IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION,
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Plaintiff,

v.

ILLUMINA, INC.,
5200 Illumina Way
San Diego, CA 92122

and

GRAIL, INC.,
1525 O'Brien Drive
Menlo Park, CA 94025

Defendants.

No. _____ CV _____

FILED UNDER SEAL

COMPLAINT

Plaintiff, the Federal Trade Commission ("FTC" or "Commission"), by its designated attorneys, petitions this Court for a preliminary injunction enjoining Defendant Illumina, Inc. ("Illumina") and its subsidiaries, from consummating its proposed acquisition (the "Acquisition") of GRAIL, Inc. ("Grail"). The Commission seeks this relief pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b), and Section 16 of the Clayton Act, 15 U.S.C. § 26. Absent such relief, Illumina and Grail (collectively, "Defendants") have represented that they would be free to consummate the Acquisition after 11:59 p.m. on March 30, 2021.

A temporary restraining order enjoining the Acquisition is necessary to preserve this

Court's ability to provide full and effective relief after considering the Commission's motion for a preliminary injunction. Preliminary injunctive relief is imperative to preserve the *status quo* and to protect competition while the Commission adjudicates whether the Acquisition is unlawful. The Commission has already initiated the administrative trial, pursuant to Sections 7 and 11 of the Clayton Act, 15 U.S.C. §§ 18, 21, and Section 5 of the FTC Act, 15 U.S.C. § 45, by filing an administrative complaint on March 30, 2021. Pursuant to FTC regulations, the administrative trial will begin on August 24, 2021. Allowing the Acquisition to proceed would harm consumers and undermine the Commission's ability to remedy the anticompetitive effects of the Acquisition if it is ultimately found unlawful after a full administrative trial on the merits and any subsequent appeals.

NATURE OF THE CASE

1. This is an action to preliminarily enjoin the consummation of Illumina's proposed acquisition of Grail. If consummated, the Acquisition would substantially lessen competition in the U.S. multi-cancer early detection ("MCED") test market by diminishing innovation and potentially increasing prices and reducing the choice and quality of MCED tests. In other words, it is likely to harm U.S. consumers.

2. MCED tests are poised to revolutionize how cancer is detected and treated, having the potential to save millions of lives in the United States and around the world. Although cancer is the second leading cause of death in the United States, healthcare providers currently are able to screen for only a small number of cancer types, testing for one cancer at a time. Doctors currently lack the option to broadly screen for multiple types of cancer using a single test. As a result, the vast majority of cancers are only detected after patients exhibit symptoms, when it is often too late to treat the cancer effectively.

3. Rather than wait for cancer symptoms to arise, MCED tests use a "liquid biopsy" process to examine fragments of DNA in the bloodstream to determine whether cancer cells have shed any DNA. The vast majority of tumors shed cancer cells, making detection of cancer through liquid biopsy possible at very early stages of the disease and allowing for early treatment that could dramatically improve patients' outcomes. The MCED testing workflow is as follows: First, a phlebotomist collects a blood sample from a patient and ships it to a laboratory. At the laboratory, the DNA in the sample is extracted and analyzed using a next-generation sequencing ("NGS") platform (which includes the NGS equipment and designated consumables such as cells/cartridges and reagents). The NGS platform quickly and accurately identifies the order of the component blocks—called nucleotides—in the DNA sample, and it produces a data read-out that is used to determine whether a patient has mutations and/or other biomarkers associated with any of the cancers analyzed by the MCED test.

4. Defendant Grail, with its Galleri MCED test, is racing against several other firms to develop and ultimately commercialize this revolutionary technology. Grail and its rivals are developing MCED tests that seek to shift the cancer paradigm by simultaneously screening for multiple cancers, including those not screened for today, using blood samples. MCED tests will [redacted] ultimately saving lives. Illumina recognizes the life-saving benefits of MCED tests and estimates that "[e]ach year of testing can potentially avert [approximately] 100,000 cancer-related deaths . . . ." Grail, its rivals, and others in the industry view MCED tests as a major advancement in the war on cancer.

5. Illumina's NGS platforms are an essential input for the development and commercialization of MCED tests. Grail's Galleri test, along with its rivals' MCED tests in

development, must and do rely on Illumina's NGS platforms. They use Illumina's platforms to sequence the short fragments of DNA found in the bloodstream, known as cell-free DNA or "cfDNA," to determine whether any DNA comes from cancerous tumors and potentially where in the body that tumor is located.

6. Illumina is a dominant provider of NGS platforms, which are used for a wide array of applications in addition to developing MCED tests. Illumina accounts for the vast majority of NGS instrument and reagent sales in the United States, and its platforms produce more than 90 percent of the world's sequencing data. With respect to the application relevant to this case—MCED tests—Grail's rivals have no substitutes for Illumina's NGS platforms. Due to the technical limitations of other NGS and non-NGS products, Grail's rivals cannot use any product other than Illumina's NGS platforms to develop a clinically effective and commercially viable MCED test capable of competing with Grail's Galleri test.

