PUBLIC

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

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

COMPLAINT COUNSEL'S OPPOSITION TO RESPONDENT GRAIL, INC.'S THIRD MOTION FOR *IN CAMERA* REVIEW OF CERTAIN TRIAL EXHIBITS

August 27, 2021, Respondent GRAIL, Inc. submitted its third motion for *in camera* review for certain trial exhibits. Respondent avers: "The Court denied both motions without prejudice, and instructed that GRAIL (1) provide additional details regarding its request, (2) reduce the amount of documents identified for *in camera* treatment, and (3) shorten the amount of time requested for *in camera* treatment." Resp. Third Mot. at 1. This oversimplified recollection of the Court's Orders on August 12, 2021 (hereinafter "August 12 Order") and August 24, 2021 (hereinafter "August 24 Order") fails to heed this Court's admonitions. In particular, Respondent continues to designate information that is either publicly available or fails to clear Rule 3.45(b)'s strict standard for seeking *in camera* treatment. If Respondent's motion is granted, the public would be deprived of access to significant portions of the trial record in this matter. Complaint Counsel therefore respectfully requests that the Court deny Respondent's third motion for *in camera* treatment without prejudice until Respondent fully satisfies the requirements of Rule 3.45(b). *See* Commission Rule 3.42(c)(11), 16 C.F.R. § 3.42(c)(11)

(enumerating the powers of Administrative Law Judges, including, *inter alia*, to "deny *in camera* status without prejudice until a party complies with all relevant rules").

I. STATEMENT OF FACTS

On August 5, 2021, Respondent Grail filed a motion for *in camera* treatment of approximately 850 trial exhibits that allegedly contain confidential information. Respondent grouped these documents into seven categories: (1) Trade Secrets and Product Development; (2) Financial Data; (3) Pricing and Pricing Strategy; (4) Sales and Marketing Strategy; (5) Regulatory Strategy; (6) Strategic Initiatives; and (7) Sensitive Personal Information. (Grail Mot. at 3).

On August 12, 2021, the Court denied Respondent's motion without prejudice with respect to most confidentiality designations. The Court, however, granted Respondent's motion with respect to sensitive personal information—provided Respondent redacted that information where practical.

On August 17, 2021, Respondent submitted a second motion seeking *in camera* treatment for certain trial exhibits and grouped documents by the same seven categories as the first motion. This motion listed approximately 67 trial exhibits that had been redacted, and it provided a basic description of what information it deemed confidential in each document. For the remainder of those documents, Respondent requested complete *in camera* treatment.

On August 24, 2021, the Court denied Respondent's motion without prejudice. There, the Court warned: "If GRAIL cannot comply with these directives, its next motion may be denied, without the right to refile." August 24 Order at 3.

On August 27, 2021, Respondent submitted a third motion seeking *in camera* treatment for certain trial exhibits and grouped documents by the same seven categories as the previous motions. Respondent reduced the number of documents designated confidential from 895

documents to 674 documents. In select places, Respondent also shortened the requested amount of time for *in camera* treatment.

II. ARGUMENT

Respondent's request for *in camera* treatment is overbroad in scope to meet "the Commission's strict standards" for *in camera* treatment. *In re Otto Bock HealthCare North America, Inc.*, 2018 FTC LEXIS 123, at *14 (Jul. 2, 2018).

A. Legal Standard

Under Commission Rule 3.45(b), the Court may grant a request for *in camera* treatment for material "only after finding that its public disclosure will likely result in a clearly defined, serious injury to the person, partnership, or corporation requesting *in camera* treatment or after finding that the material constitutes sensitive personal information." 16 C.F.R. § 3.45(b). An applicant for *in camera* treatment "must 'make a clear showing that the information concerned is sufficiently secret and sufficiently material to their business that disclosure would result in serious competitive injury.'" *In re Otto Bock HealthCare North America, Inc.*, 2018 FTC LEXIS 123, at *2 (Jul. 2, 2018) (quoting *In re General Foods Corp.*, 95 F.T.C. 352, 1980 FTC LEXIS 99, at *10 (Mar. 10, 1980)). If the applicant for *in camera* treatment is able to "make[] this showing, the importance of the information in explaining the rationale of FTC decisions is 'the principal countervailing consideration weighing in favor of disclosure.'" *Id.*

Because "[t]he Federal Trade Commission recognizes the 'substantial public interest in holding all aspects of adjudicative proceedings, including the evidence adduced therein, open to all interested persons,' the party requesting that documents be placed *in camera* bears 'the burden of showing good cause for withholding documents from the public record.'" *In re Otto Bock HealthCare North America, Inc.*, 2018 FTC LEXIS 123, at *3 (Jul. 2, 2018). As this Court recently explained, "[a] full and open record also provides guidance to persons affected by its

actions and helps to deter potential violators of the laws the Commission enforces." *In re Altria Group, Inc.*, 2021 WL 2258803, at *1. Moreover, "there is a presumption that *in camera* treatment will not be accorded to information that is more than three years old." *In re Otto Bock HealthCare North America, Inc.*, 2018 FTC LEXIS 123, at *3–4 (Jul. 2, 2018). To overcome this presumption, "an applicant seeking *in camera* treatment for such documents must also demonstrate, by affidavit or declaration, that such material remains competitively sensitive." *In re Otto Bock HealthCare North America, Inc.*, 2018 FTC LEXIS 123, at *3–4 (Jul. 2, 2018).

