test in April 2021, evidence shows that competing MCED tests will be close substitutes to Galleri. Grail recognizes as much, acknowledging in an internal report that "MCED [testing is] evolving into highly competitive landscape," (CCFF ¶ 3459), and warning of the threat

that {[redacted]} (CCFF ¶ 3451). Grail developed strategies to {[redacted]} *See, e.g.*, (CCFF ¶¶ 3264, 3453, 3592). Likewise, other MCED test developers have also made efforts to enhance their own tests in response to Grail, and plan to compete against Grail on performance, price, and service. *See, e.g.*, (CCFF ¶¶ 1969, 2281, 3316, 3222, 3291, 3313).

Although Grail launched the first MCED test on the market, a superior MCED test being developed by one of Grail's many rivals could leapfrog it, taking sales from Galleri and providing Americans enormous benefits. For example, Grail's Galleri test has been clinically shown to detect seven cancers,[3] and, for many cancers it purports to detect, Galleri has low sensitivity rates, meaning high false negative rates (*i.e.*, telling patients they are cancer free, when they are not). *See* (CCFF ¶¶ 6255-58). Some of Grail's rivals, however, are launching tests with higher sensitivities, *see* (CCFF ¶¶ 2022, 2286, 3318), that focus on cancers that Galleri does not, *see* (CCFF ¶¶ 2050, 2380, 2423). These competitive threats have spurred Grail to make improvements to its own test to "continually enhance the performance and features . . . including seeking ways to improve sensitivity and reduce sequencing costs." (CCFF ¶ 411); *see also* (CCFF ¶ 413).

While innovation is vibrant in this "rapidly evolving market landscape," (CCFF ¶ 3405), this innovation relies on Illumina's NGS platforms to find early signs of cancer in the blood, which, essentially, is like finding "a needle in a haystack," (CCFF ¶ 298). Accordingly, MCED test developers must run their tests on specialized sequencing technology, known as NGS, to accurately and effectively detect cancer. Freenome's CEO likened NGS to an "anchor tenant" of an MCED

[3] Although Grail claims that its Galleri test can detect over 50 cancers, there is no clinical evidence for this claim. (CCFF ¶¶ 6295-344).

test, like a Macy's department store at the mall, meaning it is "really foundational – [a] pillar in overall product development efforts." (CCFF ¶¶ 1144-45).

Each and every MCED test developer testified at trial that Illumina is their only option to provide this technology; there are no alternatives. MCED test developers design their tests specifically to fit Illumina's platform and must rely on Illumina throughout the development and commercialization process. Exact's CEO testified that Illumina's NGS platform is {[redacted]} (CCFF ¶ 2855). Rather than simply buy a sequencer and plug it in, MCED test developers must rely on Illumina for installation, training, service, repairs, upgrades, and regulatory support, among other things, to ensure that their development efforts run smoothly and successfully. As a Guardant executive testified, "there's a symbiotic relationship" between Guardant and Illumina. (CCFF ¶ 2880). In fact, he explained, Illumina is so omnipresent in Guardant's development efforts that "the Illumina logo could be placed on the lab." (CCFF ¶ 4490). Similarly, Singlera's co-founder and scientific advisor likened Singlera's relationship with Illumina to being a "prisoner of war." (CCFF ¶ 1174). While other NGS platforms are used in applications outside the MCED testing space, these platforms do not meet the high technological and commercial requirements necessary for sequencing an MCED test, and thus, are unsuitable for MCED testing. Given MCED test developers' necessary dependency on Illumina, one MCED test developer explained that 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." (CCFF ¶ 2844).

While prior to the Acquisition Illumina had every incentive to "encourage investment into many different NGS-based companies focused on early cancer detection to have as many shots on

goal as possible," (CCFF ¶ 3086), post-Acquisition Illumina's incentives shift dramatically. Throughout its presentations to its Board and investors, Illumina recognizes that the "early detection of cancer segment is the largest segment in the clinical market we can see for the next decade." (CCFF ¶ 3137). In fact, Illumina sees the potential profits from acquiring Grail as dwarfing its expected profits from selling NGS platforms. As Illumina's CEO explained to investors, "the acquisition positions Illumina to participate in what we expect will be a $75 billion market for NGS-based oncology tests by 2035, $60 billion higher than our oncology TAM [total addressable market] excluding GRAIL." (CCFF ¶ 3136). This opportunity, however, puts Illumina in direct conflict with its MCED test developer customers. Given the enormous profits at stake, post-Acquisition Illumina has a strong incentive to use Galleri to capture as much of the MCED Test Market as possible by impeding any competition that threatens Grail's market position. As a Guardant executive explained, "there's a much bigger market opportunity for Illumina as a screening company than there is as a sequencing company. . . . [T]herefore, you know, getting into the [cancer screening] business and controlling it through vertical integration of the technology underlying it, yeah, I mean, you would want to put us out of business." (CCFF ¶ 3150). One Grail executive even relished the post-Acquisition change in incentives, noting that MCED test developer competitor "Thrive['s] SVP is now freaking out on me and wanting info [about the Acquisition]. Obviously they feel this is not good for them. Which is entertaining." (CCFF ¶ 3149).

While the evidence is clear that Illumina has the ability and incentive to stifle competitive threats from Grail's MCED Test rivals, this Court need not doubt whether Illumina will act on its economic incentive now that it owns Grail; instead, the Court can simply look to Illumina's own

playbook. When Illumina owned the majority stake of Grail before selling it to outside investors, Illumina agreed that it would "not launch, invest in, or provide special discounts to competitive business[es]," giving Grail "Limited Exclusivity in the field of blood based cancer screening[.]" (CCFF ¶ 3698). In addition, Illumina provided Grail with certain products, services, and discounts that it did not provide to its other customers. *See, e.g.*, (CCFF ¶¶ 3704-08, 3680-92). As Illumina explained, "Illumina understands the sequencer better than anyone since they developed it and can in partnership with [Grail] optimize i[t] for ctDNA applications (e.g., improved error profile). This means that [Grail] can get better performance than someone who has to use the off the shelf version." (CCFF ¶ 2986). It was only after it sold off most of its interest in Grail that Illumina leveled the playing field for other MCED test developers, allowing Grail's competitors to thrive.

Illumina followed the same playbook, acting consistent with its economic interests, in other areas in which it is vertically integrated. For instance, in addition to selling NGS platforms, Illumina offers a therapy selection test called TruSight Oncology 500 ("TSO-500"), a clinical test designed to determine the best cancer treatment for a patient. Similar to MCED test developers, Illumina's therapy selection customers also rely on Illumina's NGS platforms. Rather than treat its therapy selection customers neutrally, though, Illumina's former VP of Business Development admitted that when negotiating key agreements with its therapy selection customers, "[w]e considered a term called 'cannibalization' - in other words, what would be the sales of Illumina's TSO-500 in the absence of these partners versus the presence of these partners - to try and decide at least a framework for summing up what the value of that partnership should be." (CCFF ¶ 3808). Based on this cannibalization assessment, Illumina required its rival therapy selection customers to pay millions of dollars in payments and royalty fees to Illumina to offset any loss of

TSO-500 sales from allowing its customers to compete, (CCFF ¶¶ 3915-16, 3951-53), or else denied its customers the necessary agreements altogether, (CCFF ¶¶ 3994, 4002).

Despite this playbook**,** Respondents now argue that the Court should simply trust Illumina not to act on its clear economic incentives, sacrificing the massive potential profits from MCED tests that it could secure by harming Grail's rivals. But Illumina's own actions have belied this claim. For example, despite agreeing that during the pendency of a regulatory review Grail "will be run as a separate entity, and where it engages with Illumina, it will do so on an arm's length basis," (CCFF ¶ 222), as soon as Illumina completed its acquisition of Grail, Illumina immediately {[redacted]}. (CCFF ¶¶ 3040-41).

Despite all of the evidence pointing to substantial competitive harm, Illumina seeks to remedy its illegal merger in the form of a twelve-year supply agreement (the "Open Offer") that it has offered to its customers. To rival MCED test developers, though, Respondents' attempt at a remedy is {[redacted]} (CCFF ¶ 4994). [redacted] } (CCFF ¶¶ 4178-79). And one need not guess how Illumina will act. Despite the Open Offer being in effect, which includes a firewall provision, (CCFF ¶ 4728), Illumina appointed its COO, who has worked at Illumina since 2013 and holds $1 million in Illumina stock, as the CEO of Grail. (CCFF ¶¶ 226, 3036). 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 show that purported efficiencies would prevent harm from the Acquisition.

The evidence presented in the record and at the evidentiary hearing tells the straightforward story of competitive harm in this case. Grail and its rivals are vigorously competing to offer the highest-performing, most affordable MCED test. Without the Acquisition, Illumina—the only supplier of a critical input for any competitive MCED test—has 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; likely increase the price of accessing these critically important tests; and risk countless lives that could have otherwise been saved. As the CEO of Freenome explained, he is "focused on beating the competitor, which is cancer," and "there's room for a lot of folks if we take that approach and that we have a fair and level playing field to achieve it." (CCFF ¶ 3576). Rather than let the free market thrive, and allow competitors to fight it out on performance, service, and price, Illumina's acquisition of Grail arrests development at the status quo, to the detriment of Americans.

Complaint Counsel has clearly established that Illumina's acquisition of Grail violates both Section 7 of the Clayton Act and Section 5 of the FTC Act. A remedy is therefore justified and required to prevent the Acquisition from harming competition. Complaint Counsel respectfully requests the Court issue its Proposed Order, which would divest Grail's business from Illumina's full ownership.

I. BACKGROUND

A. Industry Background

1. Cancer Screening and MCED Tests

Cancer is the second-leading cause of death in the United States.[4] (CCFF ¶ 227). The American Cancer Society estimates that over 1.7 million new cancer cases are diagnosed annually in the United States, and every year approximately 630,000 Americans die from cancer. (CCFF ¶¶ 227-28). In fact, about {[redacted]} of Americans are projected to die from cancer. (CCFF ¶ 229). A significant reason for the high death toll is that most cancers are not detected until after the cancer has grown or spread, when treatment is more difficult and survival rates lower.[5] (CCFF ¶¶ 255-262). {[redacted]"} (CCFF ¶ 260). Early cancer screening improves patient survival rates by increasing effective treatment options. (CCFF ¶ 264).

MCED tests are poised to revolutionize cancer detection. Today, cancer screening exists for only a few types of cancer—lung, breast, colorectal, and cervical.[6] While existing screening methods are highly effective at detecting these cancers in patients, the vast majority of cancers have no screening options. (CCFF ¶ 245). Several companies, including Grail and its MCED Test competitors, seek to upend this paradigm. These companies are developing MCED tests, designed

[4] Cancer treatment costs the United States $150 billion annually. (CCFF ¶ 230).
[5] Over half of cancers in the United States are diagnosed at Stages III and IV. {[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." (CCFF ¶ 251). 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." (CCFF ¶ 253).
[6] Lung cancer screening is "only recommended for very high-risk smokers." (CCFF ¶ 234). 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. (CCFF ¶ 235).

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 as part of a routine physical through a simple blood draw. (CCFF ¶ 381). In this way, MCED tests are a crucial development in the war against cancer.

MCED tests detect cancer by looking for biomarkers[7] within a patient's blood sample that are consistent with cancer. Nearly all cells, including cancer cells, contain DNA.[8] (CCFF ¶ 288). DNA is typically double stranded and made up of complementary pairs of nucleotides, known as base pairs. (CCFF ¶ 289). DNA resides in the nucleus of most cells in the form of long (up to hundreds of millions of base pairs) molecules called chromosomes. (CCFF ¶ 291). When a cell dies, the chromosomal DNA from the nucleus naturally disintegrates into small fragments (fewer than 200 base pairs) that spill into the bloodstream, at which point it is known as cell-free DNA ("cfDNA"). (CCFF ¶¶ 292-93). Cancerous tumor cells go through the same process; when cancer cells die, they also shed their chromosomal DNA into the bloodstream in the form of short cfDNA fragments. (CCFF ¶ 294). cfDNA originating from cancerous tumor cells is called circulating tumor DNA ("ctDNA"). (CCFF ¶ 295). ctDNA reflects the genetic makeup of the tumor cells that released it and can differ from normal non-cancerous cfDNA in a variety of ways. (CCFF ¶ 295). The levels of ctDNA in a person's blood varies by the type of cancer and the stage and size of the person's tumor. (CCFF ¶¶ 295, 299-300).

Detecting cancer signals in the blood of otherwise healthy individuals is difficult because finding ctDNA in the blood is like finding a needle in a haystack of normal cfDNA. (CCFF ¶ 298).

[7] A "biomarker is either a protein or DNA or RNA or other molecule in the body that is present when cancer is present and not present when cancer is not present." (CCFF ¶ 310).
[8] Nearly all cells, including cancer cells, also include ribonucleic acid ("RNA"). (CCFF ¶ 303).

The earlier the stage of the cancer, the more difficult it is to detect ctDNA. (CCFF ¶¶ 299, 301). While all MCED tests in development analyze cfDNA in a patient's blood to determine whether there is any ctDNA consistent with cancer, MCED test developers are competing to find the best, most accurate way to do so.[9] *See infra* § I.A.5. Specifically, MCED test developers may examine different types of biomarkers and unique sets of biomarkers within cfDNA. *See, e.g.*, (CCFF ¶¶ 400, 433, 1974, 1979, 1984, 2360, 2533). Biomarker types may include methylation patterns,[10] mutations,[11] aneuploidy (an abnormal number of chromosomes),[12] fragmentomics,[13] or various combinations thereof. *See* (CCFF ¶¶ 316, 319, 325, 327). In addition to cfDNA analyses, some MCED test developers are looking at other types of analytes found in the patient's blood, such as proteins. (CCFF ¶ 446). Although their strategies vary, all MCED tests rely on NGS technology and, specifically, Illumina's NGS platforms. *See infra* § II.D. NGS technology can rapidly assay many thousands of biomarkers simultaneously in each patient sample, enabling MCED tests to potentially detect the presence of any specific cancer, its genetic drivers, and its location in the

[9] 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 lab. (CCFF ¶ 284). 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. (CCFF ¶ 285). Following library preparation, the MCED test sample is sequenced on a sequencing instrument to identify the order of base pairs in each molecule in the library. (CCFF ¶ 286). 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. (CCFF ¶ 287).

[10] 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. (CCFF ¶ 321). Methylation changes can lead to genes becoming over-expressed, under-expressed, or silenced altogether, thus resulting in excessive, reduced, or no protein production (respectively). (CCFF ¶ 322). 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. (CCFF ¶ 322).

[11] There are multiple types of DNA mutations, such as single nucleotide changes, copy number variants, insertions, deletions, duplications, rearrangements, and more. (CCFF ¶¶ 314-15, 317). Some mutations only occur in cancer settings. (CCFF ¶ 316).

[12] 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. (CCFF ¶¶ 327-28).

[13] Fragmentomics refers to the analysis of aberrant patterns of length of DNA fragments. (CCFF ¶ 325).

body. (CCFF ¶¶ 347-48). Although other companies sell NGS platforms, only Illumina's have the capabilities required for MCED testing. *See infra* § II.D.2.

2. 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. {[redacted]} Under the existing regulatory framework, a lab may run in-house clinical tests—known as laboratory-developed tests ("LDTs")—without obtaining FDA approval.[14] (CCFF ¶¶ 498-500). LDTs are offered within a single CLIA-approved lab, typically either the test developer's lab or another CLIA-approved lab that has validated the LDT.[15] (CCFF ¶¶ 494-95). LDTs are unlikely to obtain reimbursement coverage from the Centers for Medicare & Medicaid Services ("CMS") and commercial insurers, and accordingly, LDTs typically have lower rates of adoption than FDA-approved tests. {[redacted]} Nevertheless, Grail launched its Galleri test as an LDT in April 2021, (CCFF ¶ 5480), claiming, without either scientific or regulatory validation, that its test could detect 50 types of cancers in the blood. *See* (CCFF ¶¶ 79-81, 6272-298). Some of Grail's MCED rivals {[redacted]} (CCFF ¶ 1998, 2321-22, 2387); *see also* (CCFF ¶¶ 502, 5492).

Once a test receives FDA approval, it is considered an in-vitro diagnostic ("IVD") test. (CCFF ¶¶ 537, 540). There are two types of IVD tests: single-site IVD tests and distributed, "kitted" IVD tests. (CCFF ¶¶ 537, 540). A single-site, or centralized, IVD test is approved by the

[14] 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. (*See* CCFF ¶ 500).
[15] An LDT must meet Clinical Laboratory Improvement Amendments ("CLIA") and College of American Pathologists guidelines, which are clinical lab guidelines. (*See* CCFF ¶ 500).

FDA to run in a single approved lab, typically the MCED test developer's own lab. (CCFF ¶ 537). The premarket approval ("PMA") process involves validating the test developer's lab where the developer must run the test. (CCFF ¶¶ 531, 537). Many MCED test developers, {[redacted]}, plan to seek a PMA from the FDA for the use of their test as a single-site IVD. {[redacted]} A distributed, or kitted, IVD test is approved by the FDA to be sold as a standalone kit that can be sent to and processed in third-party labs. (CCFF ¶¶ 540, 2957). Because a distributed IVD must ensure consistent quality in each lab that runs it, a distributed IVD test developer must follow FDA guidelines and submit to regular FDA audits following PMA approval. (CCFF ¶¶ 544-45). This testing model, however, allows a test to reach the largest customer base because customers across the country no longer need to send samples to the test developer for results. {[redacted]} Some MCED test developers, including Singlera, {[redacted]} are considering seeking PMA approval for use of their test as a distributed IVD. {[redacted]} Regardless of which FDA approval path an MCED test developer takes, it must work closely with Illumina to attain FDA approval for its test. *See* (CCFF ¶¶ 2963-65, 2970-71, 2974-79).

Both single-site and distributed IVD tests must go through similar FDA approval processes. The FDA classifies MCED tests as Class III medical devices. (CCFF ¶¶ 512-13, 850). A Class III device is considered the riskiest type of medical device because of its intended use and indication for use. (CCFF ¶¶ 845, 5030). The FDA typically requires that a developer of a Class III medical device submit an application for PMA approval that includes clinical and analytical validation data to determine safety and efficacy. (CCFF ¶¶ 514-520).

Because NGS platforms and their components are specified as part of the final FDA approval, an approved IVD test is "locked in" to those systems once clinical trials begin, making switching to new technology platforms exceptionally difficult. (CCFF ¶¶ 541-43). Modifying any component of the approved IVD test could require conducting additional clinical trials with the modified component. (CCFF ¶ 542, 4625). At trial multiple MCED test developers testified that once an MCED test developer begins developing an MCED test using an Illumina platform, they become increasingly tethered to Illumina. *See* [redacted] As an MCED test developer progresses to clinical trials and ultimately to FDA approval, the tether tightens; switching to another platform, if one were even available, would require restarting clinical trials, redesigning the test, and incurring substantial regulatory costs. *See, e.g.*, [redacted]

Once an MCED test receives FDA approval, test developers can then seek reimbursement coverage from third-party payers, including CMS and private insurers, to expand the MCED test's potential customer base by providing access to patients who otherwise could not afford to pay the out-of-pocket price of a test. {[redacted]} As many patients require insurance coverage to pay for these tests, obtaining widespread payer coverage is necessary to ensure broad adoption of a test. (CCFF ¶¶ 507, 560); *see also* (CCFF ¶ 508) (Grail CEO Hans Bishop testified at trial that FDA approval is "very necessary for getting American citizens access to our test.").

3. Next-Generation Sequencing

NGS is a method of DNA sequencing, the process of determining the order of nucleotides in DNA molecules. NGS is performed by preparing a DNA sample into a library of fragments,

which are then read by a next generation sequencer.[16] (CCFF ¶¶ 887-91). The library preparation process entails attaching short adapter sequences to the ends of the DNA fragments to make them compatible with a particular sequencer. (CCFF ¶¶ 285, 888, 890). The library is then loaded onto a flow cell and placed on the sequencer, which reads the DNA molecules in the library to determine the order of nucleotides in each molecule. (CCFF ¶¶ 286, 889, 891, 895). There are two types of NGS platforms, short-read and long-read, (CCFF ¶ 893), which differ in the number of DNA fragments that can be sequenced simultaneously and the length of those fragments. (CCFF ¶ 894). Illumina's NGS platforms are considered short-read platforms. (CCFF ¶ 895).

The key performance parameters of an NGS platform are throughput, cost, and accuracy. Throughput is measured by the number of DNA fragments that can be read simultaneously in one run of the instrument. (CCFF ¶¶ 935-36). A single run of a next generation sequencer can read millions, or even billions, of DNA fragments. *See* (CCFF ¶¶ 940-41). Cost is closely related to throughput, as it is measured on a per-sample basis in the context of MCED tests. *See* (CCFF ¶ 931-32, 942). Accuracy refers to the error rate and the type of errors produced by the sequencer. (CCFF ¶ 960). Although many different types of tests run on NGS sequencers, the throughput, accuracy, and cost requirements vary by test type.

[16] Illumina's NGS platform requires the use of consumables, (CCFF ¶ 10), a term which refers to the "materials that are actually consumed in a sequencing run," (CCFF ¶ 16), such as library preparation reagents and flow cells. (CCFF ¶¶ 13-15). As Illumina's Dr. Aravanis testified, for "every sequencing run you need a new set of consumables, but you use the same instrument." (CCFF ¶ 16). There are two primary types of consumables involved in NGS: library preparation reagents and core consumables. (CCFF ¶ 13). Library preparation reagents are used to prepare a sample for testing, for example by replicating DNA of interest so that it may be more easily examined. (CCFF ¶ 14). Core consumables are reagents that must be used together with an instrument to implement a sequencing assay, such as a flow cell. (CCFF ¶ 15).

Today, only a few NGS platforms are available in the United States,[17] with Illumina by far the dominant provider:

- ***Illumina.*** Illumina is the dominant provider of short-read NGS platforms and sells the only NGS platforms that meets the needs of MCED test developers. *See infra* § II.D.2. (CCFF ¶ 341). Illumina currently sells 11 models of NGS instruments, with its NovaSeq platform as its highest throughput instrument today. (CCFF ¶¶ 1022-23). Illumina's NovaSeq 6000 can read up to 20 billion DNA fragments per run, (CCFF ¶ 1739), [redacted] }. (CCFF ¶¶ 1740). [redacted] (CCFF ¶ 1745), { [redacted] } (CCFF ¶ 1737). [redacted] (CCFF ¶ 1045). [redacted] (CCFF ¶ 1755). [redacted] (CCFF ¶ 1757).

  Along with the sequencing instruments themselves, Illumina sells consumables necessary to run its instruments. Consumables make up a significant portion of Illumina's business, representing 71 percent of Illumina's 2020 revenue. (CCFF ¶ 1052). Illumina is the only supplier of the core consumables needed to run assays on Illumina's instruments. (CCFF ¶ 17). Many of Illumina's consumables are off-the-shelf products for use in a variety of sequencing applications. (CCFF ¶ 1050). However, Illumina also creates custom consumables for specific companies, particularly when they are owned by Illumina. (*See* CCFF ¶¶ 1051, 3704-08). Indeed, when Illumina owned a majority stake in Grail, Illumina provided custom consumables to Grail to accommodate Grail's particular high throughput needs. (CCFF ¶¶ 3704-08).

- ***Thermo Fisher Scientific, Inc.*** Thermo Fisher Scientific, Inc. ("Thermo Fisher"), headquartered in Waltham, Massachusetts, is a global life sciences company that sells short-read NGS platforms in the United States. Thermo Fisher's sequencing platforms have performance limitations compared to Illumina's that make them unsuitable for MCED testing. (CCFF ¶¶ 1212-68). For example, Thermo Fisher's platforms have { [redacted]

[17] Several companies are in the process of attempting to develop and commercialize NGS platforms in the United States, including BGI, Roche, Singular Genomics ("Singular"), and { [redacted] } (CCFF ¶¶ 1269-70, 1501, { [redacted] } 1655). Despite years of development, none of these companies has a commercially available product in the United States and all face a fraught path to commercialization. *See, e.g.*, (CCFF ¶¶ 1271-74, { [redacted] } Even if these companies do launch in the United States, however, MCED test developers do not view them as viable alternatives to Illumina's NGS platform. *See, e.g.*, (CCFF ¶¶ { [redacted] } 1620, { [redacted] } *see also infra* § II.F.1.

} (CCFF ¶¶ 1229-231), lower throughput, (CCFF ¶¶ 1214-18), and higher costs, (CCFF ¶ 1219), than Illumina's NGS products. At trial, Thermo Fisher executive Dr. Andrew Felton testified that Thermo Fisher { (CCFF ¶ 1220).

- ***Long-Read NGS Platforms.*** Long-read NGS platforms are capable of reading long DNA molecules, without the need to first cut them up into shorter fragments. (CCFF ¶¶ 894-95). This is useful for certain applications in which the genetic material in the starting sample comprises long molecules, such as chromosomes that are intact. It provides no advantage when working with cfDNA, which by their nature are short fragments. (CCFF ¶¶ 900, 905-07, 912). Long-read NGS platforms also have several disadvantages compared to short-read platforms, including substantially lower read counts, (CCFF ¶¶ 902, 911, 914, 1371), lower accuracy, (CCFF ¶ 913), and higher costs, (CCFF ¶¶ 907, 909-10). Indeed, long-read NGS platforms can typically only read at most, tens of millions of DNA fragments per run. (CCFF ¶ 903).

  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"). *See* (CCFF ¶¶ 896, 1371). MCED test 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. In fact, even (CCFF ¶ 901).

4. Other Technologies

Although other technologies exist to analyze DNA, no other technology can analyze as many DNA fragments as NGS or characterize every nucleotide (and therefore virtually all potential biomarkers) contained within each fragment as required for MCED tests. (CCFF ¶¶ 1400-06, 1442). For example, polymerase chain reaction ("PCR"), a technique which amplifies a specific segment of DNA, (CCFF ¶ 1441), can only test a small number of cancer-related biomarkers in a patient's tissue or blood sample and does not have the ability to screen the multitude of genetic loci required to power an MCED test. (CCFF ¶¶ 1442-52). Additionally, PCR has a high inherent error rate and cannot match the level of accuracy of NGS. { } PCR is also

limited to interrogating the presence or absence of pre-determined target sequence variations at each locus, and it is unable to detect novel genetic variants or mutations contained within library fragments and generate sufficient information for MCED test analysis. (CCFF ¶¶ 1444-47, 1493).

Similarly, microarrays are not suitable replacements for NGS in MCED tests. Microarrays are devices which provide a fluorescent signal indicating the presence of DNA. (CCFF ¶ 1409). Unlike NGS, microarrays do not provide precise readouts of fragments of DNA, (CCFF ¶ 1410), and are only able to interrogate a limited number of predefined genetic markers. (CCFF ¶ 1415). Microarrays lack the high level of sensitivity required to reliably detect ctDNA and are unable to look at certain types of genetic variations. (CCFF ¶¶ 1417-29). Additionally, microarrays have a far higher cost per sample than even Illumina's mid-throughput NGS platforms. {[redacted]} Microarrays are also limited to looking at small sections of the gene, whereas NGS can interrogate the entire genome. (CCFF ¶¶ 1425-26). Given these functional limitations, neither PCR nor microarrays are appropriate for MCED tests, which require the comprehensive information provided by NGS. *See infra* § II.C.i.

5. Grail and Its MCED Test Developer Rivals

Today, several companies, along with Grail, are racing to develop, launch, and gain widespread adoption of MCED tests, including Exact, [redacted] Guardant, Freenome, Singlera, Helio, and {[redacted]} While Grail is the only MCED test developer with a test on the market today, Grail and its rivals are competing vigorously to develop the best performing test, *see* (CCFF ¶¶ 783-84, 787-88, [redacted], 798, 1998, 3221-22, 3365), and are poised to compete head-to-head commercially as Grail's rivals begin to market and sell their tests, *see* (CCFF ¶¶ {[redacted]} 702-04). MCED tests will all serve the same purpose—providing a blood-based early cancer screening test

that can detect multiple cancers simultaneously. (CCFF ¶¶ [redacted], 2314, 2373, 2418, 2503, [redacted], 3525).

- ***Grail.*** Headquartered in Menlo Park, California, Grail is a diagnostics company that develops NGS-based oncology tests,[18] with a focus on early cancer detection. Grail's flagship test is its MCED test, called Galleri. (CCFF ¶ 74). Grail claims that Galleri has the ability to detect over 50 cancers from a single blood draw. (CCFF ¶ 79). Grail's clinical studies, however, have only shown that Galleri can detect seven types of Stage I through Stage III cancer in an asymptomatic screening population. (CCFF ¶¶ 80-81, 6283-6298). Galleri analyzes DNA methylation patterns to detect the presence of cancer in the blood.[19] (CCFF ¶ 408). To do this, Galleri relies on Illumina's NGS platform. (CCFF ¶ 2902). In response to competitive pressures, however, Grail is also {[redacted]} (CCFF ¶¶ 411-13, 3422). As Grail's internal competitive analyses detail, Grail {[redacted]} (CCFF ¶ 3422).

  Galleri became commercially available in June 2021, (CCFF ¶ 5482), and Grail is targeting as customers health systems; large, self-insured employers; concierge medicine practices; and other physicians whose clients have the financial means to enroll in preventative health programs. (CCFF ¶¶ 88, 5507, 5526). Independently of Illumina, Grail has already begun to achieve commercial success, [redacted]} (CCFF ¶ 5506, 5544-46). Grail has completed one clinical study and has three ongoing clinical studies related to the Galleri test, (CCFF ¶ 5315-16), including the "largest, real-world . . . pragmatic, randomized clinical trial" ever undertaken in genomics. (CCFF ¶ 142). [redacted]

  As of September 2020, Grail had raised $1.9 billion "through a combination of leading venture capital and strategic partners." (CCFF ¶ 5851). Prior to the Acquisition, Grail sought to raise additional money through an initial public offering ("IPO"), [redacted] (CCFF ¶ 5904). But because Illumina and Grail entered into an acquisition agreement on September 20, 2020, Grail never went public.[20] (CCFF ¶¶ 188, 197). Should

[18] In addition to its Galleri MCED test, Grail is also developing [redacted]

[19] Grail previously pursued other approaches to detecting cancer, including mutations and aneuploidy in cfDNA, but ultimately decided to focus on the use of methylation states in cfDNA as its method for its initial Galleri test. (CCFF ¶ 3649). [redacted]} (CCFF ¶ 413).

[20] 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. (CCFF ¶ 5852).

the Acquisition be undone, however, investors have expressed interest "in making a more significant investment in GRAIL."[21] (CCFF ¶ 195). Grail itself recognizes that it will be "well positioned for any outcome." (CCFF ¶ 196).

- ***Exact.*** Exact is headquartered in Madison, Wisconsin with locations across the country and in Europe. (CCFF ¶ 1904). { } (CCFF ¶ 1916), { } (CCFF ¶ 1918). Exact closed its acquisition of Thrive in early January 2021. (CCFF ¶ 1917). { } (CCFF ¶¶ 1935, 1945-48). { } (CCFF ¶ 1962). { }[22] (CCFF ¶ 2105), { } (CCFF ¶ 2109). { }[23] (CCFF ¶¶ 2070-72). { } (CCFF ¶¶ 1990-98). { } (CCFF ¶¶ 3216-18). { } (CCFF ¶¶ 3207-12). { } (CCFF ¶ 3211), (CCFF ¶¶ 3223-25). (CCFF ¶¶ 3250-53). (CCFF ¶¶ 3252-54).

[21] { } (CCFF ¶ 5964).

[22] Thrive acquired the initial developer of the CancerSEEK test, a company named PapGene. (CCFF ¶¶ 1921, 6199). { } (CCFF ¶ 2106).

[23] A registrational trial is what "devices, tests, and so on [usually seek] or companies usually seek approval by the agency, in this case the FDA, that evaluates the benefit/risk ratio and . . . can give the approval stamp to a test." The FDA's approval stamp is "very, very important for acceptance of tests in the community" and "for potential reimbursement of the test." (CCFF ¶ 2010).

- [redacted]

- ***Guardant.*** Guardant is a precision oncology company headquartered in Redwood City, California. (CCFF ¶¶ 2257-261). [redacted] (CCFF ¶¶ 2273-77). [redacted] (CCFF ¶ 433). [redacted] (CCFF ¶ 2302). [redacted] (CCFF ¶¶ 1106-08). [redacted] (CCFF ¶ 2294). [redacted] (CCFF ¶¶ 2292, 2296-99). [redacted] (CCFF ¶ 2305). [redacted] (CCFF ¶¶ 2350-52). Guardant is "really focused" on Grail, (CCFF ¶ 3290), [redacted] (CCFF ¶ 3292). [redacted] (CCFF ¶ 3433),

[24] [redacted]

[25] [redacted]

} (CCFF ¶ 3302), {
} (CCFF ¶ 3304).

- ***Freenome.*** Freenome is a biotech company with headquarters in South San Francisco, California. (CCFF ¶ 2353).
(CCFF ¶¶ 439-440, 1141-143). Although Freenome will initially launch its test as a colorectal cancer screening test, Freenome plans to "tak[e] a stepwise approach" to add additional cancers to its screening test. (CCFF ¶ 2374).
} (CCFF ¶ 2375).
} (CCFF ¶¶ 2359, 2385). {
} (CCFF ¶ 2393).
} (CCFF ¶ 2397). {
} (CCFF ¶ 3314).
(CCFF ¶¶ 3319, 3321).

- ***Singlera.*** Singlera is headquartered in Shanghai, China and has U.S. offices in La Jolla, California. (CCFF ¶ 2401). Singlera currently is developing its PanSeer MCED test, which relies on Illumina's NextSeq NGS platform.[26] (CCFF ¶¶ 447-49, 1166, 3326). PanSeer's technology is designed to detect any type of cancer using methylation patterns as biomarkers. (CCFF ¶¶ 448-49). Since beginning development in 2014, Singlera has spent as much as $100 million on PanSeer. (CCFF ¶¶ 2472-73). Singlera, which views Grail's Galleri test as a competitor to PanSeer, believes price, performance, and continuous innovation are the key drivers of competition in the MCED Test Market. (CCFF ¶¶ 3331-34).
} (CCFF ¶¶ 3338, 3428, 3434).

- ***Helio.*** Helio (formerly called Laboratory for Advanced Medicine or "LAM") is a healthcare company headquartered in Irvine, California with additional locations in China. (CCFF ¶¶ 2478-484). Helio is {
} (CCFF ¶ 2485), {
} (CCFF ¶ 2512). {
} (CCFF ¶¶ 2487, 2510). {
} (CCFF ¶ 2550).
{

[26] Singlera runs the PanSeer test on Illumina's NextSeq Dx sequencer "[b]ecause NextSeq is FDA-cleared, and we have to use [an] FDA-cleared device for [the] FDA trial." (CCFF ¶ 1171). Singlera plans to run the PanSeer test on Illumina's NovaSeq sequencer when the sequencer obtains FDA clearance. (CCFF ¶ 1176).

[redacted] (CCFF ¶ 2547). [redacted] (CCFF ¶ 2548). [redacted] (CCFF ¶¶ 3367-68). [redacted] (CCFF ¶¶ 3370-75).

- [redacted]

B. Illumina's Unlawful Acquisition of Grail

1. Illumina's Formation and Spin-Off of Grail

Illumina first became aware of the potential for detecting cancer in a blood sample during discussions with Dr. Dennis Lo of the Chinese University of Hong Kong in 2012. Dr. Lo "was the first scientist to discover the presence of circulating fetal DNA in a pregnant mother's blood," essentially inventing non-invasive prenatal testing ("NIPT"). (CCFF ¶ 4082). NIPT involves examining fetal cfDNA in a pregnant mother's bloodstream to detect genetic characteristics and abnormalities in the fetus. [redacted] Dr. Lo built upon this research to discover that, using methods similar to NIPT, cancer signals also could be detected by examining cfDNA in the bloodstream. (CCFF ¶ 368). Dr. Lo built a patent portfolio around his oncology research and, in August 2012, engaged with Illumina about a potential collaboration or licensing opportunity.

(CCFF ¶ 373). In an internal August 2012 e-mail, Illumina's Director of Corporate and Venture Development, Robert Bookstein, wrote that Dr. Lo's method of detecting cancer through cfDNA "could be built into a business rivaling or exceeding [NIPT]." (CCFF ¶ 371). Bookstein suggested that Illumina "scoop up [Dr. Lo's] entire IP portfolio and build it inside Illumina." (CCFF ¶ 372).

Around the same time, other existing NIPT companies, such as Sequenom and Natera, also began to observe cancer signals through their tests. (CCFF ¶ 21). In early 2013, Illumina decided to acquire the NIPT company Verinata Health, Inc. ("Verinata"). (CCFF ¶ 4096). Consistent with Dr. Lo's findings, Illumina similarly observed cancer signals in blood samples while running Verinata's NIPT. (CCFF ¶ 22). In mid-2015, Illumina began to consider the best way to develop a cancer detection test based on these signals. (CCFF ¶ 23).

Illumina executives identified several reasons why it would be best to create a separate company to develop the cancer-detection test, rather than perform the work internally. (CCFF ¶ 25). Illumina's leadership believed that forming a separate company had the following benefits, among others:

- A new company could be "more nimble," "make decisions more quickly [and] change directions more quickly" (CCFF ¶ 28);
- A new company could "retain[] and attract[] best-in-class people through equity, culture, and quality of the science" (CCFF ¶ 25);
- A new company could "create a novel clinical and consumer brand" (CCFF ¶ 26); and
- Forming a new company would allow Illumina to attract outside investment. (CCFF ¶ 27).

For these reasons, in January 2016, Illumina formed Grail as a separate corporate entity.[27] (CCFF ¶ 29).

a. *Illumina Favored Grail at the Expense of Grail's Rivals*

At the time of Grail's formation, Illumina held a controlling stake. (CCFF ¶ 29). While Grail was under Illumina's control, Illumina acted in ways that favored Grail relative to Grail's rivals. Illumina created reagent kits "[p]urpose built for GRAIL" to accommodate Grail's "high throughput sequencing for ctDNA." (CCFF ¶ 3706). Illumina also provided Grail with "forward pricing," which meant that Illumina charged Grail what it anticipated Grail's sequencing-related costs would be years in the future. (CCFF ¶ 30). Because Illumina anticipates that sequencing costs will fall significantly over time (CCFF ¶ 4661), forward pricing equated to providing Grail with {[redacted]} (CCFF ¶¶ 30, 3684). Nick Naclerio, Illumina's former SVP of Corporate and Venture Development who negotiated Illumina's initial supply agreements with Grail, testified that he believed it would have been difficult for Grail to develop Galleri without these discounts. (CCFF ¶ 30). More generally, during the period that Illumina owned Grail, it collaborated with Grail on project development, assay development, software and data analysis, and supply chain management. (CCFF ¶ 3704).