7. Illumina initially formed Grail in 2015 with the purpose of "[enabling] the early detection of cancer in asymptomatic individuals through a blood screen,"—the "holy grail" of early cancer detection (hence, its name). At the time, Illumina identified cancer screening as [redacted] Illumina recognized that its [redacted] For example, when Illumina first formed Grail, it offered [redacted] while simultaneously concluding that it would [redacted]

8. Two years after forming Grail, Illumina reduced its ownership interest to below 20 percent of the voting rights in the company, after concluding that [redacted]

[redacted] Today Illumina owns 14.5 percent of Grail's voting shares, while other investors including Arch Venture Partners, Jeff Bezos, Bill Gates, and Johnson & Johnson control the rest. Since reducing its stake in Grail, Illumina has [redacted]

9. Grail projects Galleri will be [redacted] and that it will be able to detect up to 50 types of cancer, often at very early stages, in asymptomatic individuals. Grail is currently conducting a [redacted] Grail plans to launch its Galleri test as a laboratory developed test ("LDT," meaning it can only be run in Grail's own laboratory) in 2021. [redacted] it plans to obtain U.S. Food and Drug Administration ("FDA") approval for Galleri.

10. Illumina recognizes that cancer screening is [redacted] worldwide, with a projected market size of tens of billions of dollars by 2035. Similarly, Grail projects Galleri could earn [redacted]

11. As the only supplier of a critical input, Illumina already possesses the ability to foreclose or disadvantage Grail's MCED rivals. Illumina has several tools available that it could use to impede the competitiveness of any MCED test developer. If Illumina determined it would maximize its profits by limiting the competitiveness of an MCED test that posed a threat to Grail's

Galleri business, among other things, it could (1) raise the test developer's prices for NGS instruments and consumables, (2) impede the rival's research and development efforts by denying important technical assistance and other proprietary information needed to obtain FDA approval or design a commercially successful MCED test, or (3) refuse or delay the execution of a license agreement required to sell distributed in vitro diagnostic ("IVD") versions of the test (or offer the license on terms that would restrict the competitiveness of the rival's IVD test). Defendants recognize the combined firm will have the ability to disadvantage Grail's rivals. For example, one Illumina executive explained that the combined firm will have the [redacted]

12. If the Acquisition is consummated, Illumina will gain the incentive to foreclose or disadvantage firms that pose a significant competitive threat to Grail and to limit the competitiveness of any MCED product that Defendants expect to compete closely with Galleri. While Illumina currently benefits from selling NGS platforms and consumables to all MCED test developers, if the Acquisition is consummated, instead of realizing profits only from the sale of NGS platforms and consumables, Illumina stands to profit significantly from sales of Grail's MCED test. In fact, Illumina projects that it will [redacted] estimating that by [redacted]

13. Grail's rivals have no alternative to using Illumina's NGS platforms to develop and commercialize their MCED tests, therefore, they will be unable to divert away from Illumina if

the combined firm raises their costs or otherwise forecloses or disadvantages them. As a result, after the Acquisition, Illumina will control the fate of every potential rival to Grail for the foreseeable future.

14. Post-Acquisition, Illumina will have the ability to monitor each company developing an MCED test using its NGS platform and the incentive to kill or disable any products that appear likely to take significant business away from Galleri. Because Defendants expect Galleri to be the [redacted] Galleri would likely recapture [redacted] all or most of the sales from Grail's rivals that the combined firm disadvantaged or foreclosed. To maximize its profits, the combined firm would have the incentive to prevent the launch, or limit the competitiveness, of each rival MCED test that appeared likely to compete closely with (and thus divert sales from) Galleri, while simultaneously promoting sales and development efforts of other Illumina NGS platform customers working on non-competing products. Preserving robust competition among MCED test developers is critically important to the public and the effort to save American lives in the war against cancer. As Grail's CEO explained, [redacted] Allowing Illumina to purchase Grail and act on the incentives created by the Acquisition would cause substantial harm to U.S. consumers, who would experience reduced innovation, as well as potentially higher costs and reduced choice and quality for these life-saving products.

15. There are no countervailing factors sufficient to offset the likelihood of competitive harm from the Acquisition. Defendants cannot demonstrate that new entry of an MCED test that

does not rely on Illumina's NGS platform would be timely, likely, or sufficient to offset the anticompetitive effects of the proposed Acquisition.

16. Defendants will be unable to show sufficient cognizable, verifiable, or merger-specific efficiencies that would offset the likely and substantial competitive harm from the Acquisition.

17. Allowing the Acquisition to proceed while the Commission adjudicates the Acquisition on its merits would harm consumers and undermine the Commission's ability to remedy the anticompetitive effects of the Acquisition if it is found unlawful.

JURISDICTION AND VENUE

18. This Court's jurisdiction arises under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), and under 28 U.S.C. §§ 1331, 1337, and 1345. This is a civil action arising under Acts of Congress protecting trade and commerce against restraints and monopolies, and is brought by an agency of the United States authorized by an Act of Congress to bring this action.

19. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), provides in pertinent part:

> Whenever the Commission has reason to believe
>
> (1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and
>
> (2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the interest of the public – the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond. . . .