B. Respondent Continues to Designate Publicly Available Information Confidential

In its August 12 Order, the Court ruled that documents that include publicly available U.S. Securities and Exchange Commission filings "do not meet the standards for *in camera* treatment." August 12 Order at 4. Although it no longer designates the actual public filing confidential, Respondent fails to consider the substance of the filing to assess whether it has disclosed material to the public that it now deems confidential in the context of this trial. For instance, in its Form S-1 filing submitted on September 9, 2020, Respondent discusses the following topics—many of which GRAIL's Chief Executive Officer Mr. Hans Bishop testified to in public on August 31, 2021—that have been designated confidential in documents and testimony[1]:

- Genomic Databases Linked with Population-Scale Clinical Evidence: "Our research to date has enabled us to build one of the world's largest databases of genomic and clinical data in the cancer field. Each sample that we sequence contributes additional genomic, phenotypic, and clinical data that could help inform our platform. Together with our partners at leading academic cancer institutions and large community networks, we have

[1] Cited documents attached as Exhibit A.

taken a rigorous approach to the design of our clinical programs and collection of population-scale clinical data, which to date includes approximately 115,000 enrolled participants in four studies."[2]

- FDA Pre-Market Approval: "We are engaged in ongoing discussions with FDA regarding the data that will be needed to support a successful PMA for a multi-cancer test for our planned indications, including whether we would need to provide additional analyses and information beyond that which we are currently planning to produce based on the designs of our current and planned clinical studies. There can be no assurance that our products for which we may seek clearance or approval will be approved or cleared by FDA or a comparable foreign regulatory authority on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with our anticipated claims or adequate to support continued adoption of, and reimbursement for, our products. If our products receive clearance or approval but there is uncertainty about our products among providers

[2] *Compare* Grail, Inc., General Form for Registration of Securities under the Securities Act of 1933 (Form S-1) at 6 (Sept. 9, 2020), https://sec.report/Document/0001628279-20-000227/#grails-1.htm, *with* {[redacted]}

or payors, or if the approved indication or other labeling claims FDA or a comparable foreign regulatory authority allows us to make are more limited than we expect, reimbursement may be adversely affected and we may not be able to sell our products. Compliance with FDA or comparable foreign regulatory authority regulations will require substantial costs, and subject us to heightened scrutiny by regulators and substantial penalties for failure to comply with such requirements or the inability to market our products. The lengthy and unpredictable approval process, as well as the unpredictability of the results of our clinical studies, may result in our failing to obtain regulatory clearance or approval to market our products, which would significantly harm our business, results of operations, reputation, and prospects."[3]

[3] *Compare* Grail, Inc., General Form for Registration of Securities under the Securities Act of 1933 (Form S-1) at 40 (Sept. 9, 2020), https://sec.report/Document/0001628279-20-000227/#grails-1.htm, *with In the Matter of Illumina, Inc., et al.*, Trial Tr. 1323-24, 1330, 1344-47 (Aug. 31, 2021); [redacted]

- Reimbursement Strategy: "We are exploring all reimbursement pathways to obtain broad Medicare coverage for Galleri, including working with payors, regulators and policy-makers to explore pathways for coverage and reimbursement. We plan to launch Galleri as an LDT. We plan to pursue approval by FDA of Galleri (or a subsequent, enhanced version of Galleri) by submitting a premarket approval application (PMA) as early as 2023, which we believe will be a requirement prior to certain significant payors, including Medicare, considering coverage of our test. All of these steps could take several years to complete. Accordingly, Galleri will likely not be covered or reimbursed by Medicare for a number of years because currently, coverage decisions for preventive services are not made prior to FDA approval."[4] And further stating that GRAIL plans to "facilitate adoption in the following key channels": large, self-insured employers (estimated total addressable U.S. market: 24 million people); progressive, integrated health systems (estimated total addressable U.S. market: 27 million people); and physician-directed channels, including concierge practices and executive health programs (estimated total addressable U.S. market: 1 million people).[5]

To properly justify *in camera* treatment, Respondent should have reviewed its public filings and statements and cross-checked that publicly revealed material against its designations. To the extent it believed overlapping subject matter should still be considered confidential, Respondent