[27] Grail became the third example of Illumina vertically integrating into clinical testing. Illumina is also vertically integrated with two other clinical tests. First, Illumina offers its TSO-500 therapy selection test, {[redacted]} (CCFF ¶ 3756). Second, Illumina sells an NIPT product, which screens a pregnant woman's blood sample for a range of fetal chromosomal abnormalities, including Down syndrome. (CCFF ¶ 351. Illumina acquired this NIPT offering when it acquired Verinata in 2013. (CCFF ¶ 4096).

b. ***Illumina Gave Up Control of Grail and "Leveled the Playing Field" Between Grail and Grail's Rivals***

In 2017, however, Illumina found that the continued investment Grail required had become "untenable." (CCFF ¶ 44). Among other things, Grail had expanded its clinical trials from one study involving 50,000 individuals to five clinical trials involving over a million individuals. (CCFF ¶ 50). As a result, Grail's research and development projections moved back by two years and its associated costs increased from approximately $400 million to $1.5 billion. (CCFF ¶ 51). Grail's increased spending without corresponding revenues would have significantly diluted Illumina's reported earnings. (CCFF ¶ 52). According to former Illumina Executive Chairman and CEO Jay Flatley, Illumina's board believed that its shareholders would not have tolerated this magnitude of dilution. (CCFF ¶ 53). Therefore, despite concerns that relinquishing control of Grail could result in the "[l]oss of [h]uge [u]pside potential in market value of GRAIL," the "[l]oss of [r]oyalty future value to [Illumina]," and a potential "[i]mpact to [Illumina's] external credibility" (CCFF ¶ 54), Illumina decided to reduce its share in Grail by seeking additional outside investors through a round of financing. (CCFF ¶¶ 43-46). {[redacted]}. (CCFF ¶ 43).

Once Illumina no longer owned the majority of Grail's shares, the Illumina-Grail dynamic shifted from an affiliate relationship to a supplier-customer relationship. (CCFF ¶ 45). Internal Illumina documents reflect that Illumina was cognizant of this change, noting that Grail transitioned from being an Illumina "[c]ollaborator" to an Illumina "[c]ustomer." (CCFF ¶¶ 64, 66). Before Illumina reduced its share in Grail, "[Grail] had access to technology and pricing that was preferential to [Illumina's other] customers." (CCFF ¶ 48). After Illumina's reduction of its

share in Grail, Grail had "access to technology on [the] same terms and price as [Illumina's] other large customers." (CCFF ¶ 49).

In communications prepared for investors, Illumina boasted that the shift "leveled the playing field" for Illumina's other customers (CCFF ¶ 47), and "[would] accelerate the liquid biopsy market for all." (CCFF ¶ 49). Prior to the spin-off of Grail, Illumina was hesitant to "go after markets . . . using a subsidiary of Illumina . . . that could compete more favorably with existing customers [Illumina] had in the marketplace." (CCFF ¶ 57). According to Illumina's former CEO and Executive Chairman Jay Flatley, Illumina believed its customers might not want to participate in markets where Illumina had a presence, in part "because they'd believe that Illumina could always underprice them if we wanted to." (CCFF ¶ 58). In talking points for a 2020 investor call, Illumina thus explained the market-wide benefits of separating Grail from Illumina: "We spun out GRAIL ***to encourage investment into many different NGS-based companies focused on early cancer detection*** to have as many shots on goal as possible." (CCFF ¶ 59) (*emphasis added*). Illumina CEO Francis deSouza elaborated:

> Our thinking was we wanted to see which approach would work so that we could figure out in the end what was the right way to go, because it wasn't clear to anybody in the market which way to go, and we didn't want to be tied to just one approach. So it gave us the opportunity to assess which way the market was going to go and which technology would work.
>
> (CCFF ¶ 3730).

2. Grail Thrived After Illumina Gave Up Control

a. *Grail Successfully Raised Funds as an Independent Company*

As an independent company, Grail succeeded in raising the funds needed for its continued operations and development. During the roughly four years of its existence outside of Illumina,

Grail raised $2 billion through four rounds of private financing. (CCFF ¶ 5850). Grail's investors have included a combination of venture capital firms and strategic partners (CCFF ¶ 5851), Jeff Bezos and Bill Gates among them. (CCFF ¶ 5855). Putting this funding to good use, Grail has {[redacted]} (CCFF ¶¶ 72, 5358) across a diverse range of functions including R&D, sales, market access, and government and regulatory affairs (CCFF ¶ 73). Grail was well-capitalized with over $600 million in cash on hand when it was acquired by Illumina in September 2020. (CCFF ¶¶ 5853-54).

b. ***Grail Has Invested Heavily in Research and Development of its Assays***

To develop and validate Galleri, Grail recognized {[redacted]} (CCFF ¶ 6291). While Grail has yet to clinically validate that its test can detect 50 cancers, Grail has successfully built an infrastructure to support clinical validation and utility studies. Indeed, Grail raised funds for and has launched "one of the largest clinical study programs ever conducted in genomic medicine." (CCFF ¶ 5299). To date, Grail has directly enrolled over 130,000 participants in its clinical studies. (CCFF ¶ 111).

According to Grail's Chief Medical Officer, Joshua Ofman, "there should be robust analytical and clinical validation at population scale to support [an MCED] test's deployment in the population." (CCFF ¶ 6275). Analytical validation means ensuring that a test measures what it purports to measure at certain levels of precision. (CCFF ¶ 519). Analytical validation is typically followed by clinical validation, which means demonstrating that a test performs as indicated to detect the given disease in the intended use population. (CCFF ¶¶ 520, 6272). Clinical validation is critical for the commercialization of a test such as Galleri, as it is necessary to receive FDA approval, Medicare coverage, and reimbursement by private insurance. (CCFF ¶¶ 509, 6274-

75). Evidence of clinical utility overlaps with evidence for clinical validation. Like clinical validation, demonstrating clinical utility requires evidence that a test can detect disease in the intended use population. (CCFF ¶ 522). Establishing clinical utility also involves assessing how a test's results may impact patient management and outcomes. (CCFF ¶ 523). Because evidence of clinical validity and clinical utility overlap, a single study may develop evidence of both clinical validity and clinical utility, such as Grail's Pathfinder 1, Clinical Practice Learning Program, Strive, Summit, and NHS studies. (CCFF ¶ 524).

Though Illumina lacked the stomach for a $1.5 billion investment in the clinical studies necessary for development and validation of Galleri while Grail was under Illumina's control (CCFF ¶ 3719), Grail itself succeeded in raising approximately $2 billion across four rounds of private financing. (CCFF ¶ 5850). As a result, Dr. Ofman testified that Grail {[redacted]} (CCFF ¶ 5296). Notably, Grail designed and launched its clinical study program as an independent company, (CCFF ¶ 5304), and Illumina has had {[redacted]} (CCFF ¶ 5306). Grail's clinical studies relating to Galleri involve more than ten times the number of patients that Illumina has enrolled in its own clinical studies. (CCFF ¶ 5311). Grail's studies, the first of which launched in 2016 and which continue through the present day, involve dozens of partner organizations, such as Memorial Sloan-Kettering, the Mayo Clinic, the Dana-Farber Cancer Institute, and the United Kingdom's National Health Service across hundreds of test sites:

- **Circulating Cell-Free Genome Atlas (CCGA) (2016-2024)**. { } (CCFF ¶ 114). CCGA assesses Galleri's ability to detect cancer signals in individuals already diagnosed with or suspected of having cancer. (CCFF ¶ 6238); *see also* (CCFF ¶ 122).

- **Strive (2017-2022)**. { . (CCFF ¶¶ 125, 6260). { } (CCFF ¶ 5321); *see also* (CCFF ¶ 5322).

- **MSK Discovery (2017-2022)**. MSK Discovery is { (CCFF ¶ 147).

- **Pathfinder 1 (2019-2022)**. Pathfinder 1 is an interventional,[29] real-world, clinical practice study of 6,600 individuals with no suspicion of cancer. (CCFF ¶¶ 131, 6283); *see also* (CCFF ¶ 135)

- **Summit (2019-2023)**. Summit is an { } (CCFF ¶ 127). } (CCFF ¶ 128).

- **UK NHS (2021-2025)**. The United Kingdom's National Health Service will administer Galleri in an { } (CCFF ¶¶ 136, 139). This trial is the largest trial ever conducted for a cancer screening test. (CCFF ¶ 5336); *see also* (CCFF ¶ 141).

- **Pathfinder 2 (to launch late 2021 (**CCFF ¶ 5332**)**. Pathfinder 2 will be } (CCFF ¶ 145).

[28] In an observational study, test results are not returned to the patients. Rather, the patients are tracked over the duration of the study, and Grail compares the results of its tests with the patients' cancer diagnoses at the conclusion of a predetermined period. (CCFF ¶ 115).

[29] In an interventional study, patients' test results are returned to the health care provider, who then apply those results to aid their patients. (CCFF ¶ 3267). } (*See* CCFF ¶ 525). Because evidence of clinical utility relates to how a test changes patient management and outcomes, interventional studies are an important step in the generation of clinical utility evidence. (CCFF ¶¶ 526-27).

- **Clinical Practice Learning Program (prospective)**. { (CCFF ¶ 534). { } (CCFF ¶ 535).

c. ***Grail Is Capable of Processing Galleri Tests at Scale***

{}, *see, e.g.*, (CCFF ¶ 3646), Grail began to offer Galleri for sale in April 2021, prior to the closing of the Acquisition. (CCFF ¶ 5480). Patients in the United States between the ages of 50 and 80 can order a Galleri test through their doctor. (CCFF ¶ 5484). Grail's Galleri test currently costs $949, (CCFF ¶ 92), and is not yet covered by Medicare or private insurance, (CCFF ¶ 563). Grail also has entered into a partnership agreement with Quest Diagnostics for nationwide collection of blood samples from Galleri patients. (CCFF ¶ 5485). Grail estimates that, as an independent company, it could attain annual revenues {}, (CCFF ¶ 101), and penetrate 13 to 16 percent of Galleri's total addressable market of 108 million patients. (CCFF ¶ 5494).

{ } (CCFF ¶ 104). Grail currently processes Galleri tests at its lab in Menlo Park, California, (CCFF ¶ 5802), which { } (CCFF ¶ 5803). { } (CCFF ¶ 5805). The Research Triangle Park lab is highly sophisticated, encompassing automation and robotics to reduce turnaround times and costs. (CCFF ¶ 5808). According to Aaron Freidin, Grail's SVP of Finance, {

[redacted]}. (CCFF ¶ 5814). {[redacted]} (CCFF ¶ 5816).

Though Illumina suggests that it could enhance Grail's lab operations, Illumina executives testified that [redacted]} (CCFF ¶ 5836).

d. ***Grail Is Pursuing a Sophisticated Regulatory Strategy***

To gain widespread commercialization and reimbursement of a MCED test, developers will need a PMA from the FDA. (CCFF ¶¶ 510-13). Evidence shows that PMA approval is likely required for Medicare coverage and, in turn, widespread private insurer coverage, of MCED tests. (CCFF ¶¶ 506, 578, 582, 5574). Grail therefore has built a regulatory team that has engaged {[redacted]}. *See* (CCFF ¶¶ 5291-95, 5342-47).

Grail made its {[redacted]} (CCFF ¶ 84). Since that time, Grail has made {[redacted]} (CCFF ¶ 83). In light of this progress, {[redacted]} (CCFF ¶ 85).

At the same time, Grail has actively developed a strategy to {[redacted]} (CCFF ¶ 95). Though individual patients can pay for Galleri out-of-pocket, {[redacted]} (CCFF ¶ 96). For this reason, Grail has made its reimbursement strategy a priority of the company, (CCFF ¶ 5562), and according to Grail Chief Medical Officer Joshua Ofman, has given this priority the attention that it needed, (CCFF ¶ 5563). Further, Grail has assembled a capable team in Washington, D.C., to advocate for accelerated Medicare coverage of Galleri and MCED tests, (CCFF ¶ 97), and is working to {[redacted]}, (CCFF ¶ 587). Dr. Ofman testified at trial that he is {[redacted]} (CCFF ¶¶ 5570-71); *see also* (CCFF ¶ 591).

e. *Grail Is Successfully Marketing Galleri Even Prior to Reimbursement*

Though Grail seeks to encourage {[redacted]} Grail's market research has "indicate[d] that there is a significant addressable market opportunity [Grail] can access even before approval under traditional fee-for-service Medicare reimbursement." (CCFF ¶ 5504). Accordingly, Grail's various marketing units—including a sales team of 30 to 40 individuals, (CCFF ¶ 5496), a growth strategy team, (CCFF ¶¶ 5525, 5555), an employer partnership team, (CCFF ¶ 5543), and a health systems team (CCFF ¶ 5521)—have aggressively pursued deals for the sale Galleri even prior to reimbursement, with promising results.

Grail already has entered into agreements with several organizations to offer Galleri to their patients. These organizations include {[redacted]} (CCFF ¶ 5510), such as {[redacted]} (CCFF ¶¶ 5511-14). At the time of trial, Grail also had signed contracts with 15 concierge medical providers,[30] including the two largest concierge networks in the United States, to offer Galleri. (CCFF ¶¶ 5537-38). Finally, two Grail executives testified at trial that Grail had already {[redacted]} (CCFF ¶¶ 5544-46). Notably, Grail {[redacted]} (CCFF ¶ 5547).

Beyond these already-signed deals, Grail's marketing teams continue to pursue other opportunities with organizations interested in using Galleri prior to regulatory approvals. As of {[redacted]} (CCFF ¶ 5548). Some of these noteworthy {[redacted]} (CCFF ¶ 5520). The {[redacted]} among others. (CCFF ¶ 5548). Finally, Grail's growth strategy team continues to

[30] A "concierge" provider is typically a primary care practice where patients pay a fee for preferred access to highly qualified doctors. (CCFF ¶ 5523). Through its own market research, Grail learned that concierge providers "tend to be early adopters of new products" (CCFF ¶ 5527) with relatively {[redacted]} (CCFF ¶ 5533).

pursue additional innovative channels for the sale of Galleri, such as { } (CCFF ¶ 5555).

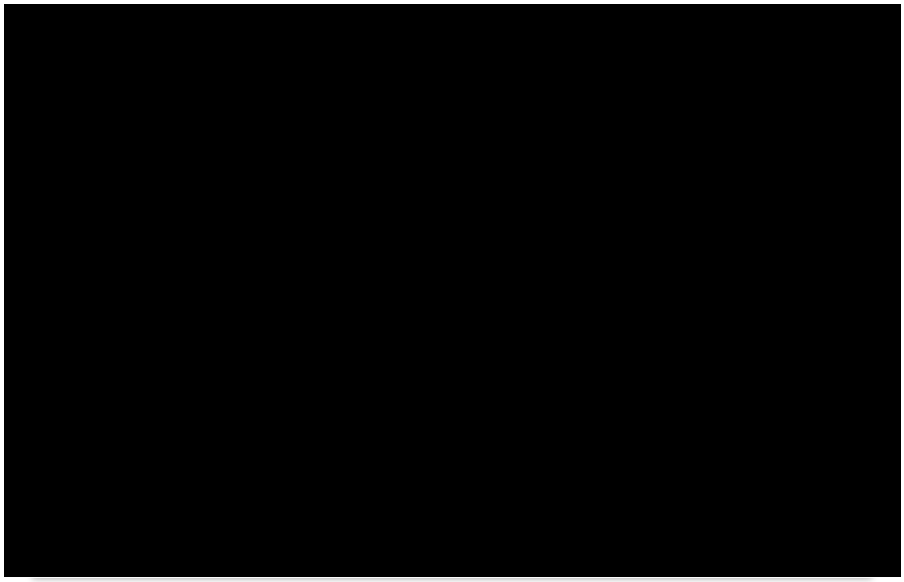
f. *Grail Was Pursuing an IPO Prior to Illumina's Offer*

As { } with an IPO to raise additional money to fund the launch and commercialization of Galleri. (CCFF ¶¶ 172, 5891). In its S-1 filings with the SEC, Grail explained that funds raised through the IPO would fund its research, facilitate market access, and scale Grail's technology and lab operations. (CCFF ¶ 5895). Through a series of { }, (CCFF ¶ 5927), Grail generated { } (CCFF ¶¶ 5939, 5947). In particular, { } (CCFF ¶ 5935). Grail's board of directors expected that { }, (CCFF ¶ 5952), with { }. (CCFF ¶¶ 5948, 5952). Despite the { } however, Illumina and Grail entered into an Agreement and Plan of Merger on September 20, 2020, and Grail never went public. (CCFF ¶ 197); *see also* (CCFF ¶ 5961).

3. Illumina's Decision to Acquire Grail

Internal Illumina documents from around 2020 reflect a growing realization that { } (CCFF ¶¶ 210, 3107-09). In an August 2020 presentation to Illumina's board

of directors, Illumina's Chief Technology Officer, Chief Medical Officer, and Chief Strategy & Development Officer wrote that, {



(} Illumina's executives recommended that Illumina {

} (CCFF ¶ 483). Illumina's SVP of Corporate Development and Strategic Planning Joydeep Goswami, {

} (CCFF ¶ 3113). Illumina thus undertook {

} (CCFF ¶ 209); *see also* (CCFF ¶ 3131).

Given that {

} (CCFF ¶ 211). Accordingly, Illumina

assessed its options for an acquisition. Illumina evaluated {[redacted]} (CCFF ¶ 3478). However, Illumina ultimately decided that {[redacted]} (CCFF ¶ 214). Through an acquisition of Grail, Illumina calculated that its {[redacted]}[31] (CCFF ¶ 3134). As Illumina's CEO, Francis deSouza, testified, "by participating directly in that segment with our own solution, it allows Illumina to get a larger percentage of the value created in that solution rather than just being the platform provider." (CCFF ¶ 3139); *see also* (CCFF ¶ 3138).

On September 20, 2020, Respondents entered into an Agreement and Plan of Merger for Illumina to acquire all of Grail's outstanding voting shares, for a combination of cash and stock consideration valued at about $7.1 billion. (CCFF ¶ 197). Soon before the evidentiary hearing began in this matter, Illumina and Grail closed the Acquisition on August 18, 2021. (CCFF ¶ 200).

II. ARGUMENT

A. Illumina's Acquisition of Grail Violates Section 7 of the Clayton Act

All facets of this case point to a fundamental fact: Illumina's acquisition of Grail has a reasonable probability of substantially lessening competition in the MCED Test Market. Illumina is the only provider of a critical input that MCED test developers rely on in the race to develop, commercialize, and win widespread adoption of their tests. Illumina has now acquired one of its

[31] Illumina's decision to acquire Grail was not without its critics, however. For example, in an analyst report shortly after the announcement of the acquisition, JPMorgan wrote: "Grail . . . represents a far stretch from [Illumina]'s core expertise, as early cancer detection through liquid biopsy requires significant market development involving lengthy large-scale clinical trials and regulatory approvals, clinical guidelines and reimbursement, as well as commercial infrastructure investment from scratch, none of which have much to leverage from [Illumina]'s core business today." (CCFF ¶ 5460). Cowen Equity Research similarly wrote: "[W]e don't see the clear fit for acquiring a company that . . . is still at a stage where clinical studies and clinical product development are still critical and will be for years, and . . . would benefit from true clinical commercial infrastructure/reach that does not really exist at Illumina, and . . . arguably would benefit most from accessing new technologies that do not currently reside at Illumina." (CCFF ¶ 5461).

MCED test developer customers, Grail, which competes head-to-head against other MCED test developers. While prior to the Acquisition Illumina benefited from the expansion of the MCED Test Market generally, Illumina's incentives have changed. Now, Grail's success is Illumina's success. And the more Grail succeeds at the expense of its rivals, the more Illumina succeeds. The overwhelming evidence shows that the combined Illumina-Grail will have both the ability and incentive to harm Grail's downstream rivals.

1. Vertical Mergers May Substantially Lessen Competition Under Section 7

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. "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 Co. v. United States*, 370 U.S. 294, 323 (1962)) (emphasis in original); *see also In re Tronox Ltd.*, Docket No. 9377, 2018 WL 6630200, at *6 (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.") (quotations and citations omitted).

"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."[32] *FTC v. Procter & Gamble Co*., 386 U.S. 566, 577 (1967); s*ee also Brown Shoe*, 370 U.S. at 323-34

[32] "Economic arrangements between companies standing in a supplier-customer relationship are characterized as 'vertical.'" *Brown Shoe*, 370 U.S. at 323. Illumina supplies its customer, Grail, with NGS platforms, a critical input for Grail's MCED test. The Acquisition is considered a "vertical merger" and Section 7 applies.

(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) (upholding order requiring the divestiture of assets from a vertically merged company because the merger would create "every incentive to . . . maintain the virtually insurmountable barriers to entry" in the relevant market, and rejecting Ford's argument that the merger made the acquired firm "a more vigorous and effective competitor" in the relevant market). Congress intended Section 7 to have a lower standard than the Sherman Act for judging the legality of business combinations. *Brown Shoe*, 370 U.S. at 318 ("Congress rejected, as inappropriate to the problem it sought to remedy, the application to § 7 cases of the standards for judging the legality of business combinations adopted by the courts in dealing with cases arising under the Sherman Act, and which may have been applied to some early cases arising under original § 7.").

Congress passed the Celler-Kefauver Anti-Merger Act of 1950 in part to amend Section 7 of the Clayton Act to cover vertical mergers.[33] With this intention, Congress extended Section 7 to address vertical mergers that "deprive . . . rivals of a fair opportunity to compete" and, as the Supreme Court interpreted, stop arrangements that "act as a 'clog on competition.'" *Brown Shoe*, 370 U.S. at 323-24 (quoting *Standard Oil Co. of Cal. v. United States*, 337 U.S. 293, 314 (1949);

[33] "As enacted in 1914, § 7 of the original Clayton Act prohibited . . . [acquisitions that] would result in a substantial lessening of competition *between the acquiring and the acquired* companies."[33] *Brown Shoe*, 370 U.S. at 312. "The Act did not . . . appear to preclude [acquisitions] other than a direct competitor." *Id.* at 313. In 1950, Congress deleted the "acquiring-acquired" language of the original text "to make plain that § 7 applied not only to mergers between actual competitors, but also to vertical and conglomerate mergers whose effect may tend to lessen competition in any line of commerce in any section of the country." *Id*. at 317; *see also* H.R. Rep. No. 81-1191, at 11 (1949) (The purpose of eliminating the "acquiring and the acquired" language in Section 7 was "to make it clear that the bill applies to all types of mergers or acquisitions, vertical and conglomerate as well as horizontal, which have the specified effects of substantially lessening competition. . . .").

H.R. Rep. No. 81-1191, at 8 (1949)).[34] And it is precisely these anticompetitive dangers that courts have condemned for at least 60 years, in dozens of cases, across numerous industries. *See Ford Motor*, 405 U.S. at 569; *Brown Shoe,* 370 U.S. 294 (1962); *In re Ash Grove Cement Co.*, 85 F.T.C. 1123 (1975), *aff'd*, 577 F.2d 1368 (9th Cir. 1978); *Heatransfer Corp. v. Volkswagenwerk, A.G.*, 553 F.2d 964 (5th Cir. 1977); *Gulf & Western Indus., Inc. v. The Great Atl. & Pac. Tea Co. Inc.*, 476 F.2d 687 (2d Cir. 1973); *Mississippi River Corp. v. FTC*, 454 F.2d 1083 (8th Cir. 1972); *U.S. Steel Corp. v. FTC*, 426 F.2d 592 (6th Cir. 1970); *OKC Corp. and Oklahoma Land & Cattle Co.*, 77 F.T.C. 1342 (1970); *In re Marquette Cement Mfg. Co.*, 75 F.T.C. 32 (1969); *In re Scott Paper Co.*, 57 F.T.C. 1415 (1960); *In re Union Carbide Corp.*, 59 F.T.C. 614, 1961 WL 65409, (1961); *Harnischfeger Corp. v. Paccar, Inc.*, 474 F. Supp. 1151 (E.D. Wis. 1979); *Filtrol Corp. v. The Slick Corp.*, No. 69-607-ALS, 1969 WL 219 (C.D. Cal. Dec. 29, 1969); *United States v. Kimberly-Clark Corp*., 264 F. Supp. 439 (N.D. Cal. 1967); *United States v. Standard Oil Co. (N.J.)*, 253 F. Supp. 196 (D.N.J. 1966); *United States v. Kennecott Copper Corp*., 231 F. Supp. 95 (S.D.N.Y. 1964); *United States v. Bethlehem Steel Corp.*, 168 F. Supp. 576 (S.D.N.Y. 1958); *United States*

[34] Despite the clear Congressional intent to extend the Clayton Act to vertical mergers, Respondents suggest that the lack of FTC and DOJ vertical merger litigation in recent years allows them to ignore the vertical merger precedent from the Supreme Court, appellate courts, the Commission, and this Court. *See, e.g.*, Resp. Pretrial Br. at 85-86. This ignores the DOJ and FTC's robust record of vertical merger enforcement actions, as well as recent opinions affirming the principles and analysis outlined in long-standing vertical merger precedent. *See In re Zinc Antitrust Litig.,* No. 14-cv-3728, 2016 WL 3167192, at *22-23 (S.D.N.Y. 2016) (invoking *Brown Shoe* and its progeny's vertical merger framework before assessing whether a Section 7 claim survived a motion to dismiss); *Yankees Entm't & Sports Network, LLC v. Cablevision Sys. Corp.*, 224 F. Supp. 2d 657, 673 (S.D.N.Y. 2002) (describing how the degree to which "foreclosing competitors . . . from access to a potential source of supply, or from access on competitive terms" is one of the primary ways a vertical merger "may increase barriers to entry in the market or reduce competition"); *United States v. AT&T, Inc.*, 916 F.3d 1029, 1045-46 (D.C. Cir. 2019) (citing *Ford Motor* as precedent for concluding that decreased product quality and reduced innovation are valid harms from vertical mergers); *see also United States v. American Cyanamid Co.*, 719 F.2d at 566-67 (Despite newer economic theories regarding vertical mergers, "*Brown Shoe* and its progeny . . . nonetheless continue to constitute the current state of the law as prescribed by the Supreme Court, which circuit and district courts are bound to follow. We believe it was an error to apply 'contemporary economic theory' to the extent it may be distinct from precedent, and to fail to apply the standard framework of analysis [of the legality of vertical mergers outlined in *Fruehauf*].").

v. Md. & Va. Milk Producers Ass'n, 167 F. Supp. 799 (D.D.C. 1958), *aff'd in rel. part by* 362 U.S. 458 (1960); *American Cyanamid*, 719 F.2d 558 (2d. Cir. 1983); *Yankees Entm't & Sports Network, LLC v. Cablevision Sys. Corp.*, 224 F. Supp. 2d 657 at 673 (S.D.N.Y. 2002); *see also In re Zinc Antitrust Litig*., No. 14-cv-3728, 2016 WL 3167192 (S.D.N.Y. June 6, 2016) (describing *Brown Shoe* vertical merger analysis before assessing whether a Section 7 claim survived a motion to dismiss).[35] As a result, antitrust agencies have routinely taken law enforcement actions against vertical mergers that threaten downstream foreclosure[36] or other competitive harm.[37]

This case is no different. Illumina, through its acquisition of Grail, has a reasonable probability of clogging competition in the MCED Test Market. Such anticompetitive "tendencies" are precisely the kind that Congress sought to "arrest . . . in their incipiency" by extending Section 7 of the Clayton Act to vertical mergers. *Brown Shoe*, 370 U.S. at 317-18.

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[35] Courts analyze potential input foreclosure and customer foreclosure similarly. *See, e.g.*, *Brown Shoe*, 370 U.S. at 328-29 (analyzing the degree of potential foreclosure before looking to other relevant factors to determine whether the merger tends substantially to lessen competition); *Filtrol Corp.*, 1969 WL 219 (similarly analyzing vertical foreclosure, finding that the "vertical acquisition by Slick of its own supplier[] would give Slick control of from 80% to 90% [of the upstream product] and would thereby give Slick dominant control of the principal source of supply of an indispensable commodity needed by it and by its competitors. . . . thereby gain[ing] a preferred position vis-à-vis its competitors"); *U.S. Steel*, 426 F.2d at 600 ("While no precise percentage terms have been set forth as yardsticks for vertical mergers, the 9.8% [share of the downstream acquired firm] and 11.4 per cent [share of the upstream acquiring firm] are well within the range of numbers which have been held to be unduly high in the past.") (citing cases).

[36] Foreclosure in the vertical merger context can mean either "foreclosing competitors of [one party] from access to a potential source of supply, or from access on competitive terms." *Yankees Entm't*, 224 F. Supp. 2d at 673; *see also Sprint Nextel Corp. v. AT&T, Inc.*, 821 F. Supp. 2d 308, 330 (D.D.C. 2011) (explaining rivals "paying more to procure necessary inputs" is the type of injury "that the antitrust laws were designed to prevent").

[37] *See* Steven Salop & Daniel Culley, *Vertical Merger Enforcement Actions: 1994-April 2020*, Georgetown Law Faculty Publications and Other Works (2020), https://scholarship.law.georgetown.edu/facpub/1529/ (last visited April 9, 2022) (summarizing 66 vertical merger enforcement actions taken by the DOJ and FTC since 1994); *see also Ford Motor*, 405 U.S. 562 (1972); *U.S. Steel,* 426 F.2d 592 (6th Cir. 1970); *Mississippi River*, 454 F.2d 1083 (8th Cir. 1972); *Ash Grove Cement*, 85 F.T.C. 1123 (1975), *aff'd*, 577 F.2d 1368 (9th Cir. 1978).

2. Courts Analyze Vertical Mergers Under the *Baker Hughes* Burden-Shifting Framework

Courts and the Commission have traditionally analyzed Section 7 claims under a burden-shifting framework outlined in *Baker Hughes* and its progeny, *see United States v. Baker Hughes, Inc.*, 908 F.2d 981, 982-83 (D.C. Cir. 1990); *In re Otto Bock HealthCare N. Am., Inc.*, 2019 WL 5957363, at *11 (F.T.C. Nov. 1, 2019); *In re Polypore Int'l, Inc.*, Docket No. D-9327, 2010 WL 9549988, at *9 (F.T.C. Nov. 5, 2010), and the same burden-shifting framework applies to both horizontal and vertical mergers. *See United States v. AT&T, Inc.*, 310 F. Supp. 3d 161, 191 n.17 (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 "has the burden to account for all of defendants' proffered efficiencies as part of making its prima facie case"). Respondents do not dispute that the *Baker Hughes* burden-shifting framework applies here. Resp. Pre-Trial Br. at 43.

Under this burden-shifting framework, "[f]irst, the government must establish a prima facie case that an acquisition is unlawful." *Polypore*, 2010 WL 9549988, at *9; *see also Baker Hughes*, 908 F.2d at 982. "The burden of producing evidence to rebut [the *prima facie* case] then shifts to the defendant." *Baker Hughes*, 908 F.2d at 982. "If the defendant successfully rebuts the [*prima facie* case], the burden of producing additional evidence of anticompetitive effect shifts to the government, and mergers with the ultimate burden of persuasion, which remains with the government at all times." *Id.* at 983. Although Complaint Counsel has the ultimate burden in this case, Respondents bear the burden of proving their factual propositions. Initial Decision, *In re Altria Group, Inc. and Juul Labs, Inc.*, Docket No. 9393, at 5 (F.T.C. Feb. 15, 2022) ("[C]ounsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual

proposition shall be required to sustain the burden of proof with respect thereto.") (quoting 16 C.F.R. § 3.43(a)).

3. Complaint Counsel Met Its *Prima Facie* Burden by Showing That Illumina's Acquisition of Grail Poses a Reasonable Probability of Competitive Harm

As both Complaint Counsel and Respondents agree,[38] in the first step of the burden-shifting framework, the Government may make a *prima facie* case through a fact-specific showing that a merger may pose a reasonable probability of competitive harm. The Government's burden of production at this stage is low. The Government need only provide evidence "sufficient to raise an inference [of anticompetitive effect] to shift the burden to Respondent[s] for rebuttal." *In re Otto Bock HealthCare N. Am., Inc.*, 2019 WL 2118886, *27 n.25 (F.T.C. May 6, 2019) (Chappell, A.L.J.) (declining to consider whether the FTC's additional arguments strengthen its case at the "prima facie stage of analysis," noting that the burden to produce additional evidence shifts back to the Government if the defendant successfully rebuts the *prima facie* case) (quoting *Baker Hughes*, 908 F.2d at 983).

Non-price competitive harms—such as the harm to ongoing innovation in the MCED Test Market resulting from the Acquisition—are sufficient to establish a *prima facie* case under Section 7. *See United States v. Anthem, Inc.*, 855 F.3d 345, 361 (D.C. Cir. 2017) (noting a "threat to innovation is anticompetitive in its own right"); *AT&T*, 916 F.3d at 1045-46 (D.C. Cir.) (citing *Ford Motor*, 405 U.S. at 567-69).[39] Not only is the innovation competition in the MCED Test

[38] Answer and Defenses of Respondents Illumina, Inc. and GRAIL, Inc., *In re Illumina, Inc., and GRAIL, Inc.,* Docket No. 9401 at 5 (F.T.C. Apr. 13, 2021) (noting that the FTC "must make a 'fact-specific' showing that the proposed merger is anticompetitive") [hereinafter "Answer"].

[39] Slower innovation and other non-price effects have also been recognized as anticompetitive harms outside the context of Section 7. *See, e.g.*, *United States v. Visa U.S.A., Inc.*, 163 F. Supp. 2d 322, 406 n.28 (S.D.N.Y. 2001) (recognizing that "output reduction" can include "a decline in the rate of improvement or innovation that is committed

Market important to protect in and of itself, but the Federal Trade Commission has recognized the special importance of protecting competition in emerging markets:

> While monopolies are to be abhorred wherever they appear, it is of particular importance that they be arrested in an infant industry which appears destined for far greater expansion and growth. Strong and vigorous competition is the catalyst of rapid economic progress. Any lessening of competition is therefore doubly harmful in a new industry since its inevitable effect is to slow down the growth rate of the industry.
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> *Union Carbide*, 1961 WL 65409, at *35.

In a vertical merger, such as here, anticompetitive harm may arise from the combined firm having the power to foreclose "competitors of the purchasing firm in the merger from access to a potential source of supply, or from access on competitive terms." *Yankees Entm't & Sports Network*, 224 F. Supp. 2d at 673. The Government may meet its initial burden by making a fact-specific showing that the vertical merger poses a reasonable probability of competitive harm. To meet its burden the Government may present evidence of the combined firm's ability and incentive to foreclose or disadvantage its competitors. *See, e.g*, *AT&T*, 310 F. Supp. 3d at 243-45 (D.D.C.) (analyzing whether AT&T had the ability and incentive to foreclose or restrict rival video programming distributors' access to Time Warner content). Although competing vigorously in this new market, MCED test developers have no alternatives to Illumina. *See infra* § II.D.2. MCED test developers testified that Illumina's NGS sequencers are inextricably intertwined with

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to a particular market") (quoting Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 2401a); *McWane, Inc. v. FTC*, 783 F.3d 814, 827 (11th Cir. 2015) ("'The concern with exclusive dealing arrangements is that creating or increasing market power through exclusive dealing is the means by which the defendant is likely to increase prices, restrict output, reduce quality, slow innovation, or otherwise harm consumers.'") (quoting Jonathan M. Jacobson, *Exclusive Dealing, "Foreclosure," and Consumer Harm*, 70 Antitrust L.J. 311, 328 (2002)) (original brackets and ellipses omitted); *United States v. Microsoft Corp.*, 253 F.3d 34, 67, 79 (D.C. Cir. 2001) (per curiam) (noting that "[p]laintiffs plainly made out a *prima facie* case of harm to competition in the operating system market by demonstrating that Microsoft's actions increased its browser usage share and thus protected its operating system monopoly from a middleware threat," which the court described as a "nascent competitive technolog[y]").

their MCED tests—developers tailor their tests specifically to Illumina's NGS platform and rely on Illumina's platform technically, functionally, and commercially at every stage in the development and commercialization process. *See infra* § II.E.1.a. Moreover, Illumina itself has explained its incentives for this Acquisition—to access and extract profits from the potentially multi-billion-dollar MCED Test Market. *See infra* § II.E.1.b.i. With no timely and sufficient NGS alternatives to Illumina, Complaint Counsel has made a fact-specific showing that Illumina has the ability and incentive to foreclose or disadvantage Grail's rivals to the benefit of the merged company.

Brown Shoe and its progeny also provide that the determination of a merger's likely competitive effects may be based on an analysis of several specific factors. While only a subset of those factors may be relevant to the fact-specific inquiry of a given case, courts have held that "the Clayton Act will, of course, have been violated" when "the share of the market foreclosed is so large that it approaches monopoly proportions." *Brown Shoe*, 370 U.S. at 328-29; *see also American Cyanamid*, 719 F.2d 566; *Fruehauf Corp. v. FTC*, 603 F.2d 345, 352 (2d Cir.1979) (noting that there is no *per se* rule that potential foreclosure "amount[s] to a violation of § 7" without more, "except where the share of the market foreclosed reaches monopoly proportions") (citations omitted). Courts also assess the nature and purpose of the acquisition as well as escalating barriers to entry. *Brown Shoe*, 370 U.S. at 328-34 (examining the amount of foreclosure, the "very nature and purpose of the arrangement," and other evidence relating to the "prognosis of the probable *future* effect of the merger") (emphasis in original); *U.S. Steel.*, 426 F.2d at 599 (identifying "indicia of the requisite anti-competitive effect," including "foreclosing of the competitors of either party from a segment of the market otherwise open to them," the "'nature

and purpose' of the vertical arrangement,'" and "the ease with which potential entrants may readily overcome barriers to full entry and compete effectively with existing companies"). Here, Illumina is the exclusive provider of NGS platforms to the MCED Test Market, and as such it has the ability to foreclose any and all of Grail's rivals. This evidence is corroborated by the nature and purpose of the Acquisition (in part to gain access to the large potential profit pool of the MCED Test Market); increased barriers to entry (Illumina will enlarge the competitive moat around Grail's MCED test); and collectively, assessment of these factors establishes a reasonable probability of competitive harm to the innovation and commercialization of MCED Tests.

4. Respondents Failed to Rebut Complaint Counsel's Strong *Prima Facie* Case

Complaint Counsel has adduced sufficient evidence under well-established precedent to meet its fact-specific showing that this Acquisition poses a reasonable probability of harming competition in the MCED Test Market. The burden then shifts to Respondents to rebut Complaint Counsel's fact-specific showing of potential competitive harm. Although Respondents have attempted to present evidence of the elimination of double marginalization ("EDM") and efficiencies in this case, no court has held that such evidence could immunize an otherwise anticompetitive merger. *See Penn State Hershey*, 838 F.3d at 347-48 ("Contrary to endorsing [an efficiencies] defense, the Supreme Court has instead, on three occasions, cast doubt on its availability. . . . Based on [the Supreme Court's past statements] and on the Clayton Act's silence on the issue, we are skeptical that such an efficiencies defense even exists.") (citations omitted).[40]

[40] The Supreme Court has never recognized the efficiencies defense and—to the contrary—has suggested that efficiencies are no defense to a Clayton Act violation. *Ford Motor*, 405 U.S. 569-70 (rejecting the argument that a vertical merger "had some beneficial effect" in making one of the merging parties "a more vigorous and effective competitor" against other market participants than it would have been independently) (citing *United States v. Phila. Nat'l Bank*, 374 U.S. 321, 371 (1963) (A merger is not saved from illegality under § 7 "because, on some ultimate

But even assuming that EDM or efficiencies could show that an otherwise anticompetitive merger is benign, Respondents would bear the burden of making such a showing and they cannot do so here. *Otto Bock*, 2019 WL 5957363, at *12 (Respondents bear the burden of rebutting 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.") (quoting *Chi. Bridge & Iron Co. N.V. v. FTC*, 534 F.3d 410, 423 (5th Cir. 2008)); *Polypore*, 2010 WL 9549988, at *9; *Baker Hughes*, 908 F.2d at 982-83.

