UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS:	**Lina M. Khan, Chair** **Noah Joshua Phillips** **Rebecca Kelly Slaughter** **Christine S. Wilson** **Alvaro M. Bedoya**

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

COMPLAINT COUNSEL'S APPEAL OF THE INITIAL DECISION

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STATEMENT OF THE CASE

I. Summary of Arguments

The evidence in this case establishes that Illumina's purchase of its downstream customer Grail (the "Acquisition") poses a reasonable probability of substantially lessening competition in the race between Grail and its rivals to develop and commercialize life-saving multi-cancer early detection ("MCED") tests. This Acquisition gives Illumina, a provider of the next-generation sequencing ("NGS") platforms necessary for MCED tests, a clear increased incentive and the undeniable ability to preordain Grail as the winner of this race. By putting hurdles in the path of Grail's competitors to hinder their ability to compete fairly, or by excluding them from the race entirely, Illumina will increase Grail's market power and earn greater profits. This will deprive American consumers of the best quality products, limit choices for patients, doctors, and insurers, increase the price of accessing these critically important tests, and risk countless lives along the way.

In the Initial Decision ("Decision"), the Chief Administrative Law Judge ("ALJ") improperly dismissed Complaint Counsel's Clayton Act Section 7 claim. Despite correctly defining the market as the research, development, and commercialization of MCED tests, and determining that Illumina is the only viable supplier of a critical input (NGS) for MCED test developers, the ALJ nonetheless concluded that (1) Complaint Counsel failed to prove its *prima facie* case, and (2) Respondents' self-drafted long-term supply agreement (the "Open Offer") is not a remedy and rebuts any finding of potential competitive harm. In doing so, the Decision ignored and misapplied longstanding legal precedent and inconsistently applied its own factual findings. As the evidence—including the ALJ's own factual findings—makes clear, the Acquisition has a reasonable probability of substantially lessening competition in the research, development, and commercialization of MCED tests, and neither the Open Offer, nor any of Respondents' other rebuttal arguments, changes this anticompetitive result.

First, the Decision erred in its analysis of anticompetitive effects. In finding that Complaint Counsel had not satisfied the Supreme Court's *Brown Shoe* framework, the Decision both misapplied the legal standard and improperly ignored Illumina's position as the sole supplier of a critical input to MCED competitors. Moreover, when assessing whether Illumina possesses an ability and incentive to disadvantage Grail's MCED rivals post-Acquisition, the Decision correctly determined that Illumina possesses the ability to foreclose, but misapplied the law, economic analysis, and facts in concluding that the Acquisition did not increase Illumina's incentive to do so.

Second, the Decision erred both in holding that the Open Offer should not be considered as a remedy to the Acquisition and in finding that it effectively prevents Illumina from acting on its strong incentive to harm Grail's rivals. While the Decision considered the Open Offer to have a "real-world effect[]" on the potential for competitive harm, ID 181, it ignored that to date—over a year since the Acquisition closed—Respondents' self-styled remedy has only been selectively implemented. More importantly, the extensive holes in the Open Offer provide Illumina with ample ability to act on its incentive to harm competition. Whether reviewed as part of the transaction, or properly viewed as a remedy to the transaction, the Open Offer fails to rebut a finding of competitive harm.

The Commission now has the opportunity to correct the fundamental legal and factual errors of the Decision and protect vital competition in the research, development, and commercialization of MCED tests. *See* Commission Rule 3.54(a), 16 C.F.R. § 3.54(a).

II. Summary of the Facts

Cancer is the second-leading cause of death in the United States. Today, asymptomatic cancer screening exists only for a few types of cancers, while most types can only be detected after patients have exhibited symptoms, when it is often too late to treat effectively. Today, MCED test developers seek to change this paradigm with tests that analyze a patient's blood to detect genetic material indicating the presence of cancer. Cancer cells shed DNA and other material into the bloodstream even before symptoms appear, making detection of cancer through blood possible at very early stages and allowing for a diagnosis when more lives can still be saved.

While Grail is the first developer to launch its test, commercializing an initial version of its Galleri MCED test in April 2021, "[t]he evidence in this case demonstrates that Grail and other cancer screening companies are presently competing to develop the best performing cancer screening test, with an objective of screening for multiple cancers." ID 164. Although some of the Decision's specific factual findings are unsupported or contradicted by the weight of the evidence, *see, e.g.*, *infra* § III.B.2.e, the ALJ's factual findings acknowledged this vibrant MCED competition. Specifically, the Decision concluded that (a) "there is *existing* competition [among MCED test developers] to develop and commercialize a test," (b) "[t]hey are competing in that they are trying to develop an MCED test and to bring an MCED test to market," and (c) MCED testing is the "'area of effective competition' [and] is the relevant market in which to assess Illumina's ability and incentive to harm competition." ID 167 (emphasis in original).

Testimony and documents in the record show that post-Acquisition, Illumina possesses the ability and incentive to harm this vibrant, current competition. The Decision included numerous factual findings supporting this conclusion. Regarding ability, the Decision found that Illumina is the "only viable supplier of NGS platforms that meet the requirements of MCED test developers" "currently, and for the near future," ID 153, and that MCED test developers rely on Illumina for quality supply, service, and support. IDF 795-805. As such, MCED developers design their tests specifically to fit Illumina's platform and must rely on Illumina throughout the development and commercialization process. ID 152. As one MCED developer explained, 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.

Regarding incentive, the Decision found that Grail and other MCED developers are engaged in robust competition in the research, development, and commercialization of MCED tests. ID 164-167. For example, MCED developers "have spent hundreds of millions of dollars in the research and development of [MCED] tests," "are currently continuing to improve their tests," and "are competing against Grail in 'prelaunch activities,' associated with bringing a new medical test to market such as 'competing for mindshare with physicians, with health systems, with payers.'" ID 165 (quoting IDF 316). In response, Grail has developed strategies to [redacted] *See, e.g.*, CCFF 3264, 3453, 3592. Likewise, other MCED test developers have tried 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, [redacted]. The Decision also determined that Illumina stood to profit greatly from Grail's MCED market leadership post-Acquisition. For example, while Illumina's pre-Acquisition "strategy" did not focus on "direct participation" in the projected [redacted] downstream market for clinical testing services by 2035, IDF 815, through its Acquisition of Grail, Illumina projected its 2035 "net margin profit pool" from MCED tests would dwarf its sales of NGS platforms. IDF 821. [redacted]

[redacted] IDF 819. The Decision also found that Illumina has access to customer information, including insight into their research and development activities, IDF 746-59, and the tools to price discriminate among its customers. IDF 766-78. Finally, there is substantial record evidence showing that rival MCED tests share core features and functionality with Galleri, and Grail identifies these companies as "competitors" to Galleri, closely monitoring their MCED development, *see infra* § III.B.2.d.

These underlying facts demonstrate that the Acquisition creates a direct conflict of interest between Illumina and its MCED test developer customers. *See, e.g.*, CCFF 3148-3173, 4177, 4302. 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. Given the Decision's findings regarding the robust current innovation competition, coupled with the enormous profits at stake, post-Acquisition Illumina has a strong incentive to use Galleri to capture as much of the MCED market as possible by impeding competition—at any stage—that may threaten its market position.

QUESTIONS PRESENTED

I. **Whether the Acquisition has a reasonable probability of substantially lessening competition under the Supreme Court's *Brown Shoe* framework?**

II. **Whether post-Acquisition Illumina possesses the ability and incentive to harm competition in the research, development, and commercialization of MCED tests, and whether such a showing is sufficient to establish that the Acquisition has a reasonable probability of substantially lessening competition?**

III. **Whether the Open Offer is a remedy for which Respondents bear the burden to show it rebuts a *prima facie* showing of competitive harm and whether Respondents established the Open Offer will offset competitive harm?**

ARGUMENT

I. The Research, Development, and Commercialization of MCED Tests is a Relevant 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 (Clayton Act). 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 Co. v. United States*, 370 U.S. 294, 324 (1962). It is undisputed that the geographic market is the United States. ID 161. The Decision held that Complaint Counsel had met its burden to show that the relevant product market is the research, development, and commercialization of MCED tests. ID 167. The Decision adopted a "pragmatic, factual approach to the definition of the relevant market," *United States v. Anthem, Inc.*, 236 F. Supp. 3d 171, 193 (D.D.C. 2017), and found persuasive evidence of "*existing* competition to develop and commercialize a test," and that "all the cancer screening companies researching and developing an MCED test are on the same racetrack[.]" ID 167 (emphasis in original). The Decision properly concluded that "[t]he evidence in this case demonstrates that Grail and other cancer screening companies are presently competing to develop the best performing cancer screening test, with an objective of screening for multiple cancers." ID 164; *see also* ID 167 (finding that the research, development, and commercialization of MCED tests is the "area of effective competition").

