

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

In the Matter of

Illumina, Inc.
a corporation,

and

GRAIL, Inc.
a corporation,

Respondents.

Docket No. 9401

**RESPONDENT GRAIL, INC.’S MOTION FOR *IN CAMERA* REVIEW OF
CERTAIN TRIAL EXHIBITS**

GRAIL, Inc. (“GRAIL”) respectfully moves under 16 C.F.R. § 3.45 for *in camera* treatment of confidential and competitively sensitive information on the parties’ final proposed exhibit lists. As explained here and in the accompanying declaration of Marissa Lee Song., General Counsel of GRAIL (the “Song Declaration”), the public disclosure of this information “will likely result in a clearly defined, serious injury” to GRAIL. 16 C.F.R. § 3.45(b).

I. LEGAL STANDARD

Parties to a Part 3 proceeding may move the Court to “obtain *in camera* treatment for material, or portions thereof, offered into evidence.” *Id.* *In camera* treatment is appropriate if public disclosure of the information is likely to “result in a clearly defined, serious injury to the person, partnership, or corporation requesting *in camera* treatment.” *Id.* “[M]aterial made subject to an *in camera* order will be kept confidential and not placed on the public record of the proceeding in which it was submitted.” 16 C.F.R. § 3.45(a). “Only respondents, their counsel, authorized Commission personnel, and court personnel concerned with judicial review may have

access thereto, provided that the Administrative Law Judge, the Commission and reviewing courts may disclose such *in camera* material to the extent necessary for the proper disposition of the proceeding.” *Id.*

In camera treatment may be granted if “public disclosure will likely result in clearly defined, serious injury.” § 3.45(b). In considering whether to grant *in camera* treatment, the Court may consider (1) the extent to which the information is known outside of the business; (2) the extent to which it is known by employees and others within the business; (3) the extent of measures taken to protect the information’s secrecy; (4) the value of the information to the business and its competitors; (5) the effort or investment made in developing the information; and (6) the ease of difficulty with which the information could be acquired or duplicated by others. *In re Bristol-Meyers Co.*, 90 F.T.C. 455, 456-57 (1977). *In camera* review may be appropriate not just for trade secrets and highly detailed cost data, but also many ordinary business records “such as customer names, pricing to customers, business costs and profits, as well as business plans, marketing plans, or sales documents.” *In the Matter of 1-800 Contacts, Inc.*, No. 9372, 2017 FTC LEXIS 55, at *5-6 (Apr. 4, 2017). In addition, “sensitive personal information”—like telephone numbers, home addresses, and/or social security numbers—warrants *in camera* treatment. *In the Matter of Otto Bock Healthcare N. Am., Inc.*, No. 9378, 2018 WL 3491602, at *3 (F.T.C. July 2, 2018); 16 C.F.R. § 3.45(b)(3).

II. ARGUMENT

The parties’ final proposed exhibit lists in this case contain voluminous confidential and competitively sensitive material that, if disclosed, would cause serious injury to GRAIL. Protection is warranted for the documents and selected portions of deposition transcripts in each of the below categories as trade secrets, sensitive personal information, or business records which if disclosed would result in serious competitive injury to GRAIL. The below chart lists

each category of documents for which GRAIL seeks *in camera* treatment, the paragraph discussing each category in the Song Declaration, and the time period for which GRAIL requests *in camera* treatment.

Category	Song Declaration	Time period for <i>In Camera</i> Treatment
Trade Secrets and Product Development	¶8	10 years
Financial Data	¶9	10 years
Pricing and Pricing Strategy	¶10	10 years
Sales and Marketing Strategy	¶11	10 years
Regulatory Strategy	¶12	10 years
Strategic Initiatives	¶13	10 years
Sensitive Personal Information	¶14	Indefinite

A. Trade Secrets and Product Development

Documents that contain trade secrets, such as the technical specifications of GRAIL’s multi-cancer early detection test, Galleri, and GRAIL’s development of future tests and versions those tests, warrant *in camera* treatment. *See 1-800 Contacts*, 2017 FTC LEXIS 55, at *5 (“Examples of trade secrets meriting indefinite *in camera* treatment include secret formulas, processes, other secret technical information, and information that is privileged.”); *In the Matter of Altria Group, Inc. and JUUL Labs, Inc.*, No. 9393, 2021 WL 2258803 at *4 (F.T.C. May 19, 2021) (granting *in camera* treatment for a period of ten years to trade secrets, specifications and product development plans).