Respondents' vague assertions that the Acquisition will generate "efficiencies" that may result in "potential benefits," Resp. Pretrial Br. at 84-85, fails to rebut Complaint Counsel's *prima facie* case. *See Ford Motor*, 405 U.S. 569-70 (rejecting an argument that a vertical merger "had some beneficial effect" in making one of the merging parties "a more vigorous and effective competitor" against other market participants than it would have been independently); *see also U.S. Steel.*, 426 F.2d at 603 (noting that lower unit costs of integration do not necessarily benefit customers when the associated lower prices are used only as "more selective instrument[s]" or "weapons of economic discipline" in oligopolistic industries); *Procter & Gamble*, 386 U.S. at 580 ("Possible economies cannot be used as a defense to illegality. Congress was aware that some

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reckoning of social or economic debits and credits, it may be deemed beneficial. A value choice of such magnitude is beyond the ordinary limits of judicial competence, and in any event has been made for us already, by Congress when it enacted the amended § 7."); *see also U.S. Steel.*, 426 F.2d at 603 (noting that lower unit costs of integration do not necessarily benefit customers when the associated lower prices are used only as "more selective instrument[s]" or "weapons of economic discipline" in oligopolistic industries); *Procter & Gamble*, 386 U.S. at 580 ("Possible economies cannot be used as a defense to illegality. Congress was aware that some mergers which lessen competition may also result in economies but it struck the balance in favor of protecting competition."). Lower federal courts have recognized as much. *FTC v. H.J. Heinz Co.*, 246 F.3d 708, 720 (D.C. Cir. 2001) (recognizing that "the Supreme Court has not sanctioned the use of the efficiencies defense in a section 7 case"); *Penn State Hershey*, 838 F.3d at 347-48 ("Contrary to endorsing such a defense, the Supreme Court has instead, on three occasions, cast doubt on its availability."); *Saint Alphonsus Med. Ctr.-Nampa Inc. v. St. Luke's Health Sys., Ltd.*, 778 F.3d 775, 788-89 (9th Cir. 2015) ("The Supreme Court has never expressly approved an efficiencies defense to a § 7 claim.").

mergers which lessen competition may also result in economies but it struck the balance in favor of protecting competition."). Even assuming an efficiencies defense is cognizable, despite Supreme Court guidance casting doubt on the defense, Respondents would bear the burden of producing "clear evidence showing that the merger will result in efficiencies that will *offset* the anticompetitive effects and ultimately benefit consumers." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *Penn State Hersey*, 838 F.3d at 350) (emphasis added); *accord* Initial Decision, *Altria*, Docket No. 9393, at 5 ("[C]ounsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto.") (quoting 16 C.F.R. § 3.43(a)); *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)); U.S. Dep't of Justice & Fed. Trade Comm'n, 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"). The stronger the *prima facie* case "the greater the [Respondents'] burden of production on rebuttal." *Polypore*, 2010 WL 9549988, at *9; *see also FTC v. H.J. Heinz*, 246 F.3d 708, 725 (D.C. Cir. 2001); *Baker Hughes*, 908 F.2d at 991. Moreover, "[t]he greater the potential adverse competitive effect of a merger, the greater must be the cognizable efficiencies, and the more they must be passed through to customers.'" *United States v. Anthem, Inc.*, 236 F. Supp. 3d 171, 236 (D.D.C. 2017) (quoting *Horizontal Merger Guidelines* § 10); *accord Saint Alphonsus Med. Ctr.-Nampa Inc. v. St. Luke's Health Sys., Ltd.*, 778 F.3d 775, 790 (9th Cir. 2015) (stating that "[w]e remain skeptical about the efficiencies defense in general and about its scope in particular," but that, assuming such a defense

exists, "a successful efficiencies defense requires proof that a merger is not, despite the existence of a prima facie case, anticompetitive").

As the record evidence shows, and as Complaint Counsel explains below, the Acquisition will result in grave harm to American consumers. Today, Grail faces intense competition in the MCED Test Market. Illumina possesses the related product—its NGS platform—which serves as a critical input for Grail and its MCED competitors. The effect of aligning Illumina's interest with Grail's is clear: Illumina can, and will, insulate Grail from competition to reap astronomical profits in the MCED Test Market. Respondents have failed to present evidence that undermines these fundamental facts. Likewise, they present no evidence of cognizable procompetitive benefits or viable means of replacing the competitive harm, falling far short of their burden to rebut Complaint Counsel's case. For these reasons the merger should be permanently enjoined, and Illumina should be required to take all steps necessary to restore the competitive dynamics within the relevant market.

B. The Research, Development, and Commercialization of MCED Tests is a Relevant Product Market

Section 7 of the Clayton Act prohibits acquisitions "where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly." 15 U.S.C. § 18. The Supreme Court has recognized that Section 7 thereby prohibits acquisitions that would "substantially lessen competition within the area of effective competition." *Brown Shoe*, 370 U.S. at 324 (quoting *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 593 (1957) (internal quotations omitted). To determine the "area of effective competition," courts "reference . . . a product market (the 'line of commerce') and a geographic market (the 'section of the country')[.]"

Brown Shoe, 370 U.S. at 324. "Often, the first steps in analyzing a merger's competitive effects are to define the geographic and product markets affected by it." *ProMedica Health Sys., Inc. v. FTC*, 749 F.3d 559, 565 (6th Cir. 2014). Whether the transaction at issue is horizontal or vertical, courts use the same set of analytic tools to define the affected market. *See Brown Shoe*, 370 U.S. at 324-28.

It is well settled that "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. 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). 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." *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 27 (D.D.C. 2015). Here, both practical indicia and economic testimony are sufficient to define the relevant product market as the MCED Test Market.

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

The "practical indicia" identified by the Supreme Court in *Brown Shoe* 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 Otto Bock*, 2019 WL 2118886, at *5 (Chappell, A.L.J.); *Sysco*, 113 F. Supp. 3d at 27; *United States v. Aetna, Inc.*, 240 F. Supp. 3d 1, 21 (D.D.C. 2017); *United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36,

51 (D.D.C. 2011).[41] These practical indicia identify MCED Tests as a distinct product market for purposes of assessing the Acquisition's competitive effects.

Peculiar Characteristics and Uses. MCED Tests have unique characteristics that set them apart from other oncology tests. *See* (CCFF ¶¶ 605-07, 609-10). Considered the "holy grail" of liquid biopsies, MCED tests can detect multiple types of early-stage cancer in asymptomatic individuals simultaneously by examining the presence of ctDNA in the bloodstream. (CCFF ¶ 606). The characteristics and uses of MCED Tests are different from other oncology tests, existing cancer screening tests, and single-cancer screening tests, giving MCED Tests a novel and distinct role in cancer detection. *See* (CCFF ¶ 638).

First, MCED Tests have different intended uses and characteristics than oncology tests used for symptomatic patients or patients already diagnosed with cancer, including other NGS-based or blood-based tests like DAC tests, therapy selection tests, and MRD tests. (CCFF ¶ 609). MCED tests have been developed to detect multiple cancers simultaneously in asymptomatic, otherwise healthy individuals. (CCFF ¶¶ 605, 608, 616, 705, 709). In contrast, DAC tests, [redacted] } (CCFF ¶¶ 616, 629-33). 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. (CCFF ¶¶ 618-23). And

[41] Not all of *Brown Shoe*'s practical indicia are required to find a relevant market. *See Int'l T. & T. Corp. v. General T. & E. Corp.*, 518 F.2d 913, 932-33 (9th Cir. 1975) ("These indicia were listed with the intention of furnishing practical aids in identifying zones of actual or potential competition rather than with the view that their presence or absence would dispose, in talismanic fashion, of the submarket issue. Whether or not a court is justified in carving out a submarket depends ultimately on whether the factors which distinguish one purported submarket from another are 'economically significant' in terms of the alleged anticompetitive conduct.").

MRD tests are intended for monitoring for cancer in already diagnosed patients following completion of therapy.[42] {[redacted]}.

Second, MCED Tests also have different intended uses and characteristics than current standard-of-care screening tests. Today, the vast majority of cancers have no screening options at all. (CCFF ¶¶ 245, 248, 636, 660). In fact, only four types of cancers have screening tests recommended by the U.S. Preventative Services Task Force ("USPSTF"), an independent group of experts which "set[s] the standards" for cancer screening: lung, breast, colorectal, and cervical. (CCFF ¶¶ 233-35, 600). Market participants, including Respondents, recognize that MCED tests will "complement" these "standard of care screening tests . . . rather than replace them." (CCFF ¶¶ 469, 646-59). As Grail publicly represents on the front page of the website for its Galleri test, Galleri "is intended to be used in addition to and not replace other cancer screening tests." (CCFF ¶ 650); *see also* (CCFF ¶¶ 471-73, 630, 651-56). In addition, Grail's former CEO Hans Bishop testified at trial that MCED tests "should be used alongside existing standard of care oncology screenings," which are "optimized" for the cancers they detect and are therefore more sensitive than MCED tests. (CCFF ¶¶ 654, 656). Likewise Illumina, in its {[redacted]} (CCFF ¶ 651). Even one of Respondents' own experts, Dr. Richard Abrams, {[redacted]} (CCFF ¶ 657). Respondents' views are consistent other industry participants, who testified that MCED tests will

[42] 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.

be used in conjunction with existing screening technologies, either to detect cancers for which there are no current screens, or to serve as a {[redacted]} before proceeding to USPSTF recommended screenings. (CCFF ¶¶ 466-70, 474-75, 640, 646-49, 658-59).

For similar reasons, other single-cancer screening tests—including blood-based single-cancer screening tests—are also not close substitutes for MCED tests. (CCFF ¶¶ 634, 671-72). As Grail recognized in its ordinary course documents, MCED tests "[d]etect[] multiple deadly cancer types at early stages rather than creating multiple single cancer tests which may be logistically impractical and more costly overall."[43] (CCFF ¶ 669); *see also* (CCFF ¶¶ 663-64). Illumina agrees, explaining in an ordinary course document that "[t]he potential benefits of a multi-cancer test are much larger than that of a single cancer test. For cancers like pancreatic cancer which have lower prevalence, but very deadly, it would be difficult to implement as a single cancer test vs part of a multi-cancer test that has a much higher aggregate prevalence." (CCFF ¶ 665). As Illumina executives told their Board of Directors, {[redacted]} (CCFF ¶¶ 670-72; 745). These documents are further bolstered by trial testimony, with former Grail CEO Hans Bishop testifying that Grail intends for Galleri "to be used alongside" single-cancer tests, (CCFF ¶ 472), and other Illumina and Grail executives testifying similarly. (CCFF ¶¶ 673, 675-78, 680). Grail's MCED Test rivals also do not view NGS-based single-cancer early detection tests as directly competitive with MCED tests. (CCFF

[43] A planned Morgan Stanley IPO Roadshow investor presentation on Grail to investors noted that "screening for single cancers individually 'misses the forest for the trees'" as "3x as many cancer cases can be found with a test that is able to detect multiple cancers at the same time that someone would otherwise be in a doctor's office for screening today." (CCFF ¶ 664).

¶¶ 682-87). 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 cancers at one particular time and also value for the physician who could do so in an efficient fashion." (CCFF ¶ 684); *see also* (CCFF ¶ 685).

Distinct Customers. Because MCED tests are targeted towards patients who do not have symptoms of cancer and have not been treated for it, MCED test developers expect to market and sell their tests to primary care physicians or other physicians conducting annual wellness screenings. (CCFF ¶¶ 709-11, 715-17). {[redacted]} (CCFF ¶ 711). This contrasts with other oncology tests—including the DAC and MRD tests [redacted] and the therapy selection tests offered by Illumina—which are marketed to oncologists and other cancer specialists. DAC tests are intended for {[redacted]} who would see the patients experiencing symptoms. (CCFF ¶¶ 727, 729). As the patient is undergoing treatment for cancer, these same oncologists would use therapy selection tests to help inform the treatment. (CCFF ¶¶ 728-29). Finally, once a patient has been treated for cancer, oncologists who have engaged in the patient's treatment will use MRD tests to monitor the patient for cancer recurrence. (CCFF ¶ 731).

Distinct Prices. MCED test developers plan to set prices for their MCED tests distinctly from other oncology tests. Unlike non-screening tests designed for the "niches" of patients with a suspicion or diagnosis of cancer, (CCFF ¶ 688); *see also* (CCFF ¶ 706), MCED tests are targeted

toward a more general population, with the goal of screening a large portion of asymptomatic adults in the United States. (CCFF ¶¶ 378-79, 688, 705-06). Accordingly, these tests must be priced low enough to become widely adopted in the marketplace because out-of-pocket costs to patients will be the {[redacted]} for primary care physicians in choosing among screening tests. (CCFF ¶¶ 691, 700). As Illumina's CEO Francis deSouza testified, {[redacted]} (CCFF ¶ 690). Grail internally performed its own analysis of {[redacted]} (CCFF ¶ 692). Grail likewise projected that the price of its Galleri MCED test {[redacted]} (CCFF ¶¶ 693). Moreover, many MCED test developers expect their tests to compete with Galleri on price, {[redacted]} (CCFF ¶¶ 696-97, 761). Accordingly, Grail regularly monitors the pricing of its MCED Test rivals, including {[redacted]} (CCFF ¶¶ 695-97); *see also* (CCFF ¶ 704).

Industry Recognition of MCED Tests as a Separate Market. Respondents' own documents and testimony, as well as those of other market participants, unambiguously reveal that the industry recognizes MCED Tests as a distinct product category. Grail identifies itself in its documents as {[redacted]} (CCFF ¶¶ 732-37), and refers to the {[redacted]}

[redacted]}[44] (CCFF ¶ 737). Grail also considers other MCED test developers as its [redacted]}, (CCFF ¶¶ 436-37, 444-45, 451-52, 458-59, 736, 756, 760-61, 765-66, 3231-84, 3294-3307, 3319-25, 3335-3350, 3370-75), and they view Grail as the same. (CCFF ¶¶ 3211-30, 3289-93, 3313-18, 3331-34, [redacted], 3364-69, [redacted]). In addition, Grail {[redacted]} (CCFF ¶ 742). Illumina, in its own ordinary course documents, likewise {[redacted]} (CCFF ¶¶ 744-45, 3471-73). For example, in one internal document, Illumina explained that the {[redacted]} (CCFF ¶ 745). Furthermore, Illumina executives have recognized that acquiring Grail would mean potentially {[redacted]} (CCFF ¶¶ 746-48, 762, 6073).

Respondents' views of an MCED Test Market are consistent with those of other MCED test developers, as well as other industry stakeholders. (CCFF ¶¶ 777-821). At trial, test developers referred to their tests as MCED tests. *See, e.g*, (CCFF ¶ 778). For example, when describing the CancerSEEK test, former Chief Innovation Officer and Co-Founder of Thrive explained that "we call it a multicancer test. That's in stark contrast to single organs test[s] that only look for one particular organ [cancer]." (CCFF ¶ 785). Moreover, internal documents of

[44] This is consistent with testimony from Grail's executives. *See, e.g.*, (CCFF ¶¶ 736, 738-40).

MCED test developers refer to their tests as "multi-cancer screening" tests, distinct from other oncology tests. *See, e.g.*, {[redacted]} And, even outside of test developers themselves, people familiar with the industry differentiate MCED tests from other oncology tests.[45] The U.S. House of Representatives and Senate introduced the Medicare Multi-Cancer Early Detection Screening Coverage Act of 2021, which states that MCED tests "can complement the covered early detection tests," rather than replace them. *See* Medicare Multi-Cancer Early Detection Screening Coverage Act of 2021, H.R.1946, 117th Cong. (2021); S. 1873, 117th Cong. (2021). This bill would authorize CMS to cover MCED tests once approved by the FDA, leap-frogging the USPSTF's review process. *See* (CCFF ¶ 809-10).

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

Along with the practical indicia set out in *Brown Shoe*, courts 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); *see also Penn State Hershey*, 838 F.3d at 338; *In re ProMedica Health Sys., Inc.*, 2012 WL 1155392, at *14 (F.T.C. Mar. 28, 2012); *Sysco*, 113 F. Supp. 3d at 33-34; *H&R Block,* 833 F. Supp. 2d at 51-52; *Horizontal Merger Guidelines* § 4.1.1.[46] Under the hypothetical monopolist test, a candidate market constitutes a relevant antitrust market if a hypothetical monopolist could profitably impose a "small but significant and non-transitory

[45] Industry reports and investors consider MCED tests to be distinct from other oncology tests and recognize MCED test developers as Grail's competitors. *See, e.g.*, (CCFF ¶ 820); *see also* (CCFF ¶ 821) (discussing "concerns around potential cannibalization into ILMN's existing customers that compete with Grail (GH, Freenome, Thrive, etc.)").
[46] Courts regularly use the hypothetical monopolist test set forth in the *Horizontal Merger Guidelines* as one means to define a relevant market. *Sysco*, 113 F. Supp. 3d at 33. 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 "small but significant non-transitory increase in price" ("SSNIP") over those products.

increase in price" ("SSNIP"), or reduce quality or availability, on at least one product of the merging parties in the candidate market, or whether customers switching to alternative products would make such a price increase unprofitable. *See Horizontal Merger Guidelines* § 4.1.1; *see also Otto Bock*, 2019 WL 2118886, at *6 (Chappell, A.L.J.). Applied here, the test would ask whether a hypothetical monopolist owning Grail's Galleri test and all other third-party MCED tests could profitably impose a SSNIP, or a reduction in test quality or availability, on one of the tests; if it could, then MCED Tests would constitute a relevant product market.

The analysis conducted by Complaint Counsel's economic expert, Dr. Fiona Scott Morton, confirms that a relevant product market consisting of MCED Tests satisfies the hypothetical monopolist test. (CCFF ¶¶ 823-24). As described more fully in her expert report, Dr. Scott Morton found that {[redacted]} *See* (CCFF ¶¶ 823-24). {[redacted]}

[47] {[redacted]} *See* (CCFF ¶ 828); *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.").

(CCFF ¶¶ 825-26). Dr. Scott Morton's conclusion stands unrebutted, as {[redacted]} (CCFF ¶ 830).

3. Differentiation in MCED Tests Does Not Undermine the Relevant Product Market

Respondents argue that rival MCED tests are "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[.]"[48] Answer at 10. Products, however, need not be identical to fall within the same relevant 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*, CV 19-06926, 2020 WL 3041309, at *4, n.2 (C.D. Cal. Mar. 9, 2020) (explaining "it is wrong" to suggest that because two products "are not identical" they are not in the same relevant product market).[49] Here, all MCED test developers are pursuing the same goal of creating the best MCED test. Contrary to Respondents' claims, the evidence shows that MCED tests will ultimately be quite similar. But they are unlikely to be identical. While Respondents assert that such differentiation reflects an absence of competition, this misconstrues the competitive dynamics in the MCED Test Market. In an innovative market, such as the MCED

[48] Respondents' [redacted] (CCFF ¶ 3530).
[49] Respondents' economic expert conceded that differentiated products can be substitutes. (CCFF ¶ 3529).

Test Market here, differentiation and new approaches are *attributes of competition*, not indicia of its absence.[50]

Every MCED test is designed for the same purpose—detecting multiple cancers simultaneously in asymptomatic people—which can be realized in different ways using different methods. [redacted] Even Grail, which is currently {[redacted]} (CCFF ¶ 413); *see also* (CCFF ¶ 411-12). Similarly, MCED tests that detect multiple cancers are not excluded from the market simply because Galleri might detect more or different cancers. While some MCED test developers plan to start with one or a few cancers, and add other cancers later, they all share the same ultimate goal—to detect a wide range of cancers simultaneously in a single test.[51] (CCFF ¶¶ 422, 426, 441,

[50] For example, {[redacted]}. Singlera also expects that "continuous improvement, innovation, to reduce cost, improve accuracy and improve convenience will always be [ ] nonstop of any company" because you "have to innovate to survive." (CCFF ¶ 3661-62). [redacted] (CCFF ¶ 3422).

[51] Some MCED test developers have made the strategic choice to start with a test that detects one cancer and add additional cancers later. While some MCED test developers first plan to seek regulatory approval for single-cancer screening tests, these efforts represent an initial step towards their ultimate goal of commercializing MCED tests to

447, 2373). As Respondents' own expert Dr. Richard Abrams testified, the exact number of cancers is just one factor that might cause him to switch between MCED tests, with accuracy being "first and foremost" the most important factor, along with other factors such as price. (CCFF ¶ 3547). As Dave Daly, former CEO of Thrive and former SVP and General Manager of the Americas at Illumina, testified:

[redacted]

(CCFF ¶ 3525).

Respondents use a similar ploy, claiming Grail's Galleri test can detect 50 cancers in an apparent attempt to distinguish Grail from other MCED test developers. But Grail has failed to demonstrate Galleri's ability to detect anywhere close to that number in the prospective studies needed to gain regulatory approval. (CCFF ¶¶ 6204-6394). Instead, as Respondents' expert, Dr. Cote, admitted, Grail has only demonstrated the ability to detect seven cancer types in asymptomatic individuals. (CCFF ¶ 6298). Meanwhile, other MCED test developers are planning to launch MCED tests that can detect many of the same cancers as Galleri's test, as well as focus on cancers that Grail does

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rival Galleri. [redacted] (CCFF ¶¶ 2292, 2298). As Guardant's Getty explained, starting with colorectal cancer makes "it a little bit easier to bring a test to market in a faster fashion," and Guardant's strategy of "pursuing a singular tumor and then adding on tumors is just a little bit of a different view of the same coin that Grail has." (CCFF ¶ 2284). [redacted] (CCFF ¶ 3389, 3427, 3437-38, 3444); *see also* (CCFF ¶ 767) (a Grail internal document noting that "MCED evolving into highly competitive landscape, though many seem to be starting with one cancer type, with intent to add more").

not. (CCFF ¶¶ 2050, { } 2423-04, { }). For example, as Dr. Christoph Lengauer, former Chief Innovation Officer and Co-Founder of Thrive, testified, { } (CCFF ¶ 414).

The differences among MCED tests arise naturally from the ongoing innovation race among MCED test developers: the very essence of competition. As Chief Medical and Scientific Officer for the American Cancer Society, Dr. William 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." (CCFF ¶ 3643). Even the CEOs of both Illumina and Grail recognize the benefits of having multiple approaches to the development of MCED tests. Grail's former CEO, Hans Bishop, testified that patients benefit from having multiple MCED tests in development, explaining: "difficult problems are, by definition, hard to solve, and having a multitude of different approaches is a good thing." (CCFF ¶ 3520). 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." (CCFF ¶ 3519). 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." (CCFF ¶ 3516). These approaches, Bishop emphasized, all intend to reach the same goal—"to get to the highest-performing technology." (CCFF ¶ 3517). 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.
>
> (CCFF ¶ 55).

Rather than delineating entirely separate product markets, differences among MCED tests will simply be factors that a physician weighs in choosing among competing MCED tests.[52] *See* (CCFF ¶¶ 234, 3522). As Dr. Cance, Chief Medical and Scientific Officer of the American Cancer Society, explained, "[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." (CCFF ¶ 3650).

C. The United States Is the Relevant Geographic Market

The relevant market in which to assess the anticompetitive harms of the 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 Advocate Health Care Network*, 841 F.3d at 476 (citing *Phila. Nat'l Bank*, 374 U.S. at 357); *Horizontal Merger Guidelines* § 4.2. Here, the United States is the relevant geographic market in which to analyze

[52] Respondents' own expert, Dr. Richard Abrams, wrote in his report that [redacted] (CCFF ¶¶ 3512-13).

the effects of the Acquisition because American physicians and patients require tests that are approved by U.S. regulators.

Regulatory requirements are a well-recognized factor in determining the scope of geographic markets. *Horizontal Merger Guidelines* § 4.2. When "customers in the United States must use products approved by U.S. regulators," then "[t]he geographic market is defined around U.S. customers." *Horizontal Merger Guidelines* § 4.2.2; *see also Otto Bock*, 2019 WL 2118886, at *5-6 (Chappell, A.L.J.); Complaint, *In re Össur Hf., Össur Am. Holdings, Inc., and College Park Indus., Inc.*, Docket No. C-4712, at 2-3 (F.T.C. May 28, 2020) (defining the relevant geographic market for a medical device as the United States); Complaint, *In re Stryker Corp. and Wright Med. Grp. N.V.*, Docket No. C-4728, at 2 (F.T.C. Dec. 17, 2020) (same).

The United States has unique regulatory and reimbursement realities that distinguish it from other areas in the world with respect to the sale of MCED tests. MCED tests are regulated in the United States by the FDA and CMS (via the CLIA). (CCFF ¶¶ 492-551); *see also supra* § I.A.2. In the United States, the FDA is responsible for regulating and approving medical devices for their safety and effectiveness, as set forth in Section 201(h)(2) of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 321 (defining the term "device" to include "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals"); *see also Morgan v. Medtronic, Inc.,* 172 F. Supp. 3d 959, 965 (S.D. Tex. 2016) ("Congress enacted the [Medical Device Amendments to the Federal Food, Drug, and Cosmetic

Act 'MDA'] in 1976 and granted the FDA authority to regulate the safety and effectiveness of medical devices sold in the United States.") (citing 21 U.S.C. § 321).

Evidence indicates that broad commercialization of an MCED test in the United States will require full FDA approval. There are two major sources of insurance in the United States: CMS and private payers. (CCFF ¶ 555). Broad commercialization of an MCED test requires favorable coverage decisions from both CMS and private payers. (CCFF ¶ 556, 561-62). FDA approval is a necessary input to achieve Medicare coverage of MCED testing from CMS. (CCFF ¶ 582). Given that the intended use population for MCED tests is generally individuals aged 50 and older (CCFF ¶ 712, 714), Medicare coverage will be particularly important for MCED test reimbursement because "many other U.S. payors look to the Medicare policies as a benchmark and model for their own." (CCFF ¶ 865).

Respondents concede that both FDA approval and payer coverage are necessary to commercialize an MCED test at scale in the United States. (CCFF ¶ 554) (agreeing that FDA approval will likely be a prerequisite for getting broad-based reimbursement for Galleri); *see also* (CCFF ¶¶ 561, 863); *accord* (CCFF ¶ 856). This is because {[redacted]} (CCFF ¶ 864). FDA approval also lends credibility to MCED tests, which many primary care physicians will likely require before prescribing MCED tests to patients. (CCFF ¶ 580). Physicians also look to CMS in deciding what tests to recommend to patients. (CCFF ¶ 874). Accordingly, as Grail's CEO testified at trial, FDA approval is "very necessary for getting American citizens access to our test." (CCFF ¶ 508).

Respondents' documents further confirm that the United States is the appropriate relevant geographic market. Grail's Form S-1 filing, for example, references a United States-specific "early detection market." (CCFF ¶ 878). An internal Illumina due diligence document presented to the company's Board of Directors applied distinct "geographic adoption assumptions" to the United States and markets outside the United States. (CCFF ¶ 879). Respondents have previously referenced other "international markets" (distinct from the United States) and the "country-by-country process of commercializing" medical devices in previous court filings related to the transaction. (CCFF ¶ 880); *see also* (CCFF ¶ 883). Based on this record evidence, Complaint Counsel's expert, Dr. Scott Morton, testified that "it is unlikely that U.S. MCED test customers facing a SSNIP would switch to a non-FDA approved MCED test outside the United States." (CCFF ¶ 884).

D. Illumina's NGS Platforms Are Related Products to MCED Tests

While both horizontal and vertical mergers define a relevant market in which the competitive harm is likely to occur, it is also helpful in the context of a vertical merger to identify a *related* product. The purpose of identifying a related product differs from the formal relevant market definition exercise. The purpose of defining a *relevant* market is to determine the "area of effective competition" in which "the effect [of an acquisition] may be substantially to lessen competition" under the Clayton Act. *See Brown Shoe*, 370 U.S. at 324 (quoting *du Pont*, 353 U.S. at 593); 15 U.S.C. § 18. In contrast, identifying a *related* product may assist in the Government's fact-specific inquiry to assess the likely anticompetitive effects of the vertical merger.

The Government need not prove that the related product constitutes a relevant antitrust market. *See Brown Shoe*, 370 U.S. at 325, 334 (finding a Section 7 violation without requiring a

showing that a related product constituted a relevant antitrust market); *du Pont*, 353 U.S. at 593-95 (same); *AT&T*, 310 F. Supp. 3d at 195-97, 226-27 (D.D.C.) (scrutinizing the "measure of customer loss" underpinning the Government's "increased-leverage theory" without requiring proof of the upstream firm's "'market power' in the programming market"). And no court has held that the Government must prove monopoly power in a related product market to prove that a merger violates the Clayton Act. Instead, the proper inquiry here is whether Illumina supplies related products on which Grail's rivals rely. *See, e.g.*, *AT&T*, 310 F. Supp. 3d at 195-97 (D.D.C.) (finding relevant antitrust product market for downstream multichannel video distribution in which alleged harm from transaction would occur, but not defining a related antitrust product market around upstream programming); Steven C. Salop, *Invigorating Vertical Merger Enforcement*, 127 Yale L.J. 1962, 1975 (2018) ("The paradigmatic input foreclosure concern entails the upstream merging firm raising prices or refusing to sell its critical input to one or more actual or potential rivals of the downstream merging firm.").

Here, the trial record shows that Illumina's NGS instruments and consumables are related products to the MCED Test Market, serving as critical inputs necessary to their development and commercialization. As Grail detailed in its Form S-1, "[w]e rely on Illumina, Inc. as a sole supplier for our next-generation sequencers and associated reagents." (CCFF ¶ 1067). Grail's corporate designee testified that Grail {[redacted]} While there are a limited number of NGS platforms available for use in the United States, none of them (aside from Illumina) meet the requirements necessary for the MCED Test Market. *See infra* § II.D.2. Instead, MCED test developers must

depend on Illumina's NGS platforms to develop and run their tests because no other technology—NGS or otherwise—can meet the MCED test developers' requirements of high accuracy, high throughput (specifically high read count), and low cost, all of which are {[redacted]}[53] (CCFF ¶ 927). It is no surprise, then, that every MCED test developer relies on Illumina today.[54] *See* (CCFF ¶¶ 1053-1200).

1. MCED Test Developers Require Highly Accurate, High-Throughput NGS Platforms

MCED test developers must solve the difficult problem of finding "very subtle" cancer signals in the blood of otherwise healthy patients. (CCFF ¶¶ 298, 915, 923). This is notoriously challenging because finding ctDNA in the blood is like finding a needle in a haystack of normal cfDNA. (CCFF ¶ 298) *see also* (CCFF ¶ 923). Christoph Lengauer, former Chief Innovation Officer and Co-Founder of Thrive, testified that {[redacted]} (CCFF ¶ 919); *see also* (CCFF ¶ 920). As Grail illustrated in an external presentation, {[redacted]}

[53] There is overwhelming testimony that MCED test developers depend on Illumina. *See* (CCFF ¶¶ 1053-1200).
[54] Complaint Counsel is not aware of any MCED test developer creating an MCED test that does not rely on NGS technology. While one company, {[redacted]}

[redacted]

([redacted]} Accordingly, the MCED Test Market highly accurate, high-throughput NGS platforms. (CCFF ¶¶ 925, 927-28); *see also* (CCFF ¶¶ 926-1002).

a. ***MCED Tests Require Accurate Sequencing Platforms***

For MCED tests, accuracy means {[redacted]}

Accuracy is paramount for MCED testing, where an incorrect reading of even a single base pair could cause significant harm to patients by missing, or misdiagnosing, the patient's cancer. (CCFF ¶¶ 387, 392-94, 1268). To avoid these unacceptable harms, 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. (CCFF ¶¶ 384, 971). A false-positive test result is a "potentially damaging, worrisome thing" that could lead to unnecessary follow-up screening, if not more invasive

interventions. (CCFF ¶¶ 387, 392-94). Second, an MCED test must have high sensitivity, meaning that the test indicates for cancer when a patient does, in fact, have cancer. A false-negative result could leave a patient with life-threatening cancer undiagnosed. (CCFF ¶¶ 386, 397, 958). To deliver sufficiently accurate results, MCED test developers must use sequencing technology with low error rates. (CCFF ¶¶ 960, 972). As Dr. Lengauer of Thrive testified at trial, Illumina's NGS technology is {[redacted]}[55] (CCFF ¶ 1091).

b. ***MCED Tests Require High-Throughput Sequencing Platforms***

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. (CCFF ¶¶ 395, 936). 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. (CCFF ¶¶ 933-36). For MCED tests, read count per run is the critical measure of throughput, as that determines the number of cfDNA molecules that can be analyzed, (CCFF ¶¶ 937-38, 941-40), and, in turn, the number of patient samples that an NGS platform can process in a given period of time.[56] *See, e.g.*, (CCFF ¶¶ 932, 936). Moreover, as MCED testing increases in scale to reach a broader population, as is the goal of MCED test developers, {[redacted]} having a

[55] Likewise, other MCED test developers testified that Illumina is the only NGS platform capable of running liquid biopsy tests. (CCFF ¶¶ 969, 1061, 1084, 1087, 1102, 1108, 1194); *see also* (CCFF ¶¶ 1053-1200).

[56] On the other hand, as Dr. Darya Chudova of Guardant testified at trial, [redacted] (CCFF ¶ 4681). Because short strands of ctDNA have few nucleotides, an instrument with a high throughput only in *gigabases* per run {[redacted]} (CCFF ¶ 4681).

sequencer able to process a high number of patient samples per run becomes increasingly important. (CCFF ¶¶ 942, 943, 952, 1127, 1180, 1235); *see also* (CCFF ¶¶ 1110, 1150). As Guardant's SVP of Technology, Dr. Darya Chudova, testified, {[redacted]} (CCFF ¶ 943).

c. *MCED Tests Require Cost-Effective Sequencing Platforms*

Finally, high-throughput NGS platforms also reduce 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. (CCFF ¶¶ 942, 945, 950, 980). For as many Americans to have access to these life-saving tests as possible, low costs are critical. *See supra* § II.D.1a-b. As Dr. Bert Vogelstein, a cancer researcher at Johns Hopkins University School of Medicine, testified, "the cost and the throughput of the sequencing are key" to achieve the goal of "ultimately creat[ing] tests that are affordable for all." (CCFF ¶ 995).

2. Illumina Has the Only NGS Platform that Meets the Requirements of MCED Tests

As the trial record demonstrates, Illumina's NovaSeq is the only NGS platform that meets MCED test developers' requirements and allows MCED tests to achieve their goal of saving patient lives.[57] First, in terms of accuracy, no other NGS platform can compare to the Illumina's

[57] Illumina's NGS platforms, including the NovaSeq, use short-read sequencing technology that "work[s] exceptionally well" for sequencing circulating tumor DNA fragments. (CCFF ¶ 1358); *see also* (CCFF ¶ 2). Although the NovaSeq is Illumina's highest-throughput platform to date, {[redacted]} (CCFF ¶ 1045).

low error rates, which are critical for MCED tests to help, rather than hurt, patients. (CCFF ¶¶ 1084, 1093); *see also* (CCFF ¶¶ 1052-1200). Grail considers Illumina {[redacted]}[58] (CCFF ¶ 403). Second, Illumina's NovaSeq is also the only platform with sufficient throughput (read count per run) to accommodate MCED testing, (CCFF ¶¶ 928, 949, 951, 1084, 1091, 1103, 1111, 1152, 1159), {[redacted]} The high throughput allows MCED test developers to perform "millions of tests a year." (CCFF ¶ 948). As Guardant's Dr. Chudova testified, {[redacted]} (CCFF ¶ 1235); *see also* (CCFF ¶ 941). Given its high-throughput capabilities, the NovaSeq is also the only cost-effective technology for these tests. (CCFF ¶¶ 1159,1173). As Freenome's former CEO Gabe Otte testified, {[redacted]} (CCFF ¶ 950). Dr. Bert Vogelstein of Johns Hopkins University agreed, testifying that "[t]he only technology available for short-read sequencing that is at a throughput and cost that would enable liquid biopsy to be analyzed is sold by Illumina." (CCFF ¶ 1208).

a. *MCED Test Developers Cannot Substitute Existing Short-Read NGS Platforms for Illumina*

MCED test developers, including Grail, rely on Illumina's NGS platform as the only option for the development and commercialization of their tests.[59] *See, e.g.*, (CCFF ¶¶ 1084, 1159). One

[58] As Respondents' Counsel acknowledged during opening statements at trial, "for [MCED testing] I think for many people [Illumina's NGS platform is] the best choice." Op. Stmt. (Resp.) Tr. 61.
[59] MCED test developers testified that they rely on Illumina for NGS platforms for the research, development, and commercialization of their tests. *See, e.g.*, (CCFF ¶¶ 949, 1062, 1084, 1091, 1099, 1107, 1129, 1132-34, 1152, 1165, 1168, 1174, 1191, 1194, 1847, 1185).

MCED test developer analogized developing an MCED test on a non-Illumina platform as akin to making {[redacted]} As Exact's CEO, Kevin Conroy, testified, Illumina is the [redacted] (CCFF ¶ 1089). Freenome's CEO, Michael Nolan, agreed, testifying that Freenome {[redacted]} (CCFF ¶ 1155); *see also* (CCFF ¶ 1143). [redacted] 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," (CCFF ¶ 1067), and, in an internal document, identified its {[redacted]} (CCFF ¶ 1077).

As discussed, *supra* § I.A.3, Illumina's NGS platforms, including its NovaSeq, are characterized as short-read platforms, meaning that they sequence small fragments of genetic material. (CCFF ¶ 895). Other than Illumina, Thermo Fisher offers the only short-read NGS platforms of any consequence. But Thermo Fisher's NGS platforms are incapable of MCED testing. (CCFF ¶¶ 1208, 1236, 1246). Thermo Fisher's own VP of Product Management, Dr. Andrew Felton, {[redacted]} (CCFF ¶ 1222); *see also* (CCFF ¶ 1584). He testified that MCED tests are more suited to "a very high throughput system," whereas "our systems are generally suited to . . . smaller amounts of patient samples."[60] (CCFF ¶ 1225). As Dr. Felton explained, {[redacted]}

[60] In addition, Dr. Felton testified at trial that the cost per read on Thermo Fisher's platform is higher than Illumina's NovaSeq. (CCFF ¶ 1219).

[redacted] (CCFF ¶ 1224). For its part, Illumina admits that its NovaSeq 6000 instrument [redacted] (CCFF ¶¶ 1027-28).