II. Illumina's NGS Platforms Are Related Products

In assessing a vertical merger's potential competitive effects, it can be helpful to identify a related product in addition to defining a relevant market. Here, Complaint Counsel identified the related product as Illumina's NGS platforms (including consumables and reagents). As the

Decision noted, MCED test developers require highly accurate, high-throughput NGS platforms, CCB § II.D.1; CCFF § V.C, and Illumina is the only NGS platform provider that meets these needs. CCB § II.D.2; ID 149-53. Per the Decision, "the evidence demonstrates that currently, and for the near future, Illumina is the only viable supplier of NGS platforms that meet the requirements of MCED test developers." ID 153; *see also* IDF 601-34 (finding that MCED test developers rely on Illumina's NGS platforms).

III. The Decision Erred in Concluding that Complaint Counsel Failed to Prove a *Prima Facie* Case

Despite defining the market for the research, development, and commercialization of MCED tests and identifying Illumina as the only viable supplier of NGS platforms for MCED test developers, the Decision found that "Complaint Counsel has failed to prove its asserted *prima facie* case that Illumina's post-Acquisition ability and incentive to foreclose or disadvantage Grail's alleged rivals is likely to result in a substantial lessening of competition in the relevant market for the research, development, and commercialization of MCED tests." ID 193. In reaching this conclusion, the Decision erred when assessing the likelihood of competitive harm under both the *Brown Shoe* factors and the ability and incentive framework. As explained in Complaint Counsel's post-trial briefing, a proper application of the record evidence to the correct legal standard shows that this Acquisition has a reasonable probability of substantially lessening competition. CCB 79-132.

A. The Decision Misapplied the Supreme Court's *Brown Shoe* Framework

Brown Shoe and its progeny provide that the determination of a vertical merger's legality is usually based on a two-step analysis—first, an evaluation of potential foreclosure and then an assessment of several specific anticompetitive indicia, referred to herein as "functional factors." The Decision misapplied caselaw in two ways that contradict controlling precedent: (1) it failed to engage in the initial step of determining the extent of potential foreclosure, and (2) it misapplied the functional factors in assessing the Acquisition's likelihood of competitive harm.

1. The Decision Failed to Determine the Extent of Potential Foreclosure

Under *Brown Shoe*, a court must first determine if the share of the market potentially foreclosed is *de minimis*, approaching monopoly proportions, or somewhere in between. As the Supreme Court explained, "[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. Alternatively, if foreclosure is "of a de minimis share of the market" then it "will not tend 'substantially to lessen competition.'" *Id.* at 329. Only after a court determines that "the foreclosure is neither of monopoly nor de minimis proportions" should it engage in the second step—considering the relevant functional factors. *Id*.

Directly contradicting Supreme Court precedent, the Decision ignored the initial step of assessing whether potential foreclosure was of *de minimis* or monopoly proportions, noting only that the extent of foreclosure "will seldom be determinative." ID 132. But the Decision also held that Illumina is "currently, and for the near future . . . the only viable supplier of NGS platforms that meet the requirements of MCED test developers." ID 153. Because Illumina controls complete access to a critical input—NGS platforms necessary for MCED tests—Illumina can foreclose a monopoly proportion of the market, which is itself determinative of a likelihood of anticompetitive effects. 370 U.S. at 328; *see also Fruehauf Corp. v. FTC*, 603 F.2d 345, 352 (2d Cir. 1979) (recognizing a "per se rule . . . where the share of the market foreclosed reaches monopoly proportions"). These facts establish a *prima facie* violation of the Clayton Act under *Brown Shoe*.

2. The Decision Misapplied the *Brown Shoe* Functional Factors

If a court determines that potential foreclosure falls between "de minimis" and "approach[ing] monopoly proportions," the second step of the inquiry is to examine *Brown Shoe*'s functional factors.[1] 370 U.S. at 328-29. These factors include the degree of potential foreclosure, even if not approaching monopoly proportions; the "nature and purpose" of the vertical arrangement; the level of any trend toward concentration, including any trend towards domination by a few leaders; the existence of a trend towards vertical integration and consolidation in previously independent industries; the ease with which potential entrants may readily overcome barriers to full entry and compete effectively with existing companies; and any actual and reasonably likely adverse effects upon local industries and small businesses. *See U.S. Steel Corp. v. FTC*, 426 F.2d 592, 599 (6th Cir. 1970) (describing the "functional factors" as "indicia of the requisite anti-competitive effect").

The Decision misinterpreted *U.S. Steel*, a case applying *Brown Shoe*, to suggest that the Government must prove all factors in every case because the *U.S. Steel* court had found "very substantial evidence" on each. ID 192. This interpretation contravenes successful vertical merger challenges in which the plaintiff *did not* prove all six factors. For example, in *Ford Motor Co. v. United States*, the Supreme Court found a vertical acquisition unlawful where only three factors were considered. 405 U.S. 562, 566-70 (1972). In its decision, the Supreme Court did not engage in a point-by-point assessment of each *Brown Shoe* factor, instead focusing on a subset: the nature and purpose of the acquisition, increased entry barriers, and concentration trends. *Id.* at 566-70; *see also Gulf & Western Indus., Inc. v. Great Atlantic & Pac. Tea Co., Inc.*, 476 F.2d 687, 675 (2d

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[1] The Commission does not need to address the *Brown Shoe* functional factors because the degree of potential foreclosure is sufficient to find a reasonable probability of substantially lessening of competition under the Clayton Act.

Cir. 1973) (finding sufficient likelihood of success to grant a preliminary injunction because four of the six *Brown Shoe* factors were met). As these cases show, *Brown Shoe*'s functional factors are considerations for assessing whether potential foreclosure between *de minimis* and monopoly proportions has a reasonable probability of substantially lessening competition—they are not elements or prerequisites for finding an anticompetitive effect.

While not necessary in this matter, if the Commission proceeds to analyze the second step of the *Brown Shoe* inquiry, record evidence shows that at least three of the functional factors—potential foreclosure, nature and purpose of the acquisition, and entry barriers—are present, as Complaint Counsel's post-trial briefing explains in full. CCB § II.E.2.

B. The Decision's Ability and Incentive Analysis Is Legally and Factually Erroneous

The Decision held that it is not "sufficient to prove that Illumina has an ability and incentive to take action to harm Grail's rivals post-Acquisition" to "meet [the] *prima facie* burden to show that a merger is likely to substantially lessen competition." ID 196-97. Instead, the Decision appears to hold that Complaint Counsel must show both an ability and incentive *and* some additional evidence of competitive harm. ID 168-69, 196. In doing so, the Decision missed the fundamental point that the ability and incentive analysis is, itself, a means by which courts can make a fact-specific determination of the likelihood of anticompetitive effect. Simply put, if a vertical merger allows the merged firm to profitably use its control of the related product to weaken or remove a competitive constraint, there is no requirement to then prove any additional elements.[2] *AT&T*, 310 F. Supp. 3d at 243-45 (assessing the Government's foreclosure theory solely under the

[2] Respondents and their counsel endorsed the ability and incentive framework in their briefing and statements. *See, e.g.*, RB 131 (citing *AT&T* and concluding that "it was Complaint Counsel's burden to demonstrate that Illumina has the ability and incentive to foreclose during the relevant timeframe . . ."); RRB 53 (same); Marriott (Illumina Counsel) Tr. 65 ("So to make out their case, the FTC has to show at least two things, in our judgment. They have to show, one, that Illumina would have an incentive to raise costs to GRAIL's rivals . . . . And they have to show that GRAIL's rivals couldn't avoid the increased costs by switching to platforms other than Illumina's.").

ability and incentive framework). Rather, showing a post-merger ability and incentive to harm competition is sufficient to show that the "effect [of the merger] may be substantially to lessen competition." *Brown Shoe*, 370 U.S. at 324. As Complaint Counsel explained in its extensive post-trial briefing, a correct application of the facts in evidence to caselaw shows that Respondents have the post-Acquisition ability and incentive to foreclosure Grail's rivals. CCB 79-119, 125-32. The Decision's holding to the contrary relies on a heightened standard unsupported by caselaw and an improper assessment of the facts in evidence.

1. The Decision Applied the Incorrect Standard in Assessing Illumina's Ability to Foreclose

The Decision correctly concluded that "the evidence proves that—absent the Open Offer—Illumina has the ability to use its control as a dominant provider of NGS to adversely impact MCED test developers." ID 171; *see also id.* ("Illumina possesses an ability to affect price, supply, and quality of NGS products and services"). However, the Decision also found that "such proof is less significant to this case" because "Illumina's status as the only viable supplier of a necessary input for MCED test development existed before the Acquisition, and therefore, Illumina's asserted abilities to raise prices, withhold supply, or decrease the quality of products or services, also existed before the Acquisition." *Id.* at 171-72, 191. The fact that Illumina was the dominant supplier before the Acquisition and remained the dominant supplier after the Acquisition does not inoculate this transaction. If anything, Illumina's entrenched position in the market reinforces the competitive harms associated with the Acquisition.

Some mergers impact a firm's ability to foreclose rival competitors, while other mergers impact a firm's incentive to foreclose. Ultimately, while the merged firm must possess the ability and incentive to foreclose, the merger itself only needs to either increase the combined firms' ability or incentive but need not do both. *AT&T*, 310 F. Supp. 3d at 243-45; *see also* Steven C.