20. Defendants are, and at all relevant times have been, engaged in activities in or affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

21. The FTC Act, 15 U.S.C. § 53(b), authorizes nationwide service of process, and personal jurisdiction exists where service is effected pursuant to federal statute. Fed. R. Civ. P. 4(k)(1)(C). Venue is proper in the District of Columbia under 28 U.S.C. § 1391(c)(3), as well as under 28 U.S.C. § 1391(c)(2).

THE PARTIES AND THE PROPOSED ACQUISITION

22. Plaintiff, the Federal Trade Commission, is an agency of the United States government, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. §§ 41 *et seq.*, with its principal offices at 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The Commission is vested with authority and responsibility for enforcing, *inter alia*, Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45.

23. Defendant, Illumina, is a publicly-traded Delaware corporation, headquartered in San Diego, California. Illumina develops, manufactures, and markets life sciences tools and integrated systems for the large-scale analysis of genetic variation and function. Founded in 1998, Illumina's main product offerings are short-read NGS systems and the associated consumables. Illumina's NGS platforms are used for DNA sequencing. In the United States, Illumina sells the only NGS platforms capable of being used by MCED test developers. In 2020, Illumina earned $3.24 billion in revenue worldwide, 49 percent of which was from U.S. sales.

24. Defendant, Grail, is a private pre-commercial diagnostics company, headquartered in Menlo Park, California. Grail develops NGS-based oncology tests, with a focus on early cancer detection. Grail's development pipeline includes three NGS-based oncology tests with distinct

applications: Galleri, an MCED test that screens for early signs of cancer in asymptomatic patients; a diagnostic aid to cancer ("DAC") test, which confirms cancer diagnoses in patients suspected to have cancer; and a minimal residual disease ("MRD") test, designed to assess cancer recurrence after a patient has already undergone treatment. Today, Grail has no revenue but has raised approximately $2 billion in private funding since 2016.

25. Grail's flagship test, Galleri, has been designed to detect over 50 different types of cancer from a single blood draw, most of which have "no existing recommended screening tests." Grail's goal is for Galleri to be used in all patients over the age of 50 to detect cancer early, even in asymptomatic, otherwise healthy patients. [redacted] Grail plans to launch Galleri in the United States as an LDT in 2021 and to obtain FDA approval for Galleri in [redacted] Grail also plans to [redacted] All of Grail's tests depend on the use of Illumina's NGS platforms.

26. Grail was originally formed by Illumina in 2015. Starting in 2017, Illumina reduced its ownership of Grail to below 20 percent of the company's voting interest. Currently, Illumina retains 14.5 percent ownership of Grail's voting shares and [redacted] On September 20, 2020, Illumina entered into an Agreement and Plan of Merger to acquire the approximately 85.5 percent of Grail voting shares outstanding that it does not already own for cash and stock consideration valued at approximately $7.1 billion and additional contingent payments to Grail's non-Illumina stockholders valued at approximately $1.2 billion.

27. On March 30, 2021, by a 4-0 vote, the Commission found reason to believe that the Acquisition would substantially lessen competition in violation of Section 7 of the Clayton Act,

15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45. On March 30, 2021, the Commission commenced an administrative adjudication proceeding to determine whether the Acquisition is unlawful. An administrative trial before an Administrative Law Judge, is scheduled to begin on August 24, 2021. The ongoing administrative trial provides a forum for all parties to conduct discovery, followed by a merits trial with up to 210 hours of live testimony. *See* 16 C.F.R. § 3.41. The decision of the Administrative Law Judge is subject to appeal to the full Commission, which, in turn, is subject to judicial review by a United States Court of Appeals.

28. In authorizing the filing of this complaint, the Commission has determined that (1) it has reason to believe the Acquisition would violate the Clayton Act and the FTC Act by substantially lessening competition in one or more lines of commerce, and (2) an injunction of the Acquisition pending the resolution of the Commission's administrative trial and any appeals will promote the public interest to minimize harm to customers and the American public, and to preserve the Commission's ability to grant an adequate remedy if it concludes, after the administrative trial, that the Acquisition is unlawful.

INDUSTRY BACKGROUND

29. Cancer is the second leading cause of death in the world. In 2020, nearly two million new cases of cancer were diagnosed in the United States and over six hundred thousand Americans died from the disease. Most cancers are detected only after a patient exhibits symptoms, when the tumor has grown and the cancer has often metastasized, or spread, to other parts of the body. At this advanced stage, it is frequently too late for effective treatment and, unfortunately, the patient often dies from the disease.

30. Currently in the United States, very few asymptomatic individuals are screened for many types of cancer. In fact, the U.S. Preventive Services Task Force ("USPSTF") provides

screening recommendations for only four cancers—lung, breast, colorectal, and cervical. The screening recommendations for these four cancers allow cancer to be detected at very early stages when chances of survival are high. Other cancers go undetected until a patient shows symptoms at later stages, resulting in worse treatment options and prognoses.

31. Grail and other MCED test developers are researching, designing, and working to commercialize products that will shift the cancer screening and treatment paradigm. Their MCED tests are designed to simultaneously screen for multiple cancers, including cancers that are not screened for at all today, using blood samples. The tests compare DNA fragments in patients' blood samples with a clinical database of known biomarkers or patterns that indicate the presence of cancer. Thus, the more clinical data that an MCED test developer acquires, the better the test performs.