Documents that contain GRAIL’s product development plans are also highly sensitive and should be protected from public disclosure. As FTC concedes, multi-cancer early detection is a nascent technology and while there are other companies developing other types of early cancer detection tests, those tests are many years behind GRAIL in development. Information about GRAIL’s current and future products is competitively sensitive and the disclosure of this otherwise confidential material would allow competitors to copy GRAIL’s technology, develop

commercial strategies designed to undermine GRAIL's current products. Because GRAIL would experience a clearly defined, serious injury if its trade secrets and product development plans were publicly disclosed, GRAIL respectfully requests ten years of protection for these documents, which is consistent with protections granted by this Court in previous proceedings. *See, e.g., Altria*, 2021 WL 2258803 at *4.

B. Financial Data

Documents that contain detailed financial information—including but not limited to sales, costs and margin data—also warrant in camera treatment. *See In the Matter of 1-800 Contacts*, 2017 FTC LEXIS 55, at *9 (protecting “financial metrics, customer and supplier data, and market growth indicators.”); *see also In the Matter of McWane Inc.*, No. 9351, 2012 FTC LEXIS 143, at *26-27 (Aug. 17, 2012) (protecting “purchase and sales data”). Recently, in *In the Matter of Altria Group, Inc. and JUUL Labs, Inc.*, the Court granted in camera treatment for similar sales, costs and margin data that the company described as “fundamental to its operations.” *Altria*, 2021 WL 2258803 at *4. The Court should reach the same result here.

This financial data is fundamental to GRAIL's operations, and because GRAIL is a privately held company this information is not publicly available. Disclosure of this data would provide competitors and third parties insight into GRAIL's financial and commercial performance, including regarding its current and projected cost of goods sold, research and development costs, current and future cash flows and investment requirements, and the confidential financial terms of supply agreements, licenses, and royalties. This data could be used by competitors of GRAIL to obtain a competitive advantage, or to aid their development of strategies related to sales and marketing. For example, having knowledge of GRAIL margins for a particular product could allow a potential competitor to target GRAIL's sales to particular distributors or customers. In addition, access to this data could undermine GRAIL's negotiations

with its trade partners. Because GRAIL would experience a clearly defined, serious injury if the financial data in these documents were publicly disclosed, GRAIL respectfully requests 10 years of protection for these documents. Ten years of protection is warranted due to the nascence of the industry and the extent to which information regarding GRAIL's longstanding license and royalty agreements as well as other financial information could be used by third parties to extrapolate competitively sensitive information about GRAIL's costs. *See, e.g., In the Matter of E.I. DuPont de Nemours & Co.*, No. 9108, 1990 FTC LEXIS 134 at *5-6 (Apr. 25, 1990) (granting ten year in camera protection for financial data that could be extrapolated by third parties).

C. Pricing and Pricing Strategy

Detailed information regarding GRAIL's current and future prices to its customers, prices and pricing strategies also should be protected in camera. This includes details on prices charged to GRAIL's customers, price negotiations, the process GRAIL goes through to set prices and deliberations regarding potential future changes to prices. *See 1-800 Contacts*, 2017 FTC LEXIS 55, at *11 (protecting documents containing "pricing ... and internal analyses of customer demographics and buying patterns"); *McWane*, 2012 FTC LEXIS 143, at *7-8 (protecting documents containing "customer data, pricing and cost information, business strategies, and negotiating strategies"); *Altria*, 2021 WL 2258803 at *4 (protecting documents reflecting pricing information).

This pricing information is competitively sensitive and its disclosure would provide GRAIL's competitors with insight into GRAIL's pricing methods and strategies for obtaining reimbursement from payors in the future, causing harm to both GRAIL and potentially to consumers. Disclosure could also harm GRAIL's relationships with its customers and partners and undermine GRAIL's negotiating positions, resulting in competitive and commercial harm to

GRAIL. GRAIL's strategies for approaching third-party payors related to reimbursement of the Galleri test and other potential products involve detailed discussions of GRAIL's test and product strategies. Because GRAIL would experience a clearly defined, serious injury if the information on pricing and pricing strategy in these documents were publicly disclosed, GRAIL respectfully requests 10 years of protection for these documents. Ten years of protection is warranted due to the uniqueness of GRAIL's strategies and negotiations with payors to reimburse the Galleri test. Potential competitors may not have a commercial product available for seven years or more, meaning that GRAIL's confidential strategies regarding pricing and payor reimbursement may still have competitive utility ten years from now. *See, e.g., E.I. DuPont de Nemours & Co.*, 1990 FTC LEXIS 134 at *5-6 (granting ten years of *in camera* protection for unique information whose competitive utility was not likely to diminish due to the characteristics of the industry at issue).