Salop, *Invigorating Vertical Merger Enforcement*, 127 Yale L.J. 1962, 1975 (2018). Any requirement that the merger must change *both* the combined firm's ability and incentive would, paradoxically, exempt from Clayton Act review any vertical acquisition by a monopolist provider of a critical input. Such an exemption exists nowhere in the statutes or caselaw and contravenes the purpose of the Clayton Act.

2. The Decision Misapplied Law and Evidence in Assessing Illumina's Post-Acquisition Incentive

The Decision incorrectly concluded that Illumina lacks the incentive to foreclose or disadvantage Grail's MCED competitors by misapplying the legal standard and ignoring key factual findings and record evidence. As a result, the Decision made numerous flawed arguments, including: (1) harm to competition was not "probable and imminent" because future profits from Grail's MCED test would not be realized for "more than 12 years," ID 173; (2) Illumina lacked an incentive to harm MCED rivals because it could result in the loss of NGS sales to non-MCED customers, ID 173-174; (3) Complaint Counsel did not account for Illumina's pre-merger 12% ownership stake in Grail, ID 174-175; (4) foreclosure of Grail's MCED rivals would not result in meaningful diversion to Grail, ID 175-177; (5) Galleri is too differentiated from rivals' MCED tests to be close substitutes once commercialized, ID 145-47; and (6) evidence of Illumina's past conduct when it vertically integrated was irrelevant, ID 183 n.61. Each of these justifications was wrong.

a. Probable and Imminent Harm

The Decision reasoned that "the potential for profit more than 12 years in the future fails to demonstrate that Illumina has a current or near-term incentive to harm Grail's rivals, which undermines any conclusion that resulting harm to competition is 'probable and imminent.'" ID 173 (quoting *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 115 (D.D.C. 2004)). First, this argument incorrectly focuses only on incentives related to future revenue from commercial competition, ignoring incentives that exist today to stifle innovation competition. Taking the Decision's reasoning at its face would essentially create a safe harbor from antitrust enforcement in developing markets. But Section 7 of the Clayton Act is not limited to competition among products in their final commercial forms or in fully developed markets. 15 U.S.C. § 18. Rather, well-established precedent shows that harm to ongoing innovation in the market is sufficient to establish a *prima facie* case under Section 7 and that antitrust harm can occur in a developing, dynamic market such as this one. *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"); *FTC v. Actavis*, 570 U.S. 136, 158 (2013) (recognizing that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects" despite there being only the monopolist patent holder on the "market" to date).

The Decision defined the relevant product market as the research, development, and commercialization of MCED tests, ID 167, and found that Grail and its rivals were "competing in that they are trying to develop an MCED test and to bring an MCED test to market," and that "[t]his 'area of effective competition' is the relevant market in which to assess Illumina's ability to harm competition." ID 167. Analogizing this competition to a racetrack where "commercialization is the finish line," the Decision found that "all the cancer screening companies researching and developing an MCED test are on the same racetrack." ID 167; *see also* CCFF 1902-2594; IDF 278, 281, 316-20, 354-58, 394-96, 491, 493. The Decision depicted Grail as having "crossed the finish line." ID 167. But [redacted]; *see also* IDF 214 (Grail has developed two versions of Galleri and is currently developing a third version of Galleri, [redacted]). Further, the conclusion that Grail is "finish[ed]" with developing Galleri is contradicted by the Decision's finding that MCED test developers must obtain FDA approval and reimbursement coverage to "gain widespread commercialization" and "expand[] the MCED test developer's customer base by providing access to patients who otherwise could not afford to pay the out-of-pocket price of a test." ID 129; IDF 198-200. In other words, the finish line is not simply having an MCED test available for sale, but rather having an FDA-approved test covered by insurance companies. To date, no company has crossed that finish line.

The market dynamics identified by the Decision give rise to two incentives to foreclose today. First, Illumina has the incentive to suppress innovation competition. For example, the Decision found that "Exact/Thrive is currently competing against Grail in 'prelaunch activities,' associated with bringing a new medical test to market such as 'competing for mindshare with physicians, with health systems, with payers,'" ID 165 (citing IDF 316), as well as competing for the "scientists and talent for its research and development efforts." ID 165 (citing IDF 317). This current pre-commercialization competition has resulted in benefits already as this innovation competition spurs MCED competitors to improve their tests and accelerate their commercialization efforts. For example, the Decision found that [redacted] Likewise, [redacted] The Decision's findings that Grail and its MCED rivals are currently competing along numerous dimensions to research and develop MCED tests are fundamentally inconsistent with the Decision's reasoning that there is no "probable and imminent" incentive for Illumina to disadvantage Grail's rivals.

Pre-Acquisition, Illumina possessed some incentive to assist all MCED tests and earn NGS sales revenue from them. CCFF § VII.B.1.a. [redacted] CCFF 3100-02. Indeed, the Decision found that Illumina expects to lose almost [redacted] from Grail by 2026 as part of these commercialization efforts. IDF 828. Given this post-Acquisition hit to its balance sheet, any measures Illumina can take to reduce that loss benefits its bottom line. Yet Illumina's potential losses from foregone NGS sales to Grail's rivals—even assuming complete foreclosure—are insignificant. Illumina's CEO told investors 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."[4] CCFF 3140. Despite recognizing many of the underlying facts supporting this conclusion, the Decision ignored how these market dynamics impact Illumina's incentive to disadvantage Grail's rivals today.

Second, consideration of the financial impact of commercialization strengthens Illumina's present incentive to foreclose. In the race to successfully commercialize an MCED test, there are

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[3] Post-Acquisition, Illumina's behavior toward Grail's MCED rivals is likely to chill innovation in the MCED testing space by reducing rivals' incentives to invest. [redacted]

[4] The actual lost profits would even be less because Illumina possesses numerous tools to disadvantage rival MCED developers short of total foreclosure, and thus, need not sacrifice NGS sales to MCED customers entirely. *See infra* § IV.A.

enormous benefits to being the first to cross the finish line. Picking Grail as the winner would entrench its position as the market leader [redacted] IDF 815-817. As Illumina told its Board of Directors, acquiring Grail will enable it to add [redacted] to its bottom line and account for over [redacted] of its revenue by [redacted]. ID 173. Assuming, of course, that Grail succeeds. Record evidence—including Grail's internal documents—reveals [redacted] Given the massive profits awaiting the winner, IDF 818-20, 826-27, Illumina cannot risk that someone beats Grail to full commercialization. As Grail itself identified internally, it must [redacted] Thus, while much of the financial payoffs for its current efforts lie in the future, Illumina possesses a *present incentive* to ensure that it wins the race, as it has everything to gain—and very little to lose (given the small value of NGS sales to MCED developers)—by hamstringing its competitors now.

Indeed, if one were to accept the Decision's logic that Illumina possesses no incentive today because profits lie years in the future, ID 167, Illumina would lack a business rationale for the Acquisition itself. As the Decision noted, Illumina paid $8 billion for Grail and projects that it will lose millions of dollars annually as a result of the Acquisition until 2026. IDF 827. In accepting these present financial costs, Illumina concluded it possessed a *current financial incentive* to acquire Grail; specifically, it conducted a discounted cash flow analysis of revenues from Galleri *years in the future* when valuing Grail. CCFF 3134-36. Thus, it belies logic to conclude that Illumina possesses no present incentive to disadvantage the competitors who threaten this multibillion-dollar benefit, particularly when Illumina's deal was premised on the determination that it must transform from [redacted] [5] CCFF 3131; *see* IDF 818-20.

b. Price Discrimination and Reputation

In assessing price discrimination and reputation, the Decision reasoned:

> [a] potential result of an attempt by Illumina to raise prices or otherwise foreclose or harm its MCED customers is that these customers, as well as the non-MCED clinical testing customers who learned of any such attempt, would choose to no longer invest in current or future NGS applications on Illumina systems. This could result in the loss of Illumina's NGS sales for both MCED and non-MCED applications and would be contrary to Illumina's stated strategy with the Acquisition to continue serving the NGS segment.

ID 174 (internal citations omitted). With respect to MCED applications, this rationale is nonsensical: causing MCED customers to no longer invest in current or future MCED NGS applications is a harm that will result from the Acquisition. With respect to non-MCED NGS applications, this argument ignores the ALJ's own finding that Illumina possesses the ability to identify Grail's competitors and price discriminate by application and, therefore, can target only MCEDs with its tactics and avoid impacting non-MCED NGS sales.[6] CCB § II.E.1.a.i; CCFF 2608-2701. For example, the Decision found that Illumina has insight into how its NGS customers are using its products and "tools available to price discriminate among customers based on the

[5] A contrary conclusion—that a firm possesses no incentive to foreclose a rival until that rival has launched a commercial product or service—implies that markets in which companies routinely improve products to enhance their competitive position (or change products in response to competitive pressures) would be immune from antitrust scrutiny. But that is not the law. *See United States v. Anthem, Inc.*, 855 F.3d 345, 361 (D.C. Cir. 2017) (A "threat to innovation is anticompetitive in its own right."); *In re Union Carbide Corp.*, 59 F.T.C. 614, 1961 WL 65409, at *35 (1961) (noting it is particularly important to prevent monopolies in "infant industr[ies] which appear[] destined for far greater expansion and growth. Strong and vigorous competition is the catalyst of rapid economic progress."); *In re Otto Bock HealthCare N. Am., Inc.*, 2019 WL 5957363, at *25 (F.T.C. Nov. 1, 2019) (holding that acquiring a firm poised to launch a product that would "intensify" competition was a "further likely harm to competition"). Respondents' own economic experts concede that innovation competition, including innovating to differentiate along product features and functions, is important. *See* CCFF 3570 (Respondents' expert Dr. Carlton testifying that innovation harm is "a concern you should worry about" when examining the effects of a merger, and Dr. Katz testifying that "stifled" innovation "would be in my view a very bad thing").