Because Thermo Fisher's highest-throughput platform is insufficient for MCED tests, MCED test developers similarly recognize that Thermo Fisher is not a viable option. For example, [redacted] Other MCED test developers echoed this conclusion. [redacted] Accordingly, no MCED test developer is developing an MCED test on a Thermo Fisher NGS platform, nor do they have plans to do so in the future. Due to Thermo Fisher's numerous shortcomings, MCED test developers consider its use [redacted]

b. *Long-Read NGS Platforms Are Not Suitable for MCED Tests*

Long-read NGS platforms are also not alternatives to Illumina's short-read NGS platform for MCED tests.[61] 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.[62] (CCFF ¶ 1348). 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. (CCFF ¶¶ 292, 1351). Illumina's short-read NGS platform is capable of sequencing entire strands of cfDNA, rendering long-read sequencing technology unnecessary. (CCFF ¶¶ 1351, 1357). Not only does long-read sequencing convey no benefit when sequencing circulating tumor DNA, long-read sequencing is priced at a significant premium. As Christian Henry, CEO of long-read NGS platform provider PacBio, testified, {[redacted]} (CCFF ¶ 1353). Because MCED test developers have no use for long-read sequencing capabilities, they would be paying a premium for a technology that they do not need. In addition, long-read sequencing platforms have higher error rates and much lower throughput (on the critical metric of read count per run) than Illumina's NGS platforms. (CCFF ¶¶ 1364, 1371, 1373-74, 1380, 1398). For these reasons, MCED test developers dismissed long-read NGS platforms for MCED tests. [redacted]

[61] For a discussion of the differences between long-read and short-read sequencing, *see supra* § I.A.3.
[62] Long-read NGS platforms "are particularly beneficial for applications such as human whole-genome sequencing because it is easier to determine the entire genomic sequence by assembling fewer longer sequence fragments than by

[redacted]

(CCFF ¶ 1387).

[redacted]

NGS platform providers also testified that long-read sequencing is a poor fit for MCED tests, where high throughput and accuracy are paramount. Thermo Fisher's Dr. Felton testified that long-read platforms "are really not suited to [MCED] testing." (CCFF ¶ 1584). Illumina's SVP and Chief Technology Officer, Alex Aravanis, described Illumina as "superior [to long-read platform provider Oxford Nanopore] in a meaningful way . . . around data accuracy, so the accuracy of the Oxford Nanopore reads is not as good as the Illumina reads." (CCFF ¶ 1360). The CEO of PacBio, another long-read sequencing platform provider, [redacted]

assembling many short ones. Using the puzzle analogy, it is easier to piece together a puzzle with fewer larger pieces than many smaller ones." (CCFF ¶ 1350).

[redacted]} (CCFF ¶ 1353). Even Francis deSouza, Illumina's CEO, told investors that short-read NGS platforms are much more suitable for detecting ctDNA fragments. (CCFF ¶ 1358). 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 [sic] 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.
>
> (CCFF ¶ 1358).

3. Non-NGS Technologies Are Not Suitable 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, microarrays, and proteomics, "are expected to be used for cancer screening tests in the future," Answer at 5, there has been no evidence presented at trial or otherwise to support their claims. First, PCR-based detection technology is only capable of identifying a small number of known mutations or biomarkers. (CCFF ¶ 1462). PCR-based detection technology is poorly suited for MCED tests because it lacks the ability to analyze the number of biomarkers required to test for several cancers simultaneously. (CCFF ¶¶ 1458, 1472, 1480, 1487-89). [redacted]

[redacted]

[redacted] (CCFF ¶ 1473). Ken Chahine, Helio's Chief Medical and Scientific Officer, [redacted] (CCFF ¶ 1474). Similarly, Dr. Gary Gao, Singlera's Co-Founder and Scientific Advisor, testified that "[o]bviously you cannot use PCR to do, you know, 500 readings . . . in a cost-effective way." (CCFF ¶ 1460). Even Dr. Felton of Thermo Fisher, a leading PCR-based technology provider, acknowledged PCR's inability to handle MCED testing. 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." (CCFF ¶ 1446). He also noted that it would "almost certainly" cost more to run MCED tests on PCR, and likely "orders of magnitude" more. (CCFF ¶ 1455).

Similar to PCR-based technologies, other non-NGS technologies such as microarrays and proteomics are not options for MCED testing. Microarrays determine whether specific sequences are present within a sample. (CCFF ¶ 1408). Nitin Sood, Guardant's SVP 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 number of DNA molecules present[.]" (CCFF ¶¶ 1424-25). Other MCED test developers agree that microarrays are incapable of running MCED tests due to their lack of sensitivity and throughput. (CCFF ¶¶ 1415, 1423, 1430). [redacted]

[redacted] (CCFF ¶ 1432) *see also* (CCFF ¶ 1439). [redacted] (CCFF ¶ 1438).

Proteomics also is not a standalone alternative to Illumina's NGS platforms for MCED tests. Proteomics analyzes protein levels as a biomarker for cancer. (CCFF ¶ 1496). 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. [redacted] It is, therefore, no surprise that MCED tests using proteomics still cannot function without an NGS platform. [redacted] 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 novel platform capable of doing so. (CCFF ¶¶ 1497-98).

E. The Acquisition Has a Reasonable Probability of Substantially Lessening Competition in the U.S. MCED Test Market

As the Supreme Court has explained, "[t]he primary vice of a vertical merger . . . is that, by foreclosing the competitors of either party from a segment of the market otherwise open to them, the arrangement may act as a clog on competition, which deprives rivals of a fair opportunity to compete." *Brown Shoe*, 370 U.S. at 323-24 (internal quotations omitted). Foreclosure in the vertical merger context can mean either "foreclosing competitors of [one party] from access to a potential source of supply, or from access on competitive terms." *Yankees Entm't*, 224 F. Supp. 2d at 673; *see also Sprint Nextel*, 821 F. Supp. at 330 (explaining rivals "paying more to procure necessary inputs" is the type of injury "that the antitrust laws were designed to prevent"). The

latter is often referred to as "raising rivals' costs."[63] *See AT&T*, 310 F. Supp. 3d at 242-43 (D.D.C.); Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 1000d (5th ed. 2021) ("The theory of RRC is an inescapable conclusion from marginalist economics, . . . [and has been] implicitly recognized in the antitrust case law at least as far back as *American Can*, . . . The theory of RRC rests on the simple observation that a practice that makes it more costly for a competitor to do business can harm competition even though the firm is not forced out of the market."); *see also United States v. American Can Co.*, 230 F. 859, 875 (D. Md. 1916) ("The record amply justifies the assertion that for a year or two after defendant's formation it was practically impossible for any competitor to obtain the most modern, up-to-date, automatic machinery, and that the difficulties in the way of getting such machinery were not altogether removed until the expiration of the six years for which the defendant had bound up the leading manufacturers of such machinery."); Salop, *Invigorating Vertical Merger Enforcement*, *supra* at 1967 ("[A] rational vertical merger policy would analyze

[63] Raising rivals' costs was endorsed as an example of competitive harm in the most recent Vertical Merger Guidelines. These Guidelines were adopted on June 30, 2020, by the Department of Justice and the FTC. U.S. Dep't of Justice & Fed. Trade Comm'n, Vertical Merger Guidelines (2020). Illumina and Grail entered into an Agreement and Plan of Merger on September 20, 2020, (CCFF ¶ 197), and the FTC issued its Administrative Complaint on March 30, 2021. The Vertical Merger Guidelines were subsequently withdrawn by the FTC on September 15, 2021. *See* Statement of Chair Lina M. Khan, Commissioner Rohit Chopra, and Commissioner Rebecca Kelly Slaughter on the Withdrawal of the Vertical Merger Guidelines, Commission File No. P810034 (Sept. 15, 2021), https://www.ftc.gov/public-statements/2021/09/statement-chair-lina-m-khan-commissioner-rohit-chopra-commissioner-rebecca. The statement of the FTC majority confirmed that "foreclosing rivals, raising rivals' costs, or misuse of competitively sensitive information" remain "important mechanisms by which vertical mergers can lessen competition." *Id.* at 6. Accordingly, evidence establishing the conditions for input foreclosure or raising rivals' costs as set forth in the withdrawn Vertical Merger Guidelines and drawn from case law indicates a substantial lessening of competition. The majority statement explained a reason for the withdrawal was that the Guidelines' "flawed discussion of the purported procompetitive benefits (i.e., efficiencies) of vertical mergers, especially its treatment of the elimination of double marginalization ('EDM'), could be difficult to correct if relied on by courts." *Id.* at 2. As discussed *infra* § II.F.2.b., the evidence from trial shows that any purported EDM efficiency attributable to the Acquisition would be negligible at best. Respondents' experts Carlton and Willig both testified that their analyses and conclusions would not change had they not applied the Vertical Merger Guidelines. *See* (PX7134 (Carlton Dep. at 70)); (PX7132 (Willig Dep. at 87)).

the likely ability and incentives of the merging firms to engage in various types of foreclosure conduct.").

Long-standing court precedent has set forth a framework for evaluating whether a vertical merger violates Section 7 of the Clayton Act. First, case law and economic literature have looked to whether the merged firm has the ability and incentive to harm downstream rivals when evaluating the legality of a vertical combination. *See, e.g.*, *AT&T*, 310 F. Supp. 3d at 243-45 (D.D.C.) (analyzing whether AT&T had the ability and incentive to foreclose or restrict rival video programming distributors' access to Time Warner content); *Union Carbide,* 1961 WL 65409, at *19 (Lipscomb, A.L.J.) (finding anticompetitive harm where the merged firm "has the power to exclude" competing producers from a segment of the market); Salop, *Invigorating Vertical Merger Enforcement*, *supra* at 1967. The relevant inquiry does not require proof that the merged firm will actually withhold all of its output from rivals, but rather whether they have the "power to exclude" competing producers from a segment of the market. *Union Carbide,* 1961 WL 65409, at *19 (Lipscomb, A.L.J.).

Second, courts, including the Supreme Court, have analyzed other factors laid out in *Brown Shoe*'s vertical merger framework when evaluating competitive harm. Specifically, courts look at whether the "share of the market foreclosed is so large that it approaches monopoly proportions." *Brown Shoe Co*., 370 U.S. at 328-29. This alone could be sufficient to show a reasonable probability of competitive harm. Here, however, the Court does not have to rely on just that factor, as it is corroborated by other factors such as "the nature and economic purpose of the arrangement" and escalating barriers to entry by new firms. *Brown Shoe*, 370 U.S. at 328-29, 333; *see also American Cyanamid*, 719 F.2d at 566; *Fruehauf*, 603 F.2d at 352-53 (noting that

there is no *per se* rule that foreclosure "amount[s] to a violation of § 7 without more, . . . except where the share of the market foreclosed reaches monopoly proportions") (citations omitted); *Mississippi River*, 454 F.2d at 1091; *U.S. Steel*, 426 F.2d at 598-99.

Analysis of both Illumina's post-Acquisition ability and incentive and the *Brown Shoe* framework supports the same conclusion: Illumina's acquisition of Grail will result in harm both to current innovation competition in the MCED Test Market and competition between the commercialized versions of Grail's Galleri and rival MCED tests. First, Grail and its MCED Test rivals are racing to develop, launch, and gain widespread adoption of MCED tests that can revolutionize how cancer is detected and treated in the United States, saving American lives. Today, Grail, Exact, [redacted] Guardant, Freenome, Singlera, Helio, and {[redacted]} 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. *See* (CCFF ¶¶ 1902-2594). For example, Exact has completed several clinical studies for its CancerSEEK MCED test and is {[redacted]} *See* (CCFF ¶¶ 2015-2104, 3215). As Exact's CEO testified, {[redacted]} (CCFF ¶¶ 3214, 3216-18, 3222). With the Acquisition, however, Illumina gained the ability and incentive to foreclose or disadvantage its rivals from participating in this race, resulting in decreased MCED Test innovation that would otherwise have given patients better, more accurate tests in the fight against cancer.

Second, Grail's rivals are poised to imminently launch their products commercially in direct competition with Grail. {[redacted]} These MCED test developers expect to continue competing head-to-head against Grail on price, performance, and service. *See, e.g.*, (CCFF ¶¶ 3224-29, 3290-93, 3316, 3333-34, [redacted], 3367-68, [redacted]. In fact, record evidence shows that these MCED tests will be close substitutes to Grail's Galleri test post-launch, (CCFF ¶¶ 3207-08, 3364), which Grail itself recognized naming Exact, Guardant, Singlera, and Helio as competitors in its Form S-1 SEC filing, (CCFF ¶¶ 3241, 3298 3339, 3372). Thus, any "[f]oreclosure of the second MCED test entrant will result in 100% of the entrant's lost sales being captured by Illumina-Grail." *See* (CCFF ¶ 3099); *see also* (CCFF ¶ 5909) {[redacted]}. As a result, even if Illumina does not disadvantage Grail's MCED Test rivals during the current, pre-commercial innovation race, it will have an enormous incentive to do so post-commercialization. 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, (CCFF ¶¶ 3189, 3582), but their success or failure depends on Illumina, the only viable supplier of a critical input for the entire MCED Test Market, *see* (CCFF ¶¶ 1019-1211). Accordingly, any foreclosure of rival MCED test developers post-commercialization will decrease competition, resulting in higher prices and lower quality for patients.

1. Complaint Counsel Meets Its *Prima Facie* Burden to Make a Fact-Specific Showing that this Merger Has a Reasonable Probability to Substantially Lessen Competition

Both Complaint Counsel and Respondents agree that the Government may establish its *prima facie* case through a "fact-specific" showing that a merger has a reasonable probability of substantially lessening competition. *See* Resp. Pretrial Br. at 42. Both case law and economic literature have set forth that such a fact-specific showing 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 AT&T*, 310 F. Supp. 3d at 243-45 (D.D.C.); *Union Carbide,* 1961 WL 65409, at *19 (Lipscomb, A.L.J.); Salop, *Invigorating Vertical Merger Enforcement*, *supra* at 1967; *see also* Resp. Pretrial Br. at 56 (arguing that Respondents "lack both the ability and incentive to foreclose"). Here, record evidence shows that post-Acquisition the combined firm has both the ability and incentive to disadvantage Grail's competitors, leading to competitive harm in the MCED Test Market.

a. *Illumina Has the Ability to Harm Grail's Rivals*

Illumina's NGS technology serves as a critical input to MCED tests during both the development and commercialization stages, (CCFF ¶¶ 1019-1211), and there are no alternatives to it, (CCFF ¶¶ 1212-1500). MCED tests are {[redacted]} to fit Illumina's platform, similar to how a key is designed for a lock, [redacted] so as the tests are developed and commercialized, test developers' reliance on Illumina grows. [redacted] Additionally, Illumina's MCED test developer 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. *See, e.g.*,

(CCFF ¶¶ 2805-2809, 2829-2917; 2955-2977). This expansive reliance gives Illumina unique insight into its customers' activities and allows Illumina the ability to specifically target those companies that pose a threat to Grail and its success. Illumina can, at any point during a customer's development or commercialization, 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 such 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 NGS products and services.

i. *Illumina Can Identify and Target Its Rivals*

As Illumina's Vice President and General Manager, Americas, Nicole Berry, explained, pre-Acquisition, Illumina considered its customers to be its {[redacted]} (CCFF ¶ 2829). 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 have given Illumina insight into how its customers are using its products, (CCFF ¶¶ 2661-88), and Illumina can use that knowledge to target those that become threats to Grail's market position. First, Illumina can learn about its customers' end uses from their purchase history. (CCFF ¶ 2664). Certain Illumina consumables are better suited for certain applications, meaning that based on which consumables a company is buying, Illumina can infer what type of test they are developing. (CCFF ¶¶ 2609, 2664-65). For example, when {[redacted]}

(CCFF ¶ 2668). 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 for the best results. (CCFF ¶¶ 2612, 2669). As {[redacted]} (CCFF ¶ 3017). Second, Illumina learns about its customers' applications through one-on-one negotiations. During supply agreement negotiations with {[redacted]} (CCFF ¶ 2635). And, finally, Illumina gathers information on its customers' end uses through its sales and servicing of customer equipment. As Berry testified, customers may seek Illumina's assistance when they {[redacted]} (CCFF ¶ 2683). In order for Illumina to provide effective service, {[redacted]}[64] (CCFF ¶ 2683).

Given the broad exchange of information between Illumina and its customers, Illumina can identify which MCED test developers pose a threat to Grail's competitive position and can take action to frustrate their development and commercialization efforts. Already, Illumina knows which of its customers compete against Grail. For example, before announcing its Acquisition,

[64] 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 {[redacted]} (CCFF ¶¶ 2675-78). [redacted] (CCFF ¶¶ 2680-82).

{[redacted]} (CCFF ¶ 2697). These {[redacted]} (CCFF ¶ 4199). Similarly, in a text message exchange between Berry and another Illumina executive, Jeremy Preston, Berry and Preston discussed that post-Acquisition, Illumina would be "competing with our customers" that are "in the same segment" as Grail, including "Guardant, Thrive, Freenome, Natera, Tempus, FMI . . ." (CCFF ¶ 2701). Illumina can {[redacted]} *See* (CCFF ¶¶ 2666-67, 2672). As former Illumina executive Dave Daly testified, {[redacted]} (CCFF ¶ 2672).

Illumina can use, and has used, its knowledge of customer applications to offer different pricing and terms to certain customers and applications in the past. *See, e.g.*, (CCFF ¶¶ 2750-54). {[redacted]} (CCFF ¶ 2753). In addition, Illumina has {[redacted]}

(CCFF ¶¶ 2745-49). To do this, Illumina sometimes imposes "field of use" clauses in its clinical agreements {[redacted]} (CCFF ¶ 2759). For example, Illumina has invoked a field of use clause when it was {[redacted]} (CCFF ¶ 2761). {[redacted]} (CCFF ¶ 2762).

ii. *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. As Illumina's Vice President and General Manager of the Americas, Nicole Berry, testified at trial, Illumina's NGS platform is not "plug-and play"; "[i]t's not like plugging in a refrigerator." (CCFF ¶ 6063). Rather, from the time of the initial purchase of the NGS platform to the development and commercialization of an assay using the platform, Illumina is intimately involved in its customers' success. As Berry explained, Illumina {[redacted]} (CCFF ¶ 2829). This is echoed by Illumina's MCED customers. [redacted]

[redacted] 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 and commercialization in multiple ways.

a) Illumina Can Completely Foreclose Grail's Rivals

As discussed *supra,* Grail's MCED rivals are totally dependent on Illumina's NGS platforms for their MCED tests to work. There are no viable alternatives. *See supra* § II.D. If post-Acquisition Illumina were to foreclose an MCED test developer from access to its products,[65] it would completely extinguish the rival's ability to compete. (CCFF ¶¶ 1137, [redacted]). As Guardant's Getty testified, echoing other MCED test developers, "[w]ithout [Illumina], Guardant doesn't exist." (CCFF ¶ 1137); *see also* [redacted]

[65] While complete foreclosure would reduce Illumina's overall sales of its NGS instruments and reagents, Illumina told investors that its MCED test developer customers "represent roughly 2% of our revenue." (CCFF ¶¶ 2700, 3140). Such a loss would have little impact on Illumina's overall business.

b) Illumina Can Increase Prices

Because there are no viable alternatives to Illumina, Illumina can increase the price it charges to Grail's rivals (or fail to decrease prices to the extent it would absent the Acquisition) during both the research and development and the commercialization of their MCED tests. 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. *See supra* § II.B.1. Given that Illumina's NGS inputs represent a significant portion of an MCED test's costs and are necessary and critical for each test, (CCFF ¶¶ 977, 984-86), any change to Illumina's prices directly impacts the profitability and competitiveness of rival tests, (CCFF ¶¶ 2780-85). As Singlera's Gary Gao testified at trial, "Illumina can choose the price, set the price of the sequencer, and also the reagent." (CCFF ¶ 2850).

Illumina uses a [redacted]

[66] 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.3.b.ii; (CCFF ¶ 4641). The Open Offer does nothing to account for the [redacted]

[redacted] (CCFF ¶¶ 2736-39). 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 relative increase in prices by Illumina will squeeze the profitability of Grail's rivals and, ultimately, diminish competition innovation in the market. (CCFF ¶¶ 2781-85). 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 forward to where they can become a reality for doctors and patients." (CCFF ¶ 2780). Illumina's MCED test developer customers agree. *See, e.g.*, (CCFF ¶ 2785) (Singlera's Gary Gao testifying that "Illumina can jack up the price of reagent or machine . . . and then we will not be able to compete."); (CCFF ¶¶ 2784, 2787). For example, Guardant's Getty testified that the cost of producing a MCED test is "highly indexed" to the cost of sequencing, (CCFF ¶ 3601), and that [redacted] (CCFF ¶ 2782). He explained, "as a public company . . . profitability is critical to our shareholders. And very quickly we would find it very difficult to invest in the R&D necessary or the commercialization necessary to make, you know, improvements and impact patients' lives."[67] (CCFF ¶ 2783).

[67] Illumina has used its upstream position to assert control over its customers pricing structure when it has been vertically integrated in the past. For example, [redacted]

c) Illumina Can Impact Supply

Because Illumina is their sole-source supplier for a critical input, MCED test developers depend on Illumina to provide consistent and quality instruments and reagents in a timely manner during both the development and commercialization of their tests. [redacted] According to Guardant's VP of Commercial, Cancer Screening Core, William Getty, "Guardant wouldn't exist without access to Illumina's products." (CCFF ¶ 1130). {[redacted]} (CCFF ¶ 1129).

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, directly impeding the ability of its customers to operate. Pre-Acquisition, when there was an issue with a customer's purchase or supply, Illumina claimed to "do our best to resolve customer issues quickly." (CCFF ¶ 2857). One way Illumina did this was by making sure that products get to its customers when they want them. (CCFF ¶ 2858). For example, when {[redacted]} (CCFF ¶ 2858). As Conroy testified, {[redacted]} (CCFF ¶ 2848).

[redacted] (CCFF ¶ 4124).

Issues with supply, however, can and do arise, particularly where Illumina is vertically integrated. In therapy selection, for example, Illumina offers a clinical test called TSO-500, which competes with a therapy selection test from {[redacted]} (CCFF ¶¶ 3755, 3772).

{[redacted]} While supply issues may be a normal part of business, Illumina's MCED test developer customers are concerned that Illumina may create, or resolve, supply issues

in a way that disadvantages them relative to Grail.[68] *See* (CCFF ¶ 2837) {[redacted]}; (CCFF ¶ 4543).

d) Illumina Can Diminish Service and Support

The evidence shows that Illumina's MCED customers regularly rely on Illumina for the assistance, service, and support of their NGS products throughout their customer relationships. *See* (CCFF ¶¶ 2805-2809, 2829-2917; 2955-2977). This includes installation of the equipment, training on using the machines, routine maintenance of the machines, equipment repairs, technical support, and assistance upgrading to new technology. (CCFF ¶¶ 2805-06, 2860-69, 2887). As Exact's CEO, Kevin Conroy, testified at trial, {[redacted]} (CCFF ¶ 2855). Because Illumina's NGS products are "highly tuned machines," (CCFF ¶ 2878), Illumina's service team offers {[redacted]} (CCFF ¶ 2857). According to Freenome's CEO, Michael Nolan, {[redacted]} (CCFF ¶ 2882). Exact's Conroy echoes this, testifying that {[redacted]} (CCFF ¶ 2894). And, when

[68] Because supply issues do happen in the ordinary course of business, this makes Illumina's proposed remedy even harder to monitor. *See infra* § II.F.3.iv. 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.

problems do arise, customers need Illumina to fix the issue quickly. (CCFF ¶¶ 2883, 2886). In fact, service and support are so crucial to a customer's business operations, that some Illumina customers even have full-time Illumina service technicians onsite. {[redacted]}

Customers have expressed concerns that any corrosion of this service and support would harm their ability to compete in the development and commercialization of their products. *See, e.g.*, (CCFF ¶¶ 2924, 2927). Pre-Acquisition, when customers had issues with their equipment, Illumina did its "best to resolve customer issues quickly." (CCFF ¶ 2857). For example, when {[redacted]} (CCFF ¶ 2881). Post-Acquisition, however, if a customer's equipment goes down and Illumina does not resolve the issue in a timely manner, {[redacted]} (CCFF ¶ 2927). As Guardant's Getty explained, Illumina could easily say things like "'[w]e can't get a technician out to your sequencers until next Friday' or 'the Friday after,' and that could create challenges around turnaround time and disappoint customers and therefore hurt us competitively." (CCFF ¶ 2919).

e) Illumina Can Delay or Deny Access to New Technology

Illumina also has the ability to delay or deny access to, or advanced knowledge of, its new, improved technology to Grail's rivals. Every few years {[redacted]} Illumina also makes improvements to the consumables that run

with the platform and implements software updates to the underlying technology. (CCFF ¶¶ 2790-93, 2804). These updates may also improve user experience, improve performance, {[redacted]} (CCFF ¶¶ 2790, 2795, 2823). Illumina's customers rely on Illumina for access to this new technology for their tests. (CCFF ¶¶ 2816, 2820, 2823). 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. (CCFF ¶ 2816).

Illumina also can control who has advanced knowledge of its new products. Because new technology can lead to better tests, notice of Illumina's forthcoming developments can give customers a competitive advantage. (CCFF ¶¶ 4598-9, 4605). As Dr. Bert Vogelstein of Johns Hopkins University explained, "advanced knowledge of future product developments and refinements . . . could alter the research and development of new or modified tests for the earlier detection of cancer. For example, if researchers become aware that a new sequencer or product improvements would enable the field to analyze many more genes in one test than it can do now, researchers could use that information to begin developing tests that would be more accurate and, perhaps less expensive, to perform." (CCFF ¶ 4559). Illumina has the power to choose which of its customers have knowledge of its new developments, and which do not. *See, e.g.*, (CCFF ¶¶ 2815, 2820, 2824).

In addition to providing customers notice of or access to its new technology, Illumina also has assisted its customers in switching to its upgraded products. Pre-Acquisition, when customers sought to upgrade their NGS instruments, Illumina would send a technician to get the new instruments "up and running and to assist in troubleshooting matters." (CCFF ¶ 2805). As Illumina's Vice President and General Manager of the Americas, Nicole Berry, testified, Illumina

would "work 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." (CCFF ¶ 2806). According to Christoph Lengauer, former Chief Innovation Officer and Co-Founder of Thrive, {[redacted]} (CCFF ¶ 2887). In addition to technical support, Illumina often would provide the customer with {[redacted].} (CCFF ¶ 2736). {[redacted]} (CCFF ¶ 2736).

Grail's rivals have raised concerns that post-Acquisition, Illumina could impede their access to technology upgrades or hamper their ability to use these new products. (CCFF ¶¶ 2815-16, 2997, 4410). While prior to the Acquisition, Illumina has {[redacted]} (CCFF ¶ 2824), post-Acquisition, Illumina has no reason to do so. {[redacted]} (CCFF ¶ 2997). Guardant's Getty similarly testified that post-Acquisition Illumina could "provide favored status or development opportunities to their internal partners in Grail, which would convey potentially a lack of

opportunity for us to advance our technology at a faster rate, and . . . thus hurt us competitively." (CCFF ¶ 3610). And these concerns are not merely hypothetical. In discussing Illumina's product upgrades, Illumina's Chief Commercial Officer, Susan Tousi, {[redacted]} (CCFF ¶ 2825).

f) Illumina Can Develop Products Specifically for Grail

In addition to delaying or denying access to new technology to Grail's rivals, Illumina also has the ability to develop or design products specifically for Grail, disadvantaging other MCED test developers in the innovation race. Although Illumina's CEO told the Court at trial that Illumina cannot, and will not, make improvements to technology specifically geared toward Grail, (CCFF ¶ 2826), this is simply untrue. The trial record, instead, shows that when Grail is part of Illumina (as it was when it was initially founded and now, post-Acquisition), Illumina customizes products for Grail in a way that it does not do for "external" customers. For example, when Illumina first formed Grail, it noted that "Illumina understands the sequencer better than anyone since they developed it and can in partnership with [Grail] optimize i[t] for ctDNA applications (e.g., improved error profile). This means that [Grail] can get better performance than someone who has to use the off the shelf version." (CCFF ¶ 2986). Once Grail was formed, Illumina lived up to its plans, {[redacted]} (CCFF ¶¶ 2827, 2987, 3704-08). This included collaborating on consumables "built specifically for Grail" that could improve Grail's results and accommodate Grail's high-throughput sequencing needs. (CCFF ¶¶ 3704-08). When Illumina later discussed

spinning off Grail as an independent entity, it noted that the spin off "will result in Illumina functioning as a supplier compared to a product development partner." (CCFF ¶ 66). Specifically, Illumina noted that, as an independent company, Grail would move from a collaborator in assay development and software and data analysis to merely a customer. (CCFF ¶¶ 64-66). To Illumina, this meant that Illumina and Grail were "no longer collaborating on developing of [library prep] and sequencing kits." (CCFF ¶ 66); *see also* (CCFF ¶ 3742). It follows then, as an Illumina executive confirmed, that once Grail was no longer under Illumina's ownership, {[redacted]} (CCFF ¶ 68). In addition, Illumina commonly customizes its library preparation products for its customers. As Illumina's Vice President and General Manager of the Americas, Nicole Berry, admitted, Illumina designs and sells library prep products "specific to a customer's request." (CCFF ¶ 2613).[69] Now that Illumina once again owns Grail, there is no reason that Illumina cannot design products specifically to benefit Grail at the expense of other customers.

g) 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 once commercialized.[70] 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. (CCFF ¶¶ 2946, 2956). Once MCED tests become more widely accepted and used, it will likely be important for MCED test

[69] Library preparation products are not addressed in the Open Offer. (CCFF ¶¶ 4551-53). {[redacted]} (CCFF ¶ 4554).

[70] 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* (CCFF ¶ 2945).

developers to offer distributed IVD tests to customers. (CCFF ¶¶ 2948-49, 2951-52). Because they allow samples to be processed locally, distributed IVD tests improve turnaround time for test results and alleviate capacity constraints at test developers' centralized labs, which will likely be critical for test developers as MCED tests become routinely used in the market. (CCFF ¶ 2954).

FDA approval for a distributed IVD test requires close cooperation from Illumina, typically in the form of an IVD partnership agreement (or "IVD rights").[71] (CCFF ¶¶ 2958-60, 2965, 2972, 2977). {[redacted]} (CCFF ¶ 2845). This means that a company {[redacted]} (CCFF ¶ 2970). Because Illumina decides with whom it will enter into IVD agreements, Illumina dictates which tests can obtain approval as a distributed IVD and only accepts customer proposals that make financial sense to Illumina. (CCFF ¶ 2985). Thus, post-Acquisition, Illumina can restrict Grail's rivals from offering distributed tests by denying them IVD rights or charging excessive fees.[72]

[71] 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. (CCFF ¶ 3994). [redacted] (CCFF ¶ 4010). PGDx's pharmaceutical customers said that "they would not consider a companion diagnostic program with [PGDx] without an IVD co-development agreement," and prospective investors told PGDx "that they would not make an investment without [PGDx] having the IVD co-development agreement with Illumina." (CCFF ¶¶ 4031-32). As Illumina noted in an internal presentation to Illumina's CEO, [redacted] (CCFF ¶ 3779).

[72] While Illumina's Open Offer provides standardized IVD partnership agreements, these agreements require similar substantial payments that {[redacted]} *See* (CCFF ¶¶ 3952-53). Specifically, the standardized IVD partnership agreement in the

In the past, a vertically integrated Illumina has denied IVD rights or charged substantial fees to certain customers to protect its own competitive position downstream. As Illumina's former VP of Business Development, John Leite, testified at trial, when negotiating IVD agreements with customers, Illumina considered whether its customers' tests would compete with Illumina's own tests, such as its TSO-500 therapy selection test. (CCFF ¶ 3800). With respect to IVD agreements with therapy selection competitors, Leite testified that "the ability to maximize penetration into the oncology market was always a consideration. . . . We considered a term called 'cannibalization'—in other words, what would be the sales of Illumina TSO-500 in the absence of these partners versus the presence of these partner—to try to decide at least a framework for summing up what the value of that partnership should be." (CCFF ¶ 3808). This is supported by Illumina's internal documents. As Leite explained in an email, {[redacted]} (CCFF ¶ 3804). In addition, in a presentation on strategic partnerships, Leite explained that in order to {[redacted]} (CCFF ¶ 3892). This means that Illumina will {[redacted]

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. (CCFF ¶ 3953).

[redacted]

[redacted].

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

[redacted]

[redacted]

[redacted]

[redacted]

(CCFF ¶ 3857). As Leite testified at trial, there was {[redacted]} (CCFF ¶ 3906). {[redacted]} (CCFF ¶ 3957). According to Leite, Illumina required these up-front payments and other fees because "there was a potential for downside risk that we needed to offset through some financial consideration." (CCFF ¶ 3958). Illumina also initially rejected PGDx's request for IVD rights for its own therapy selection test because Illumina thought it would "devalue our competitive position significantly." (CCFF ¶ 3996).[73] Similarly, {[redacted]} (CCFF ¶ 4138).

Withholding of IVD rights can impact innovation. {[redacted]}

[73] [redacted] (CCFF ¶ 4003).

[redacted] } (CCFF ¶ 2969). 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 [PGDx] without an IVD co-development agreement," and prospective investors told PGDx "that they would not make an investment without [PGDx] having the IVD co-development agreement with Illumina." (CCFF ¶¶ 4032-33). Reduced investment impaired PGDx's ability to fund its research and development projects. (CCFF ¶ 4034).

b. Illumina Has a Strong Incentive to Harm Grail's Rivals at Both the Development and Commercialization Stages

While "it is the power [to harm competitors] that counts, not its exercise," *Union Carbide,* 1961 WL 65409, at *19 (Lipscomb, A.L.J.), courts may examine a merged firm's incentives to foreclose the relevant market when considering whether there is the potential for competitive harm. *See, e.g.*, *Ford Motor*, 405 U.S. at 568-71 (Because Ford "made the acquisition in order to obtain a foothold" in the aftermarket spark plug market, "it would have every incentive to . . . maintain the virtually insurmountable barriers to entry" in that market through foreclosure.); *AT&T*, 310 F. Supp. 3d at 243-45 (D.D.C.) (analyzing whether AT&T had the ability and incentive to foreclose or restrict rival video programming distributors' access to Time Warner content). As the trial record demonstrates, the Acquisition fundamentally alters Illumina's incentives towards its MCED test developer customers, giving Illumina ample motivation to exercise its power to disadvantage Grail's rivals both prior to their launch and post-commercialization.

i. *The Expected Size and Profitability of the MCED Test Market Dwarfs the Size and Profitability of Illumina's Continued NGS Sales*

While Illumina's CEO, Francis deSouza, testified to this Court that Illumina's "core business is to sell sequencers and consumables. That's how we make the vast majority of our revenue," (CCFF ¶ 3111), his statements ignore {[redacted]} In its 2021-2025 Strategic Plan, {[redacted]} (CCFF ¶ 3120). {[redacted]} *See* (CCFF ¶ 3121). And deSouza told investors that the "early detection of cancer segment is the largest segment in the clinical market we can see for the next decade."[74] (CCFF ¶ 3137); *see also* (CCFF ¶ 3115) {[redacted]}; (CCFF ¶¶ 3112, 3119). Illumina {[redacted]} will only reap the benefits promised to shareholders by ensuring that its Grail business is as profitable as it had forecasted.

Illumina's own ordinary course documents detail its {[redacted]} In presentations to its Board, Illumina estimated that the market for NGS-based oncology testing was expected to {[redacted]}

[74] {[redacted]} For example, Guardant estimated a market size exceeding $50 billion, {[redacted]} *See* (CCFF ¶¶ 485, 487, 489, 3143).

[redacted]}[75] (CCFF ¶¶ 478, 483, 3123). According to Illumina, clinical testing services, which include Grail's offerings, would become the {[redacted]} (CCFF ¶ 3125); *see also* (CCFF ¶ 3109). {[redacted]}[76] (CCFF ¶ 3122). As Illumina explained to its Board, {[redacted]} (CCFF ¶ 3109).

Beyond just revenue, Illumina recognized that net margins would {[redacted]} (CCFF ¶ 3129). {

[75] {[redacted]} *See* (CCFF ¶ 3115).

[76] Other industry participants estimate a similarly sized MCED Test Market. For example, Guardant's VP of Commercial, Cancer Screening Core, William Getty, projects that, on the low end, the MCED Test Market will reach $50 billion. (CCFF ¶ 3145); *see also* {[redacted]} (CCFF ¶ 3147) (Singlera's Gao estimating that the global market for early-stage cancer screening will exceed $100 billion). As 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." (CCFF ¶ 3154).

[redacted]

Thus, Illumina's own analyses show that it can earn {[redacted]} Given this expansive opportunity, Illumina expects Grail to be the {[redacted]} (CCFF ¶ 3130). As Grail is already the first commercialized MCED test, Illumina has a strong incentive to protect Galleri's leading position in this lucrative emerging market. Given the disparity in {[redacted]} a combined firm thus has the financial incentive to protect Galleri's sales by foreclosing MCED test rivals, even if it means sacrificing some NGS sales to those rivals. *See* (CCFF ¶¶ 3174-88).

Grail's MCED Test rivals recognize that Illumina's incentives will shift post-Acquisition, given the lucrative market opportunity in cancer screening tests. As Guardant's VP of Commercial, Cancer Screening Core, William Getty, testified:

> [I]n the future, if they have access to this massive market, and that market is now, let's say, a $50 billion opportunity, and Grail can become a $25-billion-a-year company based on that other screening market, well, guess what, {[redacted]} so why would you want to keep us happy at the same time and also have a competitor that splits that $50 billion by another, you know, third or half. It just, you know, it—it is completely in their best interest that we are not around.
>
> (CCFF ¶ 3153).

Thrive's VP of Business Development, Josephine Harada, {[redacted]} (CCFF ¶ 4183). Likewise, Singlera's Co-Founder and Scientific Advisor, Dr. Gary Gao, testified that Illumina has an "inherent conflict of interest" when it comes to Grail. Whereas prior to the Acquisition, Illumina would want every company to succeed "so they can supply the machine and reagent," post-Acquisition Illumina is incentivized to "have GRAIL succeed" and "other compan[ies] slow down. There's no incentive for Illumina to support other people other than GRAIL." (CCFF ¶ 4177). And Dave Daly, former CEO of Thrive and former SVP and General Manager of the Americas at Illumina, testified that {[redacted]} (CCFF ¶ 5003). For this reason, when Illumina decided to spin off Grail, {[redacted]} (CCFF ¶ 6151). According to Daly, {[redacted]}

[redacted]} (CCFF ¶ 3173). Even Grail understands that its competitors are rightfully afraid of their ability to compete post-Acquisition. As one Grail executive told his colleagues when the Acquisition was announced, "Thrive['s] SVP is now freaking out on me and wanting info [about the Acquisition]. Obviously they feel this is not good for them. Which is entertaining." (CCFF ¶ 3149).

This Court need not find that the changed incentives are the result of any nefarious conduct by Illumina, but instead, that they are a natural consequence of a profit-maximizing firm acting in the best interest of its investors. As deSouza testified, Illumina owes a fiduciary duty to its shareholders, which requires Illumina to try to increase the value of its company, including trying to increase the company's revenue. (CCFF ¶ 6086). When acquiring Grail, deSouza told Illumina's investors that the Acquisition will create more value to Illumina's shareholders than simply selling instruments and reagents to Grail. (CCFF ¶ 3094). The best way to provide this value is to ensure Grail's success in the MCED Test Market, even at the expense of Illumina's other customers. As Guardant's VP of Commercial, Cancer Screening Core, William Getty, explained, if you own a competitor in a certain market, "you have all the incentive in the world to optimize their information ahead of their competitive set" because "you likely have significant financial ties associated with that competitive advantage." (CCFF ¶ 4187). Illumina's financial future is tied up with Grail, so ensuring Illumina's success depends heavily on ensuring the success of Grail.

ii. *Illumina Will Benefit from Lost Sales or Diminished Performance of Grail's Rivals*

Given the immense potential profitability of the MCED Test Market, Illumina has the incentive to harm Grail's rivals as soon as they pose a threat to Grail's market position. Evidence

shows that Illumina recognizes that a {[redacted]} (CCFF ¶ 3522), and that more commercialization threatens Grail's market share. (CCFF ¶¶ 3391, 3451, 3496). As Grail is the only MCED test commercially available on the market today, any new or better MCED test that launches will necessarily take sales from Grail, and {[redacted]} *See* (CCFF ¶ 3099). Due to the high diversion from competing MCED tests to Grail's Galleri test, Illumina stands to profit from derailing Grail's rivals in both their development and commercialization efforts. While foreclosing or disadvantaging MCED Test rivals may result in fewer NGS sales for Illumina, the lost profits from such a foreclosure strategy are more than made up for in MCED test sales that will be recouped by Galleri. *See* (CCFF ¶¶ 3174-3188).