D. Sales and Marketing Strategy

Recent detailed information regarding GRAIL's strategy and considerations related to sales and marketing also warrant *in camera* treatment. *See 1-800 Contacts*, 2017 FTC LEXIS 55, at *11 (protecting documents containing "marketing and bidding strategies").

By way of example, this category includes documents that provide insight on GRAIL's commercial planning related to GRAIL's thought processes regarding which distribution channels to target and why, they identify specific potential customers that GRAIL has approached or intends to approach in the future; they disclose GRAIL's sales strategy for approaching those customers. These materials serve as the basis for the formulation of GRAIL's business plans, and disclosure of these confidential materials would provide GRAIL's competitors with previously unavailable details about GRAIL's sales and marketing strategies, which they could use in their own negotiations with retailers or as they consider marketing plans

to compete with GRAIL. Moreover, disclosure could undermine GRAIL's relationships and negotiating positions with its customers, resulting in competitive and commercial harm to GRAIL. Because GRAIL would experience a clearly defined, serious injury if the information on sales and market strategies in these documents were publicly disclosed, GRAIL respectfully requests 10 years of protection for these documents. Ten years of protection is warranted for information in this category due to the nascent. *See, e.g., In the Matter of E.I. DuPont de Nemours & Co.*, No. 9108, 1990 FTC LEXIS 134 at *5-6 (Apr. 25, 1990) (granting ten year in camera protection for unique information whose competitive utility was not likely to diminish due to the characteristics of the industry at issue).

E. Regulatory Strategy

Documents that reflect GRAIL's regulatory strategy and efforts – including confidential details regarding the design and execution of its clinical trials – are also highly competitively sensitive and should not be disclosed publicly. This information is sensitive because it provides direct insight into GRAIL's regulatory strategy and deliberative process related to obtaining FDA approval for multi-cancer early detection tests, and its interactions with the FDA. Disclosure of this information could impact GRAIL's ongoing discussions with the FDA, which are essential to GRAIL's ability to obtain FDA approval. In addition, providing potential competitors with insight into this information may give them an unfair advantage over GRAIL in the FDA approval process, resulting in competitive and commercial harm to GRAIL. Because GRAIL would experience a clearly defined, serious injury if the information on regulatory strategy in these documents were publicly disclosed, GRAIL respectfully requests 10 years of protection for these documents. *See, e.g., Altria*, 2021 WL 2258803 at *6. Ten years of protection is warranted for information regarding GRAIL's regulatory strategy due to the unique issues raised by GRAIL's attempts to obtain FDA approval for a multi-cancer early detection

test, which has never been granted by the FDA before. Today, no one knows whether the competitive value of this data will diminish or when it will diminish. *See, e.g., In the Matter of E.I. DuPont de Nemours & Co.*, No. 9108, 1990 FTC LEXIS 134 at *5-6 (Apr. 25, 1990) (granting ten year in camera protection for unique information whose competitive utility was not likely to diminish due to the characteristics of the industry at issue).

F. Strategic Initiatives

Strategic initiatives – such as GRAIL Board of Directors’ analyses of potential transactions, financing options and timing, and other strategic initiatives – contain confidential information about the company’s strategic direction and also require in camera treatment. *See I-800 Contacts*, 2017 FTC LEXIS 55, at *9 (protecting documents including “evaluations of market factors, market risks, company advantages, company disadvantages, and company risks, and which also review future strategic plans”); *see also McWane*, 2012 FTC LEXIS 143, at *7-8 (protecting documents “which contain. . . . business strategies, and negotiating strategies”).

Disclosure of this information could result in serious injury to GRAIL because it would reveal GRAIL’s internal analyses of its business and provide direct insight into the company’s deliberative process with respect to strategic initiatives. *Altria*, 2021 WL 2258745 at *5 (granting in camera status to documents that reflect “discussions among or presentations to Altria’s board of directors or top executives about what opportunities to pursue and how such decisions are made.”). Moreover, disclosure of this information could undermine GRAIL’s position in future corporate transactions or financing efforts by revealing GRAIL’s internal targets for such financing or rationales for future transactions. Because GRAIL would experience a clearly defined, serious injury if the information on strategic initiatives in these documents were publicly disclosed, GRAIL respectfully requests 10 years of protection for these documents, due to the nascency of the multi-cancer early detection test industry and the

potentially long time horizon before other potential test developers bring any cancer screening tests to market. *See, e.g., E.I. DuPont de Nemours & Co.*, 1990 FTC LEXIS 134 at *5-6 (granting ten year in camera protection for unique information whose competitive utility was not likely to diminish due to the characteristics of the industry at issue).