[6] Moreover, this ignores the clear language of the Open Offer which shields Illumina from any potential reputational harm by requiring a *confidential* arbitration process. *See infra* § IV.A; *see also* CCFF 4934.

customers' uses for the instruments and reagents." IDF 766; *see also* IDF 746-759, 767-78; CCFF 2745-49, 2759.

Given this broad exchange of information between Illumina and its customers, Illumina can identify which MCED developers pose a threat to Grail's competitive position and frustrate their development and commercialization efforts without raising prices or otherwise harming its other customers. IDF 746-759; 766-78. Already, Illumina knows which of its customers compete against Grail. As the Decision recognized, Illumina had performed an analysis of whether a given customer competes with Grail, specifically identifying "the degree to which any [customer] may be developing a multicancer screening test." IDF 515; *cf. FTC v. Whole Foods Mkt.*, 548 F.3d 1028, 1039–40 (D.C. Cir. 2008) (seller charged higher prices for products sold primarily to "core customers").

c. Margin Analyses

The Decision incorrectly concluded that the Acquisition does not change Illumina's incentive when analyzing Illumina's ownership interest and pre-merger versus post-merger margins. Specifically, the Decision held that, "[a]s shown by calculations performed by Respondents' expert witness, Dr. Dennis Carlton, Illumina's pre-Acquisition profits from the sale of MCED tests through Grail are already substantially higher than the profits Illumina would earn on MCED tests sold through another, hypothetical MCED test seller, given Illumina's pre-Acquisition 12% stake." ID 175. The Decision thus appeared to conclude that Illumina had an equivalent incentive to favor Grail pre-Acquisition and post-Acquisition. This analysis suffers from multiple errors.

First, the Decision erroneously focused on whether Illumina possessed some incentive to favor Grail pre-Acquisition rather than analyzing whether the Acquisition increased this incentive. The Decision compared Illumina's profits received from a Grail MCED sale (when it had a 12%

ownership interest) to profits from a rival MCED sale; while those calculations might show that, prior to the Acquisition, Illumina possessed an incentive to favor Grail, the relevant question is whether the Acquisition *increases* those incentives to favor Grail. [redacted] Indeed, elsewhere the Decision appeared to correctly find that Illumina will receive higher profits from a Grail sale post-merger than pre-merger, ID 174, as is obvious from the mere fact that Illumina's ownership interest in Grail increased eight-fold. *See* CCFF 3185; IDF 57-58. This finding is itself a sufficient basis to conclude that Illumina's financial incentive to foreclose Grail's MCED rivals is thus much stronger post-Acquisition.

Second, the Decision's conclusion that Illumina lacks an incentive to disadvantage Grail's rivals based on analysis of margins is erroneous because it assumes that total foreclosure (or a raising rivals' costs strategy) is the only means by which Illumina could disadvantage other MCED tests. As detailed *infra* § IV.A and as acknowledged in the Decision, Illumina possesses a variety of means to frustrate the development efforts of Grail's competitors, and thus, does not necessarily need to sacrifice all of its NGS margins while favoring Grail. IDF 795-805; *United States v. Sybron Corp.*, 329 F. Supp. 919, 928–29 (E.D. Pa. 1971) ("[T]here are many more subtle avenues available to an integrated firm . . . .").

d. Diversion

The Decision erroneously concluded that Complaint Counsel failed to prove that there would be sufficient diversion to establish Illumina possesses an incentive to disadvantage Grail's rivals. This finding is based on misapplication of law and contradicted by record evidence.

First, the Decision is flawed to the extent it suggests that calculation of specific diversion ratios is necessary to find an incentive to foreclose. ID 176. Caselaw does not require proof of specific diversion calculations as part of the Government's *prima facie* case in a vertical merger challenge. Despite decades of successful vertical merger challenges, no court has required the Government to prove a certain degree of "divert[ed] sales to [the merged firm] from [downstream] rivals." RB 97; *Brown Shoe*, 370 U.S. 294; *Ford Motor*, 405 U.S. 562; *U.S. Steel*, 426 F.2d 592; *In re Union Carbide Corp.*, 59 F.T.C. 614, 1961 WL 65409 (1961).

Second, extensive documentary and testimonial evidence of similarity among MCED tests, as well as evidence that MCED test developers and Respondents view each other as competitors, demonstrate that customer diversion will likely occur between Galleri and other MCED test. *See* CCB § II.E.1.b.ii; CCRB § I.B; CCFF 3231-84, 3294-3307, 3319-25, 3335-50, [redacted] 3370-75, [redacted] 3389-93, 3424-68, 3471-92. [redacted] Despite consistency across MCED test developer witness testimony, this Commission need not rely on MCED test developers' statements alone. Respondents' ordinary course documents validate the testimony of the MCED test developers that their tests are likely to be close commercial substitutes for Galleri, thereby indicating significant diversion is likely. *See, e.g.*, CCFF 3231-3284, 3294-3307, 3319-25, 3335-50, 3[redacted]3370-75, [redacted] 3389-93, 3424-68, 3471-92. For example, in a March 2020 presentation, Grail identified [redacted] and noted that Grail [redacted]. Grail's Director of Growth Marketing, Chris Della Porta, [redacted]. In fact, [redacted] It would make no sense for Grail to identify these companies as "competitors" to Galleri, track their MCED development efforts, and respond competitively unless it expected close competition—and thus diversion—between Galleri and the other MCED tests.

Based on this type of evidence, [redacted] PX6090 (Scott Morton Report) ¶¶ 147-49, 268; PX6091

(Scott Morton Rebuttal Report) ¶¶ 50-51, 57. Such evidence is more than enough to demonstrate that diversion is likely. *See, e.g.*, *Otto Bock*, 2019 WL 5957363, at *26 (F.T.C.) ("[W]e need not conclude that, without question, the Quattro would have cut into the C-Leg's sales or induced Otto Bock to improve the C-Leg. The requirements of Section 7 are satisfied when a 'reasonable likelihood' of a substantial lessening of competition in the relevant market is shown.") (quoting *United States v. Penn-Olin Chem. Co*., 378 U.S. 158, 171 (1964)).

e. Differentiation

The Decision's conclusion that Galleri is too differentiated from its MCED rivals—and thus Illumina possesses no incentive to foreclose—rests on an inflated characterization of Galleri's capabilities based in part on Respondents' unreliable expert testimony, as well as the incorrect assessment that "[m]ost of the tests in development are too underdeveloped to permit a meaningful comparison of their features" except for Exact/Thrive's CancerSEEK and Singlera's PanSeer. ID 146. Products need not be identical or commercialized to provide sufficient competitive pressure to give rise to an incentive to foreclose. As explained fully in Complaint Counsel's post-trial briefing, ordinary course documents, as well as witness testimony, show that rival MCED tests are sufficiently developed for Grail to assess each test's capabilities and identify rival tests as competitors. CCB 18-23, 109-16.

As the Decision recognized, MCED test developers seek to offer products that fulfill the same purpose: to detect multiple cancers in asymptomatic patients through a blood draw. IDF 130, 132. Likewise, the Decision appeared to acknowledge that MCED tests all possess the key characteristics that allow detection of a multitude of cancers and that MCED developers are planning to commercialize tests to detect for more than two or three cancers. IDF 132, 135, 284, 359, 395, 433; *see also* CCRB 51-53; CCFF 1935-40, 2274, 2319-2421, 2513, 2539-42, [redacted]

Nonetheless, the Decision assumed that Galleri is significantly differentiated from its MCED rivals and, therefore, Respondents have no incentive to foreclose Galleri's rivals.

In the first instance, the Decision appeared to conclude that Grail's MCED rivals are significantly differentiated from Galleri because Respondents' expert witnesses claim that rival MCED tests "are capable of screening for two or three cancer types" versus Grail's unverified 50-cancer screening capability. ID 145. To reach that conclusion, the Decision overly relied on the testimony of Dr. Cote, who is not a fact witness and has no first-hand knowledge of any MCED test's features or commercialization plans. CCRRFF 1960; CCRB 29-30. [redacted] The Decision's out-sourcing of factual findings to a non-percipient witness with no explanation was improper and contradicted by the MCED test developers' testimony, which is based on their real-world experience developing MCED tests and is corroborated by ordinary course business documents supporting that they are developing tests to detect for *more than* two or three cancers. *See e.g.,* IDF 132, 284, [redacted] CCRB 51-53. Moreover, Dr. Cote contradicted his own views at trial, admitting that Galleri has only been clinically shown to detect seven early-stage cancers in asymptomatic patients while Exact/Thrive's CancerSEEK has been shown to detect for eight. CCRB 40-46; 52; CCFF 2056-2057.