32. An MCED test may be initially launched as a LDT. An LDT can only be run in a test developer's own proprietary laboratory because it has not undergone the rigorous FDA pre-market approval process. LDTs provide only a limited commercial opportunity because payers may not reimburse LDTs as they have not yet received FDA approval for cancer screening.

33. IVD MCED tests must undergo the FDA's premarket approval process, or PMA. An IVD test can either be approved as a single-site IVD test, meaning each laboratory site where samples will be processed must be approved by the FDA including the MCED test supplier's own laboratory, or as a distributed IVD test, meaning tests can be sold as "kits" to third-party laboratories to run in their own laboratories. As more patients receive access to MCED tests generally, it will likely become more important for MCED tests developers to offer distributed or kitted IVD tests. As a former Illumina executive explained, [redacted] Industry participants anticipate that

selling distributed IVD versions of MCED tests will be important to the effective long-term commercialization of these products because distributed IVD tests, unlike single-site IVDs, can be performed at third-party laboratories. Many customers are expected to prefer distributed IVD tests.

34. To analyze DNA fragments in the blood, MCED tests require the use of an NGS platform and consumables to determine the order of DNA components and identify mutations or patterns consistent with the presence of cancer. While Grail and its rivals are currently at different stages of development, they all rely on Illumina's NGS platform and sequencing reagents (today and in the future) to develop, launch, and eventually market their MCED products. No other NGS platform has the cost, accuracy, and throughput necessary for use in MCED tests. As one MCED test developer explained, [redacted] As a result, Grail's competitors are self-described as Illumina's [redacted] because if Illumina chose to stop supplying its instruments or reagents, or significantly increased its prices, that would end or derail their development efforts or greatly diminish their competitiveness.

35. MCED test developers depend on Illumina at every stage of the development process. For example, when a developer is designing its MCED test, it specifically tailors the test to work with a particular sequencer and reagents. Further, because MCED tests are designed to work with a specific Illumina NGS platform, if an MCED test developer decides to seek FDA approval for its product, its approval is contingent on the test's performance on Illumina's platform, and the MCED test developer must rely on Illumina to supply vital information, such as design files, quality and accuracy data, or distributed IVD agreements. Moreover, post-launch, third-party MCED test developers competing with Grail would need to rely on a vertically-

integrated Illumina in order for those MCED test developers to grow and better penetrate the MCED market.

THE RELEVANT ANTITRUST MARKET IS MCED TESTS

36. The Acquisition would substantially lessen competition in the market for the research, development, and commercialization of MCED tests in the United States and cause harm to American consumers.

A. MCED Tests is the Relevant Product Market

37. MCED tests are being designed to detect multiple types of early-stage cancer in asymptomatic individuals. When cells in the body die, they shed DNA into the bloodstream, known as cfDNA. cfDNA that comes from cancerous cells is referred to as circulating tumor DNA or "ctDNA." MCED tests look for ctDNA by examining the small cfDNA fragments (approximately 150-180 base pairs), sometimes in conjunction with other analytes such as RNA, using an NGS platform to determine whether any cfDNA has been shed from cancerous cells. Because cancerous cells begin to shed DNA at very early stages, MCED tests are designed to detect cancer before a patient manifests any symptoms.

38. Because existing cancer screening methods, like a mammography for breast cancer or a pap smear for cervical cancer, can only screen for a specific cancer type and are unlikely to expand to screen for more types of cancers, existing screening methods are not substitutes for MCED tests and are properly excluded from the relevant product market. The USPSTF [redacted] for cancer screening and recommends cancer screening tests for only four types of cancer—lung, breast, colorectal, and cervical. MCED tests are [redacted] by detecting other types of cancer for which there are no screening options today. These cancers, such as pancreatic, liver, and stomach cancer, are, instead, typically only detected after patients have more advanced cancer (after exhibiting symptoms),

which is often too late to treat the cancer effectively. Also, unlike existing screening methods, MCED tests can screen for multiple types of cancer at the same time. A single MCED test can look for thousands or tens of thousands of potential biomarkers (such as mutations or methylation patterns) consistent with cancer in asymptomatic individuals, allowing it to look for early signs of many cancers at once and providing detailed information about the specific cancer, its genetic drivers, and often the cancer's location in the body.

39. One existing testing technology, polymerase chain reaction ("PCR"), can be used to look for certain changes in a gene or chromosome, which may help with finding a specific genetic condition or a disease. However, PCR-based tests can only search for the existence of a few cancer-related biomarkers per each run of the platform. As a single cancer can have dozens or hundreds of possible biomarkers located throughout the genome, the utility of these tests as an oncology screening tool is severely limited compared to MCED and is unlikely to be a substitute for MCED tests in the near future.

40. NGS-based single-cancer early detection tests are also unlikely to be substitutes for MCED tests in the near future. Although several single-cancer early detection tests utilize the same technology as MCEDs, Grail recognizes that MCED tests [redacted] Defendants' [redacted]

41. Finally, a tissue biopsy is not a substitute for MCED tests. Unlike a minimally invasive liquid biopsy, a tissue biopsy requires the removal of a tissue sample from a patient to

analyze. This process is not only invasive, but some tumors are inaccessible for biopsy and others do not provide sufficient tissue to elicit conclusive results. As a result, a tissue biopsy is often difficult to do, costly, time-consuming and may sometimes cause further spread of the cancer. Moreover, a tissue biopsy typically is used for assessing the presence of cancer in symptomatic patients where the location of the suspected cancer is known.