First, Illumina has the incentive to harm Grail's rivals immediately as they compete against Grail to develop the best-quality MCED test. Although Grail was the first MCED test developer to launch its test, Grail and its rivals are competing today in an innovation race to develop the best quality MCED test for patients. *See* (CCFF ¶¶ 3639-68); *see also infra* § II.E.3.a. Specifically, MCED test developers are currently competing head-to-head in test performance, test features, clinical trials, and other research and development activities. *See, e.g.*, (CCFF ¶¶ 3214, 3265, 3368). {[redacted]}

[redacted]

Like its rivals, Grail has also been spurred to innovate due to existing competitive pressures from other MCED test developers. During the development of its MCED test, Grail formed a competitive intelligence team, known as its "CIA team" [redacted] (CCFF ¶¶ 3427-28, 3434); *see also* (CCFF ¶¶ 3435-36, 3438, 3444). This team had the objective to [redacted] (CCFF ¶ 3404). In one presentation, Grail's CIA team strategized to [redacted] (CCFF ¶ 3422); *see also* [redacted] In another document, Grail stated that most of its [redacted]

[redacted] **(CCFF ¶ 3453).** Grail also closely monitors its competitors' [redacted] (CCFF ¶ 3271).

While Grail currently has a 100 percent share of the MCED Test Market, a better-quality test could allow a competitor to leapfrog existing competition and take market share from Grail or other MCED Test rivals. *See* [redacted] In fact, test performance will be a critical factor in how physicians ultimately choose between MCED tests. [redacted] Respondents' own expert, Dr. Richard Abrams, admits that he is "not the least bit reticent to make a change if a new test is superior to the existing [test]."[77] (CCFF ¶ 3515). According to Abrams, [redacted] (CCFF ¶ 3513). Illumina SVP of Corporate Development and Strategic Planning, Joydeep Goswami, agreed, testifying that [redacted] (CCFF ¶ 3522). Thus, to prevent rivals from surpassing Grail on quality and leading more customers to choose the better-quality test, the combined firm has the incentive to stifle research and development prior to commercialization.

[77] [redacted]

Second, as the vigorous innovation competition taking place today evolves into commercial competition, Illumina also has the incentive to harm Grail's rivals as they launch and sell their tests, leading to higher prices, less choice, and diminished performance for patients. Ultimately, the extent of Illumina's incentive to foreclose or disadvantage MCED Test rivals will depend, in part, on the degree of diversion between any foreclosed rival and Grail**.** {[redacted]} Although Respondents want this Court to believe that Grail will be unique and have no substitutes, evidence shows that Grail's Galleri test will be a close substitute for other MCED tests post-launch, resulting in high diversion between Galleri and its rivals. *See* (CCFF ¶¶ 3207-08, 3364). First, as noted *supra,* evidence reveals a high degree of similarity between Galleri and other MCED tests in terms of how they function, *see* (CCFF ¶¶ 3236, 3346); the types of cancers detected, (CCFF ¶¶ 2050, 2380, 2423); the target patient population and expected customers, (CCFF ¶¶ 705-717); and target accuracy. (CCFF ¶¶ 3236, 3334). While Grail claims that its Galleri test can detect more than 50 types of cancer, in fact Galleri has been shown to detect only *seven* types of Stage I-III cancers in asymptomatic patients. (CCFF ¶¶ 6288, 6298). Grail's rivals can detect many of these seven cancers in their own tests, in addition to several more.[78] (CCFF ¶¶ 2050, 2380, 2423). As Dr. Lengauer of Thrive testified at trial, there is {[redacted]} (CCFF ¶¶ 3207-08). Second, every MCED Test rival {[redacted]} (CCFF ¶¶ 703, 3211-12, 3219, 3290, 3292, 3316, 3333, [redacted], 3367,

[78] While some other MCED test developers initially will detect fewer cancers, their tests focus on the most prevalent cancers. For example, {[redacted]}

[redacted] } Likewise, { [redacted] } Third, Grail itself has identified { [redacted] } For example, Grail assembled a { [redacted] } (CCFF ¶ 3253); *see also* (CCFF ¶¶ 3250-84).

Given the significant overlap, once another MCED test launches, { [redacted] } physicians will likely choose one MCED test among the available options in the market. (CCFF ¶¶ 3508-11). As Respondents' expert Dr. Richard Abrams, who himself is a primary care physician, testified at trial, he expects to order no more than one MCED test per patient. (CCFF ¶¶ 3511). For example, Dr. Abrams explained, he does not expect to order both Grail's Galleri and Exact's CancerSEEK simultaneously for patients, (CCFF ¶ 3511), instead choosing the { [redacted] } (CCFF ¶ 3512). { [redacted] }

And other MCED test developers think the same. (CCFF ¶¶ 3508, 3510). Grail itself {[redacted]} and raising concerns that when "Thrive (and future other competitors) get closer to launch, they will use tactics to sell against Grail." (CCFF ¶ 3456). Specifically, Grail noted that {[redacted]} (CCFF ¶ 3439). Accordingly, evidence shows that {[redacted]} (CCFF ¶ 3099), and thus Illumina has the incentive to use its tools to ensure that its customers do not enter or else lose sales post-launch.

Any harm to Grail's rivals will have little effect on Illumina's overall platform sales, further solidifying Illumina's changed incentives. First, because MCED test developers have no alternatives to Illumina, *see supra* § II.D.2, any MCED test developer that remains in the market post-Acquisition will continue purchasing Illumina's platforms. Second, although foreclosing or otherwise disadvantaging Grail's rivals could lead those customers to have less success in the MCED Test Market or leave the market altogether, in turn decreasing their purchases of Illumina's NGS platforms, evidence shows that any impact to Illumina would be minimal. In a discussion with investors about the Grail Acquisition, Illumina's CEO, Francis deSouza, acknowledged that MCED customers account for "roughly 2% of [Illumina's] total revenue" and was aware of "maybe 20 out of [its] 6,600 customers who are targeting a commercial screening test." (CCFF ¶ 3140).[79] In other words, even if all of Illumina's impacted MCED test developer customers exited

[79] deSouza admitted at trial that these customers include the very customers concerned about the Acquisition—Guardant, Roche, Freenome, Singlera, and Exact. (CCFF ¶ 3472).

the MCED Test Market, Illumina's lost sales to these customers would not alter its post-Acquisition incentives.

iii. *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 financial incentives that will result from Illumina's acquisition of Grail. The most relevant example is when Illumina wholly owned Grail, before spinning it off to outside investors in 2017. Illumina formed Grail in 2015 to {[redacted]} (CCFF ¶ 606). Illumina recognized that, through its dominant position in NGS platforms, it had "the technology and cost structure to do [asymptomatic cancer screening] years before anyone else." (CCFF ¶ 3686). By forming Grail, Illumina could "capitalize on [the] screening market years earlier AND own a substantial portion of the value created." (CCFF ¶ 34). To ensure it could capture the bulk of that market, Illumina planned to provide Grail with "[s]pecial [p]ricing," a 75 percent discount that would save Grail $100 million over three years. (CCFF ¶ 5635). Additionally, Illumina would grant Grail "[l]imited [e]xclusivity in the field of blood based cancer screening," whereby Illumina would "not launch, invest in, or provide special discounts to competitive business[es]." (CCFF ¶ 3698). Because Illumina had existing customers developing oncology tests, Illumina was concerned that its ownership and exclusive partnership with Grail would create conflict with its customers. (CCFF ¶ 3695). Before deciding whether to partner exclusively with Grail rather than act as an equal supplier to all potential MCED test developers, Illumina explicitly modeled how much revenue it would lose because "others (FMI, Natera, Guardant, etc.) would have purchased

instruments and reagents to go after the same opportunity had we not partnered exclusively with Python [Grail]." (CCFF ¶ 3695). Ultimately, in {[redacted]} 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. (CCFF ¶¶ 40, 51, 3712). {[redacted]} After giving up its majority interest in Grail, Illumina terminated Grail's exclusivity and "[s]pecial [p]ricing." (CCFF ¶¶ 3729, 5635); *see also* (CCFF ¶ 3734). Illumina also began operating at arm's length to Grail and transitioned from treating Grail as a "collaborator" to a "customer." (CCFF ¶¶ 64, 3737, 3741). In draft talking points explaining its decision to divest its interest in Grail, Illumina noted that it had "leveled the playing field" and that "[divesting Illumina's interest in Grail] will accelerate the liquid biopsy market for all." (CCFF ¶¶ 3735, 3743).

Further, Illumina's past negotiations for IVD rights with {[redacted]} for competing downstream therapy selection tests highlight how Illumina's financial incentives change when it vertically integrates into a market where it competes with its existing customers, and how it acts on those incentives to limit the competition it faces. As discussed *supra*, § II.E.1.a.ii.g, {[redacted]}

[redacted]

While Illumina's past behavior when vertically integrated illustrates that Illumina will act in accordance with its economic incentives—just as the evidence similarly demonstrates in this case—there is also evidence that Illumina's incentive to harm its competing customers is even more heightened here. As deSouza told investors, "the early detection cancer market dwarfs the clinical markets we see today, NIPT and therapy selection for oncology combined." (CCFF ¶

3138). Thus, no matter Illumina's behavior towards its customers that it also competed with in the therapy selection market, its incentives to promote Grail's success to the detriment of its other customers are much higher here. Further, as discussed *supra*, even in the dwarfed markets of NIPT and therapy selection, Illumina engaged in actions to stifle its customers that directly threatened its own market position. Although Respondents claim that Illumina's "long-standing and core strategy is to catalyze development and expansion of sequencing," Answer at 7, now that Illumina is vertically integrated, 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. *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").

2. The *Brown Shoe* Vertical Merger Framework Supports a *Prima Facie* Case of Competitive Harm

While the record is clear that the Acquisition raises a reasonable probability of competitive harm due to the merged firm's unbridled ability and incentive to disadvantage participants in the relevant market post-Acquisition, Complaint Counsel's *prima facie* case is further bolstered by additional factors recognized by vertical merger precedent.

As the Supreme Court explained in *Brown Shoe*, "[i]f the share of the market foreclosed is so large that it approaches monopoly proportions, the Clayton Act will, of course, have been violated." 370 U.S. at 328-29; *see also American Cyanamid*, 719 F.2d at 566; *Fruehauf,* 603 F.2d

at 352; *Zinc Antitrust Litig.,* 2016 WL 3167192. Given the MCED Test Market's exclusive reliance on Illumina, the Acquisition gives Illumina the power to foreclose or otherwise disadvantage the entirety of market participants from an essential input, harming the vibrant innovation competition today and the head-to-head commercial competition tomorrow. Such foreclosure is exactly the type of competitive harm Section 7 has sought to prevent. *See* H.R. Rep. No. 81-1191, at 11 (1949); *Brown Shoe*, 370 U.S. at 312-13, 328-39; *Kennecott Copper*, 231 F. Supp. at 105 ("The fundamental purpose of Section 7 of the Clayton Act is to halt just such increasing concentration.").

As discussed *supra*, MCED test developers have no alternatives to Illumina. *See supra* § II.D. As such, each and every Grail rival testified that they are beholden to Illumina. *See* (CCFF ¶ 1191) {[redacted]}; (CCFF ¶ 2843) ("Illumina is a sole supplier for [Guardant] and our business rests on our ability to sequence and leverage [Illumina's] services in order to maintain those sequencers"); (CCFF ¶ 2974) {[redacted]}; (CCFF ¶ 4487) {[redacted]}; (CCFF ¶¶ 928, 951, 1102-3, 1165, 1185). As Singlera's Co-Founder and Scientific Advisor Gary Gao testified, Illumina is "obviously the 800-pound gorilla in the room. . . . Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies, too." (CCFF ¶ 2849). Guardant's VP of Commercial, Cancer Screening Core, William Getty, explained, {[redacted]} (CCFF ¶ 2968); *see*

also (CCFF ¶ 4490) (testifying that "the Illumina logo could be placed on the [Guardant] lab," it is so omnipresent).[80] Illumina is "in a position where they could take significant advantage by kneecapping [Guardant's] ability to run our lab, which would of course flow through to our inability to compete." (CCFF ¶ 2844). Even Grail admitted that {[redacted]}, (CCFF ¶ 1062), further noting to investors that "an alternative supplier for Illumina . . . may not be available at all." (CCFF ¶ 1083). Given Illumina's position as the only viable provider of NGS platforms for the MCED Test Market, case law makes clear that Illumina has the ability to foreclose the market and, thus, deems mergers such as this one harmful. *See Brown Shoe*, 370 U.S. at 328-29; *see also American Cyanamid*, 719 F.2d at 566; *Fruehauf*, 603 F.2d at 352.

Although today Illumina is the only supplier of NGS platforms to Grail and its rivals, the Clayton Act does not require that there be complete foreclosure to run afoul of antitrust laws. *See Brown Shoe*, 370 U.S. at 323 n.39 (citing S. Rep. No. 81-1775, at 4298 (1950)) (explaining that the goal of Section 7 is "to arrest restraints of trade in their incipiency and before they develop into full-fledged restrains violative of the Sherman Act."); *see also id.* at 328-29 ("[T]he tests for measuring the legality of any particular economic arrangement under the Clayton Act are to be less stringent than those used in applying the Sherman Act."). Additionally, even if this Court were to find that Illumina's dominance as an NGS platform provider, alone, is insufficient to

[80] Illumina's market power is evident in its negotiations with customers. As MCED test developers testified, Illumina can dictate the terms of its customer agreements. For example, Guardant's Getty explained that Guardant has "[v]ery little" leverage in negotiating with Illumina. (CCFF ¶ 1139). "[W]hatever terms, conditions, and pricing they want to put forward, they can do so. And they can use their monopoly power in order to . . . drive to whatever conclusion they'd like." (CCFF ¶ 2715); *see also* (CCFF ¶ 2719) (Singlera's Gao testifying "[t]heir way is my way or the highway. If you gave me that profit margin, well, I'm—you know, I can allow you to survive. If not, you just die."). {[redacted]} (CCFF ¶ 2718).

establish the Government's *prima facie* case, an analysis of the other factors in the *Brown Shoe* framework demonstrate that the Acquisition is likely to result in competitive harm.

First, the Supreme Court recognized that "the very nature and purpose of the arrangement" was a factor to examine to determine the legality of a vertical merger. *Brown Shoe*, 370 U.S. at 329; *see also U.S. Steel*, 426 F.2d at 599; *Fruehauf*, 603 F.2d at 353. For example, in *Ford Motor Co. v. United States*, the Supreme Court held that Ford "made the acquisition in order to obtain a foothold in the aftermarket" spark plug market and "[o]nce [Ford] established [a foothold], it would have every incentive to . . . maintain the virtually insurmountable barriers to entry" in that market by foreclosing manufacturers from selling to Ford. 405 U.S. at 568-71. As discussed *supra*, *see* § II.E.1.b, {[redacted]} (CCFF ¶ 208). {[redacted]} (CCFF ¶ 3121); *see also supra* § II.E.1.b.i. {[redacted]} (CCFF ¶ 3120). {[redacted]} (CCFF ¶ 211). As the plain language of Illumina's own statements makes clear, Illumina acquired Grail to fundamentally transform its business into the more profitable clinical testing space; once the Acquisition gives Illumina a foothold into the MCED Test Market, as in *Ford*, Illumina has every incentive to ensure its investment is successful to the detriment of Grail's competitors.

Second, courts have held that the creation or increase of entry barriers can militate in favor of prohibiting a vertical merger. *See U.S. Steel*, 426 F.2d at 605; *Ford Motor*, 405 U.S. at 568-71. As the court explained in *U.S. Steel Corp. v. FTC*, such barriers can include "possible reliance on suppliers from a vertically integrated firm with whom [a new entrant in the relevant market] is also competing" and "the psychological 'fears' of smaller rivals competing with large integrated concerns." 426 F.2d at 605 (citing *Procter & Gamble*, 386 U.S. at 578). Here, the Acquisition has increased barriers to entry in the MCED Test Market because, in order to offer a viable product, MCED test developers must rely on Illumina's supply of NGS instruments and reagents, *see supra* § II.D, while now also competing against it in the MCED Test Market. *See, e.g.*, (CCFF ¶ 4272) [redacted][81] Because developing and launching an MCED test requires hundreds of millions of dollars in investment and years of research and development, (CCFF ¶¶ [redacted], 3582, 3587), this vertical integration of a key supplier and rival has caused MCED test developers to reevaluate their appetites to innovate and compete. (CCFF ¶¶ 3607, 3609, 3620-23). [redacted]

[81] [redacted] (CCFF ¶ 3103).

[redacted]}[82] (CCFF ¶ 3621). Illumina's former CEO and Executive Chairman Jay Flatley shared {[redacted]} concerns when Illumina initially formed Grail, noting that its customers might not want to participate in markets where Illumina has a presence, in part "because they'd believe that Illumina could always underprice them if we wanted to." (CCFF ¶ 58). {[redacted]} Clearly here, as is recognized in past vertical cases, the "presence of such a large industrial factor" can affect smaller rivals in the relevant market. *See U.S. Steel*, 426 F.2d at 604 (citing *Procter & Gamble*, 386 U.S. at 578). As explained in *Procter & Gamble*, "[t]here is every reason to assume that the smaller firms would become more cautious in competing due to their fear of retaliation by" the large dominant firm, 386 U.S. at 578, such that "the ability [of] non-integrated [firms] (to compete) may be substantially impaired." *U.S. Steel*, 426 F.2d at 604. To avoid the risk of reliance on a competitor, potential MCED test developers would either have to enter with their own vertically integrated NGS platform, an extremely expensive and difficult feat, *see infra* § II.F.1.a, or partner with a non-Illumina NGS platform capable of running MCED tests, an option that does not exist, *see supra* § II.D.2; *infra* § II.F.1. Furthermore, even if Illumina were hypothetically to continue to supply a subset of the MCED Test Market—those tests that did not pose a significant threat to Grail—"[t]he fact that entry has occurred does not necessarily

[82] Similar to the therapy selection space, Illumina's NIPT competitors allege that Illumina's behavior towards them changed when Illumina acquired Verinata and became vertically integrated in NIPT. [redacted]

preclude the existence of 'significant' entry barriers." *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1440 (9th Cir. 1995). In sum, analysis of these different factors in the Supreme Court's *Brown Shoe* framework leads to the same conclusion as an ability and incentive analysis: the Acquisition is likely to result in anticompetitive harm, harming innovation and ultimately impacting the ability of patients to obtain effective access to this life-saving technology.

3. The Acquisition Will Harm Innovation and Commercial Competition

As the evidence makes clear, Illumina's dominance as the only provider of NGS platforms to MCED test developers, along with the vast profits Illumina stands to gain through Grail's MCED test sales, gives Illumina the ability and incentive to stifle innovation and commercialization in the MCED Test Market. Today, Grail and its rivals are currently competing in the research and development of their MCED tests and soon will compete head-to-head in the sale of MCED tests. To reap the maximum value of its significant investment in Grail, as it has the fiduciary duty to do, Illumina can use its many tools to suppress its customers' innovation efforts that threaten Grail's dominance in the MCED Test Market. And, as more MCED tests near launch, Illumina can impair Grail's rivals to thwart their potential commercial success. While Illumina may be acting as a rational, profit-maximizing firm post-Acquisition, its actions will harm the vibrant innovation competition happening today and the head-to-head commercial competition poised to commence in the near future. This harm will ultimately lead to decreased quality and choice for Americans.

a. *The Acquisition Will Harm Innovation in the MCED Test Market*

Anticompetitive harm under Section 7 includes harm to innovation. *See Otto Bock*, 2019 WL 5957363, at *2 (finding that the acquisition "is likely to cause future anticompetitive effects

in the form of higher prices and less innovation"); Initial Decision, *Altria*, Docket No. 9393, at 97, 99-100 (analyzing harm to innovation competition, along with price and shelf space competition, as a potential effect of the investment agreement between the parties); *In re Polypore Int'l, Inc.*, No. 9327, 2010 WL 9434806, at *211 (F.T.C. Mar. 1, 2010) (Chappell, A.L.J.) (finding that in one market "innovation competition has been eliminated post-acquisition"); *In re R.R. Donnelley & Sons Co.*, No. 9243, 1995 WL 17012641, at *73 (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." 916 F.3d at 1045-46 (D.C. Cir.).[83] Respondents' own economic experts agree to as much. *See* (CCFF ¶¶ 3192, 3570).

As discussed *supra*, today MCED test developers are actively and aggressively competing and innovating to develop their products. It is undisputed that MCED test developers have already invested hundreds of millions of dollars and years of development on their MCED tests. *See* Resp. Pretrial Br. at 17; [redacted] Specifically, MCED test developers have spent incredible efforts to improve test performance, add test features, enhance

[83] 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*, 916 F.3d at 1045-46 (D.C. Cir.) (citing *Ford Motor*, 405 U.S. 562 (1972)).

the patient experience, and reduce costs in response to competitive threats from rivals.[84] *See, e.g.*, (CCFF ¶ 1969) ({ }); *see also* (CCFF ¶ 3644, 3661-62, 3665). This 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 they have a disease" when they do not. (CCFF ¶ 2328). When Illumina initially spun off Grail as an independent entity, it informed investors that it did so "to encourage investment into many different NGS-based companies focused on early cancer detection to have as many shots on goal as possible." (CCFF ¶ 3086). 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."[85] (CCFF ¶ 3652). Respondents' own experts agree. Dr. Richard Abrams testified, "if there are multiple laboratories and companies developing better and better products, that would be a great advantage to me as a physician and, most importantly, to my patients." (CCFF ¶ 3575). Likewise, Dr. Katz testified, if innovation is "stifled," "that would be in my view a bad thing." (CCFF ¶ 3570). Even Grail's former CEO, Hans Bishop, testified that

[84] For example, } (CCFF ¶ 3590). Singlera is working to "reduce cost, improve accuracy, and improve convenience" of its test. (CCFF ¶ 3661). { } *See* (CCFF ¶¶ 413, 3453).

[85] 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." (CCFF ¶ 3574).

"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." (CCFF ¶ 3520).

Without innovation competition in this vibrant and evolving market, customers will be harmed. As discussed *supra*, Illumina will benefit from diminished innovation from Grail's rivals as it will eliminate the threat of a better-quality MCED test leapfrogging Grail's market position. *See* § II.E.1.b.ii. Thus, post-Acquisition, patients may be stuck with the status quo of Grail's Galleri test, without competitors spurring Grail to make improvements or offering their own alternative tests. While the Respondents appear to argue that the performance and capabilities of Grail's Galleri test far surpass its rivals, the evidence shows otherwise. Despite Grail's marketing claims that Galleri can detect 50 cancers, Galleri has been clinically shown to detect only seven types of Stage I through Stage III cancers in asymptomatic patients. (CCFF ¶¶ 6288, 6298). For some cancers that Galleri purports to detect, Grail reports extremely low levels of sensitivity, meaning high false-negative rates. (CCFF ¶¶ 6255-58). For example, Grail's clinical study showed that Galleri had a sensitivity of 27.5 percent in detecting cancer in patients previously diagnosed with Stage I and Stage II cancers, meaning that Galleri failed to detect a cancer signal in 72.5 percent of individuals who had early-stage cancer. (CCFF ¶¶ 6257-58). And for specific cancers that Galleri purports to detect, the sensitivities are even worse, including a 5.7 percent sensitivity in detecting Stage I-III prostate cancer, (CCFF ¶ 6371), and a 7.8 percent sensitivity in detecting Stage I-III kidney cancer, (CCFF ¶ 6380). Such low sensitivity gives patients a false sense of security that they are cancer free when they are not, leading these patients to escape diagnoses "until either they become symptomatic or they will be diagnosed with another modality," when the cancer is at more advanced stages. (CCFF ¶¶ 386, 392, 394-95). Absent the

Acquisition, however, some of Grail's rivals are launching tests with higher sensitivities, (CCFF ¶¶ 2022, {[redacted]}), that focus on cancers that Galleri does not. (CCFF ¶¶ 2050, {[redacted]} 2423-4, {[redacted]}). These competitive threats have spurred Grail to make improvements to its own test to "continually enhance the performance and features . . . including seeking ways to improve sensitivity and reduce sequencing costs." (CCFF ¶¶ 411, 413, 3592). As the evidence shows, in order for the ultimate goal of MCED tests to be realized—the ability to detect multiple cancers in patients simultaneously through a simple blood test—innovation competition must be allowed to flourish.

b. *The Acquisition Will Harm Commercial Competition between MCED Tests*

While MCED test developers are competing today in the research and development of their tests, this competition is evolving into commercial competition as MCED test developers prepare to launch their MCED tests.[86] The Acquisition gives Illumina the ability and incentive to harm Grail's rivals as they commercialize, leading to higher prices, decreased choice, and lower performance in the MCED Test Market.

Commercial competition between Grail's Galleri and its MCED Test rivals is imminent. Several of Grail's rivals are on the verge of launching their tests commercially in the next few years, with {[redacted]}

[86] As MCED test developers commercialize their tests, innovation competition will remain vibrant, as MCED test developers plans to continue improving their tests post-launch to better compete in the market. *See, e.g.*, (CCFF ¶¶ 1970-71, {[redacted]} 3662).

[redacted] } (CCFF ¶ 3447).

Moreover, when analyzing the competitive harm to the commercialization of MCED tests, "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,* 240 F. Supp. 3d at 79 (internal citation omitted). As this Court explained in *In re Altria Group, Inc. and Juul Labs, Inc.*, this means looking at whether competition "would have existed in the 'near future,'" where "near" is "defined in terms of the entry barriers and lead time necessary for entry in the particular industry." Initial Decision, *Altria*, Docket No. 9393, at 106, 111-12 (quoting *BOC Int'l, Ltd. v. FTC*, 557 F.2d 24, 29 (2d Cir. 1977)).[87] In the MCED Test Market, launching an MCED test takes years of lead time, *see, e.g.*, Resp. Pretrial Br. at 17; (CCFF ¶¶ [redacted], 2473, 3585), and millions of dollars in investment, *see* (CCFF ¶¶ 2105, 2109-10, [redacted], 2350-51, 2352, 2548), creating high barriers of entry for future competitors. For example, {[redacted] And Grail only launched its MCED test as an LDT "[a]fter more than {[redacted]} million of R&D spend and more than five years of research." Resp. Pretrial Br. at 18. Given the difficulties and time it takes to develop an MCED

[87] Although this Court in *Altria* recognized that "the presence of [a] regulatory scheme and need for approval" may "convert[] what might have been deemed antitrust injury in a free market into only speculative exercise," *see* Initial Decision, *Altria*, Docket No. 9393, at 108, here Grail and its rivals can and are competing even prior to FDA approval of their products. As Respondents explained during trial, Grail launched its Galleri test as an LDT in April 2021, (CCFF ¶ 5480), and several MCED test developers plan to also launch their tests as LDTs in competition with Grail, {[redacted]} While FDA approval is a step towards widespread adoption and reimbursement, any future regulatory stages do not diminish the vibrant and aggressive competition beforehand.

test, Grail's MCED Test rivals are nearing the finish line in the development process, with several launching imminently. *See, e.g.*, {[redacted]}

With the context of this industry in mind, record evidence shows that, absent the Acquisition, Grail and its MCED Test rivals will compete head-to-head commercially in the near future. As explained *supra*, *see* § II.E.1.b.ii, MCED test developers view Grail as their primary competitor in the MCED Test Market and expect to compete directly against Grail on price, performance, and service. (CCFF ¶¶ 698, 798, 806, 2401, 3211, 3219, 3225, 3290, 3292, 3316, 3333, [redacted], 3367, [redacted]). Grail, likewise, views other MCED test developers—{[redacted]} *see* (CCFF ¶¶ 756, 3433-34), and sought to defend against these threats by lowering prices and improving its product and service. In 2020, for example, Grail created an internal presentation entitled {[redacted]}

[redacted] (CCFF ¶ 3348). Moreover, Grail's rivals have altered their own commercial plans in response to competitive pressures from Grail. [redacted]

While the harm to ongoing innovation competition that will result from the Acquisition is itself sufficient to find a violation of Section 7, the harm to commercial competition that Galleri will face in the near future is an independent basis. As the evidence shows, Grail and its rivals expect to compete vigorously on price, service, and performance once on the market. This commercial competition will ultimately lead to lower prices and improved products. (CCFF ¶ 3573). Stifling competition today will diminish quality and choice for patients tomorrow. In other words, [redacted] (CCFF ¶ 3503). This harm isn't abstract. America is engaged in a war against cancer. And the more high-quality choices that patients have, the better armed Americans will be in that war.

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

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

"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 anti-competitive nature of an acquisition." *Chi. Bridge*, 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." *Anthem*, 236 F. Supp. 3d at 222-24 (D.D.C) (examining the "inability of new firms to gain traction" to assess "how difficult it is for new entrants to compete on the same playing field as the merged firm," and dismissing the testimony of Dr. Robert Willig—Respondents' economic expert in this case—who offered mere "breezy assurances" that developing a provider network is "not a big barrier to entry or expansion") (citations omitted). Respondents bear the burden of providing evidence that "ease of entry" rebuts Complaint Counsel's *prima facie* case. *Otto Bock*, 2019 WL 5957363, at *12 (citing *Heinz*, 246 F.3d at 715 n.7); *see also H&R Block*, 833 F. Supp. 2d at 73 (noting that defendants "carry the burden to show" that entry or expansion is sufficient "to fill the competitive void" that would result from the merger) (internal quotations omitted). Here, MCED test developers have no alternative available to Illumina's NGS platform today, and there is little evidence to suggest that new entry of NGS platform providers is likely in the next several years. Moreover, even if new entry occurs, it is highly unlikely that any of the 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 testing are

substantial. And, even if new NGS platforms became available, switching to these platforms due to any foreclosure by Illumina would still cause harm, delaying commercialization, increasing the cost, and reducing quality of MCED tests, risking American lives. Although Respondents identify any company attempting to develop an NGS platform as an entrant, *see* Resp. Pretrial Br. at 4-5, this is simply not the case. To meet their burden, Respondents must show that entry is timely, likely, and sufficient to satisfy the strict requirements for MCED tests, *see supra* § II.D.1; mere entry by an inadequate competitor[88] is not enough.

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 Acquisition. Today, Illumina dominates sales of NGS instruments and reagents in the United States, and it has been difficult for competitors or potential entrants to chip away at Illumina's dominance.[89] (CCFF ¶ 1564). 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]}

[88] For example, if a new NGS platform lacks the throughput or accuracy that MCED tests require, or offers only unnecessary long-read sequencing, such an entrant is insufficient to replace Illumina and counteract the competitive harms here.

[89] Even large, established companies have struggled to successfully develop and commercialize an NGS instrument. {[redacted]}

[redacted]

[redacted]} In addition to time and effort, the monetary investment required to create and commercialize an NGS platform is significant. {[redacted]}

In addition to investing considerable resources in NGS platform development, a prospective NGS entrant must navigate a broad and dense intellectual property landscape. As Jorge Velarde, Senior Vice President of Corporate Development and Business Strategy of NGS platform developer Singular, testified at trial, {[redacted]} (CCFF ¶ 1521). Illumina holds numerous NGS-related patents, which it has used to initiate patent infringement litigation against numerous

potential competitors.[90] (CCFF ¶ 1518). 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. *Illumina, Inc. v. QIAGEN N.V.*, 207 F. Supp. 3d 1081 (N.D. Cal. 2016); *see also* Stipulated Consent J., *Illumina, Inc. v. QIAGEN N.V.*, 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). [redacted]. Illumina also won a permanent injunction against BGI for patent infringement, preventing BGI from selling its sequencers in the United States. *Illumina, Inc. v. BGI Genomics Co., Ltd.*, No. 3:19-cv-03770, slip op., 2022 WL 899421 (N.D. Cal. Mar. 27, 2022). At least one MCED test developer doubts that any new NGS entrant could navigate the NGS IP landscape successfully and maintain freedom to operate. (CCFF ¶ 1522).

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. (CCFF ¶¶ 1583, 1617). Clinical testing, including MCED testing, requires high-throughput, highly accurate NGS platforms. *See supra* § II.D.1. [redacted]

[90] In recent years, Illumina has filed more than a dozen patent suits against competitors, such as NGS entrants, and downstream rivals-customers in the NIPT market. (*See, e.g.*, *Illumina, Inc. v. Guardant Health, Inc.*, No. 1:22-cv-00334 (D. Del. filed Mar. 17, 2022); *Illumina, Inc. v. APExBIO Tech. LLC*, No. 4:21-cv-02611 (S.D. Tex. filed Aug. 11, 2021); *Illumina, Inc. v. BGI Genomics Co., Ltd.*, No. 3:20-cv-01465 (N.D. Cal. filed Feb. 27, 2020); *Illumina, Inc. v. BGI Genomics Co., Ltd.*, No. 3:19-cv-03770 (N.D. Cal. filed June 27, 2019); *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, No. 3:18-cv-02847 (N.D. Cal. filed May 15, 2018); *Illumina, Inc. v. Natera, Inc.*, No. 3:18-cv-01662 (N.D. Cal. filed Mar. 16, 2018); *Illumina, Inc. v. QIAGEN, N.V.*, No. 3:16-cv-02788 (N.D. Cal. filed May 24, 2016); *Illumina, Inc. v. Oxford Nanopore Technologies, Inc.*, No. 3:16-cv-00477 (S.D. Cal. filed Feb. 23, 2016); *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, No. 3:15-cv-02216 (N.D. Cal. filed May 18, 2015); *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, No. 3:14-cv-01921 (N.D. Cal. filed Apr. 25, 2014); *Illumina, Inc. v. Complete Genomics, Inc.*, No. 3:12-cv-01465 (S.D. Cal. filed June 15, 2012); *Illumina, Inc. v. Life Technologies Corp.*, No. 3:11-cv-03022 (S.D. Cal. filed Dec. 27, 2011); *Illumina, Inc. v. Complete Genomics, Inc.*, No. 1:10-cv-00649 (D. Del. filed Aug. 3, 2010); *Illumina, Inc. v. Affymetrix, Inc.*, No. 3:09-cv-00665 (W.D. Wis. filed Nov. 2, 2009)).

[redacted] } (CCFF ¶ 1641). 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:[91]

- **BGI:** Due to a lawsuit by Illumina, BGI is currently enjoined from providing NGS instruments and consumables in the United States, and therefore is not an option for MCED test developers. *Illumina, Inc. v. BGI Genomics Co.,* No. 19-CV-03770-WHO, 2022WL 899421, at *25 (N.D. Cal. Mar. 27, 2022); *see also* (CCFF ¶ 1328). Even if it became available, however, MCED test developers have serious reservations about using BGI for their tests. First, MCED test developers recognize that BGI could be at risk of additional patent infringement lawsuits, which would pose a substantial business risk to customers. (CCFF ¶¶ 1286-92, 1295, 1575). Second, MCED test developers expressed doubts about the reliability, accuracy, and quality of BGI's instruments. (CCFF ¶¶ 1326-27, 1341-44). Respondents argue that BGI will be a viable platform for MCED tests. However, Illumina recently moved successfully for a permanent injunction against BGI's infringing technology in federal court, arguing that BGI's sequencing platform is "unproven and not ready for market" that the sequencing industry does not have "comfort in the quality of the data on the BGI systems." Pl.'s Reply in Support of Mot. for Permanent Inj. at 14, *Illumina, Inc. v. BGI Genomics Co., Ltd.,* No. 3:19-cv-03770,(N.D. Cal Feb. 16, 2022). The court, in balancing hardships an injunction would impose on each party, found after hearing testimony from BGI that an injunction would cause only minimum harm to BGI because the BGI technology being enjoined is "neither mature nor commercially viable." *BGI Genomics*, slip op., 2022 WL 899421, at *25 (finding BGI's CoolMPS sequencing technology is "neither mature nor commercially viable"). Third, MCED test developers have raised concerns about BGI's long-standing ties to the Chinese government. (CCFF ¶¶ 1304-06, 1312). Specifically, as Illumina executives recognized, [redacted] and privacy concerns regarding "data from the instruments, you know, being sent to China, perhaps without customers' knowledge." (CCFF ¶¶ 1299-1301). Moreover, the U.S. Department of Commerce added certain BGI subsidiaries to an economic blacklist, restricting their trade with the United States {[redacted]

[91] Importantly, by the time any of the potential NGS technologies may theoretically become available, {[redacted]

[redacted]

- [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 Acquisition. [redacted]

[redacted]

[redacted]

[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 SVP of Technology, Darya Chudova, emphasized that [redacted] (CCFF ¶¶ 1569-70). According to Dr. Chudova, [redacted] (CCFF ¶ 1553). Francis deSouza, Illumina's CEO, similarly recognized that [redacted] (CCFF ¶ 1537).

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 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. {[redacted]} (CCFF ¶ 1768). Likewise, according to Nitin Sood, Guardant's SVP of Product, "Illumina is central to what we do. . . . [W]e built part of our world around the Illumina ecosystem." (CCFF ¶ 1776). Thus, as Singlera's Co-Founder and Scientific Advisor explained, switching to a new NGS platform would mean that "many years [have] gone down the drain and there's hundreds of million[s of] dollar[s] down the drain" which would be bad for business and for investors. (CCFF ¶ 1829). Evidence indicates that switching NGS platforms would cost {[redacted] a cost that {[redacted]} (CCFF ¶ 1822). As {[redacted]} (CCFF ¶ 1773).

To switch to a new platform, an MCED test developer must redesign its test to be compatible with the new NGS platform, which although "theoretically possible" involves a "significant amount of development work." (CCFF ¶ 1811; *see also* CCFF ¶¶ [redacted], 1826, [redacted]). Furthermore, as MCED test developers continue developing their tests, they gather more

and more data that {[redacted]} (CCFF ¶¶ 1802, 1819). Switching to a new NGS platform would {[redacted]} (CCFF ¶ 1820). 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." (CCFF ¶¶ 1807, 1810). Switching may also require redoing entire clinical trials or obtaining new regulatory approvals, {[redacted]} (CCFF ¶¶ 1826, 1823, 1875, 1877). As Singlera Co-Founder and Scientific Advisor Dr. Gao 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." (CCFF ¶ 1826).

Switching an MCED test to a new NGS platform {[redacted]} would likely take at least {[redacted]} (CCFF ¶¶ 1784, 1814, 1823, 1876). 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] As Guardant's SVP 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[.]" (CCFF ¶ 1816). 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.