G. Sensitive Personal Information

Documents that contain details regarding individuals' compensation, their job performance, personal phone numbers, personal email addresses, and home addresses. *See Otto Bock*, 2018 WL 3491602, at *3; 16 C.F.R. § 3.45(b)(3). Information regarding compensation and job performance is particularly sensitive and its disclosure within GRAIL is limited to the named individual and those who need it to perform their job. Disclosure of this material could have the effect of embarrassing the named individuals or impacting their careers, and personal contact information need not be disclosed to the public in connection with this case. *Altria*, 2021 WL 2258803 at *3. GRAIL respectfully requests indefinite protection for these documents.

III. CONCLUSION

Given the serious risk that public disclosure of these materials would cause serious injury to GRAIL's business or reveal personal identifying information, GRAIL respectfully requests an *in camera* order to protect the exhibits and deposition testimony listed in Exhibit 1 to the Song Declaration from public disclosure.

Dated: Aug. 5, 2021

Respectfully submitted,

/s/ Anna M. Rathbun

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CERTIFICATE OF SERVICE

I hereby certify that on Aug. 5, 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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Aug. 5, 2021

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**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
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In the Matter of

**Illumina, Inc.
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Docket No. 9401

[PROPOSED] ORDER

Upon consideration of Respondent GRAIL Inc.'s ("GRAIL") Motion for *In Camera* Review of Certain Trial Exhibits, it is hereby

ORDERED, that GRAIL's motion is GRANTED, and it is further

ORDERED, that pursuant to Rule 3.45(b) of the Federal Trade Commission Rules of Practice, 16 C.F.R. § 3.45(b), the exhibits and testimony identified in Exhibit 1 to the Motion, and any related trial testimony, shall be subject to *in camera* treatment and will be kept confidential and not placed on the public record of this proceeding.

Date: _____

D. Michael Chappell
Chief Administrative Law Judge

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

In the Matter of

**Illumina, Inc.
a corporation,**

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Respondents.

Docket No. 9401

**DECLARATION OF MARISSA LEE SONG IN SUPPORT OF RESPONDENT GRAIL,
INC.'S MOTION FOR *IN CAMERA* REVIEW OF CERTAIN TRIAL EXHIBITS**

I, Marissa Lee Song, declare as follows:

1. I am the General Counsel and Corporate Secretary at GRAIL, Inc. (“GRAIL”), a defendant in the above-listed action. I have been employed by GRAIL since September 30, 2019.

2. I make this declaration in support of GRAIL’s motion for in camera review of certain trial exhibits. GRAIL seeks in camera treatment for the trial exhibits and portions of exhibits identified in Exhibit 1, which are also attached in Exhibit 2. I have personal knowledge of the competitive significance and confidential nature of these documents. Based on my review of Exhibit 1, my conversations with the individuals who reviewed the documents at my direction, my knowledge of GRAIL’s business, and my knowledge of the confidential nature of these documents, I respectfully submit that disclosure of the exhibits listed in Exhibit 1 to the public would either result in clearly defined, serious injury to GRAIL or would reveal sensitive personal information.

3. In the ordinary course of business, GRAIL treats this information as strictly confidential and limits its disclosure to employees that need to know it to perform their business functions. GRAIL also takes reasonable steps to protect its network and electronically stored information to prevent access by outside parties.

4. Each exhibit identified in Exhibit 1 was designated as “Confidential Material” pursuant to the Protective Order entered on March 30, 2021.

5. The Motion is narrowly tailored to protect GRAIL’s confidential information. GRAIL’s counsel carefully reviewed the exhibits and provided me with the exhibits identified in Exhibit 1. I reviewed Exhibit 1, and GRAIL’s outside counsel described to me the approach used to identify the exhibits listed on Exhibit 1 and the categories of confidential information that appear in the listed exhibits.

6. GRAIL has grouped the exhibits listed in Exhibit 1 into the following categories:

- a. Trade Secrets and Product Development
- b. Financial Data
- c. Pricing and Pricing Strategy
- d. Sales and Marketing Strategy
- e. Regulatory Strategy
- f. Strategic Initiatives
- g. Sensitive Personal Information

7. Each category describes materials that either (a) disclose confidential and competitively sensitive information or (b) reveal sensitive personal information. Third parties with access to this information would either gain a significant business advantage at the expense of GRAIL or obtain sensitive personal information to the detriment of the individual whose

information is revealed. For each document, Exhibit 1 identifies the exhibit number and a description of the relevant category of information, and the duration of in camera treatment sought.