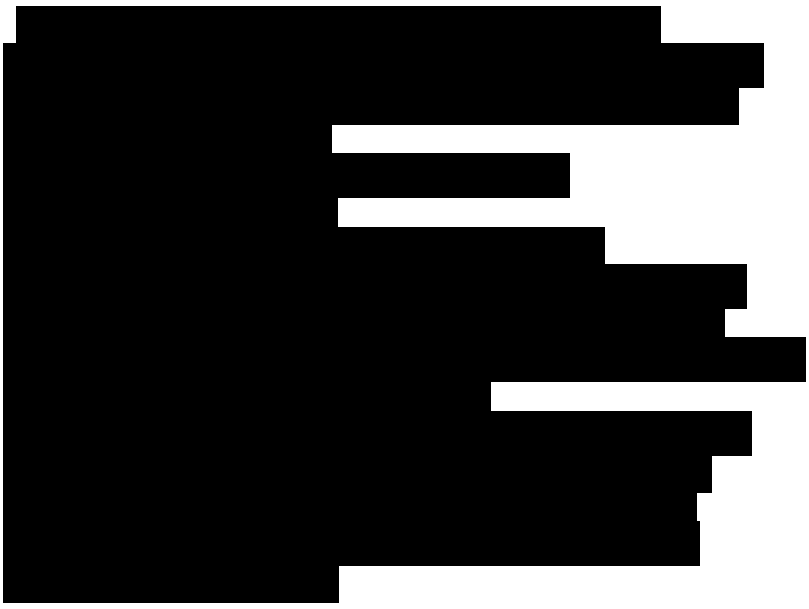
[4] *Compare* Grail, Inc., General Form for Registration of Securities under the Securities Act of 1933 (Form S-1) at 40 (Sept. 9, 2020), https://sec.report/Document/0001628279-20-000227/#grails-1.htm, *with In the Matter of Illumina, Inc., et al.*, Trial Tr. 1330-31, 1344, 1403-05 (Aug. 31, 2021); [redacted]

[5] *Compare* Grail, Inc., General Form for Registration of Securities under the Securities Act of 1933 (Form S-1) at 40 (Sept. 9, 2020), https://sec.report/Document/0001628279-20-000227/#grails-1.htm, *with In the Matter of Illumina, Inc., et al.*, Trial Tr. 1331-34 (Aug. 31, 2021); [redacted].

should have articulated precisely why subject matter that has been publicly revealed takes on a confidential character in the context of documents or testimony that was used at trial. Respondent did no such thing.

C. Respondent Fails to Satisfy Its Burden of Clearly Showing Disclosure Would Result in Serious Injury under Rule 3.45

Respondent also designates a number of vague statements that surely will not result in serious competitive injury. For example, GRAIL's Chief Executive Officer Hans Bishop has said about the consummated transaction: "The merger with Illumina will get the Galleri test to people far faster. We aim to accelerate this process so the test will be available in doctors' offices everywhere, fully reimbursed. A one-year acceleration of access to the Galleri test for the US population has the potential to save 10,000 lives over a 9-year period."[6] In short, Mr. Bishop has publicly stated that a benefit of the deal is to accelerate access to the Galleri test. But Respondent designates the following testimony—and similar testimony elsewhere—confidential:



[6] Press Release, Illumina, Inc., Illumina Acquires GRAIL to Accelerate Patient Access to Life-Saving Multi-Cancer Early-Detection Test (Aug. 18, 2021)

[redacted]

}

Breaking this testimony down, it becomes clear that this testimony does not merit *in camera* treatment. In particular, {[redacted]

[redacted]

[7] {[redacted]}

[redacted]

None of this is confidential, and to the extent there is an iota of sensitive information here, it surely does not rise to the standard of causing serious injury to GRAIL. Indeed, Mr. Bishop testified to much of this in public session at trial.[8] This is but one of several instances where Respondent (yet again) over designates *in camera* material.[9]

III. CONCLUSION

For the foregoing reasons, Complaint Counsel respectfully requests that the Court deny Respondent's motions for *in camera* treatment without prejudice until it fully satisfies the requirements of Rule 3.45(b).

[8] *In the Matter of Illumina, Inc., et al.*, Trial Tr. 1371-72, 1403-06, 1424-27 (Aug. 31, 2021).

[9] *See, e.g.*, [redacted] (non-exhaustive list).

Date: September 2, 2021

Respectfully submitted,

/s/ Nandu Machiraju

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EXHIBIT A

CONFIDENTIAL - REDACTED IN ENTIRETY

CERTIFICATE OF SERVICE

I hereby certify that on September 2, 2021, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

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The Honorable D. Michael Chappell
Administrative Law Judge
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I also certify that I caused the foregoing document to be served via email to:

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