2. Respondents' Claimed Efficiencies and EDM Are Not Cognizable and Do Not Outweigh the Acquisition's Anticompetitive Harm

Respondents claim the Acquisition will lead to a number of efficiencies, including acceleration of FDA and payer approval of Galleri, R&D efficiencies, supply chain and lab operations efficiencies, machine learning efficiencies, acceleration of international testing and expansion of Galleri, and acceleration of other MCED test developers' FDA approval processes. Op. Stmt. (Resp.) Tr. 67-68; (RX3864 (Carlton Rebuttal Report) ¶¶ 96-129). Respondents also assert that the Acquisition will result in EDM and the elimination of a royalty paid by Grail to Illumina. Op. Stmt. (Resp.) Tr. 116; (RX3864 (Carlton Rebuttal Report) ¶¶ 101-11). Importantly, no court has ever held that efficiencies or EDM rebutted a *prima facie* case that the merger is illegal. *See Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (observing that "[r]esearch does not reveal a case that permitted an otherwise unlawful transaction to proceed based on claimed efficiencies."); *see also Penn State Hershey*, 838 F.3d at 347-48 ("Contrary to endorsing [an efficiencies] defense, the Supreme Court has instead, on three occasions, cast doubt on its availability . . . . Based on [the Supreme Court's past statements] and on the Clayton Act's silence on the issue, we are skeptical that such an efficiencies defense even exists.") (citations omitted).

Even assuming that the efficiencies defense is cognizable under the Clayton Act, Respondents bear the burden of producing "clear evidence showing that the merger will result in efficiencies that will *offset* the anticompetitive effects and ultimately benefit consumers." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *Penn State Hersey*, 838 F.3d at 350) (emphasis added); *see also FTC v. Hackensack Meridian Health, Inc.*, 2022 WL 840463, at *10

(3d Cir. 2022). In assessing such efficiency claims, courts have applied strict standards in their review. *Heinz*, 246 F.3d at 720-21; *H&R Block*, 833 F. Supp. 2d at 890. Specifically, "the court must undertake a rigorous analysis of the kinds of efficiencies being urged by the parties in order to ensure that those 'efficiencies' represent more than mere speculation and promises about post-merger behavior." *Heinz*, 246 F.3d at 721; *see also FTC v. Wilh. Wilhelmsen Holding ASA*, 341 F. Supp. 3d 27, 72 (D.D.C. 2018); *FTC v. CCC Holdings, Inc.*, 605 F. Supp. 2d 26, 72-73 (D.D.C. 2009). Accordingly, assuming *arguendo* that the efficiency defense is even potentially available, Respondents would bear the heavy burden to show that their efficiencies claims are cognizable, meaning that they are "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *Horizontal Merger Guidelines* § 10; *see also Hackensack*, 2022 WL 840463, at *10-11*; Heinz*, 246 F.3d at 720; *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016); *Sysco*, 113 F. Supp. at 82. To substantiate each efficiency, Respondents would be required to demonstrate 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.'" *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *H&R Block*, 833 F. Supp. 2d at 89); *see also Hackensack*, 2022 WL 840463, at *10-11; *Horizontal Merger Guidelines* § 10. And, to demonstrate merger specificity, Respondents would need to "present a type of cost saving that could not be achieved without the merger[.]" *Wilhelmsen*, 341 F. Supp. at 72; *see also Hackensack*, 2022 WL 840463, at *11 ("*i.e.*, the efficiencies cannot be achieved by either party alone").

Respondents fail to meet their burden here. While Respondents claim the Acquisition will have "the procompetitive advantage" of accelerating Grail's FDA approval and payer acceptance, achieving R&D efficiencies, and creating supply chain and other efficiencies, Op. Stmt. (Resp.) Tr. 68, Respondents have failed to provide any evidence sufficient to either verify these efficiency claims or demonstrate their merger specificity. Similarly, Respondents' claimed cost savings derived from EDM and the elimination of royalty are not cognizable because they are not verifiable, merger-specific, or shown to be passed through to consumers. In fact, Respondents' ordinary course documents, made prior to litigation, admit that "[w]e do not expect material synergies to the transaction."[94] (CCFF ¶ 5040). As such, Respondents have not come close to carrying their burden to rebut the prima facie case.

a. *Respondents' Alleged Efficiencies Are Not Cognizable*

i. *Respondents' FDA and Payer Acceleration Claims Are Not Cognizable*

Respondents claim that Illumina can accelerate the "widespread adoption" of Grail's Galleri test "by at least a year."[95] Op. Stmt. (Resp.), Tr. 114. Specifically, Respondents claim that the Acquisition will accelerate both the FDA approval and payer coverage of Galleri. This efficiency is not verifiable because Respondents fail to adequately substantiate this claim, offering only surface-level claims of "acceleration" without any details as to how they will achieve either FDA and payer acceleration, nor quantifying the costs associated with achieving this efficiency. Further, Respondents fail to demonstrate that such alleged acceleration is merger specific. As

[94] Another Illumina document similarly noted that {[redacted]} (CCFF ¶ 215). And, {[redacted]} (CCFF ¶ 5124).

[95] Respondents have never described what specifically is meant by "widespread adoption."

Illumina's former Chief Medical Officer recognized when forming Grail, "that "Illumina has no IP, no special data or expertise or idea to put into this company." (CCFF ¶ 5028).

a) Respondents' FDA and Payer Acceleration Claims Are Not Verifiable

First, Respondents fail to substantiate this claim. As this Court has explained, to verify an efficiency claim, a respondent must provide evidence 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)[.]" *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *H&R Block*, 833 F. Supp. 2d at 89). Yet, here, Respondents offer no such evidence. One of Respondents' economic experts, Dr. Dennis Carlton, purports to quantify the *magnitude* of this efficiency in terms of both lives saved and life-years gained through the alleged acceleration. Setting aside the myriad of methodological issues with Dr. Carlton's estimates of the magnitude of the efficiencies,[96] Respondents have failed to demonstrate that the claimed FDA and payer acceleration is *likely* to occur. Dr. Carlton admitted that he was not opining that Illumina could accelerate FDA or payer approval—he was merely relying on Illumina's claims that it could achieve such acceleration. (CCFF ¶¶ 5075, 5077, 5432). He explained that {[redacted]} (CCFF ¶¶ 5079-80). Notably, he did not offer any

[96] {[redacted]}

testimony as an expert on the FDA's regulatory approval process, analyze the relative capabilities of Illumina or Grail, or perform a detailed analysis of what specific capabilities Illumina could contribute to accelerate FDA approval. (CCFF ¶¶ 5076, 5078). Such a cursory analysis, devoid of any methodology, is by definition not verifiable.

Similar to Dr. Carlton, Respondents' business executives fail to explain how Illumina would accelerate Grail's FDA and payer approval with sufficient precision to allow the claimed efficiency to be verified. First, Illumina and Grail's ordinary course documents do not model any FDA or payer acceleration efficiencies. *See* (CCFF ¶¶ 5040-80; 5420-32). For example, {[redacted]} (CCFF ¶ 5055). Similarly, a September 2020 Illumina FAQ document relating to Illumina's acquisition of Grail, an "Employee FAQ" section stated: "We do not expect material synergies to the transaction." (CCFF ¶ 217). Second, Illumina and Grail have not identified specific steps towards FDA and payer approval that Illumina would accelerate. *See* (CCFF ¶¶ 5081-94, 5433-43). Indeed, Dr. Febbo, Illumina's Chief Medical Officer, testified at trial that Illumina will not be able to "work together [with Grail] and find those specific areas where we can help them accelerate" Galleri's FDA approval until Illumina and Grail are combined. (CCFF ¶ 5094). Multiple Illumina and Grail executives confirmed at trial that, despite Illumina consummating the transaction in August 2021, no such integration planning has occurred. *See* (CCFF ¶¶ 5095-126, 5433-43). Finally, Illumina admits that it has not yet identified the costs associated with this efficiency, *see* (CCFF ¶¶ 5127-35, 5444-65), despite indication by Respondents' experts and executives that {[redacted]}

(CCFF ¶ 5129). As Ammar Qadan, Illumina's VP and Global Head of Market Access, testified, {[redacted]}. (CCFF ¶ 5129).

In essence, Respondents ask this Court to credit their mere assertions that such an efficiency will occur. However, there is substantial evidence in the record suggesting it is unlikely Illumina would achieve the claimed acceleration. First, although Illumina claims it can help accelerate Grail's FDA approval, the actual evidence shows that Illumina, itself, has had little success navigating the FDA process.[97] To date, Illumina has only received one PMA from the FDA, the type of FDA approval which would be required for Grail's Galleri test. (CCFF ¶ 5146). Illumina has no experience conducting the large-scale clinical trials that Grail, as a standalone company, has already begun to obtain FDA approval. In fact, Illumina had to rely on a partner to sponsor the clinical study required for its own PMA approval. (CCFF ¶ 5169). Illumina's other [redacted]

[97] Indeed, Illumina initially chose to spin Grail off as a separate company, rather than continue Grail's development internally. In spinning Grail off, one benefit Illumina recognized was that a new company could "retain[] and attract[] best-in-class people through equity, culture, and quality of the science." (CCFF ¶ 25). In fact, Illumina stated in internal Q&A bullets that it "believe[d]" that divesting Grail would "accelerate the liquid biopsy market for all." (CCFF ¶ 5843).

[redacted]

Given Illumina's lack of relevant FDA experience and ongoing struggles with the FDA process, there is little evidence to show how Illumina can accelerate Grail's test. Second, the relevance of Illumina's limited experience working with payers in other settings to obtaining payer approval for an MCED is speculative. *See* (CCFF ¶¶ 5466-78). As Dr. Navathe explained, [redacted]

(CCFF ¶ 5469). In sum, by failing to provide even nominal support regarding the likelihood of realizing the claimed efficiency and the costs of achieving the claimed efficiency, Respondents have failed to verify this claimed efficiency by reasonable means.

b) Respondents' FDA and Payer Acceleration Claims Are Not Merger Specific

Respondents have also failed to demonstrate that the claimed acceleration efficiency is merger specific. Merger specificity requires that Respondents demonstrate that their claimed acceleration efficiency "cannot be achieved by either party alone". *Hackensack*, 2022 WL 840463, at *11.

Evidence indicates that Grail can accelerate FDA approval and reimbursement on its own, without the Acquisition. First, Grail is already pursuing FDA acceleration independently. *See*

(CCFF ¶¶ 5259-363). Specifically, Grail has created a well-established regulatory team, *see* (CCFF ¶¶ 5291-95), is increasing the team's headcount and budget, *see* (CCFF ¶¶ 5358-63), has launched the largest clinical study program of its kind, *see* (CCFF ¶¶ 5296-341), has met regularly with the FDA, *see* (CCFF ¶¶ 5342-47), has achieved breakthrough device designation for Galleri from the FDA (which can streamline the PMA process for Grail) and has received FDA approval of an investigational device exemption application for Galleri, *see* (CCFF ¶¶ 5351-57), and has already exceeded many of its regulatory-related targets, *see* (CCFF ¶¶ 5348-50). In fact, {[redacted]} (CCFF ¶ 5349). With respect to payer approval, Grail already is marketing Galleri to health systems, concierge physicians, self-insured employers, and life science companies and has brought in a highly skilled group of professionals to help achieve Grail's reimbursement strategy. *See* (CCFF ¶¶ 5479-630). Hans Bishop, Grail's former CEO, testified at trial that Grail has "built all the infrastructure, laboratory infrastructure, necessary to reliably deliver [Galleri] in full compliance with all the regulatory requirements of running such a test in a lab." (CCFF ¶ 5384). In fact, Respondents' own expert, Dr. Patricia Deverka, testified that she believes Grail can obtain reimbursement and coverage for Galleri on its own. (CCFF ¶ 5479) Thus, evidence indicates that independently Grail is on track—in fact ahead of schedule—to receive FDA approval and payer reimbursement for Galleri.

Even if Grail needed assistance outside of its own resources to achieve FDA approval and reimbursement, Grail can do so absent the Acquisition. As Complaint Counsel's expert Dr. Rothman testified, {[redacted]}

[redacted] And as Aaron Friedin, Grail's Chief Financial Officer, testified, [redacted] (CCFF ¶ 5388). In fact, FDA consultants have guided Grail's competitors through the FDA approval process. [redacted] (CCFF ¶¶ 5394-95). [redacted] (CCFF ¶ 5392). And, other companies in the industry possess more experience than Illumina marshalling products through the FDA's PMA process and could provide alternatives to the Acquisition. For example, Dr. Ofman, Grail's Chief Medical Officer, testified that FMI has successfully obtained FDA approval for NGS-based IVD tests. (CCFF ¶ 5405). Specifically, FMI has obtained a Class III, single-site PMA for three different NGS-based diagnostic tests and holds more Class III PMAs for NGS-based diagnostic tests than Illumina. (CCFF ¶¶ 5406-07). Dr. Ofman also testified that Myriad Genetics Laboratories has successfully obtained FDA approval for an NGS-based IVD test. (CCFF ¶ 5405). Illumina fails to offer any evidence that its own capabilities to accelerate Grail's "widespread adoption" exceed that of any other company that has obtained at least one approval. For all of these reasons, Illumina has failed to demonstrate that its claimed acceleration claims "cannot be achieved by either party alone." *Hackensack*, 2022 WL 840463, at *11.

ii. *Respondents' Claimed R&D Efficiency Is Not Cognizable*

Respondents and their experts claim the Acquisition will result in R&D efficiencies, which they allege "will help accelerate new breakthroughs in oncology and other fields." Answer at 13; (RX3864 (Carlton Rebuttal Report) ¶¶ 127-29). Respondents, however, provide almost no evidence whatsoever to verify this claim. *See* (CCFF ¶¶ 5721-51). Respondents similarly have not demonstrated their claimed R&D efficiency is merger specific. As discussed *supra*, Respondents demonstrate quite the opposite—that the claimed breakthroughs have already been discovered by Grail, and simply require investment to materialize. (Aravanis (Illumina) Tr. 1955) ("There's initial evidence that many of these diseases have signals in the blood that could be detected with the GRAIL technology."). As Dr. Alex Aravanis, Illumina's SVP and Chief Technology Officer, testified at trial, "GRAIL has some preliminary findings that methylation technology can be useful for detecting fatty liver disease," and "there's evidence of other types of diseases that can be detected using GRAIL's methylation technology." (CCFF ¶ 5753). If Grail has already made the "breakthroughs in oncology and other fields," Illumina's claimed R&D efficiency cannot be merger specific.[98]

iii. *Respondents' Supply Chain and Lab Operations Efficiency Claim Is Not Cognizable*

Respondents also claim the Acquisition will result in cost savings from "supply chain efficiencies" and "lab operation efficiencies."[99] (PX6050 (Illumina) at 003-005 (Aravanis

[98] To the extent that the "breakthroughs" claimed by Respondents simply require investment, Grail would be able to attain such investment through less anticompetitive means than the Acquisition. For example, prior to the Acquisition, {[redacted]} (CCFF ¶¶ 5864, 5904). Grail stated in its Amended Form S-1 its intention to use these proceeds "for current and future product development[.]" (CCFF ¶ 5895). Additionally, the availability of cash investment would be available from other potential acquirers, indicating this efficiency claim is not merger specific.

Investigational Hearing Notes, Mar. 30, 2021)). But Respondents have not offered any reliable evidence sufficient to substantiate this efficiency claim. Instead, Respondents and their experts point to a single document in support of their claim. (CCFF ¶¶ 5791-93). However, as Complaint Counsel's efficiency expert, Dr. Rothman, noted, this document is {[redacted]}[100] (PX6092 (Rothman Rebuttal Report) ¶ 93 n.151). Respondents' expert Dr. Dennis Carlton testified that he did not otherwise verify this efficiency claim. (CCFF ¶¶ 5797, 5799). Nor did Dr. Carlton opine whether any of these supply chain efficiencies would be merger specific. (CCFF ¶ 5800). Thus, Respondents fail to show that these alleged variable cost savings are cognizable.

iv. *Respondents' Claimed Machine Learning Efficiency is Not Cognizable*

Respondents' economic expert, Dr. Carlton, claimed that {[redacted]} (RX3864 (Carlton Rebuttal Report) ¶ 96). This efficiency assumes that there would be an acceleration of the commercialization of Galleri as a result of the transaction. (PX7134 (Carlton Dep.) at 168-69). Given that Respondents have failed to substantiate their acceleration claims, *see supra* § II.F.2.a.i, they similarly fail to show that this efficiency is cognizable.

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[99] Respondents did not include this claimed efficiency in their Answer. *See* Answer at 11-14. In other documents, Respondents appear to refer to these claimed efficiencies as {[redacted]} *See* (PX2613 (Illumina) at 004-005 (Presentation "Appendix A: Illumina/GRAIL Efficiency Analysis")). {[redacted]} *See* (PX5042 (Illumina) Tab "DCF" (Illumina's Deal Model, Oct. 5, 2020)). Respondents have never explained the relationship between these various efficiency claims.

[100] Similarly, the document summarily claims these efficiencies with no underlying data. For example, the document claims Illumina will {[redacted]} (CCFF ¶ 5794). In the same document, Respondents presume {[redacted]} without providing any additional information. (CCFF ¶ 5795).

Even assuming that some acceleration of Galleri occurred, however, Respondents' machine learning efficiency still is not verifiable. First, Dr. Carlton admitted that he did not quantify the machine learning efficiency in his report. (CCFF ¶ 5845). Second, Dr. Carlton testified that he did not quantify how much the acceleration of Grail's sales (which in turn would accelerate the collection of data) may improve the accuracy of Grail's assay. (CCFF ¶ 5846). Finally, Dr. Carlton admitted that he did not identify which additional types of cancer may be detected through acceleration of Grail's sales. (CCFF ¶ 5847).

v. *Respondents' Claims that the Acquisition Would Accelerate Other Test Developers' FDA Approval Processes and International MCED Testing Are Not Cognizable*

Respondents' economic expert, Dr. Carlton, also asserted that the Acquisition would result in accelerated international MCED testing and expansion of Galleri outside of the United States, but he failed to quantify the benefit of the alleged acceleration and expansion, or estimate any costs associated with achieving this alleged efficiency. (RX6000 (Carlton Trial Dep. at 55-56)). Further, even assuming such acceleration and expansion occurs, it is admittedly outside the United States—the relevant geographic market. Similarly, Dr. Carlton, asserted that the Acquisition would result in "acceleration of other test developers' FDA approval processes." (RX3864 (Carlton Rebuttal Report) ¶ 96). Dr. Carlton admitted, however, that he never quantified this efficiency. (CCFF ¶ 5844).

b. *Respondents Cannot Demonstrate That Any EDM Would Offset the Harm from This Anticompetitive Acquisition*

Respondents claim the Acquisition will result in "hundreds of millions of dollars" from EDM, as well as the elimination of a royalty that Grail owes to Illumina.[101] Op. Stmt. (Resp.) Tr. 117; *see also* (RX3864 (Carlton Rebuttal Report) ¶ 96). According to Respondents' economic expert, EDM is a {[redacted]} (RX3864 (Carlton Rebuttal Report) ¶ 101). Respondents suggest that Complaint Counsel must disprove the possibility of EDM to establish a *prima facie* case. *See* Resp. Pretrial Br. at 105 ("It is widely acknowledged that a vertical merger cannot be shown to be anticompetitive without balancing any alleged anticompetitive effects against likely EDM efficiencies."). No court, however, has adopted Respondents' position, and the Third Circuit recently rejected similar arguments in *Hackensack*. 2022 WL 840463, at *10-13.

First, Respondents bear the burden of producing "clear evidence showing that the merger will result in efficiencies that will *offset* the anticompetitive effects and ultimately benefit consumers." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *Penn State Hershey*, 838 F.3d at 350) (emphasis added). Respondent's' own economic expert concedes EDM is a "well-documented efficiency," and no court has held that it should be analyzed any differently from other claimed efficiencies.

[101] Relatedly, Respondents claim "the transaction will eliminate the royalty that GRAIL owes to Illumina." Op. Stmt. (Resp.) Tr. 117. Dr. Carlton, however, acknowledged in his report that {[redacted]} (CCFF ¶ 5778).

Second, in *FTC v. Hackensack Meridian Health, Inc.*, the defendant ("Hospitals") offered "a panoply of procompetitive benefits that may be reaped from the merger: upgrades and increased capacity limits at Englewood, the expansion of complex tertiary and quaternary care at HUMC, cost-savings that will result from service optimization between the Hospitals, and quality improvements at both Hospitals." *Hackensack*, 2022 WL 840463, at *11. Similar to Respondents in the case at hand, the Hospitals claimed that "they [we]re not making an efficiencies defense, thus the stringent standard developed in other circuits need not apply." *Hackensack*, 2022 WL 840463, at *11. Instead, the Hospitals argued that "procompetitive effects must simply be weighed in the balance together with anticompetitive effects when considering whether [the defendants] have rebutted the FTC's prima facie case." *Hackensack*, 2022 WL 840463, at *11. The Third Circuit rejected the Hospitals' characterization of their procompetitive claims, explaining that "[t]he Hospitals' argument that there would not likely be a substantial lessening of competition when both pro- and anti-competitive effects were duly considered, is merely a different way of saying there would not likely be a substantial lessening of competition because the procompetitive effects offset the anticompetitive effects of the merger. Thus, the Hospitals' procompetitive benefits argument *is an efficiencies defense*" and, accordingly, the efficiencies defense standard was appropriate for evaluating the Hospitals' claims of procompetitive benefits. *Hackensack*, 2022 WL 840463, at *11 (internal quotations and citations omitted) (emphasis added).

Respondents' EDM claims are no different than the alleged procompetitive benefits advanced by the hospitals in *Hackensack*. Moreover, it is well established that "where 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." *Smith*, 568 U.S. at 112 (internal quotations and citations omitted); *accord*

Initial Decision, *Altria*, Docket No. 9393, at 5 ("[C]ounsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto.") (quoting 16 C.F.R. § 3.43(a)). As such, even assuming that efficiency defenses are permissible, it is Respondents' burden to show that EDM is a cognizable efficiency and that it eliminates the anticompetitive harm established in the Government's *prima facie* case. *See Smith*, 568 U.S. at 112; Initial Decision, *Altria*, Docket No. 9393, at 5; *Horizontal Merger Guidelines* § 10 (explaining that "much of the information relating to efficiencies is uniquely in the possession of the merging firms"). Respondents cannot, however, reliably quantify the claimed value of EDM resulting from the Acquisition, nor can they demonstrate that their claims are merger specific or would be passed through to consumers.

i. *Respondents' Claimed EDM Would Not Offset the Acquisition's Anticompetitive Harm*

Respondents' economic expert, Dr. Dennis Carlton, concedes that {[redacted]} (CCFF ¶ 5712). Dr. Carlton testified that he performed {[redacted]} (RX6000 (Carlton Trial Dep.) at 65),[102] {[redacted]} Dr. Carlton admits that he did not create such a vertical model. (CCFF ¶¶ 5710). Unable to even

[102] Respondents' expert further emphasized that {[redacted]} RX6000 (Carlton Trial Dep. at 65). Respondents' expert later clarified that he did not create a full vertical model to account for these different factors. (CCFF ¶ 5710; RX6000 (Carlton Trial Dep.) at 136-37).

quantify the amount of EDM (if any) that would allegedly result from the Acquisition, Respondents patently fail to satisfy their burden to substantiate this claim, and therefore, it is not cognizable.

In addition, Respondents have failed to show that the claimed EDM efficiency is merger specific. To the contrary, Complaint Counsel's expert found that Respondents' incentive to set profit-maximizing margins exists absent the merger. As Dr. Scott Morton explained in her testimony, {[redacted]} (CCFF ¶ 5680). {[redacted]} (CCFF ¶ 5679). Here, Dr. Scott Morton found that such complex pricing was available to Illumina and Grail, where both companies {[redacted]} (CCFF ¶ 5683). She further noted that {[redacted]} (CCFF ¶ 5682). {[redacted]} (CCFF ¶ 5694).

Lastly, even if Respondents could quantify their claimed EDM efficiency and demonstrate its merger specificity, Respondents have not demonstrated that the EDM would outweigh the Acquisition's anticompetitive harm. Dr. Carlton also concedes that {[redacted]}

[redacted] (CCFF ¶ 5715). Instead, Dr. Carlton [redacted] though he concedes that he did not "estimate[] a model or estimate passthrough." (CCFF ¶ 5706); *see also* (CCFF ¶ 5715-16). Complaint Counsel's economic expert, Dr. Scott Morton, nevertheless accounted for the possibility of EDM in her economic analysis. She ultimately concluded that, [redacted] (CCFF ¶ 5705).

ii. *Respondents' Claimed Elimination of Royalties Would Not Offset the Acquisition's Anticompetitive Harm*

Similar to their EDM claim, Respondents' claim that another efficiency is the elimination of the royalty that Grail paid to Illumina. (RX3864 (Carlton Rebuttal Report) ¶ 96). This efficiency is not verifiable, however, as the royalty payments that Grail previously paid to Illumina were (at least partially) offset by Contingent Value Rights ("CVRs") that Illumina issued to certain Grail shareholders and equity award holders when the royalty was eliminated. (CCFF ¶ 5781). Respondents' economic expert did not analyze the tax treatment of CVRs compared to the royalty, (CCFF ¶ 5785), and thus, the net effect is unclear.

Additionally, the reduction in royalties is not a merger-specific efficiency. Prior to the Acquisition, Grail had already been in negotiations with Morgan Stanley, seeking both a reduction in the royalty it paid to Illumina, as well as lower input prices from Illumina. (CCFF ¶¶ 5763, 5765, 5773). There is nothing that precluded Respondents from reaching such an agreement, and thus, even Respondents' economic expert testified that he did not specifically opine on whether

the royalty that Grail paid to Illumina could have been eliminated absent the merger. (CCFF ¶ 5777).

In sum, Respondents have failed to substantiate any verifiable, merger-specific efficiencies.[103]

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

Respondents assert that Illumina's Open Offer will remove the Acquisition's potential for anticompetitive harm. Answer at 10-11. Respondents "bear the burden of showing that any proposed remedy would negate any anticompetitive effects of the merger[.]" *Otto Bock,* 2019 WL 5957363, at *44 (quoting *Staples*, 190 F. Supp. 3d at 137 n.15 (D.D.C. 2016)). The purpose of a remedy in Section 7 cases is "to restore competition lost through the unlawful acquisition." *Otto Bock*, 2019 WL 5957363, at *43. Here, Respondents' Open Offer is a remedy proposal. *See, e.g.*, Mot. For Conference to Facilitate Settlement, *In re Illumina, Inc. and GRAIL, Inc.*, Docket No. 9401, at 6-7 (F.T.C. July 13, 2021) (characterizing the Open Offer as "a consent agreement with protections in place to address the FTC's purported concerns"). To meet their burden, Respondents must show that the Open Offer would "replac[e] the competitive intensity lost as a result of the merger." *Aetna*, 240 F. Supp. 3d at 60 (quoting *Sysco*, 113 F. Supp. 3d at 72) (emphasis in original). As explained by both third-party witnesses as well as the Respondents' own witnesses, they have not done this.

[103] To the extent this Court were to credit any of Respondents' purported efficiencies as cognizable, they nonetheless do not offset the massive competitive harm that is likely to occur from the Acquisition. *See* (CCFF ¶ 5705) (Dr. Scott Morton concluding in her report that [redacted]).

"The purpose of relief in a Section 7 case is to restore competition lost through the unlawful acquisition." *ProMedica*, 2012 WL 1155392, at *48-50. In a Part III proceeding, the Commission has "wide discretion in its choice of a remedy deemed adequate to cope with the unlawful practices[.]" *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 611 (1946); *see also Polypore Int'l, Inc. v. FTC*, 686 F.3d 1208, 1218-19 (11th Cir. 2012) ("The Commission has broad discretion in the formulating of a remedy for unlawful practices."). As the Commission has explained, "[s]tructural remedies are preferred for Section 7 violations." *In re Evanston Northwestern Healthcare Corp.*, 2007 WL 2286195, *77 (Aug. 6, 2007) (citing *United States v. E.I. du Pont de Nemours & Co.,* 366 U.S. 316, 329 (1961) [hereinafter "*du Pont 1961*"] (noting "an undoing of an acquisition is a natural remedy" of a Section 7 violation). This is because a structural remedy is "simple, relatively easy to administer, and sure" to preserve competition. *du Pont 1961*, 366 U.S. at 331; *see also Cal. v. Am. Stores Co.*, 495 U.S. 271, 280-81 (1990) ("[I]n Government actions divestiture is the preferred remedy for an illegal merger or acquisition."). There are also "greater long-term costs associated with monitoring the efficacy of a conduct remedy than with imposing a structural solution." *Evanston Northwestern*, 2007 WL 2286195, at *77.

The determination of the appropriate remedy is made only after there is a determination of liability for the allegations in the Complaint. *See, e.g.*, *du Pont 1961*, 366 U.S. at 334 (stating "once the Government has successfully borne the considerable burden of establishing a violation of law, all doubts as to the remedy are to be resolved in its favor"); *Evanston Northwestern*, 2007 WL 2286195, at *76 ("Having found that Evanston's acquisition of Highland Park violated Section 7 of the Clayton Act, we turn to fashioning the appropriate remedy."). Only then may Respondents introduce rebuttal evidence that a proposed remedy will "effectively preserve competition in the

relevant market." *Otto Bock*, 2019 WL 2118886, at *48 (Chappell, A.L.J.) (quoting *Aetna*, 240 F. Supp. 3d at 60). To meet its burden, it is insufficient that the remedy replaces some or most of the lost competition but rather Respondents must show that the remedy completely "replac[es] the competitive intensity lost as a result of the merger." *Aetna*, 240 F. Supp. 3d at 60 (quoting *Sysco*, 113 F. Supp. 3d at 72). Here, Complaint Counsel has shown that the Acquisition clearly runs afoul of antitrust laws, accordingly, "all doubts as to remedy are to be resolved in [Complaint Counsel's] favor." *Otto Bock*, 2019 WL 2118886, at *54 (Chappell, A.L.J.) (quoting *du Pont 1961*, 366 U.S. at 334); *Ford Motor*, 405 U.S. at 575.

In an apparent effort to meet their burden through the use of a non-structural remedy, Respondents have made a series of attempts to enter into long-term supply agreements with MCED test developers. These attempts have culminated in a publicly available twelve-year Open Offer posted on Illumina's website in March 2021, (CCFF ¶¶ 4479-80), and subsequently a revised version published in the middle of trial in September 2021, (CCFF ¶ 4483). Rather than "replac[ing] the competitive intensity" lost from the Acquisition, *Aetna*, 240 F. Supp. 3d at 60, Respondents' attempted behavioral remedy only applies to a small fraction of the relevant market who signed the Open Offer, and barely scratches the surface of reversing the Acquisition's anticompetitive harms. 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.

a. *The Open Offer Was Made for Litigation Rather Than to Alleviate Harm*

Understanding that its customers would have grave concerns about the Acquisition, Illumina sought, from the outset, to quiet its customers with surface-level assurances so that

Illumina could close its deal quickly.[104] Although Illumina engaged in one-on-one outreach to Grail's rivals and attempted to enter into long-term supply agreements with them, (CCFF ¶¶ 746-49, 2694-99), it dismissed any customer who engaged in meaningful, substantive negotiations with Illumina as "simply . . . not credible" and having "patently unreasonable demands." Resp. Pretrial Br. at 8. Instead, Illumina pushed on its customers its Open Offer, a series of unilaterally imposed behavioral commitments that do little to assuage the significant anticompetitive harms of the Acquisition. As a federal court explained when enjoining a merger in which the merging parties made a behavioral commitment not to raise prices, "the mere fact that such representations had to be made strongly supports the fears of impermissible monopolization." *FTC v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 67 (D.D.C. 1998).

Illumina's executives recognized the Acquisition's harm to Illumina's MCED test developers even before the Acquisition was announced. When Nicole Berry—Illumina's Vice President and General Manager of the Americas who leads customer-facing activities for Illumina—learned about the potential Acquisition in March 2020, she had concerns that her customers "would perceive this as a shift in Illumina's strategy" and "have questions about [how] the acquisition would impact their commercial relationship with Illumina." (CCFF ¶¶ 4234-35). Berry proceeded to voice her concerns to other executives within Illumina. In June 2020, Berry agreed with another Illumina executive that that the Acquisition would "piss off a ton of [Illumina's] customers," adding that "[i]t would be disastrous." (CCFF ¶ 4233). That same day,

[104] Illumina even implemented a {[redacted]} with the goal to {[redacted]} (CCFF ¶ 3485). Part of the campaign, which was shared with Grail's CEO, was to [redacted] (CCFF ¶ 3487).

{ } (CCFF ¶ 6072). Like Berry, { } (CCFF ¶ 4223-25). And, days before the Acquisition was announced, { } (CCFF ¶ 6073). Illumina's own internal documents also reflect the concerns of competing with customers post-Acquisition. *See* (CCFF ¶ 4238) { }; (CCFF ¶ 3473) (deSouza explaining { }

Given these anticipated customer concerns, Illumina developed a plan to quell customer opposition to the Acquisition. One day before the public announcement, { } (CCFF ¶ 4196). To { }[105] (CCFF ¶ 2697). After {

[105] Illumina's CEO reiterated Berry's testimony, explaining that { } (CCFF ¶ 2655).

[redacted]}[106] (CCFF ¶ 4199). The purpose {[redacted]} (CCFF ¶¶ 2694, 4200, 4203, 4240). Illumina followed this initial outreach with {[redacted]}[107] and proceeded to seek out long term supply agreements with Grail's key rivals. (CCFF ¶¶ 4338-4465).

While Illumina offered certain concessions to Grail's competitors during the supply agreement discussions, the record shows that Illumina cared less about ensuring that its customers were comfortable with their long-term agreements with a critical supplier and more about passing the Commission's and this Court's scrutiny. During its negotiations, Illumina pushed its customers to sign deals quickly, even if those deals were insufficient to the customer. For example, before several open issues were resolved, [redacted]} (CCFF ¶¶ 4428-29, 4432, 4435). Similarly, {[redacted]

[106] This list is similar to the list Illumina developed for an investor presentation of its customers that are "targeting a commercial screening test" in early cancer detection. There, Illumina recognized Guardant, Thrive, Freenome, Singlera, Exact, and Grail as early cancer screening companies. *See* (CCFF ¶ 2700).

[107] These [redacted] (CCFF ¶ 4247). After customers raised concerns that Illumina may share their competitively sensitive information with Grail post-Acquisition, Illumina sent out revised letters a few weeks later adding that Illumina will not share its customers' confidential information with Grail. (CCFF ¶ 4248).

[redacted] (CCFF ¶¶ 4360-61). According to [redacted] (CCFF ¶ 4362). [redacted] (CCFF ¶ 4362). [redacted] (CCFF ¶ 4375). [redacted] (CCFF ¶ 5007).

Despite unresolved issues with Illumina's MCED test developer customers, Respondents unilaterally published a long-term supply agreement on Illumina's website in March 2021, days before the Commission issued its Complaint in this matter. (CCFF ¶¶ 4479-80). Grail's competitors testified that after the unilateral agreement was published, supply agreement negotiations with Illumina stalled. [redacted] Similarly, [redacted]

[redacted]} As discussed below, both the March 2021 Open Offer and the additional mid-trial revision serve merely as a bandage to the bullet hole of harm from this Acquisition.

b. *The Open Offer Fails to Remedy Anticompetitive Harm from the Acquisition*

i. *The Open Offer Does Not Change Illumina's Strong Incentives to Favor Grail*

No matter how many made-for-litigation changes Illumina makes to its Open Offer, the Open Offer cannot change Illumina's post-Acquisition incentives to harm Grail's MCED Test rivals.[108] The Department of Justice's 2020 Merger Remedies Manual explains that when a remedy requires a supplier to help its customers compete against itself, "[the supplier] 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."[109] U.S. Dep't of Justice, Merger Remedies Manual (2020) § III.B.1 n.48 [hereinafter "DOJ Merger Remedies Manual"]. Here, Illumina has a multibillion-dollar incentive to ensure that Grail captures the bulk of the U.S. MCED Test Market. *See supra* § II.E.1.b . Illumina therefore has a strong incentive to delay supply, impede product quality, restrict access

[108] After its Acquisition, Illumina has already violated its own commitments to favor Grail. When Respondents closed the Acquisition despite being "prohibited from implementing the Acquisition" during the "pendency of the European Commission's review," (CCFF ¶¶ 220-21), Respondents promised to hold Grail separate from Illumina, meaning that Grail "will be run as a separate entity, and where it engages with Illumina, it will do so on an arm's length basis." (CCFF ¶ 222). Despite these assurances, however, shortly after Illumina completed its acquisition of Grail, Illumina {[redacted]} (CCFF ¶¶ 3040-41). In addition, shortly after Grail's CEO Hans Bishop testified at trial, Illumina announced that Bishop was stepping down as CEO and that Illumina's Chief Operations Officer, Bob Ragusa, would take his place. (CCFF ¶ 226). At Illumina, Ragusa held $1 million in Illumina stock, [redacted]} (CCFF ¶¶ 2709, 3036-37). Now, as CEO of Grail, can use this information to steer Grail's own strategy.

[109] Former FTC Bureau Director Bruce Hoffman also observed in a speech, "conduct remedies that only address the ability to engage in anticompetitive behavior post-merger 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." D. Bruce Hoffman, *Vertical Merger Enforcement at the FTC*, Jan. 10, 2018, at 8, https://www.ftc.gov/system/files/documents/public_statements/1304213/hoffman_vertical_merger_speech_final.pdf [hereinafter "Hoffman, *Vertical Merger Enforcement at the FTC*"].

to new technology, and otherwise fail to uphold its stated promise to "maximize customer success and satisfaction." (CCFF ¶ 4182). The court in *United States v. H&R Block, Inc.* made a similar observation when it found that the defendants' post-merger incentives compromised the efficacy of their proposed remedy. In that case, defendants pledged to maintain the same price of TaxACT, one of the merged firm's tax preparation software. The court found such a commitment to be unavailing, noting:

> Even if TaxACT's list price remains the same, the merged firm could accomplish what amounts to a price increase through other means. For example, instead of raising TaxACT's prices, it could limit the functionality of TaxACT's products, reserving special features or innovations for higher priced, HRB-branded products. The merged firm could also limit the availability of TaxACT to consumers by marketing it more selectively and less vigorously.
>
> *H&R Block*, 833 F. Supp. 2d at 82.

The *H&R Block* court recognized that when a merger decreases competition, the merged firm will find ways to capitalize on the lower competitive intensity by circumventing any specific commitments designed to prevent anticompetitive consequences.

Because Illumina will have a strong incentive to prevent MCED test developers from competing significantly with Galleri, the Open Offer would need 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. (CCFF ¶ 4955). But the evidence shows that creating such a contract under these conditions is impossible. As Respondents' economic expert, Dr. Willig, testified, "if the incentives aren't right, then the contract is not going to be successful . . . the parties try to build in the protection that they think they can get into the contract, but the real details of how the business is going to work evolve from appropriate business incentives shared by the parties." (CCFF ¶ 4248). 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 Acquisition (which is the source of Illumina's changed incentives).[110] *See* (CCFF ¶ 4181).

At trial, Illumina's own customers shared with the Court their concerns that Illumina's shifting incentives post-Acquisition make a behavioral remedy, such as the one offered here, futile.