The Decision likewise erred in finding that Galleri is significantly differentiated from other MCED tests because of its cancer signal of origin ("CSO") capabilities. ID 146-47. Specifically, the Decision erroneously stated that Galleri's MCED test does not "requir[e] further diagnostic tests." ID 136. This conflicts squarely with Grail's *own website*, which states that its MCED test "requires confirmatory diagnostic evaluation" through follow-up procedures such as imaging. PX0063 at 002. Moreover, Grail's former CEO admitted at trial that certain patients may have to undergo a body scan following a positive Galleri test to identify the cancer signal of origin. CCFF 3565. [redacted] Similarly, the Decision overinflated differences in the sensitivity, specificity, and positive predictive value ("PPV") of the tests. ID 146. As with CSO and number of cancers, Grail cannot say today what the sensitivity, specificity, or PPV of Galleri will be in Galleri's intended use population (i.e., in an asymptomatic screening population) given that [redacted]

Any differences between Galleri and its rival MCED tests in number of cancers, sensitivity, specificity, PPV, and CSO are evidence of current competition rather than evidence of a lack thereof. As MCED test developers have explained, they are continuing to improve their tests and expect such features to be facets of competition in the research, development, and commercialization of MCED tests. CCFF 2053-58, [redacted]; IDF [redacted], 499; ID 164-65. For example, many MCED test developers are prioritizing certain cancers to compete with Galleri and are developing CSO capabilities to do the same. CCRB 58-60.

The Decision also erred by suggesting that other MCED developers' efforts are too preliminary for meaningful comparison to Galleri. The Decision's erroneous conclusion (a) understates the legitimacy of their efforts thus far, and (b) downplays their commitment to commercializing a product. MCED test developers have each invested hundreds of millions of dollars in their tests and plan to continue to do so through commercialization. *See* IDF 274, [redacted] 498. Several MCED test developers began the MCED test development process almost ten years ago and have either published data on their tests or have undertaken efforts to generate and publish data soon. *See* IDF 282, 349, [redacted] CCFF [redacted] 2112-[redacted] These MCED test developers have concrete paths to commercialization, IDF 305, 388, [redacted] [redacted] 493; [redacted] as they represented to their boards of directors and investors and to which they testified under oath. In the context of the MCED market, Grail's rivals are close to commercialization and nipping at its heels. Grail's internal competitive assessments confirm that its MCED rivals tests are sufficiently developed to spur current competition. *See* IDF 263-67; CCFF [redacted]

Indeed, Grail's ordinary course documents identified other MCED test developers as competitive threats and adjusted its development and commercialization plans to defend against these threats. ID 166; IDF 261-267; 326-331; [redacted] Rival MCED test developers have done the same. ID 167. The Decision erred by ignoring this evidence of competition when assessing incentives, holding that "Complaint Counsel has failed to persuade that it is likely that a better-quality test is on the horizon in any reasonable timeframe." ID 149. Again, the Decision asked the wrong question. An incentive to compete (and to disadvantage one's rivals) arises well before the rivals commercialize their products. It exists as soon as rivals' research and development efforts become sufficient competitive threats, which Grail's documents already reflect. *See, e.g.*, IDF 263-67 (noting Grail's internal "Competitive Threats to Galleri After Launch" presentation identified "Top Tier" threats such as Exact/Thrive, Guardant, Singlera, and Freenome). [redacted]

f. Illumina's Prior Vertical Integration

The Decision improperly dismissed the relevance of Illumina's past conduct when vertically integrated, noting that it is "not probative evidence that Illumina will harm Grail's alleged competitors post-Acquisition."[7] ID 183. In doing so, the Decision contravened Supreme Court precedent. *Brown Shoe*, 370 U.S. at 332 (relying in part on "past behavior of Brown" to find vertical merger illegal). Those situations provide real-world evidence that when Illumina is vertically integrated it can and will act in its own economic interest to the detriment of its customers' ability to compete. For example, as discussed extensively in Complaint Counsel's briefings, after Illumina vertically integrated into therapy selection tests (which, like MCED tests, also require NGS), it considered the competitive threat posed by competing with these customers when deciding whether to enter into in-vitro diagnostic agreements (necessary for FDA approval) with them. CCB 99-104, 116-19; CCRB 144-50. As the former Illumina executive in charge of these negotiations testified, "the ability to maximize penetration into the [therapy selection] market was always a consideration. . . . We considered a term called 'cannibalization'—in other words,

[7] The court in *AT&T*, which the Decision cited favorably, examines "prior instances of vertical integration in the video programming and distribution industry" as "real-world objective evidence" of the competitive effects of the merger. 310 F. Supp. 3d at 215. The Decision offered no reason to discount it here, especially when the prior instances involve the same acquiror—Illumina.

what would be the sales of Illumina['s therapy selection test] in the absence of these partners versus the presence of these partners—to try to decide at least a framework for summing up what the value of that partnership should be." CCFF 3808. As Illumina explained in a 2018 presentation discussing its therapy selection test strategy and whether to continue to partner with other therapy test providers, [redacted] The evidentiary record also shows that Illumina engaged in similar practices to stifle its NIPT customers after it acquired Verinata and became vertically integrated in the NIPT space. CCRB § III.F.1. These past examples of vertical integration provide "real-world objective evidence" of Illumina's likely actions here. *AT&T*, 310 F. Supp. 3d at 215.[8]

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As Complaint Counsel's post-trial briefing explains in detail, a legally proper analysis of the record evidence shows that post-Acquisition Respondents will have the incentive to exploit MCED test developers' complete reliance on Illumina's NGS platforms to stifle current innovation competition and forestall or eliminate commercial competition. CCB 104-19, 125-32. The Commission should correct the flaws in the Decision and find that Complaint Counsel has met its

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[8] Likewise, Illumina's favoritism towards Grail prior to reducing its ownership percentage is informative. CCB 23-27. While the Decision discussed this, it noted that "the Grail example from the past is readily distinguishable from extant circumstances" because at the time of Grail's formation no other oncology testing companies were developing cancer screening tests. ID 183 n.61. This is simply untrue and contradicted by record evidence, as several companies began MCED test development prior to the formation of Grail. *See* [redacted]; CCFF [redacted] 6043. Also, Illumina's documents show that it was aware that some of its customers competed with Grail at the time of Grail's formation and spinoff. *See, e.g.*, CCFF 26, 57. In fact, when Illumina spun off Grail, it 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.

prima facie burden to show that there is a reasonable probability of a substantial lessening of competition.

IV. Respondents Did Not Rebut Complaint Counsel's *Prima Facie* Case

Having erroneously concluded that Complaint Counsel did not establish a *prima facie* case, the Decision erred in concluding that Respondents' remedy would offset any competitive harm, and it reached no conclusions regarding whether Respondents could rebut a *prima facie* case with their efficiencies claims.[9] Substantial record evidence demonstrates that neither Respondents' remedy nor efficiencies claims change the potential for competitive harm post-Acquisition, and therefore, Respondents have failed to rebut Complaint Counsel's *prima facie* case.

A. The Decision Erred in Concluding that Respondents' Remedy Would Offset Any Competitive Harm

The Decision improperly held that "the Open Offer effectively constrains Illumina from harming Grail's alleged rivals." ID 178. Rather than follow the weight of the evidentiary record and the consistent, uniform testimony of market participants, the Decision assumed without analysis that Illumina will abide faithfully by the terms of its self-imposed, self-drafted contract and ignore enormous incentives to exploit the Open Offer's inherent flexibility.[10] To reach its conclusion, the Decision (1) applied the wrong legal standard; (2) trusted without scrutiny or analysis the testimony of Respondents' representatives; and (3) ignored the more relevant

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[9] Respondents failed to meet their burden to show entry would erode Illumina's ability to harm competition through its NGS platforms, as reflected in the Decision's finding that "the evidence fails to prove that the asserted alternative NGS platforms are likely to become commercially available in the near future." ID 151.

[10] Inherent in the Decision is the flawed view that the Open Offer will actually benefit MCED test developers relative to agreements they could have otherwise secured in a competitive marketplace absent the Acquisition. As the record shows, several MCED developers, including [redacted] had been negotiating more favorable terms than the Open Offer, which Illumina promptly reneged on once it closed the Acquisition. *See* CCRB 159-60; [redacted]. As [redacted] CCFF 4396.

consistent and reliable testimony of MCED test developers. The Decision's analysis was both legally and factually wrong.