B. The United States is the Relevant Geographic Market

42. The United States is the relevant geographic market to assess the competitive effects of the Acquisition. U.S. MCED customers cannot practically turn to an MCED test provider located outside the United States. Turnaround time for MCED tests is important to ensure that cancer is identified and treated quickly, making customers unlikely to turn to a foreign-based firm.

43. MCED tests will likely require approval by the FDA to receive reimbursement from healthcare payers in the United States. As such, MCED tests sold outside the United States, but not approved for sale in the United States, do not provide viable competitive alternatives for U.S. consumers. In addition, distributed IVDs will require approval by the FDA prior to use in any non-manufacturer laboratory.

C. Size and Structure of U.S. MCED Test Market

44. Although no MCED test is currently commercialized, Illumina, test developers, and others in the industry expect the U.S. MCED market to be large and have sales of tens of billions of dollars annually. As Grail noted in its amended Form S-1 Registration Statement filing, "[w]e believe Galleri has the potential to integrate directly into the healthcare delivered to individuals every year who are already going to a physician for their standard-of-care cancer screening. Over time, we expect adopting physicians to recommend our test to be ordered annually as part of an

individual's physical examination or wellness appointment, or when undertaking other screening examinations."

45. Illumina recognizes that cancer screening is [redacted] with a projected market size of tens of billions of dollars by 2035. [redacted] Other MCED tests developers have also analyzed the projected addressable U.S. MCED test market and estimated sales of tens of billions of dollars annually.

46. Multiple firms are developing MCED tests that would likely compete with Grail's Galleri test. These firms include [redacted] While in various stages of development, many have spent hundreds of millions of dollars to research, develop, and conduct clinical trials for their respective MCED tests. MCED test developers use data collected from their clinical trials to improve the quality of their MCED tests. All rely on Illumina's NGS platform to perform their tests. For example, as one MCED test developer, [redacted]

47. Grail's Galleri MCED test will likely be [redacted] launching this year as an LDT. In addition, Grail expects that its Galleri MCED test will obtain FDA approval [redacted] after the Galleri LDT is launched. [redacted] Grail projects that its Galleri test could generate [redacted] at a volume of [redacted] tests.

48. [redacted] appears closest to market [redacted]

[redacted]

49. [redacted] also plans to launch an MCED test. [redacted]

50. [redacted] expect to compete directly with Grail by launching MCED tests [redacted]

51. [redacted] also expect to launch [redacted] as first steps towards developing MCED tests that would compete with Grail's Galleri test. Similarly, [redacted] plans to launch an MCED [redacted]

52. Because the MCED market is pre-commercial, market shares do not yet exist. However, [redacted] Illumina's internal projections estimate that Grail will have [redacted] market share when it launches, [redacted]

ANTICOMPETITIVE EFFECTS

53. The Acquisition would substantially lessen competition in the U.S. MCED test market, resulting in reduced innovation and potentially increased prices and reduced choice and quality of MCED tests, thus negatively impacting the ability for Americans to receive early-stage diagnoses and successful treatment of their cancers. As the Vertical Merger Guidelines explain, a

vertical merger may diminish competition by leaving the merged firm with the ability and incentive to use its control of the related product to weaken or remove the competitive constraint from one or more of its actual or potential rivals in the relevant market. As the only provider of a critical input into MCED tests, Illumina possesses multiple means of foreclosing or disadvantaging rivals to Grail. After the Acquisition, Illumina will have an increased incentive to disadvantage close competitors to Grail because the value of foregone NGS instrument and consumable sales to disadvantaged third-party MCED test developers will be offset by the gain in MCED testing revenue captured by Grail.

I. As the Dominant Provider of NGS Platforms for MCED Tests, Illumina Has the Ability to Lessen Competition in the U.S. MCED Test Market by Raising Costs and Hindering Development Efforts of Grail's Rivals

54. MCED test developers must and do rely on Illumina's NGS platform, along with its service and support, to research, develop, launch, and sell their MCED tests successfully. As the dominant provider of NGS platforms for MCED test developers, Illumina can use its control of a critical input to foreclose or disadvantage Grail's rivals through at least the following means: by raising the test developer's prices for NGS instruments and consumables, impeding the rival's research and development efforts by denying important technical assistance and other proprietary information needed to obtain FDA approval or design a commercially successful MCED test, or refusing or delaying the execution of an agreement required to sell distributed IVD versions of the test (or offering the agreement on terms that would restrict the competitiveness of the rival's IVD test) – terms that allow rivals to compete effectively with Grail.

A. Illumina is the Dominant (and Currently Only) Provider of a Related Product and Necessary Input to MCED Tests

55. Illumina's NGS platform is the related product and is a critical input for MCED tests. As the only NGS platform option for MCED test developers, the related product gives Illumina the ability to foreclose, raise the cost of, or otherwise disadvantage Grail's MCED rivals.