[redacted]

[111] (CCFF ¶ 4178). Similarly, Exact's CEO, Kevin Conroy, testified that {[redacted]} (CCFF ¶ 4295). And Guardant's VP of Commercial, William Getty, whose company actually entered into a long-term supply agreement with Illumina, testified that although certain provisions may be helpful to Guardant, "it doesn't change the underlying premise

[110] 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." DOJ Merger Remedies Manual § III.B.1 n.48.

[111] Although after trial [redacted] *See* (CCFF ¶ 4933) ([redacted]); (CCFF ¶ 4416) ([redacted]). [redacted] does not mean that the competitive intensity pre-Acquisition has been restored. *See* (CCFF ¶¶ 4335, 4460, 5002. 5012). Instead, as Illumina is the sole supplier of a critical input to MCED test developers, these developers have {[redacted]} but to maintain a business relationship. (CCFF ¶ 4460); *see also* (CCFF ¶ 1191) ([redacted]); (CCFF ¶ 1089) ([redacted]).

of our analysis that the combined company would have the opportunity and incentives to advantage GRAIL in a competitive environment."[112] (CCFF ¶ 4468).

ii. *The Provisions of the Open Offer Are Inadequate*

As evidenced by Illumina's multiple attempts at a remedy, formulating a long-term supply agreement capable of alleviating the entirety of the anticompetitive harms from the Acquisition is difficult, if not impossible. As discussed above, MCED test developers rely on Illumina for more than just the purchase and supply of NGS instruments and consumables. *See, supra*, § II.E.1.ii. And, their dependency on Illumina will only increase as MCED test developers pursue regulatory approvals and commercialization. [redacted]. Thus, crafting contractual provisions *today* that will protect against competitive harms over the next twelve years is difficult, if not impossible, to do, and, in any event, is a poor substitute for the free market that would thrive absent the Acquisition. As [redacted] Even Illumina's own executive, Nicole Berry, testified that it is [redacted].

[112] Even though [redacted] after Guardant put forward two witnesses to testify at trial on behalf of the Government, Illumina sued Guardant in federal court, alleging violations against Guardant's founders from when they were Illumina employees over nine years ago and that Illumina allegedly learned about three years ago. *See* Complaint, *Illumina, Inc. v. Guardant Health, Inc., et. al.*, No. 1:22-cv-00334 (D. Del. Mar. 17, 2022).

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. (CCFF ¶ 4495). 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. *See, e.g.*, (CCFF ¶¶ 4496, 4502). For instance, as Illumina's own executive admits, customers would not know how fast its competitors receive service and support from Illumina. (CCFF ¶¶ 4499, 4505); *see also* (CCFF ¶ 2919) (Guardant's Getty testifying that Illumina could easily say things like "'We can't get a technician out to your sequencers until next Friday' or 'the Friday after,' and that could create challenges around turnaround time and disappoint customers and therefore hurt us competitively.").[113] In addition, the Open Offer provides that a "[c]ustomer shall have access for purchase to any Pre-Release Sequencing Product to which GRAIL or any For-Profit Entity is offered access[.]"[114] (CCFF ¶ 4555). This provision, however, does not prevent Grail from having knowledge of Illumina's new technology before its competitors, which would put Grail's rivals at a significant disadvantage.[115] (CCFF ¶¶ 4571, 4576, 4598, 4599). And, this provision does not

[113] Even Respondents' remedy expert, Margaret Guerin-Calvert, agreed in her testimony that customers will not know how fast their competitors receive service and support from Illumina. (CCFF ¶ 4508).

[114] Illumina's initial Open Offer provided that a customer will have access to pre-release sequencing products "within 45 days of when GRAIL" is offered such access, (CCFF ¶ 4555), and Illumina's revised Open Offer shortens this time period to five days. (CCFF ¶ 4566).

[115] The revised Open Offer provides that customers "shall have access to the same information about final product specifications" of any new product "within 5 days of when GRAIL is provided such information," (CCFF ¶ 4566), [redacted] (CCFF ¶ 4602). [redacted] (CCFF ¶ 2795). Although the [redacted] (CCFF ¶ 1736). Thus, under the terms of the Open Offer, Illumina can provide Grail, as part of Illumina, with information

prevent Illumina from making improvements to its technology specifically tailored to Grail, as Illumina has done in the past when it owned Grail. *See* (CCFF ¶¶ 2987, 3742, 4577); *see also* (CCFF ¶ 4536) (deSouza testifying that Illumina can design products that "take into account modifications that will improve GRAIL's work flow").

In addition to the non-pricing terms, a closer look at the pricing terms of the Open Offer shows that they likewise fail to recreate the competitive environment absent the Acquisition. Specifically, the Open Offer provides that Illumina will not increase prices, and that, by 2025, the volume-based price "per gigabase of sequencing using the highest throughput Illumina instrument then available . . . will be at least 43% lower" than the current price per gigabase of sequencing using the NovaSeq instrument. (CCFF ¶ 4632). Although Respondents' Open Offer commits to a *lower* price of sequencing for one specified Illumina instrument,[116] this provision represents a form of price regulation that replaces a competitive free market. Indeed, evidence shows that absent the Acquisition, a free market would likely lead to even lower sequencing prices for MCED test developers. (CCFF ¶¶ 4658-67, 4669, 4701). Illumina has claimed publicly that it intends to

about {[redacted]} but need not inform Grail's rivals. Grail can use this advanced knowledge to gain a competitive advantage in the MCED Test Market. As Dr. Bert Vogelstein explained in his declaration, "advanced knowledge of future product developments and refinements . . . could alter the research and development of new or modified tests for the earlier detection of cancer. For example, if researchers become aware that a new sequencer or product improvements would enable the field to analyze many more genes in one test than it can do now, researchers could use that information to begin developing tests that would be more accurate and, perhaps less expensive, to perform." (CCFF ¶ 4559). While Grail can benefit from such advanced knowledge, under the Open Offer its competitors will not.

[116] It is important to add that the Open Offer only provide for a 43 percent price decrease on Illumina's *highest throughput* instrument. (CCFF ¶ 4654). Today, Grail's key competitors are developing MCED tests on the NovaSeq instrument, {[redacted]} (CCFF ¶ 4655). In addition, the 43 percent price decrease only relates to the price *per gigabase* of sequencing rather than the price per read. A reduction in the price per gigabase of sequencing means little to MCED test developers due to the small number of nucleotides in each strand of cfDNA that the MCED test measures. *See, e.g.*, {[redacted]}

reduce sequencing costs to $100 per genome, from the current price of $600 per genome. (CCFF ¶¶ 4658-69). And, internally, {[redacted]} (CCFF ¶ 4669). A price decrease from $600 to $100 would be an 83 percent decrease, much higher than 43 percent. (CCFF ¶ 4662). Because the cost of sequencing is expected to decrease much faster than what is provided for in the Open Offer, Illumina's customers view the pricing terms as {[redacted]} *See* (CCFF ¶¶ 4690, 4703). Price assurances of any sort are a poor substitute for a competitive market and, accordingly, such promises "cannot rebut a likelihood of anticompetitive effects." *H&R Block*, 833 F. Supp. 2d at 82.

Furthermore, the Open Offer purports to key customer pricing to the volume-based pricing that Grail receives, which fails to remedy Illumina's ability to favor Grail and offer noncompetitive prices to Grail's rivals. First, given that Grail is under Illumina's ownership, Grail's pricing is a fiction that can be easily manipulated by Illumina. As Grail's SVP of Finance, Aaron Freidin, admitted at trial that, while he does not know how Illumina will account for Grail's purchases of Illumina products, he does know "that it all eliminates and you end up with a true cost at the end when you report your financials as a public company." (CCFF ¶ 4651). Respondents' economic expert, Dennis Carlton, likewise testified that "GRAIL doesn't technically pay a price. If you want to make up a scenario in which you force GRAIL to 'pay some price,' and you call that a transfer price . . . I'm happy to make that assumption." (CCFF ¶ 4652). Given that the Open Offer provides that a customer "will get access to the same prices" as Grail, (CCFF ¶ 4631), this would mean that Illumina would also have to provide its products to Grail's rivals at cost—something that Respondents have never alleged, and that Dr. Carlton admits "is not my understanding," (CCFF ¶

4634). Instead, it is clear that Illumina can manufacture whatever price it wants for Grail and peg the prices for other MCED test developers to that artificial transfer price. As Kevin Conroy, Exact's CEO, explained { } (CCFF ¶ 4383); *see* also (CCFF ¶ 4638) (Helio's Chahine testifying "Illumina would be Grail, so I don't know what giving Grail a price actually means in this context.").

Second, the Open Offer's pricing terms exclude the additional discretionary discounts that Illumina has commonly offered to customers prior to the Acquisition. (CCFF ¶¶ 2733, 4641-43). In pricing its products, Illumina has a { } (CCFF ¶ 2773), but also commonly offers customers discounts { } First, Illumina offers { } (CCFF ¶ 5687). These { } and can vary based on the customer's application. *See* (CCFF ¶¶ 5688-91). Second, however, Illumina offers discretionary discounts { } (CCFF ¶ 2735). These discounts are for more { } (CCFF ¶ 2736), { } (CCFF ¶¶ 2737-39). It is this discretionary discounting which determines the "ultimate[] price the customer pays." (CCFF ¶ 4643). While the Open Offer purports to equalize the volume-based discounts that MCED test developers may receive for certain levels of sales, the

Open Offer does nothing to account for these discretionary discounts. As Illumina's SVP and General Manager of the Americas, and signatory to the Open Offer, testified, under the Open Offer, customers are only eligible to receive discretionary discounts for activities that are considered "short term projects" as defined in the Open Offer, meaning the activities fall *outside* of the normal course of business. (CCFF ¶ 4642). Thus, while absent the Acquisition customers can, and do, receive discretionary discounts from Illumina for a variety of reasons {[redacted]} (CCFF ¶ 2734), Respondents' Open Offer abolishes these discounts, ultimately leading to higher prices than in a non-Acquisition world.

iii. *The Firewall is Insufficient*

Evidence also shows that the firewall provision in the Open Offer fails to prevent Grail from having access to its rivals' competitively sensitive information.[117] 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." (CCFF ¶ 4728). This undefined "firewall," however, is insufficient. As former SVP and General Manager of the Americas at Illumina, Dave Daly, testified, {[redacted]}

[117] As the U.S. Department of Justice explained in its Merger Remedies Manual, "[f]irewalls are infrequently used [in merger remedies] because, no matter how well crafted, the risk of collaboration in spite of the firewall is great." DOJ Merger Remedies Manual § III.B.1. When firewall provisions are used, they are employed "in limited circumstances to facilitate structural relief." *Id*.

[redacted] (CCFF ¶ 4774). Guardant's Getty testified that, post-Acquisition, 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 the most competitive Grail that can possibly exist in order to win the 60-billion-dollar market." (CCFF ¶ 4736).

Moreover, a firewall also may not be practical. First, Respondents tout the post-Acquisition benefits from collaboration between Illumina and Grail. Resp. Pretrial Br. at 9-12. These purported benefits are in direct contradiction with the supposed ability of the firewall to segregate access to confidential information. At trial, Illumina's CEO, Francis deSouza, testified that, post-integration, Illumina's [redacted] (CCFF ¶¶ 3043, 3055, 3057, 3059). Such close collaboration between Illumina and Grail is inherently in conflict with the apparent firewall in place. Second, as people switch between Illumina and Grail, as has been a common past practice, *see* (CCFF ¶¶ 5384-85, 6044-47), a firewall will be hard to maintain. As Exact's CEO, Kevin Conroy, testified, [redacted]

[redacted] (CCFF ¶ 4779).

While the firewall provision is inadequate on its face, this Court need not even predict whether the firewall will have any efficacy now that Illumina has acquired Grail. As Respondents indicated at trial, the Open Offer (which includes the firewall provision) is in effect because Respondent closed the Acquisition prior to this proceeding. Op. Stmt. (Resp.) Tr. 84-85. After the Acquisition closed and the firewall went into effect, however, Illumina [redacted] (CCFF ¶¶ 3040-41). In addition, Illumina's CEO, Francis deSouza, admitted at trial that, post-Acquisition, [redacted] (CCFF ¶¶ 3035, 3038-39). Illumina also appointed Bob Ragusa, Illumina's Chief Operations Officer, as CEO of Grail. (CCFF ¶ 226). Now, as CEO of Grail, Ragusa can use information from his prior executive role to dictate Grail's own MCED Test strategy. And, although post-Acquisition Illumina has appointed a new account manager to handle Grail's account, this account manager reports directly to senior sales leaders at Illumina who have [redacted] (CCFF ¶¶ 4756-58). Thus, despite the firewall provision of the Open Offer, both Illumina and Grail have access to each other's proprietary information. As Grail's own Chief Medical Officer, Dr. Joshua Ofman, testified, [redacted] (CCFF ¶ 4760).

iv. *The Open Offer Cannot be Adequately Monitored or Enforced*

Even if one could draft contractual terms that could address the plethora of post-Acquisition harms, it would be difficult—if not impossible—to monitor Illumina's compliance unless violations of the contract could be detected and enforced quickly. As a result, such a contract would not prevent Illumina from acting on its incentive to disadvantage Grail's rivals. 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 whether Grail has advanced knowledge of Illumina's pipeline products, {[redacted]} whether Illumina has developed products specifically to "improve GRAIL's work flow," *see* (CCFF ¶ 4536); the quality and timing of services Grail receives from Illumina; or even what prices Grail ultimately pays, *see* (CCFF ¶¶ 4831-33, 4558, 4579, 4503, 4753). As Guardant's Getty explained, "[a] contract is only as good as it is enforceable. And ultimately [Guardant's ability] to investigate adherence to the terms of that contract is nearly impossible." (CCFF ¶ 4804).

While the Open Offer provides for regular "audit by an independent third-party auditor selected by Illumina," (CCFF ¶ 4843), this review of Illumina's adherence to its own contractual terms falls flat. As Exact CEO Kevin Conroy testified at trial, {[redacted]} (CCFF ¶ 4853). 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.[118] 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." (CCFF ¶ 4507). [redacted] Even Respondents' experts agree that an auditor will not be able to determine whether Illumina complies with the terms of the Open Offer. For example, Respondent expert Margaret Guerin-Calvert testified that the auditing process is not "100 percent certain" because certain breaches, like breaches of the firewall provision, "may not end up falling to [the auditor] in a form that [is] detectable." (CCFF ¶ 4881). Respondent expert Robert Rock echoed Guerin-Calvert, testifying that {[redacted]} (CCFF ¶ 4776).

Second, the audit will not determine whether Illumina has breached the Open Offer, but instead, will merely "present specific findings to assist customers in evaluating" Illumina's compliance. (CCFF ¶ 4915); *see also* (CCFF ¶¶ 4880, 4916-18). Instead, after an auditor provides a report, Illumina's MCED test developer customers will have to {[redacted]

118 {[redacted]

[redacted]} through the arbitration process outlined in the Open Offer, which takes time, costs money, and puts customers in a difficult antagonistic position with their sole-source supplier. (CCFF ¶ 4854; 4936); *see also* (CCFF ¶ 4928) [redacted]} (CCFF ¶ 4932); *see also* (CCFF ¶ 4941) (Guardant's Getty testifying that "poking the bear is not exactly a good idea"). FMI's Chief Operating Officer, Konstantin Fiedler, added that a contentious relationship with Illumina may strain the partnership relationship, resulting in Illumina not "going the extra mile when it's required." (CCFF ¶ 4942). Furthermore, arbitration ties up a company's resources, which could otherwise have been spent on research and development efforts. (CCFF ¶¶ 4928, 4937-38). During this time, Illumina can {[redacted]} (CCFF ¶ 4847). As an affiliate of Illumina, however, Grail is not subject to the Open Offer and thus would not have to spend the time and money to engage in arbitration if it has a dispute with its parent company. (CCFF ¶ 4815).

v. *The Open Offer Fails to Resolve Customer Concerns*

Given the deficiencies of the Open Offer's terms, each and every MCED test developer that has reviewed the Open Offer has expressed grave concerns about Respondents' proposed

remedy. (CCFF ¶¶ 4993-5012).[119] As Guardant's VP of Commercial, Cancer Screening Core, William Getty, testified, "the offer that is put forward is nothing more than a paper tiger. It's very difficult to understand how that would alleviate our concerns about a combined GRAIL and Illumina organization," adding that "[u]ltimately, . . . we don't have an option." (CCFF ¶ 4993). Michael Nolan, Freenome's CEO, referred to the Open Offer as {[redacted]} Far from restoring the competitive intensity lost from the Acquisition, the Open Offer does little to ameliorate the substantial customer concerns.

G. Remedy

To remedy Illumina's illegal acquisition of Grail, Complaint Counsel seeks an order ("Proposed Order" or "CCPO" attached as Attachment A) requiring that Illumina divest Grail's

[119] Respondents incorrectly presented to this Court that {[redacted]} *See* Answer at 11. [redacted] (CCFF ¶ 4335). [redacted] } (CCFF ¶ 4460).

ongoing business to restore the competition lost from the Acquisition. The Proposed Order would require Respondents to submit to the Commission or the Director of the Bureau of Competition, if so delegated by the Commission, for approval a divestiture plan that requires Illumina to transfer ownership of Grail through a sale to a qualified, buyer, corporate spin-off, or public stock offering. The Proposed Order would also allow Illumina to retain an investment in Grail equal to the amount of its investment prior to the Acquisition. Divestiture of Illumina's controlling ownership in Grail is the necessary and appropriate remedy to "restore competition lost through the unlawful acquisition." *Otto Bock,* 2019 WL 2118886, at *53 (Chappell, A.L.J.) (quoting *du Pont 1961*, 366 U.S. at 329).

1. Divestiture of Grail's Ongoing Business is the Proper Remedy and Will Restore Competition

Both this Court and the Supreme Court have declared complete divestiture as "the usual and proper remedy where a violation of Section 7 has been found." *Polypore,* 2010 WL 9434806, at *256 (Chappell, A.L.J.) (citing *du Pont 1961*, 366 U.S. at 329; *Ford Motor*, 405 U.S. at 573); *see also Otto Bock,* 2019 WL 5957363, at *45 (holding that "a complete divestiture of Freedom . . . is necessary to restore competition in the MPK market"). According to the Supreme Court, "[t]he very words of § 7 suggest that an undoing of the acquisition is a natural remedy." *du Pont 1961*, 366 U.S. at 329. Divestiture of an entire ongoing business is "simple, relatively easy to administer, and sure. It should always be in the forefront of a court's mind when a violation of § 7 has been found." *du Pont 1961*, 366 U.S. at 331.

Complaint Counsel has established that Illumina's acquisition of Grail has a reasonable probability of substantially lessening competition in the MCED Test Market in violation of Section 7. Having met that burden, "all doubts as to the remedy are to be resolved in its favor." *du Pont*

1961, 366 U.S. at 334. The Commission has broad discretion to select a remedy so long as it bears a "reasonable relation to the unlawful practices found to exist." *Jacob Siegel*, 327 U.S. at 611-13. Complaint Counsel seeks the divestiture of the viable Grail business that Illumina illegally acquired. Grail's competitiveness derives from its employees, products, technology, and tangible and intangible property used to research, develop, market, and sell MCED tests and other NGS-based oncology tests. A divestiture of Grail's ongoing business is, therefore, the only way to create a viable MCED Test competitor independent from Illumina that can replace the competitive intensity that was eliminated by Respondents' illegal Acquisition.

a. *Divestiture of Grail's Ongoing Business is Straightforward Because Grail Exists as a Viable, Separate Business*

It is not necessary to reconstitute Grail because it was never fully integrated into Illumina's broader operations. Instead, soon after the Acquisition was consummated, Illumina adopted a set of commitments to hold Grail separate from Illumina, agreeing that Grail "will be run as a separate entity, and where it engages with Illumina, it will do so on an arm's length basis." (CCFF ¶¶ 222-23). To be sure, competition in the MCED Test Market has been affected by the Acquisition,[120] but nevertheless the commitments have retained Grail largely as a separate entity. So long as the hold separate commitments remain, divestiture of Grail remains a "simple, relatively easy to administer, and sure," remedy despite the consummation of the illegal Acquisition. *du Pont 1961*, 366 U.S. at 331.

[120] As soon as Illumina completed its acquisition of Grail, it {[redacted]} (CCFF ¶¶ 3040-3041), and named its own COO, as the new CEO of Grail. (CCFF ¶ 226). Moreover, MCED Test competitors have expressed reluctance to continue innovation and investment in the MCED Test Market due to risks of the Acquisition. {[redacted]}

b. *Divestiture of Illumina's Ownership in Grail Is Necessary to Minimize Execution Risks and to Fully Restore Competition*

Courts and the Commission have consistently held that "undoing of the acquisition" is the "natural remedy" to cure the anticompetitive harms of an unlawful acquisition. *du Pont 1961*, 366 U.S. at 329; *see Ford Motor*, 405 U.S. at 573 (stating that "[c]omplete divestiture is particularly appropriate where . . . acquisitions violate the antitrust laws"); *RSR Corp. v. FTC*, 602 F.2d 1317 (9th Cir. 1979), at 1326 n.5 (stating that "complete divestiture of all pre-merger assets is the usual remedy for a Section 7 violation"). As this Court recognized "[i]n a merger case, absent 'unusual circumstances,' it is presumed that total divestiture of the acquired assets is the best means of restoring competition." *Otto Bock*, 2019 WL 2118886, at *53 (Chappell, A.L.J.); *see also* DOJ Merger Remedies Manual § II ("[C]onduct remedies are inappropriate except in very narrow circumstances."). For this reason, courts and the Commission typically require structural remedies to restore competitive harm lost from an unlawful merger. *See, e.g.*, *Otto Bock,* 2019 WL 5957363, at *44; *du Pont 1961*, 366 U.S. at 329; *Ford Motor*, 405 U.S. at 573; *Polypore*, 2010 WL 9434806, at *256 (Chappell, A.L.J.). Unlike a conduct, or behavioral, remedy, a structural remedy "is more likely to restore competition if the firms . . . are not under common ownership." *Evanston Northwestern*, 2007 WL 2286195, at *77.

As discussed *supra*, Respondents have offered a conduct remedy in the form of a 12-year supply agreement, known as the Open Offer, to resolve the competitive harm from the Acquisition. A conduct remedy generally entails a series of "provisions that would, in effect, regulate the merged firm's post-merger business conduct or pricing authority." DOJ Merger Remedies Manual § II. Here, Respondents' Open Offer provides certain contractual terms, drafted by Illumina, that

Illumina claims will help its MCED test developer customers compete against Grail in the MCED Test Market.

Illumina's Open Offer conduct remedy is insufficient. As explained in the DOJ's 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." § III.B.1. Here, given Illumina's multibillion-dollar incentive to use Grail to capture the immense potential MCED test sales, *see supra* § II.E.1.b., Illumina will possess an extremely strong incentive to delay supply, impede product quality, restrict access to new technology, and otherwise violate the terms of its customer contracts. 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-merger 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." Hoffman, *Vertical Merger Enforcement at the FTC,* at 8. And, even if Illumina unequivocally abided by the provisions of its contracts, against its own economic interests, "[c]ontractual terms [of conduct remedies] are difficult to define and specify with the requisite foresight and precision" needed to remedy competitive harm. *See* DOJ Merger Remedies Manual § III.B.1. This is true here. As discussed *supra*, the terms of the Open Offer are wholly insufficient to replace the competitive intensity that existed pre-Acquisition. *See* § II.F.3.b.

Moreover, "[t]here are also usually greater long-term costs associated with monitoring the efficacy of a conduct remedy than with imposing a structural solution." *Evanston Northwestern*,

2007 WL 2286195, at *77. As discussed *supra*, it would be difficult, if not impossible, to monitor and enforce Illumina's compliance with the Open Offer. *See* (CCFF ¶¶ 4171-4172). As Dr. Scott Morton testified, {[redacted]} (CCFF ¶ 4171). Even if, as Respondents have suggested in their submissions to the Court, *see* Mot. for Conference to Facilitate Settlement, *In re Illumina, Inc., and GRAIL, Inc.,* Docket No. 9401, at 4 (F.T.C. July 13, 2021), the Commission appointed a monitor trustee to "continually monitor" Illumina's compliance with the Open Offer, the amount of oversight required would create substantial government regulation and entanglement in an industry thriving on innovation. It is for this reason that courts have generally warned that conduct remedies are "disfavored because they 'risk excessive government entanglement in the market.'" *See, e.g.*, *Steves & Sons, Inc. v. JELD-WEN, Inc.*, 988 F.3d 690, 720 (4th Cir. 2021) (quoting *Saint Alphonsus,* 778 F.3d at 793).[121]

As the Fourth Circuit explained "if courts were required to choose the remedy least burdensome to the defendant—rather than the one that best promotes competition—conduct remedies would be the norm because they generally burden defendants less." *Steves & Sons,* 988 F.3d at 720. "But that would go against Congress's policy judgment that divestiture is 'the remedy best suited to redress the ills of an anticompetitive merger.'" *Steves & Sons,* 988 F.3d at 720 (quoting *Am. Stores*, 495 U.S. at 285). Anything less than divestiture of Illumina's ownership in

[121] This is echoed by U.S. agencies. *See* DOJ Merger Remedies Manual § II (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.").

Grail would risk not restoring the competition that was lost when Illumina acquired Grail. While a series of long-term supply agreements serve Respondents' interest, these agreements would force MCED test developers and, more importantly, American consumers, to bear the considerable risk that the agreements would fail to fully restore competition for these critical tests. Risk of a failed remedy should fall on Respondents, not the patients who will ultimately rely on these life-saving tests. *See Otto Bock*, 2019 WL 5957363, at *142 (explaining that "we aim to avoid placing the risk of a failed remedy on consumers").

2. Every Provision of the Proposed Order Is Supported by Case Law and Sound Competition Policy

In its Order on Post-Trial Filings issued on March 23, 2022, the Court directed that Complaint Counsel "shall specifically include briefing in support of . . . the proposed remedy, including each and every provision of the proposed order (other than definitions, boilerplate, or non-substantive provisions)." Order on Post-Tr. Filings, *In re Illumina, Inc., and GRAIL, Inc.*, Docket No. 9401, at 3 (F.T.C. Mar. 23, 2022). In compliance with this directive, Complaint Counsel has attached as Attachment A an annotated version of its Proposed Order (the "Annotated Proposed Order"), which includes footnotes explaining the purpose of and precedent for each substantive section in the Proposed Order, as well as explanations of the need for specific provisions based on record evidence in this case.

Consistent with well-established law and typical Commission orders in merger cases, Complaint Counsel's Proposed Order seeks the full divestiture of Grail's business and assets to remedy the anticompetitive effects of the Acquisition. Section II of the Proposed Order provides for this divestiture obligation, along with related obligations typically included in Commission orders to facilitate the divestiture process. (CCPO § II). Section II describes the assets and

information that must be divested, how such assets and information are to be divested, and the timing under which they should be divested. Section II also provides for transition services that must be provided to the Acquirer[122] of the business, and provides for obligations relating to the retention, recruitment, and employment of employees that are essential to the divested business. The provisions within Section II are consistent with orders typically issued by the Commission, including the Otto Bock Order. *See* Final Order, *In re Otto Bock HealthCare North America, Inc.*, Docket No. 9378, at ¶ II (F.T.C. Nov. 1, 2019) [hereinafter "Otto Bock Order"].

The Proposed Order requires Illumina to submit, within 90 days of the date the Order becomes final, a proposed divestiture plan to the Director of the Bureau of Competition for review and approval. (CCPO ¶ II.A). Illumina is then required to divest the Grail business and assets within 180 days after receiving approval of its divestiture plan, or on a longer timeline if provided by the divestiture plan approved by the Director of the Bureau of Competition. (CCPO ¶ II.C). This approach is designed to give Illumina flexibility in proposing the manner of the divestiture and gives Illumina the option to propose something other than a traditional sale, *e.g.,* a spin-off transaction or public stock offering.[123] The Proposed Order also allows Illumina to retain an ownership stake in Grail equal to the stake it held prior to the Acquisition Date. (CCPO ¶ II.C). If Illumina fails to submit a divestiture plan on the timeline required by the Proposed Order, or if Illumina fails to secure approval for its plan within 60 days of submission, the Proposed Order provides that a Divestiture Trustee may be appointed to sell the assets. (CCPO ¶ II.B, § VI).

[122] "Acquirer" as defined in the Proposed Order means "the Person that acquires the Hold Separate Business from Respondents pursuant to this Order. In the event of a divestiture effectuated through a corporate spin-off or offering of shares directly to investors, "Acquirer" shall mean the new, independent corporate entity." (CCPO ¶ I.C).
[123] {[redacted]} (CCFF ¶ 172).

Paragraph II.D of the Proposed Order requires Illumina to return to Grail any proceeds from the divestiture in excess of Illumina's "Investment Amount," as defined in the Proposed Order. This provision prevents Illumina from realizing undue profits from its unlawful acquisition of Grail, which was consummated even though, as Illumina admitted in filings with the SEC, "Illumina was prohibited from implementing the Acquisition" during the "pendency of the European Commission's review." (CCFF ¶¶ 220-21). The provision allows Illumina to fully recoup its purchase price and investments, and to realize a reasonable return on its capital outlays, but requires that Illumina return any additional profits to the Grail business. (CCPO ¶ II.D).

The Proposed Order requires Illumina to provide typical transition services to an Acquirer (for up to two years, if needed), to ensure an orderly transfer of the business and assets. (CCPO ¶ II.H). These services are to be provided at the price set out in a Divestiture Agreement or, if no price is set forth in a Divestiture Agreement, at Direct Cost. (CCPO ¶ II.H.1.b).

Because a successful remedy requires that the employees stay with the divested business, the Proposed Order provides explicitly that the Acquirer will be allowed "to recruit and employ *any* GRAIL Employees in connection with the divestiture." (CCPO ¶ II.I) (emphasis added). Furthermore, because it is critically important that the buyer conduct adequate due diligence to avoid surprises when acquiring a divested business, the Proposed Order requires that Respondents provide the buyer with "all information and documents relating to the Hold Separate Business customarily provided in a due diligence process[.]" (CCPO ¶ II.F.1).

The Proposed Order also imposes full hold separate and asset maintenance obligations on Respondents. Section III of the Order requires that Grail be operated and maintained as a separate and independent business until the divestiture date, and that Illumina take all actions necessary to

maintain and preserve the full economic viability, competitiveness, independence, and marketability of the Grail business and assets until the divestiture is completed. (CCPO § III). Hold separate and asset maintenance obligations are common in Commission orders, including the Otto Bock Order. (Otto Bock Order ¶ IV).

As part of these obligations, Section III imposes restrictions on Illumina's use or disclosure of the confidential business information of Grail, and vice versa. (CCPO ¶ III.J-L). Section III also restricts Illumina's ability to transfer, recruit, or solicit Grail's workforce during the hold separate period, as such actions could undermine Grail's ability to carry on its business during this period. (CCPO ¶ III.G-I). Because several of these confidentiality and employee hiring provisions will also be needed to protect the Acquirer of the Grail business in the post-divestiture period, several of these provisions continue beyond the divestiture date. (CCPO ¶¶ II.K-L).

Section III also prohibits certain Illumina key executives from serving in key leadership roles with Grail, providing that "GRAIL shall not employ any person as a GRAIL Executive who has served as an Illumina Restricted Executive during the preceding 5 years." (CCPO ¶ III.F).[124] As the Annotated Proposed Order explains, these prohibitions are intended to limit and undo any (1) conflict of interests that may result from Illumina's appointment of Illumina executives to lead Grail, (2) anticompetitive flow of confidential information between Illumina and Grail, and (3) financial conflicts that exist or could arise in the future. (CCFF ¶¶ 226, 2709, 3036-3037, 4732, 4851). The Proposed Order also includes prohibitions against Illumina hiring away key Grail executives, as doing so could undermine Grail's business and allow Illumina access to Grail's

[124] "Illumina Restricted Executive" means any person serving in the following positions at Illumina (including positions that are the functional equivalent): Chief Executive Officer, President, Chief Operating Officer, and Chief Commercial Officer. (CCPO ¶ I.Z).

confidential information, technology, and processes, which Illumina could use to replicate Grail's products or technology for its own use and profit. (CCPO ¶ III.G); *see also* (CCFF ¶¶ 6044-47).

The Proposed Order appoints a Hold Separate Manager to oversee the Grail business and assets until the divestiture is completed. (CCPO ¶ IV). The Hold Separate Manager will help ensure that Grail is operated independent of Illumina and that its viability and competitiveness are maintained during the hold separate period. Hold Separate Managers are often used by the Commission in cases where hold separate obligations are imposed, including in Otto Bock. (Otto Bock Order ¶ IV.A, Appx. D, E). Section V of the Proposed Order appoints Mazars LLP as Monitor to oversee Respondents' compliance with their obligations. The Commission often appoints an independent third party to monitor compliance with its orders, including Otto Bock. (Otto Bock Order ¶ VI). Mazars already serves as the hold separate Monitoring Trustee pursuant to the European Commission's decision implementing interim hold-separate measures related to the Acquisition.[125] Appointing Mazars to serve in this similar role for the Commission promotes continuity and efficiency moving forward. Mazars is an experienced monitor and has served as a Commission-approved monitor in prior divestiture remedy matters. *See, e.g.*, Decision and Order, *In re Stryker Corp. and Wright Med. Grp. N.V.*, Docket No. C-4728, at 12 (F.T.C. Dec. 11, 2020).

On October 25, 2021, the Commission issued a policy statement providing that "[g]oing forward, the Commission returns to its prior practice of including prior approval provisions in all merger divestiture orders for every relevant market where harm is alleged to occur, for a minimum

[125] *See* Monitoring Trustee in Case M.10493 - Illumina/GRAIL (Art. 8(h5) procedure), *available at* https://ec.europa.eu/competition/mergers/cases1/202202/M_10493_8109037_452_3.pdf.

of ten years."[126] Consistent with the policy statement, the Proposed Order requires prior approval of the Commission if Illumina acquires an interest in a business developing, marketing, or selling MCED tests, or if Illumina seeks to acquire any additional ownership stake in Grail. (CCPO ¶ VII).

CONCLUSION

For the foregoing reasons, the evidence presented at trial and admitted into the record establishes that Illumina's acquisition of Grail violates Section 7 of the Clayton Act and Section 5 of the FTC Act, as alleged in the Complaint, and justifies entry of the enclosed Proposed Order and any such other relief that the Court deems necessary and proper.

Dated: April 22, 2022

Respectfully submitted,

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[126] *See* Statement of the Commission on Use of Prior Approval Provisions in Merger Orders (Oct. 25, 2021) at 2, *available at* https://www.ftc.gov/system/files/documents/public_statements/1597894/p859900priorapprovalstatement.pdf.

ATTACHMENT A

PUBLIC

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

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

[PROPOSED] ORDER

It is hereby **ORDERED:**

I. Definitions

As used in this Order ("Order"), the following definitions shall apply:

A. "Acquisition" means the acquisition by Illumina of the remaining ownership interest in GRAIL that Illumina did not own prior to the Acquisition Date.

B. "Acquisition Date" means August 18, 2021.

C. "Acquirer" means the Person that acquires the Hold Separate Business from Respondents pursuant to this Order. In the event of a divestiture effectuated through a corporate spin-off or offering of shares directly to investors, "Acquirer" shall mean the new, independent corporate entity.

D. "BC Bureau Director" means the Director or Acting Director of the Federal Trade Commission's Bureau of Competition. In the event of a vacancy or recusal, "BC Bureau Director" shall mean the Deputy Director, Acting Deputy Director, or other FTC employee, that the Chair or Acting Chair of the Commission designates to manage this matter on behalf of the Bureau of Competition.

E. "Business Information" means books, records, data, and information, wherever located and however stored, including documents, written information, graphic materials, and data and information in electronic format. Business Information includes records and information relating to sales, marketing, advertising, personnel, accounting, business strategy, algorithms, machine learning data, artificial intelligence, clinical trials and

studies, information technology systems, customers, suppliers, research and development, registrations, licenses, permits, and operations.

F. "Commission" or "FTC" or "Complaint Counsel" means the Federal Trade Commission.

G. "Confidential Information" means nonpublic Business Information.

H. "Consent" means an approval, consent, ratification, waiver, or other authorization.

I. "Contract" means an agreement, contract, lease, license agreement, consensual obligation, promise or undertaking with one or more third parties, whether written or oral, express or implied, or legally binding.

J. "Respondents" mean Illumina and GRAIL.

K. "Direct Cost" means a cost not to exceed the actual cost of labor, materials, travel, and other expenditures. The cost of any labor included in Direct Cost shall not exceed the then-current average hourly wage rate for the employee providing such labor.

L. "Divest" means to transfer ownership of the Hold Separate Business through sale to an Acquirer, or through a spin-off or public stock offering.

M. "Divestiture Agreement" means any agreement, including all exhibits, attachments, agreements, schedules, and amendments thereto, and through which Respondents (or the Divestiture Trustee) transfer ownership of the Hold Separate Business through sale to an Acquirer, or through a spin-off or public stock offering.

N. "Divestiture Date" means the date Respondents (or the Divestiture Trustee) close on a transaction to Divest the Hold Separate Business.

O. "Divestiture Trustee" means the Person appointed pursuant to Section VI of this Order.

P. "Governmental Authorizations" means a Consent, license, registration, pending application, clearance, authorization, approval, or permit that is issued, granted, given, or otherwise made available by or under the authority of any governmental body or pursuant to any legal requirement.

Q. "GRAIL" means GRAIL, LLC, its directors, officers, employees, agents, representatives, successors, and assigns; the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by GRAIL, LLC, and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.

R. "GRAIL Assets" means all rights, title, and interest in and to all tangible and intangible property and assets, of every kind and description, wherever located, and any improvements or additions thereto, used in or relating to the GRAIL Business, or acquired in connection with the Acquisition, including:

1. All real property interests (including fee simple interests and real property leasehold interests), including all easements, and appurtenances, together with all buildings and other structures, facilities, and improvements located thereon, owned, leased, or otherwise held;

2. All equipment;

3. All accounts receivable;
4. All inventories;
5. All Business Information;
6. All Intellectual Property;
7. All Contracts and all outstanding offers or solicitations to enter any contract, and all rights thereunder and related thereto; and
8. All Governmental Authorizations and all pending applications therefor or renewals thereof, to the extent transferable.

S. "GRAIL Business" means (1) the business in which GRAIL was engaged prior to the Acquisition Date, including the business of developing, marketing, and selling NGS-based oncology tests such as multi-cancer early detection ("MCED") tests, and (2) any improvements, developments, expansions, and changes to the business in which GRAIL has or is engaged since the Acquisition Date.

T. "GRAIL Employees" means all persons who were employed by GRAIL at any time between September 21, 2020, and the Divestiture Date, including contractors, representatives, and consultants.

U. "GRAIL Executive" means any person serving in a position (including positions that are the functional equivalent) of GRAIL Chief Executive Officer, Chief Medical Officer, President, Chief Financial Officer, Chief Operating Officer, Chief Security Officer, Chief Marketing Officer, Chief Commercial Officer, Chief Technology Officer, General Counsel, and anyone serving at the Vice President level (or higher) with responsibilities for sales, marketing, R&D, product development, corporate development, strategy, investor relations, regulatory affairs, government affairs, or financial planning.

V. "Hold Separate Business" means the (1) GRAIL Assets and (2) GRAIL Business.

W. "Hold Separate Manager" means the individual appointed pursuant to Paragraph IV.A of this Order.

X. "Hold Separate Period" means the period between the date this Order is issued and the Divestiture Date.

Y. "Illumina" means Illumina, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Illumina Inc., and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.