As an initial matter, the Decision applied the incorrect standard in reviewing the Open Offer, noting that it should not be viewed as a *remedy* to the Acquisition but instead be considered part of Complaint Counsel's *prima facie* case.[11] In other words, the Decision suggested it is Complaint Counsel's burden to prove that the Open Offer does not impact Illumina's ability and incentive. This is simply not the case. Here, the Open Offer was designed and serves as Respondents' proposed remedy to their illegal Acquisition,[12] and Clayton Act precedent is clear that courts only consider remedies *after* they analyze a merger's competitive effects and determine a violation has occurred. *See* CCB § II.F.3. Then it becomes the merging parties' burden to show that their proposed remedy "replace[s] the competitive intensity" lost from the Acquisition. *United States v. Aetna, Inc.*, 240 F. Supp. 3d 1, 60 (D.D.C. 2017). Given the substantial deficiencies in the Open Offer, as detailed in Complaint Counsel's post-trial briefing, CCB § II.F.3.b; CCRB § IV, Respondents have failed to meet their burden. *See California 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."); *Ford Motor*, 405 U.S. at 573 ("Complete divestiture is particularly appropriate where asset or stock acquisitions violate the antitrust laws.").

Besides a vague statement that "[h]olding the Open Offer to the standard of a remedy for a violation puts the proverbial cart before the horse," ID 182, the Decision offered no rationale as to why the Open Offer is not rightfully considered a remedy. A review of the record, as well as

[11] It is not entirely clear, however, where the Open Offer fits in the Decision's analysis. On one hand, the Decision stated that "the issue is whether the Open Offer rebuts" the likelihood of substantial harm, suggesting that this would be part of Respondents' burden. ID 182. On the other hand, the Decision claimed it considers the Open Offer a "real-world effect[]" that determines "the potential for anticompetitive harm." ID 181.

[12] As explained in Complaint Counsel's Post-Trial Brief, the Open Offer was designed to stifle customer concerns with surface-level assurances in an attempt to close the deal quickly. *See* CCB § II.F.3.a.

caselaw, shows otherwise. First, the Open Offer indicates on its face that it is intended as a remedy to the Acquisition. The preamble of Respondents' Open Offer states:

> In connection with Illumina Inc.'s proposed acquisition of GRAIL, Inc. (the 'Transaction'), Illumina is irrevocably offering to [COMPANY] the terms enclosed . . . *to allay any concerns relating to the Transaction*, including that Illumina would disadvantage GRAIL's potential competitors . . . . *To address these concerns,* these terms will be offered . . . .

PX0064 at 001 (emphasis added); CCRB 114; *see also* Respondents' Mot. for Conference to Facilitate Settlement 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"). Second, the Open Offer was conditional on the closing of the Acquisition and, unless and until a final order is entered stating otherwise, only applies to customers who actually signed the agreement and only applies *when* they sign it.[13] PX0064 at 001; CCRB 115. As the Commission has explained, a proposed fix (typically a divestiture) should be analyzed during plaintiffs' *prima facie* case only when the fix has been fully implemented across the market, such as when the challenged transaction and the divestiture occur simultaneously. *In re Otto Bock HealthCare N. Am. Inc.*, 2018 WL 2042043, at *3-*5 (F.T.C. Apr. 18, 2018). Here, the Acquisition was consummated over one year ago and the Open Offer's weak protections apply to only a subset of the market. As such, the Open Offer has not fundamentally changed the market dynamic, but rather only seeks to remedy harm on an ad hoc basis. Given the limitations of the Open Offer, Respondents have not and cannot show that it offsets the likely anticompetitive harms of the transaction. *Aetna*, 240 F. Supp. 3d at 60; *see also* CCB § II.F.3; CCRB § IV.

[13] [redacted]

Moreover, the Decision departed from clear Supreme Court guidance identifying divestiture as "particularly appropriate" for illegal vertical mergers, *Ford Motor*, 405 U.S. at 573, instead relying on inapposite caselaw to support its view of the Open Offer as a "real world effect" on the potential for competitive harm. ID 181. A review of these cases shows that the proposed commitments vary substantially and meaningfully from the Open Offer. First, in *AT&T*, the Government alleged that the combined firm could more credibly threaten blackouts (meaning the distributor would not be able to display the merged firm's content) post-merger, thereby increasing prices to distributors. *AT&T*, 310 F. Supp. 3d at 201. The merging parties proposed arbitration agreements that would prevent a blackout while arbitration was pending, thereby averting any content blackouts from taking place until post-arbitration. *Id*. at 217. According to the *AT&T* district court, the arbitration agreements (1) targeted a discrete type of easily detectable conduct; (2) prevented, rather than remedied after-the-fact, competitive harm; and (3) had already proven successful under nearly identical circumstances. *Id*. at 217. Critically, these factors are not present here.

1. In *AT&T*, potentially harmed customers would learn immediately of a threatened blackout from their direct negotiations with the merged firm and could commence arbitration at any point thereafter. 310 F. Supp. 3d at 184, 200. Here, in contrast, Illumina's MCED customers will not know in real time, if ever, whether Illumina breaches the terms of the Open Offer. [redacted] Illumina executive Nicole Berry—whom the ALJ relied on—admitted as much, testifying that customers will not know what prices its competitors are paying, what products its competitors have access to, or what level of service its competitors are getting to even know whether there is a potential breach. CCFF 4826-28; *see* CCFF 4508-09, 4705.

2. In *AT&T*, once a customer invokes arbitration, it triggers a ban on any blackout until the arbitration concludes. 310 F. Supp. 3d at 184. In other words, the alleged anticompetitive harm of a blackout will never actually take effect (assuming the merged company actually complies with the agreement). Here, even if Illumina's customers discovered a potential breach and engaged in the 120-day arbitration process, the anticompetitive harm at issue would have *already* occurred, and such harm could not be "stayed" during the arbitration process or erased by any ultimate relief. CCFF 4811-14.

3. The *AT&T* court explained that it "ha[d] reason to believe that, post-merger, AT&T will honor Turner's commitment to arbitrate" based on the "real world evidence" of similar arbitration provisions in the Comcast-NBCU consent agreement. *AT&T*, 310 F. Supp. 3d at 241 n.51. Here, Respondents even admit that an agreement like the Open Offer is completely novel to Illumina and the industry, RB at 151-52, and thus there is no "real world evidence" to support its efficacy here. Further, the "real world evidence" that does exist shows that, when vertically integrated, Illumina has acted in ways to harm its competitors and has failed to uphold its commitments. *See, e.g.*, CCB 25, 101-04, 116-19; CCRB § III.F; CCFF § VII.D; CCFF 4746, 4767.

The proposed remedy the ALJ cited from *Butterworth*—a horizontal merger of two nonprofit hospitals—likewise is inapplicable here. In *Butterworth*, the merging parties offered certain assurances to freeze prices and serve the underserved and medically needy communities. *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, 1298 (W.D. Mich. 1996). In accepting these behavioral commitments, the *Butterworth* court noted that "[o]f critical importance" was the fact that "nonprofit hospitals operate differently in highly-concentrated markets than do profit-maximizing firms," and the court ultimately concluded that "nonprofit hospitals may be treated differently under the antitrust laws." *Id.* at 1298, 1302-03; *cf. FTC v. Univ. Health, Inc.*, 938 F.2d 1206, 1224 (11th Cir. 1991) (disagreeing that a hospital's nonprofit status means there will be no substantial lessening of competition). Setting aside the inaccuracy of the *Butterworth* court's assumptions about the motives of nonprofit entities, here, Illumina is decidedly *not* a nonprofit business, but rather a profit-maximizing firm that the *Butterworth* court expressly distinguished. As Illumina's CEO testified at trial, Illumina owes a duty to its shareholders, which includes a duty to maximize the company's profits. deSouza (Illumina) Tr. 2193; CCFF 6086.

Even if the Commission adopts the Decision's standard and views the Open Offer as part of the transaction itself, rather than as a remedy, the record is clear that the Open Offer does not eliminate Illumina's ability and incentive to harm Grail's rivals and, in turn, diminish competition.

First, with respect to ability, the Decision incorrectly held that the "Open Offer constrains Illumina from using virtually any of the tools that Complaint Counsel asserts will raise rivals' costs or otherwise foreclose Grail's alleged rivals." ID 179. This ignores the extensive evidence of the incompleteness and holes in the Open Offer's apparent protections. CCFF § VIII.A. As Complaint Counsel detailed in its post-trial briefing, the Open Offer fails to effectively prevent Illumina from using its position as a monopoly supplier of a critical input to impair competition downstream. *See* CCB § II.F.3; CCRB § IV.

Rather than address head-on the intrinsic flaws of the Open Offer, the ALJ instead relied on his own view that "it cannot, and will not, be assumed that Illumina will evade its commitments or operate in bad faith." ID 188. But it also cannot be assumed that Illumina would act counter to its fiduciary duties to shareholders and its multibillion-dollar incentive.[14] While these incentives do not dictate that Illumina will explicitly violate its commitments in the Open Offer to harm competition, as written, the Open Offer has substantial holes that would allow Illumina to disadvantage rival MCED developers without breaching any of the contractual terms.