56. A critical input for MCED tests is a sequencing platform that analyzes accurately and efficiently DNA fragments that measure no more than 150-180 base pairs. The sequencing platform must be highly sensitive to detect even the lowest levels of ctDNA in the bloodstream, and highly specific to accurately identify those patients with cancer-related ctDNA. In addition to sensitivity and specificity, MCED testing requires a cost-effective sequencing technology capable of high-throughput—the ability to sequence DNA samples at a high rate at a low cost per base pair. Collectively, these technical capabilities make it possible to detect genomic variations in liquid biopsies at a sufficiently low cost to make an MCED test product both competitive and accessible to the American public.

57. Short-read NGS—the type of sequencing provided by Illumina's platforms—is the only sequencing technology that can satisfy all requirements for MCED tests, including the ability to read short fragments of DNA, high sensitivity, high specificity, fast turnaround times, high throughput, and low cost per base.

58. Long-read NGS platforms are not viable substitutes for MCED test developers. Although long-read NGS platforms are well-suited for different types of sequencing applications such as de novo whole-genome sequencing or detecting large structural rearrangements, long-read NGS platforms lack the sensitivity, specificity, throughput, and cost profile needed for companies to develop and commercialize competitive MCED tests.

59. Other sequencing technologies are not substitutes for short-read NGS for MCED tests. For example, Sanger sequencing, the original DNA sequencing technology, lacks the

necessary high-throughput, high-accuracy, and low-cost required for ctDNA sequencing. Sanger sequencing throughput is orders of magnitude less than that of NGS and would require millions of additional runs per patient.

60. Illumina is the dominant provider of short-read NGS platforms in the United States. Illumina's suite of short-read NGS platforms vary from benchtop instruments that are designed for targeted sequencing projects to factor-scale instruments geared for high-throughput projects like MCED testing. Today, Illumina's NGS platform portfolio offers higher throughput, lower cost, and higher accuracy rates than [redacted]

61. Thermo Fisher Scientific, Inc. ("Thermo Fisher") is the only other short-read NGS platform manufacturer in the United States. Thermo Fisher's sequencing platforms [redacted]

62. Aside from Illumina and Thermo Fisher, Beijing Genomics Institute ("BGI") is the only other short-read NGS platform provider in the world. BGI is currently enjoined from selling its NGS platform in the United States during the duration of a patent infringement lawsuit filed by Illumina.

63. MCED test developers recognize that Illumina's short-read NGS platform offers technical capabilities unavailable on any other platform. MCED test developers have spent hundreds of millions of dollars on Illumina products, and have developed, refined, and specifically tailored their MCED tests to work with Illumina's instruments.

64. Sufficient and timely entry of a new short-read NGS platform capable of meeting the needs of MCED test developers appears unlikely to deter or counteract anticompetitive effects from the Acquisition because launching a new NGS platform requires considerable investment of capital and time to overcome significant scientific, legal, and commercial barriers.

65. Multiple potential entrants have previously tried to enter the short-read NGS market but failed due to technological challenges. Other entrants have spent hundreds of millions of dollars over multiple years but have not succeeded in launching viable short-read NGS platforms.

66. Entry into the market for NGS platforms has also proved difficult as a result of patent protections, particularly related to patents held by Illumina. For example, soon after Qiagen N.V. ("Qiagen") launched its NGS platform, Illumina sued Qiagen for patent infringement and won an injunction that forced Qiagen out of the U.S. market. More recently, Illumina has sued potential rival BGI, winning a preliminary injunction that prevents BGI from selling its sequencers in the United States.

67. Although some firms are attempting to develop NGS platforms, they are years away from launching viable substitutes for Illumina's short-read NGS. Even if other NGS platform manufacturers enter the U.S. market, it would take years, assuming it was possible at all, for MCED test developers to switch from Illumina's NGS platforms to another platform. An MCED test developer would first have to reconfigure its MCED test to work with the new NGS platform. A switch to a new NGS platform may also require conducting new clinical trials because the extensive clinical trials required for FDA approval depend on interoperability with Illumina's platform. Switching platforms is also costly as MCED test developers would have to reconfigure their test to properly work with the new NGS platform.

B. Illumina has a Multitude of Tools to Foreclose or Reduce the Competitiveness of Grail's MCED Test Rivals

68. Illumina has multiple tools at its disposal to foreclose, raise the costs of, or otherwise disadvantage Grail's rivals. Some examples include increasing prices for its instruments and reagents, failing to provide reagents in a timely manner or otherwise diminishing service, or simply changing the payment structure by which it is compensated. By raising the price of its instruments and reagents to Grail's rivals, Illumina would likely cause the price of the rival's test to increase and [redacted] a test. Similarly, Illumina's customers are dependent on Illumina for the prompt service of Illumina's instruments, including repair parts, labor, and preventative maintenance. Illumina's customers also rely on Illumina for an assured and timely supply of the consumables needed to run tests on its NGS platform. And, Illumina has the ability to charge new, additional fees to clinical application test providers, such as per-test fees or royalties.