Z. "Illumina Restricted Executive" means any person serving in the following positions at Illumina (including positions that are the functional equivalent): Chief Executive Officer, President, Chief Operating Officer, and Chief Commercial Officer.

AA. "Intellectual Property" means all intellectual property, including: (1) all patents, patent applications, inventions, and discoveries that may be patentable; (2) all know-how, trade

secrets, software, technical information, data, algorithms, artificial intelligence, machine learning data, registrations, applications for governmental approvals, inventions, processes, best practices (including clinical pathways), formulae, protocols, standards, methods, techniques, designs, quality-control practices and information, research and test procedures and information, and safety, environmental and health practices and information; (3) all confidential or proprietary information, commercial information, management systems, business processes and practices, qualification and approval practices and information, training materials, sales and marketing materials, customer support materials, advertising and promotional materials; and (4) commercial names, all assumed fictional business names, trade names, "doing business as" (d/b/a names), registered and unregistered trademarks, service marks and applications, and trade dress; (5) all registered and unregistered copyrights in both published works and unpublished works; (6) all rights in internet web sites and internet domain names presently used; and (7) all rights in any jurisdiction to limit the use or disclosure of any of the foregoing, and rights to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, violation, or breach of any of the foregoing.

BB. "Investment Amount" means the amount equal to (1) the total consideration Illumina paid (in the form of cash, common stock, assumption of debt, and other consideration as may be applicable) to consummate the Acquisition; (2) plus the dollar value of all after-tax net free cash outflows Illumina incurred after the Acquisition Date to develop, operate, maintain, and grow GRAIL, excluding any costs Illumina incurred in connection with legal fees related to the Acquisition; (3) minus, if applicable, any recoupment or repayments of those amounts received by Illumina, and (4) plus the cost of capital.

CC. "Monitor" means the Person appointed pursuant to Section V of this Order.

DD. "Person" means any natural person, partnership, corporation, association, trust, joint venture, government, government agency, or other business or legal entity.

EE. "Transition Assistance" means technical services, personnel, assistance, training, cooperation, and other logistical, administrative, and transitional support as required by the Acquirer to facilitate the transfer of the Hold Separate Business to the Acquirer, including with respect to: audits, finance and accounting, accounts receivable, accounts payable, employee benefits, payroll, pensions, human resources, purchasing, quality control, transfer of information technology and related systems, use of any name or brand used in the GRAIL Business for transitional purposes, Governmental Authorizations, regulatory approval and compliance, research and development, sales and marketing, and supply chain management.

II. Divestiture and Other Obligations[127]

A. No later than 90 days from the date this Order becomes final and effective, Illumina shall submit to the Commission, for approval by the Commission or BC Bureau Director, if so delegated by the Commission, a detailed plan to Divest the Hold Separate Business pursuant to the requirements of this Order ("divestiture plan").[128]

B. If Illumina does not provide a divestiture plan by the date provided for in Paragraph II.A, or if Illumina does not secure the approval of the Commission or BC Bureau Director, if so delegated by the Commission, within 60 days of Illumina's submission of a divestiture plan, then, at any time thereafter and at the Commission's or BC Bureau Director's, if so delegated by the Commission, option, a Divestiture Trustee may be appointed to develop and execute a divestiture plan pursuant to Section VI of this Order.

C. No later than 180 days from the date Illumina receives approval of its divestiture plan pursuant to Paragraph II.A, Illumina shall Divest, absolutely and in good faith, and at no minimum price, the Hold Separate Business in accordance with the divestiture plan,

Provided, however, that the BC Bureau Director may approve, as part of the divestiture plan, a period longer than 180 days for Illumina to Divest the Hold Separate Business,

Provided, further, that Illumina may retain an investment in GRAIL equal to the amount of its investment prior to the Acquisition Date, which shall not exceed 12 percent on a fully-diluted basis, as provided in the divestiture plan.

D. Illumina shall return to GRAIL any proceeds from the divestiture of the Hold Separate Business that is greater than the Investment Amount.[129]

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[127] Section II of the Order describes the assets and information that must be divested, how such assets and information are to be divested, and the timing under which they should be divested. Section II also provides for transition services that must be provided to the Acquirer of the Hold Separate Business and provides a roadmap for retaining, recruiting, and employing the employees that are essential to the divested business. Section II is consistent with Orders typically issued by the Commission, including the Otto Bock Order. Final Order, *In the Matter of Otto Bock HealthCare North America, Inc*., Docket No. 9378, ¶ II (Nov. 1, 2019) [hereinafter "Otto Bock Order"]. Additional explanation is provided for certain paragraphs where Commission staff believes additional explanation will be helpful.

[128] Paragraphs II.A-II.C are structured to allow some flexibility regarding the manner of the divestiture, which may be appropriate based on the unique facts of this case. This approach gives Illumina the option to propose, e.g., a spin-off transaction or public stock offering to effectuate its divestiture obligation, in addition to the typical option of selling the business and assets to a single acquirer. This approach also allows Illumina to retain an ownership amount equal to the stake it held in GRAIL prior to the Acquisition Date. (CCFF ¶¶ 60, 3082).

[129] Paragraph II.D has been included to prevent Illumina from unfairly profiting from its premature acquisition of GRAIL, which was consummated even though, as Illumina admitted in filings with the SEC, "Illumina was prohibited from implementing the Acquisition" during the "pendency of the European Commission's review." (CCFF ¶¶ 220-21). This provision allows Illumina to recoup its investment and purchase price, along with a reasonable return on its capital outlays, while ensuring that any additional profits from the sale of GRAIL are returned to GRAIL. *See* (CCFF ¶¶ 218-23, 225).

E. Any Divestiture Agreement shall be incorporated by reference into this Order and made a part hereof, and any failure by Respondents to comply with the terms of the Divestiture Agreement shall constitute a violation of this Order,

Provided, however, that no Divestiture Agreement shall limit, or be construed to limit, the terms of this Order. To the extent any provision in the Divestiture Agreement varies from or conflicts with any provision in this Order such that Respondents cannot fully comply with both, Respondents shall comply with the Order.

F. Respondents shall:

1. Offer to furnish to prospective Acquirers all information and documents relating to the Hold Separate Business customarily provided in a due diligence process except such information or documents subject to the attorney-client privilege or work-product doctrine. Respondents shall permit prospective Acquirers of the Hold Separate Business to have reasonable access to personnel, to physical facilities for inspection, and to all financial, operational, or other documents and information customarily provided as part of a due diligence process, and

2. Require all prospective Acquirers to sign a confidentiality agreement pursuant to which that prospective Acquirer shall be required to maintain all Confidential Information obtained as part of the due diligence process as strictly confidential, including the nondisclosure of that information to all other employees, executives, or other personnel of the prospective Acquirer that were not involved in the due diligence process. Respondents shall require, as part of a confidentiality agreement, that the prospective Acquirer limit access to Confidential Information to only those employees necessary to conduct sufficient due diligence.

G. Respondents shall obtain, no later than the Divestiture Date and at their sole expense, all Consents from third parties and all Governmental Authorizations that are necessary to affect the complete transfer and divestiture of the Hold Separate Business to the Acquirer or for the Acquirer to operate any aspect of the Hold Separate Business;

Provided, however:

1. Respondents may satisfy the requirement to obtain all Consents from third parties by certifying that the Acquirer has entered into equivalent agreements or arrangements directly with the relevant third parties, or has otherwise obtained all necessary Consents and waivers; and

2. With respect to any Governmental Authorizations that are not transferable, Respondents shall, to the extent permitted under applicable law, allow the Acquirer to operate under Respondents' Governmental Authorizations pending the Acquirer's receipt of its own Governmental Authorizations, and Respondents shall provide such assistance as the Acquirer may reasonably request in connection with its efforts to obtain such Governmental Authorizations.

H. At the option of the Acquirer, Illumina shall provide the Acquirer with Transition Assistance sufficient to efficiently transfer the Hold Separate Business to the Acquirer, and assist the Acquirer in operating the Hold Separate Business in all material respects in the manner in which it was operated prior to the Acquisition and prior to the Divestiture Date.

1. Illumina shall provide such Transition Assistance:

   a. As set forth in the Divestiture Agreement, or as otherwise reasonably requested by the Acquirer;

   b. At the price set forth in the Divestiture Agreement, or if no price is set forth, at Direct Cost; and

   c. Until the Acquirer can operate the Hold Separate Business in all material respects in the manner in which it was operated prior to the Acquisition and prior to the Divestiture Date, or for a period of 2 years from the date the Hold Separate Business is transferred to an Acquirer pursuant to Paragraph II.B of this Order, whichever is later.

2. Illumina shall allow the Acquirer to terminate, in whole or part, any Transition Assistance provisions of the Divestiture Agreement upon commercially reasonable notice and without cost or penalty.

3. Illumina shall not cease providing Transition Assistance due to a breach by the Acquirer of the Divestiture Agreement, and shall not limit any damages (including indirect, special, and consequential damages) that the Acquirer would be entitled to receive in the event of Respondents' breach of the Divestiture Agreement.

I. Respondents shall allow the Acquirer to recruit and employ any GRAIL Employees in connection with the divestiture of the Hold Separate Business, including as follows:

1. No later than 5 days after execution of a Divestiture Agreement, Respondents shall (a) identify each GRAIL Employee, (b) allow the Acquirer an opportunity to interview any GRAIL Employee, and (c) allow the Acquirer to inspect the personnel files and other documentation relating to any GRAIL Employee, to the extent permissible under applicable laws.

2. Illumina shall (a) not offer any incentive to any GRAIL Employee to decline employment with the Acquirer, (b) remove any contractual impediments that may deter any GRAIL Employee from accepting employment with the Acquirer, including, any non-compete or confidentiality provisions of employment or other contracts that would affect the ability of the GRAIL Employee to be employed by the Acquirer, and (c) not otherwise interfere with the recruitment of any GRAIL Employee by the Acquirer.

3. Respondents shall (a) vest all current and accrued pension benefits within 30 days of transition of employment to the Acquirer for every GRAIL Employee who accepts an offer of employment from the Acquirer, and (b) provide all GRAIL

Employees with reasonable financial incentives to accept a position with the Acquirer.

Provided, further, that Respondents and the Acquirer will work together in good faith to determine whether any other Illumina employees should be identified and subject to the provisions of this Paragraph II.I.

J. Respondents shall transfer to the Acquirer, at Respondents' expense, all Business Information related to the Hold Separate Business, and:

1. Deliver such Business Information as follows: (a) in good faith; (b) as soon as practicable, avoiding any delays in transmission; and (c) in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;

2. Pending complete delivery of all such Business Information to the Acquirer, provide the Acquirer and Monitor with access to all such Business Information and employees who possess or can locate information for the purposes of identifying the books, records, and files that contain such Business Information and facilitate the delivery in a manner consistent with this Order.

K. Until 2 years after the Divestiture Date, the provisions of Paragraphs III.F – III.I of this Order shall remain in effect. Respondents shall implement, in consultation with the Monitor, all necessary measures to ensure its compliance with those provisions.[130]

L. Until 5 years after the Divestiture Date, the provisions of Paragraph III.K of this Order shall remain in effect. Respondents shall implement, in consultation with the Monitor, all necessary measures to ensure its compliance with those provisions.[131]

M. Illumina shall, no later than five 5 days after the date this Order becomes final and effective:

1. Require that each employee of Illumina who has, had, or may have had access to Confidential Information relating to the Hold Separate Business, and the direct supervisor(s) of any such employee, sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Information related to the Hold Separate Business as strictly confidential, including the nondisclosure of that information to all other employees, executives, or other personnel of Illumina (other than as necessary to comply with the requirements of this Order), or the use of such Confidential Information in any way.

2. Provide written notification of the restrictions on the use and disclosure of the Confidential Information related to the Hold Separate Business by Illumina's personnel to all its employees who (a) may be in possession of such Confidential

[130] Paragraphs II.K adopts and extends the obligations regarding employee hiring and solicitations, contained at Paragraphs III.F – III.I of this Order, for a period following the Divestiture Date.

[131] Paragraph II.L adopts and extends the obligations regarding the confidentiality and use of information, contained at Paragraph III.K of this Order, for a period following the Divestiture Date.

Information or (b) may have access to such Confidential Information. Illumina shall give the above-described notification by e-mail with return receipt requested or similar transmission and keep a file of those receipts for 2 years after the date this Order becomes final and effective. Illumina shall maintain complete records of all such notifications and shall provide a certification to the Commission affirming the implementation of, and compliance with, this Paragraph II.M.

III. Hold Separate and Asset Maintenance Obligations[132]

IT IS FURTHER ORDERED that during the Hold Separate Period:

A. Illumina shall not consolidate, integrate, coordinate, commingle, or otherwise combine the businesses, operations, services, locations, employees, Business Information, or products of the Hold Separate Business into or with any of its other businesses, operations, services, locations, employees, Business Information, or products.

Provided, however, that Illumina may perform its obligations as required or allowed by this Order, a Divestiture Agreement, or an arms-length Contract between Illumina and the Hold Separate Business entered in the ordinary course of business as independent entities (whether entered before or during the Hold Separate Period).

B. Illumina shall hold the Hold Separate Business separate, apart, and independent from Illumina, as required by the terms and conditions of this Order and shall vest the Hold Separate Business with all rights, powers, and authority necessary to conduct its business without involvement from Illumina. Illumina shall not exercise direction or control over the operations of the Hold Separate Business or the Hold Separate Manager, except to the extent explicitly permitted by this Order.

C. Illumina shall not sell, transfer, or otherwise encumber the Hold Separate Business.

D. Illumina shall take all actions necessary to maintain and preserve the full economic viability, competitiveness, independence, and marketability of the Hold Separate Business, including maintaining its operations, regulatory approvals, and research and development programs in the regular and ordinary course of business and in accordance with past practice, and to prevent the destruction, wasting, deterioration, or impairment of the Hold Separate Business, except for ordinary wear and tear, including among other things:

1. Provide the Hold Separate Business with sufficient funding, financial resources, and working capital necessary for it to independently operate at least at rates of operation as of the Acquisition Date, and provided for in any planning documents or budgets, to meet all capital calls, and to carry on, at least at their scheduled

[132] Section III provides that Illumina shall maintain and operate GRAIL as a separate and independent business during the Hold Separate Period. Section III also provides that during the Hold Separate Period, Illumina shall take such actions as are necessary to maintain the viability, marketability, and competitiveness of the Hold Separate Business. *See* Otto Bock Order ¶ IV.

pace, all research plans, development efforts, regulatory approvals, capital projects, budgets, business plans, and promotional activities;

2. Maintain a separate accounting and balance sheet for the Hold Separate Business, and ensure that any sales and profits of the Hold Separate Business become and remain part of the Hold Separate Business, independent of Illumina;

3. Provide such support services to the Hold Separate Business as were being provided to it as of or after the Acquisition Date, or as may be requested by the Hold Separate Manager or Monitor. For any services that Illumina may provide to the Hold Separate Business, Illumina may charge no more than the lesser of: (a) the same price, if any, charged to the Hold Separate Business for the service prior to the Hold Separate Period; or (b) its Direct Cost to provide such service;

4. Ensure that the Hold Separate Business has the resources to maintain a work force at least equivalent in size, training, and expertise to the work force of the Hold Separate Business prior to the Acquisition Date, plus any expansion provided for in any planning documents, budgets, or forecasts; and

5. Use best efforts to ensure the Hold Separate Business preserves and maintains its existing relationships with customers, suppliers, vendors, private and governmental entities, and others having business relations with the Hold Separate Business.

Provided, however, in connection with Divesting the Hold Separate Business, Illumina and the Hold Separate Manager may take actions that an Acquirer has requested or agreed to in writing and that have been approved in advance by the Monitor (in consultation with Commission staff), in all cases to facilitate the Acquirer's acquisition of the Hold Separate Business consistent with the purposes of this Order.

E. Illumina shall ensure that GRAIL Employees are provided with reasonable financial incentives to continue in their positions consistent with past practices or otherwise necessary to preserve the Hold Separate Business's viability, competitiveness, independence, and marketability. Such incentives shall include a continuation of all employee benefits, including regularly scheduled raises, bonuses, vesting of pension benefits (as permitted by law), and additional incentives necessary (including as may be determined by the Hold Separate Manager or Monitor) to ensure the continuation and prevent any diminution of the Hold Separate Business's viability, competitiveness, independence, and marketability.

F. Grail shall not employ any person as a GRAIL Executive who has served as an Illumina Restricted Executive during the preceding 5 years.[133]

[133] Paragraph III.F is included to limit the possibility of, and undue (as may be necessary), any (1) conflict of interests that may result from Illumina's appointment of Illumina Restricted Executives to lead GRAIL, (2) anticompetitive flow of confidential information between Illumina and GRAIL, and (3) financial conflicts that may arise in the future. (CCFF ¶¶ 226, 2709, 3036-3037, 4732, 4851).

Provided, further, the Hold Separate Manager shall bi-annually review each GRAIL Executive's holdings of financial interests or investments in Illumina (including stock ownership or options), as well as the GRAIL Executive's current and future compensation structure, and may require divestment of holdings or changes to the compensation structure to avoid conflicts of financial interest, as the Manager may deem appropriate to satisfy the purposes of this Order.

G. Illumina shall not hire any GRAIL Executive, or any person who served as a GRAIL Executive during the preceding 5 years.[134]

H. Illumina shall not, directly or indirectly, transfer any GRAIL employee or solicit or otherwise attempt to induce any GRAIL Employee to terminate his or her employment with the Hold Separate Business;

Provided, however, Illumina may:

1. Hire an employee whose employment has been terminated by GRAIL, as long as such termination was not solicited or induced in violation of this Order;
2. Advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, in either case not targeted specifically at one or more GRAIL Employees; or
3. Hire an employee who has applied for employment with Illumina, as long as such application was not solicited or induced in violation of this Order.

I. Illumina shall ensure that any former GRAIL Employee who works for Illumina (but not GRAIL) after entry of this Order (as allowed in Paragraph III.H):

1. Does not perform work on behalf of Illumina relating to MCED tests for at least 3 years after becoming an employee of Illumina, other than in support of GRAIL;
2. Does not use or share any GRAIL Confidential Information while he or she is an Illumina employee, except as explicitly permitted by this Order; and
3. Is eligible, at the option of the Hold Separate Manager, to be recruited and hired by the Hold Separate Business, in a capacity and on a timetable as determined by the Hold Separate Manager, and that:
    a. Any impediments to recruiting or hiring of such employee, or to the employee accepting such offer, are removed by Illumina, including any non-compete or confidentiality provisions, or other contractual impediments that may deter or affect the ability of the employee to be employed by the Hold Separate Business; and

[134] Paragraph III.G is included to prevent Illumina from hiring-away the key GRAIL executives, as this may undermine GRAIL's business and/or allow Illumina the ability to duplicate/replicate GRAIL's products or technology for Illumina's own use and profit. This provision will help ensure that any divestiture remedy remains viable and available and is not undermined by Illumina's hiring-away of key GRAIL executives. *See, e.g.*, (CCFF ¶¶ 6044-47).

b. Illumina offer no incentives to the employee to decline employment with the Hold Separate Business, and not otherwise interfere with the recruitment of any such employee by the Hold Separate Business.

J. Within 30 days of the date of this Order is issued, Respondents shall make an accounting of all Confidential Information of the Hold Separate Business that has been accessed or shared with Illumina and its employees or management, and (with the assistance and approval of the Monitor) develop and implement a plan to return all Confidential Information to the Hold Separate Business, and destroy all copies of, or notes derived from, the same, and to prevent the use of or access to the Confidential Information by Illumina or any other Person, except as may be allowed or required by this Order.

K. Respondents shall ensure, and shall implement, in consultation with the Monitor, all necessary measures to ensure, that:

1. Confidential Information is not shared or accessible between Illumina and GRAIL;

2. Confidential Information is separately maintained and stored;

3. Illumina does not obtain, use, or disclose (even to its own employees) any Confidential Information of GRAIL (including Confidential Information of third parties received by GRAIL in the ordinary course of business); and

4. GRAIL does not obtain, use, or disclose (even to its own employees) any Confidential Information of Illumina (including Confidential Information of third parties received by Illumina in the ordinary course of business).

Provided, however, that Respondents may disclose or use such Confidential Information in the course of (a) performing their obligations or as permitted under this Order, a Divestiture Agreement, or pursuant to an ordinary course, arms-length Contract between Illumina and the Hold Separate Business (whether entered before or during the Hold Separate Period) or (b) complying with financial reporting requirements, obtaining legal advice, prosecuting or defending legal claims or investigations, or enforcing actions threatened or brought against Illumina or the Hold Separate Business, or as required by law or regulation, including any applicable securities exchange rules or regulations.

L. Illumina shall implement written procedures, subject to the approval of the Monitor and consistent with the provisions of this Order, that ensure the operational independence of the Hold Separate Business, the independent management of the Hold Separate Business by the Hold Separate Manager, the Hold Separate Business has adequate funding and working capital, and there are effective restrictions on access and use of Confidential Information. Illumina shall provide notice of these procedures to its employees, and ensure that notice is provided to the employees of the Hold Separate Business, and shall:

1. Provide training on a regular schedule regarding these procedures and obligations to all employees and representatives who may receive or communicate Confidential Information pursuant to this Order;

2. Provide employees and representatives with the name and contract information of the Monitor;

3. Establish disciplinary action against any employee or representative who violates Section III of this Order; and

4. Provide the Monitor with the materials used in the trainings required by this Paragraph III.L.

IV. Hold Separate Manager[135]

A. In furtherance of the obligations listed in Section III of this Order, the BC Bureau Director shall appoint a Hold Separate Manager to independently manage and operate the Hold Separate Business during the Hold Separate Period.

B. The Hold Separate Manager shall be responsible for the operation of the Hold Separate Business, shall report directly to the Monitor, and shall manage the Hold Separate Business independently of the management of Illumina. The Hold Separate Manager shall not be involved, in any way, in the operations of the businesses of Illumina during the term of this Order, nor shall the Hold Separate Manager have any financial interest (including stock ownership or options) in Illumina. Following the Divestiture Date, Illumina shall not employ or engage the Hold Separate Manager in any capacity (including as an employee, agent, or consultant) for a period of 5 years.

C. Illumina shall authorize the Hold Separate Manager to make all decisions necessary (i) to ensure that the Hold Separate Business operates independently of Illumina and maintains its full economic viability, marketability, and competitiveness, and (ii) to prevent the Hold Separate Business's destruction, removal, wasting, deterioration, or impairment. Illumina shall cooperate with the Hold Separate Manager and take no action to interfere with or impede the ability of the Hold Separate Manager to perform his or her duties and responsibilities consistent with the terms of this Order.

D. No later than 5 days after this Order is issued, Illumina shall enter into a manager agreement with the Hold Separate Manager that, subject to the prior approval of the Monitor and Commission staff, transfers all rights, powers, and authority necessary to permit the Hold Separate Manager to perform his or her duties and responsibilities under this Order. The manager agreement shall provide that:

1. The Hold Separate Manager shall be responsible for managing the operations of the Hold Separate Business during the Hold Separate Period and shall manage the Hold Separate Business independently of the management of Illumina,

   Provided, however, the Hold Separate Manager will have the option to continue receiving any support services that have been provided to the Hold Separate

[135] Section IV provides for the appointment of a Hold Separate Manager. The purpose of this Section is to appoint a person whose responsibility is to ensure that GRAIL is maintained and operated independent of Illumina, and in a manner that GRAIL will maintain its viability and competitiveness during the Hold Separate Period. This Court approved the appointment of a Hold Separate Manager in *Otto Bock*. Otto Bock Order at Appx. D ¶ I.E.2.

Business by Illumina, and may request, in his or her discretion, additional support services from Illumina;

2. The Hold Separate Manager shall continue the management and operation of the Hold Separate Businesses in the ordinary course of business, pursuant to current and future business plans, and in accordance with the obligations of Section III of this Order;

3. The Hold Separate Manager shall serve, without bond or other security, at the cost and expense of Illumina, on reasonable and customary terms commensurate with the person's experience and responsibilities. The Hold Separate Manager shall have the authority to employ, at Illumina's expense, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Hold Separate Manager's duties and responsibilities;

4. Illumina shall indemnify the Hold Separate Manager and hold him or her harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Hold Separate Manager's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence or willful misconduct;

5. The Hold Separate Manager shall be in regular contact with the Monitor. Nothing shall preclude the Hold Separate Manager from contacting or communicating directly with the Monitor or the staff of the Commission, either at the request of the staff of the Commission or the Monitor, or in the discretion of the Hold Separate Manager;

6. The Hold Separate Manager shall have the authority to staff the Hold Separate Business with sufficient employees to maintain and restore the viability and competitiveness of the Hold Separate Business, including:

    a. Replacing any departing or departed employee with a person who has similar experience and expertise, or determining not to replace such departing or departed employee;

    b. Removing any employee who ceases to act or fails to act diligently and consistent with the purposes of this Order and replacing such employee with another person of similar experience or skills;

    c. Deciding to hire new employees, or re-hire former employees, and offering sufficient financial incentives to attract and retain such new or re-hired employees as the Hold Separate Manager shall determine in his or her judgment;

    d. Ensuring that GRAIL Employees are not involved in the operations of Illumina or Illumina's other businesses, and that Illumina's employees are

not involved in the operation of the Hold Separate Business, unless allowed or required under this Order; and

e. Ensuring that the GRAIL Employees are provided with reasonable financial incentives to continue in their positions, including a continuation of all employee compensation and benefits, regularly scheduled or merit raises and bonuses, regularly scheduled vesting of pension benefits, and additional incentives as may be necessary.

E. Illumina shall provide the Hold Separate Manager with reasonable financial compensation and incentives to undertake this position and as may be necessary to assure the continuation, and prevent any diminution of, the Hold Separate Business's viability, marketability, and competitiveness until the end of the Hold Separate Period, and as may otherwise be necessary to achieve the purposes of this Order.

F. If the Hold Separate Manager resigns or the Monitor, in consultation with Commission staff, determines that the Hold Separate Manager has ceased to act, has failed to act diligently, or is otherwise unsuited or unable to continue serving as a Hold Separate Manager, then a substitute Hold Separate Manager shall be appointed. The substitute Hold Separate Manager shall be afforded all rights, powers, and authorities and shall be subject to all obligations of this Order. Commission staff, in consultation with the Monitor, shall select the substitute Hold Separate Manager, subject to the consent of Respondents, which:

1. Shall not unreasonably withhold consent to the appointment of the selected substitute Hold Separate Manager; and

2. Shall be deemed to have consented to the selection of the proposed substitute Hold Separate Manager if, within 3 days of notice by staff of the Commission of the identity of the proposed substitute Hold Separate Manager, Respondents have not opposed in writing, including the reasons for opposing, the selection of the proposed substitute Hold Separate Manager.

V. Monitor[136]

A. Mazars LLP shall serve as Monitor in this matter with the responsibility for monitoring the organization of the Hold Separate Business, supervising the management of the Hold Separate Business by the Hold Separate Manager, monitoring the independence of the Hold Separate Business, and monitoring Respondents' compliance with all their other obligations under this Order.[137]

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[136] Section V provides for the appointment of a Monitor to oversee Respondent's compliance with the Order. The Commission often appoints an independent third party to monitor Respondents' compliance with their obligations under their order. Otto Bock Order ¶ VI.

[137] Mazars LLP already serves as the hold separate monitor pursuant to the EC's order. Monitoring Trustee in Case M.10493 – Illumina/GRAIL (Art. 8(5) procedure), *available at* https://ec.europa.eu/competition/mergers/cases1/202202/M_10493_8109037_452_3.pdf.

B. The Respondents and the Monitor may enter into an agreement relating to the Monitor's services. Any such agreement:

1. Shall be subject to the approval of Commission staff;

2. Shall not limit, and the signatories shall not construe it to limit, the terms of this Order and to the extent any provision in the agreement varies from or conflicts with any provision in this Order, Respondents and the Monitor shall comply with this Order; and

3. Shall include a provision stating that the agreement does not limit, and the signatories shall not construe it to limit, the terms of this Order, and to the extent any provision in the agreement varies from or conflicts with any provision in this Order, Respondents and the Monitor shall comply with the Order.

C. The Monitor shall:

1. Have the authority to monitor Respondents' compliance with the obligations set forth in this Order;

2. Act in consultation with the Commission or its staff, and the Hold Separate Manager;

3. Serve as an independent third party and not as an employee or agent of Respondents, the Court, or the Commission;

4. Serve without bond or other security;

5. At the Monitor's option, employ such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;

6. Enter into a nondisclosure or other confidentiality agreement with the Commission related to Commission materials and information received in connection with the performance of the Monitor's duties, and require that each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants also enter into a nondisclosure or other confidentiality agreement with the Commission;

7. Notify staff of the Commission, in writing, no later than 5 days in advance of executing an arrangement that creates a conflict of interest, or the appearance of a conflict of interest, including a financial, professional or personal conflict. If the Monitor becomes aware of such a conflict only after it has arisen, the Monitor shall notify the Commission as soon as the Monitor becomes aware of the conflict;

8. Report in writing to the Commission concerning Respondents' compliance with the Order on a schedule set by Commission staff and at any other time requested by Commission staff; and

9. Unless the Commission or its staff determine otherwise, the Monitor shall serve until 60 days after Respondents have satisfied their obligations in Sections II and III of this Order.

D. Respondents shall:

1. Cooperate with and assist the Monitor in performing his or her duties for the purpose of reviewing Respondents' compliance with their obligations under the Order, including as requested by the Monitor, (a) providing the Monitor full and complete access to personnel, information and facilities; and (b) making such arrangements with third parties to facilitate access by the Monitor;

2. Not interfere with the ability of the Monitor to perform his or her duties pursuant to the Order;

3. Pay the Monitor's fees and expenses as set forth in an agreement approved by Commission staff, or if such agreement has not been approved, pay the Monitor's customary fees, as well as expenses the Monitor incurs performing his or her duties under the Order, including expenses of any consultants, accountants, attorneys, and other representatives and assistants that are reasonably necessary to assist the Monitor in carrying out his or her duties and responsibilities;

4. Not require the Monitor to disclose to Respondents the substance of the Monitor's communications with the Commission or any other person or the substance of written reports submitted to the Commission pursuant to the Orders; and

5. Indemnify and hold the Monitor harmless against any loss, claim, damage, liability, and expense (including attorneys' fees and out of pocket costs) that arises out of, or is connected with, a claim concerning the performance of the Monitor's duties under the Order, unless the loss, claim, damage, liability, or expense results from gross negligence or willful misconduct by the Monitor.

E. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to enter into a customary confidentiality agreement, so long as the agreement does not restrict the Monitor's ability to access personnel, information, and facilities or provide information to the Commission, or otherwise observe and report on the Respondents' compliance with the Order.

F. If the Monitor resigns or the Commission staff determines that the Monitor has ceased to act, has failed to act diligently, or is otherwise unable to continue serving as a Monitor due to the existence of a conflict or other reasons, the Commission may appoint a substitute Monitor. The substitute Monitor shall be afforded all rights, powers, and authorities and shall be subject to all obligations of this Order. Commission staff shall select the substitute Monitor, subject to the consent of the Respondents. Respondents:

1. Shall not unreasonably withhold consent to the appointment of the selected substitute Monitor;

2. Shall be deemed to have consented to the selection of the proposed substitute Monitor if, within 10 days of notice by staff of the Commission of the identity of

the proposed substitute Monitor, Respondents have not opposed in writing, including the reasons for opposing, the selection of the proposed substitute Monitor; and

3. May enter into an agreement with the substitute Monitor relating to the substitute Monitor's services that either (a) contains substantially the same terms as the Commission staff-approved agreement referenced in this Order; or (b) receives approval of Commission staff.

VI. Divestiture Trustee[138]

A. If Illumina has not divested, absolutely and in good faith, the Hold Separate Business pursuant to the requirements of Section II of this Order, within the time and manner required by Section II of this Order, the Commission may at any time appoint one or more persons as Divestiture Trustee to divest the Hold Separate Business, at no minimum price, and pursuant to the requirements of Section II of this Order, in a manner that satisfies the requirements of this Order.

B. If the Commission or the Attorney General of the United States brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Illumina shall consent to the appointment of a Divestiture Trustee in such action. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Section VI shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including appointment of a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Illumina to comply with this Order.

C. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Section VI, Illumina shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to accomplish the divestiture pursuant to the requirements of Section II of this Order and in a manner consistent with the purposes of this Order.

2. Within 10 days after appointment of the Divestiture Trustee, Illumina shall execute an agreement that, subject to the prior approval of the Commission and, in the case of a court-appointed Divestiture Trustee, of the court, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture

[138] Section VI allows for the appointment of a divestiture trustee in the event that Illumina fails to divest the required assets and business within the time and manner identified in Section II. Most of the Commission's orders requiring divestiture authorize the Commission to appoint a trustee. Appointing a trustee is within the Commission's discretion. Otto Bock Order ¶ VII.

Trustee to affect the divestiture and perform the requirements of Section II of this Order for which he or she has been appointed.

3. The Divestiture Trustee shall have 12 months from the date the Commission approves the agreement described in Paragraph VI.C.2 of this Order to accomplish the divestiture ("divestiture period"), which shall be subject to the prior approval of the Commission. If, however, at the end of the divestiture period the Divestiture Trustee has submitted a plan of divestiture or believes that divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court appointed Divestiture Trustee, by the court.

4. Illumina shall provide the Divestiture Trustee with full and complete access to the personnel, books, records, and facilities related to the assets to be divested, or to any other relevant information, as the Divestiture Trustee may request. Illumina shall develop such financial or other information as the Divestiture Trustee may reasonably request and shall cooperate with the Divestiture Trustee. Illumina shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Illumina shall extend the divestiture period under this Section VI in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

5. The Divestiture Trustee shall use his or her best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission but shall divest expeditiously at no minimum price. The divestiture shall be made only to an Acquirer that receives the prior approval of the Commission, and the divestiture shall be accomplished only in a manner that receives the prior approval of the Commission;

   Provided, however, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity or entities selected by Illumina from among those approved by the Commission; provided, further*,* that Illumina shall select such entity within 10 business days of receiving written notification of the Commission's approval.

6. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Illumina, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Illumina, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for his or her services, all remaining monies (subject to the Investment Amount limitations

of Section II of this Order) shall be paid at the direction of Illumina, and the Divestiture Trustee's power shall be terminated. The Divestiture Trustee's compensation may be based in part on a commission arrangement contingent on the Divestiture Trustee's divesting the assets.

7. Illumina shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from gross negligence or willful misconduct by the Divestiture Trustee. For purposes of this Section VI, the term "Divestiture Trustee" shall include all Persons retained by the Divestiture Trustee pursuant to Paragraph VI.C.6 of this Order.

8. If the Divestiture Trustee ceases to act or fails to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Section VI for appointment of the initial Divestiture Trustee.

9. The Divestiture Trustee shall have no obligation or authority to operate or maintain the assets to be divested.

10. The Divestiture Trustee shall report in writing to the Commission every 60 days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

D. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

E. The Divestiture Trustee appointed pursuant to this Section VI may be the same Person appointed as the Monitor pursuant to this Order.

VII. Prior Approval[139]

IT IS FURTHER ORDERED that Illumina shall not, without the prior approval of the Commission, acquire, directly or indirectly, through subsidiaries, partnerships, or otherwise:

[139] Section VII provides for Commission prior approval if Illumina acquires any interest in a business developing, marketing, or selling MCED tests, as well as prior approval if Illumina acquires any additional interest in GRAIL. Provisions requiring Commission prior approval are routinely being included in merger Orders since July 2021. *See* FTC, "Statement of The Commission on Use of Prior Approval Provisions In Merger Orders" (October 25, 2021) ("Going forward, the Commission returns to its prior practice of including prior approval provisions in all merger divestiture orders for every relevant market where harm is alleged to occur, for a minimum of ten years."), *available at* https://www.ftc.gov/legal-library/browse/statement-commission-use-prior-approval-provisions-merger-orders.

A. Any ownership interest, stock, share capital, equity, or other interest in any business that, in the previous 12 months, engaged in, or had plans to engage in, the business of developing, marketing, or selling MCED tests; or

B. Following the Divestiture Date, any additional ownership, investment, or management interest in the GRAIL Business.

VIII. Compliance Reporting[140]

IT IS FURTHER ORDERED that, to allow the Commission to monitor Respondents' compliance with the provisions of this Order:

A. Respondents shall each submit:

1. Interim compliance reports 30 days after this Order is issued, and every 60 days thereafter until Illumina divests the Hold Separate Business to an Acquirer;
2. Annual Compliance Reports one year after the date this Order is issued, and annually thereafter for the next nine years on the anniversary of that date; and
3. Additional Compliance Reports as the Commission or its staff may request.

B. Each compliance report shall contain sufficient information and documentation to enable the Commission to determine independently whether Respondents are complying with this Order. Conclusory statements that Respondents have complied with their obligations under this Order are insufficient. Each Respondent shall include in its reports, among other information or documentation that may be necessary to demonstrate compliance, a full description of the measures the Respondent has implemented and plans to implement to comply with each paragraph of the Order.

C. Verify each compliance report in the manner set forth in 28 U.S.C. § 1746 by the Chief Executive Officer or another officer or employee specifically authorized to perform this function. Respondents shall submit each compliance report as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), including submitting the original electronically to the Secretary of the Commission at ElectronicFilings@ftc.gov and an electronic copies of to the Compliance Division at bccompliance@ftc.gov.

IX. Change in Respondents[141]

A. **IT IS FURTHER ORDERED** that Respondents shall notify the Commission at least 30 days prior to:

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[140] Section VIII outlines Illumina's reporting requirements to the Commission regarding its compliance with the provisions of the Order. The reporting requirements allow Staff and the Commission to monitor Illumina's compliance with the Order. Otto Bock Order ¶ VIII.

[141] Section IX provides that Illumina shall notify the Commission of any change in Respondents, including

1. any proposed dissolution of Illumina, Inc;
2. any proposed acquisition, merger or consolidation of Illumina, Inc.; or
3. any other change in Respondents, if such change might affect compliance obligations arising out of this Order.

X. Purpose

IT IS FURTHER ORDERED that the purpose of this Order is to: (A) remedy the harm to competition the Commission alleged in its Complaint; (B) ensure the Hold Separate Business is maintained in the ordinary course of business, and managed independently of Illumina during the Hold Separate Period; (C) ensure the Acquirer can operate the Hold Separate Business in a manner equivalent in all material respects to the manner in which GRAIL operated prior to the Acquisition, independent of Illumina; (D) to restore the pre-merger competitive intensity as effectively and expeditiously as possible, and (E) to remedy the competitive impact resulting from the Acquisition.

XI. Duration of Order[142]

IT IS FURTHER ORDERED that this Order shall terminate 10 years from the date it is issued.

ORDERED:

_____
D. Michael Chappell
Chief Administrative Law Judge

Date:

via dissolution or acquisition. This Section is standard, as any change to Respondents may impact compliance with the Order and the Commission needs to be made aware of such changes. Otto Bock Order ¶ IX.

[142] Section XI provides for Order timing. Termination 10 years from the date of issue is a common timeframe for Commission Orders. Otto Bock Order ¶ XI.

CERTIFICATE OF SERVICE

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

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

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

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Counsel Supporting the Complaint