For example, 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[.]" CCFF 4555. This provision, however, does not prevent Grail from having knowledge of Illumina's technology in development before its competitors, which would put Grail's rivals at a significant disadvantage. CCFF 4571, 4576, 4598, [redacted]. The ALJ also wholly ignored that the provision explicitly provides that Illumina need only provide *final product specifications* to its customers,[15]

[14] Rather, record evidence shows that Illumina consistently acts as a rational, profit-maximizing firm. *See, e.g.*, CCFF 220-21, 4491, 4746, 4770, 4774, 4985.

[15] Specifically, 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." RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021); *but see* CCFF 4571-72. The Decision only focused on the "5-day allowance" and determined it is "inconsequential" for MCED test development, *see* ID 182 n.60, ignoring the rest of the provision.

which [redacted] CCFF 4602. [redacted] CCFF 2795; IDF 579-82. Although the [redacted] CCFF 1736. Thus, under the explicit terms of the Open Offer, Illumina can provide Grail, as part of Illumina, with information about [redacted], but need not inform Grail's rivals. Grail can use this advance knowledge to gain a competitive advantage in the market. And this provision does not prevent Illumina from making improvements to its technology specifically tailored to Grail, as the ALJ recognized that Illumina has done in the past when it owned Grail. IDF 791; CCFF 2987, 3741-42, 4536, 4577.

The plain language of the Open Offer's pricing terms similarly fails to recreate the pre-Acquisition competitive environment. In the first instance, the Open Offer only provides protections for the highest throughput instrument, essentially dictating that the entire market switch to each new sequencer Illumina manufactures to even obtain the weak protections of the Open Offer. The Open Offer also plainly provides that Illumina will reduce the price 43 percent *per gigabase* of sequencing, but this provision does not address the price *per read*, which is the critical driver of per-sample costs for MCED test developers. PX0064 at 007; *see* CCB § II.F.3.b.ii; CCRB § IV.B. Critically, price *per gigabase* does not correlate with price *per read*, so Illumina can follow the plain letter of the Open Offer's pricing provisions without ever providing a price decrease to MCED test developers. *Id*. Moreover, Illumina's executive admitted at trial that the price of sequencing was plummeting. CCFF 4658-67, 4669, 4701. Thus, agreeing to a fixed 43% price decrease may have little to no impact in this market when compared to an open market absent the Acquisition. Failing to examine the plain language of the Open Offer was a critical flaw of the

Decision, and the Open Offer's easily misinterpreted terms (as evidenced by the ALJ's flawed reading) highlight Illumina's ability to circumvent its commitments even without direct breach.

Second, with respect to incentives, caselaw and economic and legal theory make clear that behavioral remedies, like the Open Offer, cannot alter a company's incentives. As the court in *United States v. H&R Block, Inc.* recognized, 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. 833 F. Supp. 2d 36, 82 (D.D.C. 2011). 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." U.S. Dep't of Justice, Merger Remedies Manual (2020) § III.B.1 n.48.

Here, the Decision instead highlighted so-called *counterincentives* created by the Open Offer as evidence that the Open Offer will restrain Illumina from harming competition downstream, but the record shows that these counterincentives are hollow. Specifically, the Decision noted that "it is logical that Illumina would not want any backlash from failing to follow through on the Open Offer's commitments." ID 183. This ignores the plain language of the Open Offer, which explicitly provides that any dispute arising over the terms of the Open Offer will remain *confidential* through a confidential arbitration process. IDF 984; CCFF 4934. In other words, Illumina crafted the Open Offer so that it will not receive any backlash from violating the terms of the Open Offer because no one will even become aware of such a violation.[16] The Decision also highlighted as a counterincentive that Illumina's representatives testified "under oath" that Illumina will abide by its commitments. ID 184. The Decision, however, failed to mention or analyze the motives and biases of Respondents' witnesses even when each of them stood to gain from the Acquisition and their testimony is directly contradicted by other record evidence, meaning it deserves little weight. *See, e.g., In re Toys "R" Us, Inc.*, 126 F.T.C. 415, 567 n.39 (1998). For example, the Decision credited Illumina executive Nicole Berry's testimony that "any discretionary discounts offered to Grail . . . must be made available to all other Open Offer customers," ID 184, but the plain language of the Open Offer provides that Illumina need only make available the same *volume-based discounts* that Grail receives to other customers, *not* discretionary discounts.[17] *See* CCFF 2733, 2735; CCB 173-74; CCRB § IV.B. The Decision also credited Respondents' expert Robert Rock that the Open Offer's audits will reveal "acts of non-compliance," ID 184, despite Rock's testimony that [redacted] Moreover, the Decision credited Respondents' expert Margaret Guerin-Calvert[18] that "the confidentiality and firewall provisions of

[16] The Decision also echoed Respondents' miscite of Complaint Counsel's expert, claiming she acknowledged that "compliance with the Open Offer will have a favorable impact on Illumina's reputation." ID 183-84. Instead, as Complaint Counsel pointed out in its Post-Trial Reply Brief, when asked about this during her trial deposition, Dr. Scott Morton repeatedly answered that she [redacted] CCRB 186 n.121; PX7138 (Scott Morton Trial Dep.) at 300.

[17] Moreover, while the Decision credited Berry's testimony on certain aspects of the Open Offer, it ignored it on other aspects. For instance, the Decision stated that "any customer with a good faith basis can ask for additional audits, with which Illumina *must* cooperate." ID 186 (citing IDF 979-980) (emphasis added). This finding goes squarely against Berry's own testimony that *Illumina* gets to decide if the customer has a good faith basis to request an additional audit. CCFF 4818.

[18] The ALJ found Guerin-Calvert credible based on her "review of government consent decrees using firewall and confidentiality provisions," ID 186, but Guerin-Calvert admitted under oath that she did not review any compliance reports related to the six consent decrees she reviewed, nor does she know whether the firewalls actually worked. CCFF 4798-803.

the Open Offer directly address the concern regarding Illumina's ability to use confidential customer information in an anticompetitive manner," ID 186, even though Guerin-Calvert admitted that she does not know how Illumina will implement its audit and firewall provisions, how Illumina will identify which employees have access to confidential information, or which information will be protected through the firewall. CCFF 4783-97.

The Decision, though, noticeably failed to mention the testimony of David Daly, a former Illumina executive. Daly testified that [redacted] CCFF 4774. According to Daly, [redacted] CCFF 4769. The Decision instead assumed, against this conflicting evidence, that Illumina will abide by its word—a sentiment that is not reflected in Illumina's past, or current, actions—and ignores the myriad ways Illumina can harm Grail's rivals while abiding by the letter of the contract. *See* CCB 25, 116-19; CCRB § III.F, 185-87.[19]

While the ALJ improperly failed to even assess the motives of Respondents' representatives, he did scrutinize the alleged "self-interest and potential bias" of MCED test developers (the customers who would be subject to the Open Offer's non-negotiated terms), who uniformly expressed their concerns with the Open Offer under oath—concerns they have held

[19] Moreover, as discussed *supra*, even if Illumina abides by the terms of the Open Offer, the Open Offer has substantial holes that would allow Illumina to harm competition regardless of the contractual terms.

consistently even prior to this litigation as reflected in testimony, and which are supported by the plain language of the Open Offer. *See* [redacted]. The ALJ's doubts are perplexing given elsewhere in the Decision the ALJ found MCED test developer testimony credible. *See, e.g.*, ID 150-52.

Despite the consistent market testimony detailing the Open Offer's flaws, the ALJ inexplicably questioned why "greater weight should be given to the opinions of certain customers over others," specifically referring to [redacted]. ID 189. The answer to the ALJ's question is clear and detailed in Complaint Counsel's Post-Trial Reply Brief. CCRB § IV.A. While the Decision cited [redacted] Likewise, the Decision cited [redacted]. The ALJ's dismissal of MCED test developers who read, negotiated, and are subject to the Open Offer in favor of

MCED test developers who have never even seen the Open Offer shows the Decision's analysis was factually flawed. The Decision also inexplicably placed great weight on the decision of MCED test developers to sign the Open Offer, noting without any support that "the fact that Grail's purported rivals have signed the Open Offer is significant and undermines Complaint Counsel's assertions that the Open Offer is illusory, unenforceable, or otherwise ineffective." ID 181. The ALJ also found, though, that "Illumina is the only viable supplier of NGS platforms that meet the requirements of MCED test developers," ID 153, which, as the ALJ recognized, indicates that Illumina's MCED customers have no choice but to seek continued supply from their sole source supplier (and therefore sign an agreement with Illumina). *See* IDF 795-805; CCFF [redacted]

Given the extensive and reliable evidence of the flaws of the Open Offer, the Commission should cure the legal and factual errors of the Decision and find that the Open Offer fails to remedy the anticompetitive harms of the Acquisition.