69. Illumina will have the ability to delay or foreclose access to its new technology and reduce the levels of its technical assistance and service to Grail's rivals – impeding rivals' research and development efforts. When Illumina releases new updates to its NGS platforms, its latest technology is typically cheaper, more accurate, and has a higher throughput than past versions, making it more attractive for MCED tests. For example, Illumina's most recent NGS platform, the NovaSeq, is capable of reading tens of billions of DNA fragments per run and generates multiple terabases of sequences per run. Simply knowing about planned updates or new technology in advance can help an MCED test developer with research and development efforts because it will know where to focus its expenditures. Denying, delaying access, or delaying disclosure of new technology to Grail's rivals could harm their ability to compete effectively with Grail.

70. When test developers seek FDA clearance to offer a distributed IVD test, [redacted] Because the FDA must ensure that every laboratory that runs the distributed test has the same quality of results, the FDA looks for an [redacted] between the test developer and the NGS platform provider during its review. [redacted] Third-parties unable to sell distributed IVD tests will likely be significantly limited in their ability to compete against Grail's Galleri test once these tests are widely adopted in the United States.

C. Illumina Will be Able to Identify and Discriminate Against MCED Test Developers Posing Competitive Threats to Grail's Galleri Test

71. Illumina will be able to identify firms developing MCED tests likely to pose a competitive threat to Grail through publicly-available information as well as other information Illumina has access to in the ordinary course of business.

72. For example, because all MCED test developers use Illumina's NGS platform, Illumina regularly negotiates and interacts one-on-one with its oncology test developer customers. A current Illumina executive explained that, during these interactions, customers will [redacted] In particular, a customer may seek Illumina's advice as to [redacted]

73. Illumina can also identify and discriminate against Grail rivals in terms of pricing. An Illumina executive explained that [redacted] Using the core consumables that customers purchase, Illumina may be

able to [redacted]

74. Another means by which Illumina can discriminate against its customers' use of Illumina's NGS platforms for MCED development is through its supply agreement terms. For example, even if a customer uses an Illumina NGS platform for multiple applications, Illumina can selectively target a customer's use of the NGS platform for MCED testing through a variety of mechanisms, [redacted] Illumina has noted that it is [redacted]

75. Any existing or potential supply agreements between Illumina and third-party MCED tests cannot offset the likely anticompetitive effects of this Acquisition because these agreements cannot account for each and every current and future method by which Illumina may foreclose, raise the costs of, or otherwise disadvantage Grail's rivals.

II. Post-Acquisition, Illumina Would Have the Incentive to Lessen Competition in the U.S. MCED Test Market by Disadvantaging Grail's Rivals

76. The Acquisition would create an incentive for Illumina to maximize its profits by foreclosing or disadvantaging Grail's rivals because it would benefit significantly in the U.S. MCED market when rivals lose sales or alter their behavior in response.

77. Several Illumina customers are poised to become close competitors with Grail in the sale of MCED tests including [redacted] Defendants have identified many of these companies as competitors and would be able to target them post-Acquisition. By disadvantaging these rivals of Grail, Illumina would maximize its total profits after the Acquisition.

78. Grail will likely be [redacted] in the United States, providing it with a dominant position in the market. Grail projects that it will launch Galleri this year as an LDT and will obtain FDA approval [redacted] after the Galleri LDT is launched, allowing the combined firm to seek reimbursement from payers for its test.

79. As the [redacted] Grail would recapture a substantial portion of sales from any disadvantaged downstream MCED-testing rival, particularly those rivals with MCED tests likely to compete closely with Grail.

80. Because the MCED market is pre-commercial, market shares do not yet exist. However, given Grail's [redacted] Illumina's internal projections estimate that Grail will have a [redacted] percent market share in [redacted]

81. The benefits of capturing or preserving a larger share of the U.S. MCED test market via Grail will outweigh any loss in NGS instrument and consumables sales to Grail's rivals. Illumina recognizes that cancer screening is [redacted] with a projected market size of tens of billions of dollars by 2035. Similarly, Grail expects its Galleri test could reach [redacted] This revenue, and associated profits from selling Grail's MCED tests, is projected to be [redacted] For example, Illumina projected, when assessing the larger oncological clinical testing space that, [redacted]

ABSENCE OF COUNTERVAILING FACTORS

82. Defendants cannot demonstrate that new entry of an MCED test that does not rely on Illumina's NGS platform would be timely, likely, or sufficient to offset the anticompetitive effects of the proposed Acquisition. Moreover, by implementing a strategy to disadvantage Grail's rivals, the combined firm may make it more difficult for Grail's rivals to obtain and/or generate additional data post-Acquisition, which creates additional barriers to entry for such rivals on any NGS or non-NGS platform.

83. Defendants fail to demonstrate that the Acquisition would likely generate verifiable, cognizable, merger-specific efficiencies that would offset the likely and substantial competitive harm from the Acquisition. According to Illumina, [redacted] To the extent that Acquisition results in any elimination of double-marginalization, Defendants cannot demonstrate that such a reduction in margin would offset the likely harm of the Acquisition.

