UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Rebecca Kelly Slaughter, Acting Chairwoman**
Noah Joshua Phillips
Rohit Chopra
Christine S. Wilson

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

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act ("FTC Act"), and by virtue of the authority vested in it by the FTC Act, the Federal Trade Commission ("Commission"), having reason to believe that Respondents Illumina, Inc. ("Illumina") and GRAIL, Inc. ("Grail") have executed a merger agreement in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, which if consummated would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint pursuant to Section 5(b) of the FTC Act, 15 U.S.C. § 45(b), and Section 11(b) of the Clayton Act, 15 U.S.C. § 21(b), stating its charges as follows:

NATURE OF THE CASE

1. Illumina, the dominant provider of DNA sequencing, proposes to acquire 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. Respondent 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]. 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). Respondents 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]

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