B. Respondents Have Failed to Meet Their Burden to Show Cognizable Efficiencies

While the Decision contained no analysis of Respondents' claimed efficiencies, the ALJ stated that his analysis of the Acquisition's competitive effects was "[f]urther complicat[ed]" because of "the recognition among academics, courts, and antitrust enforcement authorities alike that 'many vertical mergers create vertical integration efficiencies between purchasers and sellers.'" ID 133 (quoting *AT&T*, 310 F. Supp. 3d at 193) (internal quotation omitted). To the extent the ALJ's analysis of the likely competitive effects was impacted by this apparent presumption that the Acquisition would result in efficiencies, the ALJ's effects analysis is both legally and factually wrong.

First, there is no legal basis for any presumption that a vertical merger is likely to result in efficiencies. Instead, to the extent that efficiencies even can immunize an otherwise unlawful transaction,[20] the caselaw is clear that the merging parties 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." *In re Otto Bock HealthCare N. Am. Inc.*, 2019 WL 2118886, at *50 (F.T.C. May 6, 2019) (Chappell, A.L.J.) (citing *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 350 (3d Cir. 2016)) (emphasis added); *see also FTC v. Hackensack Meridian Health, Inc.*, 2022 WL 840463, at *10 (3d Cir. 2022).[21]

Second, any implicit assumption by the ALJ that the Acquisition is likely to result in any efficiencies is unsupported by the evidentiary record. As detailed in Complaint Counsel's Reply Brief, § V, Respondents failed to substantiate any of their efficiency claims "so that it is possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency, how and when each would be achieved (and any costs of doing so), how each would enhance the merged firm's ability and incentive to compete, and why each would be merger-specific.'" *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (quoting U.S. Dep't of Justice & Fed. Trade Comm'n, *Horizontal Merger Guidelines* § 10 (2010)). Although Respondents did not satisfy their burden for numerous reasons, their failure to *independently* verify their efficiency claims is fatal by itself.

In *United States v. Bertelsmann SE*, 21-cv-02886, Hearing Tr. 2772 (D.D.C. July 25, 2022), the defendants' efficiency claims were based on estimates and modeling performed by defendants'

[20] As both this Decision and numerous circuit courts have observed, no court has ever held that efficiencies immunized an otherwise anticompetitive transaction. *See Otto Bock*, 2019 WL 2118886, at *50; *see also Anthem*, 855 F.3d at 353; *St. Alphonsus Med. Ctr. - Nampa, Inc. v. St. Luke's Health Sys.*, 778 F.3d 775, 790 (9th Cir. 2015). Indeed, the Supreme Court has held that "a merger the effect of which may be substantially to lessen competition is not saved because, on some ultimate reckoning of social or economic debits and credits, it may be deemed beneficial." *United States v. Phila. Nat'l Bank*, 374 U.S. 321, 371 (1963) (internal quotations omitted).

[21] Even if the Decision's reference to "vertical integration efficiencies" is referring only to the elimination of double-marginalization ("EDM") and not Respondents' other efficiency claims, there is no legal basis to treat EDM differently. Respondent's' own economic expert describes EDM as an "efficiency," and no court has held that EDM should be analyzed any differently from other claimed efficiencies. *See* CCB § II.F.2.b.

business executives. While acknowledging that the lead executive responsible for the estimates possessed "broad experience" and was "very competent," *id.* at 2756, the court nonetheless excluded the efficiencies evidence because the defendants did not produce evidence that the efficiencies were *independently verified* by someone other than defendants' executives. *Id.* at 2768. Similarly, Respondents rely only on vague claims—unsupported by ordinary course documents—from their business executives about the purported efficiencies of the Acquisition. *See* CCB § II.F.2.b; CCRB § V. For example, Respondents' claim that the Acquisition will save lives is supported only by estimates performed by their economic expert, Dr. Carlton. RB 185. However, just as the defendants' expert in *Bertelsmann* merely relied on modeling created by the defendants' business executives, Dr. Carlton admitted that he simply relied upon Illumina's own claims that it could achieve such acceleration without opining on whether Illumina could actually accelerate FDA or payer approval.[22] CCFF 5075, 5077, 5432. This is but one of the numerous reasons why any presumption by the ALJ that the Acquisition would result in efficiencies is legally and factually wrong.

CONCLUSION

For the foregoing reasons, Complaint Counsel respectfully requests that the Commission reverse the Decision and enter the Order included in Appendix A.

22 [redacted]

Dated: October 4, 2022

Respectfully submitted,

s/ Susan A. Musser
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Counsel Supporting the Complaint

Appendix A

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS:	**Lina M. Khan, Chair** **Noah Joshua Phillips** **Rebecca Kelly Slaughter** **Christine S. Wilson** **Alvaro M. Bedoya**

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. "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.

E. “Commission” or “FTC” or “Complaint Counsel” means the Federal Trade Commission.

F. “Confidential Information” means nonpublic Business Information.

G. “Consent” means an approval, consent, ratification, waiver, or other authorization.

H. “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.

I. “Respondents” mean Illumina and GRAIL.

J. “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.

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

L. “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.

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

N. “Divestiture Trustee” means the Person appointed pursuant to Section VI of this Order.

O. “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.

P. “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.

Q. “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.

R. "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.

S. "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.

T. "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.

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

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

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

X. "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.

Y. "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.

Z. "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.

AA. "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.

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

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

DD. "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[1]

A. No later than 180 days from the date this Order is issued, Illumina shall Divest, absolutely and in good faith, and at no minimum price, the Hold Separate Business in accordance with a detailed divestiture plan[2] that has been approved by the Commission and that identifies, as applicable, the proposed buyer of the Hold Separate Business,

Provided, however, that the Commission 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.

B. Illumina shall return to GRAIL any proceeds from the divestiture of the Hold Separate Business that is greater than the Investment Amount.[3]

C. 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.

D. Respondents shall:

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[1] 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.

[2] Paragraph II.A is 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).

[3] 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).

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.

E. 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.

F. 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.

G. 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.

H. 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.

I. 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.[4]

J. 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.[5]

K. 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 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.

[4] 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.

[5] 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.

III. Hold Separate and Asset Maintenance Obligations[6]

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 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;

[6] 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.

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.[7]

Provided, however, that GRAIL shall have 60 days from the date this Order is issued to comply with this Paragraph III.F.

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

[7] 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).

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.[8]

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

[8] 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[9]

A. In furtherance of the obligations listed in Section III of this Order, a Hold Separate Manager shall be appointed to independently manage and operate the Hold Separate Business during the Hold Separate Period. Within 15 days of the date this Order is issued, Respondents shall nominate one or more qualified candidates to Commission staff for consideration, and Commission staff shall select the Hold Separate Manager, in consultation with the Monitor.

Provided that, if Respondents fail to nominate a candidate that is acceptable to Commission staff, then a Hold Separate Manager shall be selected pursuant to the process identified in Paragraph IV.F of this Section IV.

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 the Hold Separate Manager has been appointed, 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

[9] 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.

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 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[10]

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.[11]

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

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[10] 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.

[11] 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.

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[12]

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

[12] 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.

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 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[13]

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

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[14]

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

[13] 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.

[14] 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.

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[15]

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

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. Other Competition Agency Conflicts

IT IS FURTHER ORDERED that:

A. Respondents shall submit to the Commission the following regarding each legal action challenging Illumina's acquisition of GRAIL taken by a governmental entity other than the Commission ("other competition agency"):

1. The complaint;
2. All pleadings, briefs and orders relating to remedial relief (including divestiture, ring fencing and hold separate obligations) sought or opposed in such action; and
3. All pleading, briefs, reports, and other documents Respondents have submitted to the tribunal having jurisdiction over the legal action that relate to remedial relief;

Respondents shall submit all documents required by this Paragraph X.A electronically to the Secretary of the Commission at ElectronicFilings@ftc.gov and the Compliance Division at bccompliance@ftc.gov no later than 30 days after this Order is issued, or 5 days after the date such information is received or submitted, whichever is later.

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

B. To the extent Respondents are subject to any remedial provision or requirement imposed pursuant to a legal action brought by another competition agency that conflicts with any provision in this Order ("potentially conflicting provisions") such that Respondents cannot fully comply with both:

1. Respondents shall notify Commission staff, in writing, within 10 days of the date Respondents identify the potential conflict, specifying the other competition agency, the conflict (including the potentially conflicting provisions), and the reasons why Respondents cannot comply with all the potentially conflicting provisions ("X.B.1 Notification");

2. Respondents shall waive all confidentiality agreements and provisions that limit the ability of Commission staff and the other competition agency identified in the X.B.1 notification to communicate and share information, without restrictions;

3. Respondents are not required to comply with the potentially conflicting provision in the Order identified in the X.B.1 Notification, *so long as*, within 30 days after Commission staff receives the X.B.1 Notification, Commission staff has not notified Respondents, in writing, that that the potentially conflicting provisions do not conflict such that Respondents can comply with both, and the reasons for that conclusion.

XI. 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 as effectively and expeditiously as possible.

XII. Duration of Order[16]

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

By the Commission.

April J. Tabor
Secretary

SEAL:

ISSUED:

[16] Section XII 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 October 4, 2022, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

April Tabor
Secretary
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-113
Washington, DC 20580
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The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
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I also certify that I caused the foregoing document to be served via email to:

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