VIOLATION

COUNT I – ILLEGAL ACQUISITION

84. The allegations of Paragraphs 1 through 83 above are incorporated by reference.

85. As the only provider of a critical input into MCED tests, Defendant Illumina possesses multiple means of foreclosing or disadvantaging rivals to Defendant Grail. After the Acquisition, Defendant Illumina will have an increased incentive to disadvantage close competitors to Defendant Grail because the value of foregone NGS instrument and consumable sales to disadvantaged third-party MCED test developers will be offset by the gain in MCED testing revenue captured by Grail. Defendant cannot show that any cognizable efficiencies are of a character and magnitude such that the Acquisition is not likely to be anticompetitive.

86. The Acquisition, if consummated, would be likely to lessen competition substantially in interstate trade and commerce in the market for MCED tests throughout the country in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18.

LIKELIHOOD OF SUCCESS ON THE MERITS, BALANCE OF EQUITIES, AND NEED FOR RELIEF

87. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), authorizes the Commission, whenever it has reason to believe that a proposed acquisition is unlawful, to seek preliminary injunctive relief to prevent consummation of the acquisition until the Commission has had an opportunity to adjudicate the acquisition's legality in an administrative trial. In deciding whether to grant relief, the Court must balance the likelihood of the Commission's ultimate success on the merits against the public equities. The principal public equity weighing in favor of issuance of preliminary injunctive relief is the public interest in effective enforcement of the antitrust laws. Private equities affecting only Defendants' interest cannot defeat a preliminary injunction.

88. The Commission is likely to succeed in proving that the effect of the Acquisition may be substantially to lessen competition or tend to create a monopoly in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18, or Section 5 of the FTC Act, 15 U.S.C § 45. In particular, the Commission is likely to succeed in demonstrating, among other things, that:

a. The Acquisition would have anticompetitive effects in the U.S. MCED test market;

b. Substantial and effective entry or expansion is difficult and would not be timely, likely, or sufficient to offset the anticompetitive effects of the Acquisition;

c. The efficiencies and procompetitive benefits asserted by Defendants do not justify the Acquisition.

89. Preliminary relief is warranted and necessary. Should the Commission rule, after the full administrative trial that the Acquisition is unlawful, reestablishing the status quo ante if

the Acquisition has already occurred in the absence of preliminary relief would be extremely difficult. Moreover, in the absence of relief from this Court, substantial harm to competition would likely occur in the interim, even if suitable divestiture remedies were obtained later.

90. Accordingly, the equitable relief requested here is in the public interest.

Wherefore, the Commission respectfully requests that:

a. Illumina and Grail be preliminarily enjoined from taking any further steps to consummate the proposed Acquisition and any related transactions, stock assets, or acquisition of any other interests of one another either directly or indirectly; carrying out any other agreement, understanding, or plan by which Illumina would acquire control over Grail or any of its assets;

b. Retain jurisdiction and maintain the status quo until the administrative trial that the Commission has initiated is concluded; and

c. Award such other and further relief as the Court may determine is appropriate, just, and proper.

Dated: March 30, 2021

Respectfully Submitted,

SUSAN MUSSER
D.C. Bar 1531486
Senior Trial Counsel
Federal Trade Commission
Bureau of Competition
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580
Telephone: 202-326-2122
Email: smusser@ftc.gov
Attorney for Plaintiff Federal Trade Commission

Of Counsel:

MARIBETH PETRIZZI (D.C. Bar 435204)
Acting Director
Bureau of Competition
Federal Trade Commission

HEATHER JOHNSON (D.C. Bar 503465)
Acting Deputy Director
Bureau of Competition
Federal Trade Commission

REILLY DOLAN
Acting General Counsel
Federal Trade Commission

DANIEL K. ZACH
Assistant Director

STEPHEN MOHR (D.C. Bar 982570)
Deputy Assistant Director

SARAH WOHL (D.C. Bar 1016357)
NICHOLAS WIDNELL (D.C. Bar 439474)
JORDAN ANDREW
WILLIAM COOKE
ERIC EDMONDSON (D.C. Bar 450294)
SAMUEL FULLITON
LAUREN GASKIN
DAVID GONEN (D.C. Bar 500094)
MATTHEW JOSEPH (D.C. Bar 1030157)
WADE LIPPARD (D.C. Bar 1616824)
BETTY JEAN MCNEIL (D.C. Bar 888230599)
DYLAN NAEGELE (D.C. Bar 1670918)
JOSEPH NEELY
JONATHAN RIPA (D.C. Bar 1016295)
CATHERINE SANCHEZ
NICOLAS STEBINGER

Attorneys
Federal Trade Commission
Bureau of Competition
Mergers I Division

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 30th day of March, 2021, I served the foregoing on the following counsel via electronic mail:

Christine A. Varney
Sharonmoyee Goswami
Cravath, Swaine & Moore LLP
825 Eighth Avenue
New York, NY 10019
(212) 474-1140
cvarney@cravath.com
sgoswami@cravath.com

Counsel for Illumina, Inc.

Michael G. Egge
Marguerite M. Sullivan
Latham & Watkins LLP
555 Eleventh Street, NW
Washington, D.C. 20004
(202) 637-2285
michael.egge@lw.com
marguerite.sullivan@lw.com

Counsel for GRAIL, Inc.

Susan Musser
Counsel for Plaintiff Federal Trade Commission