8. **Trade Secrets and Product Development:** The documents in this category include information on trade secrets, such as GRAIL's research and development efforts and technical specifications regarding GRAIL's current and future products including the Galleri test. This information is competitively sensitive and the disclosure of this otherwise confidential material would allow other companies to develop commercial strategies designed to undermine GRAIL's current and future products, or develop strategies to better compete with GRAIL's products. Because GRAIL would experience a clearly defined, serious injury if its trade secrets and product development plans were publicly disclosed, this information should remain confidential for 10 years.

9. **Financial Data:** The documents in this category contain detailed sales, costs, and margin data and other financial information. This financial information is fundamental to GRAIL's operations, and because GRAIL is a privately held company this information is not publicly disclosed. Disclosure of this data would provide third parties with insight into GRAIL's commercial and financial performance, including details regarding its current and projected cost of goods sold, research and development costs, current and future cash flows and investment requirements, and the financial terms of supply agreements, licenses, and royalties. This data could be used by third parties to obtain a competitive advantage or to develop strategies related to development of competing products. In addition, access to this data could undermine GRAIL's negotiations with its trade and research partners and investors. Because GRAIL would experience a clearly defined, serious injury if the financial data and information in these documents were publicly disclosed, this information should remain confidential for 10 years.

10. Pricing and Pricing Strategy: The documents in this category contained detailed information on GRAIL's current and projected prices to customers, how those prices are determined, and strategies for obtaining payor reimbursement of GRAIL's products. This pricing information is competitively sensitive and its disclosure would provide third parties with insight into GRAIL's pricing methods and strategies, causing harm to both GRAIL and potentially to consumers. Disclosure could also harm GRAIL's relationships with its customers and payors and undermine GRAIL's negotiating positions, resulting in competitive and commercial harm to GRAIL. Because GRAIL would experience a clearly defined, serious injury if the information on pricing and pricing strategy in these documents were publicly disclosed, this information should remain confidential for 10 years.

11. Sales and Marketing Strategy: The documents in this category contain detailed information regarding GRAIL's strategy and considerations related to sales and marketing to patients, physicians, payors, research partners, and investors. GRAIL's documents provide insight as to how GRAIL intends to sell the first-of-its-kind multi-cancer screening test, Galleri, and other products in development in various channels and its plans to scale its tests to achieve wide range adoption. These materials serve as the basis for GRAIL's business plans and disclosure of these confidential materials would provide third parties with previously unavailable details about GRAIL's current and future sales and marketing strategies, which they could use in their own negotiations with the various stakeholders described above. Because GRAIL would experience a clearly defined, serious injury if the information on sales and marketing strategy in these documents were publicly disclosed, this information should remain confidential for ten years.

12. Regulatory Strategy: The documents in this category reflect GRAIL's analysis and efforts to obtain approval from the U.S. Food and Drug Administration ("FDA") for the Galleri test

and other products in development, including interactions with that agency. The documents also contain details regarding clinical and other studies conducted by GRAIL and its partners. This information is sensitive because it provides direct insight into GRAIL's regulatory strategy and deliberative process with respect to FDA approval, and GRAIL's interactions with the FDA. Disclosure of this information could impact GRAIL's discussions with the FDA and could provide third parties with insight into GRAIL's regulatory strategy. This insight could be used to negatively impact GRAIL's relationship with the FDA, resulting in competitive and commercial harm to GRAIL and harm to consumers. Because GRAIL would experience a clearly defined, serious injury if the information on regulatory strategy in these documents were publicly disclosed, this information should remain confidential for 10 years.

13. Strategic Initiatives: The documents in this category contain information on strategic initiatives currently or recently under consideration by GRAIL. These documents reflect consideration by GRAIL and/or GRAIL's Board of Directors of potential transactions, consideration of financing options and timing, other strategic initiatives, and contain confidential information regarding GRAIL's strategic direction. Disclosure of this information could result in serious injury to GRAIL because it would reveal GRAIL's internal analyses of its business and provide direct insight into the company's deliberative process with respect to strategic initiatives. Moreover, disclosure of this information could negatively impact GRAIL's position in future corporate transactions or financing efforts. Because GRAIL would experience a clearly defined, serious injury if the information on strategic initiatives contained in these documents were publicly disclosed, this information should remain confidential for ten years.

14. Sensitive Personal Information: The documents in this category reflect details regarding a named individual's compensation, their job performance, or their personal contact

information including home addresses. Information regarding compensation and job performance is particularly sensitive and its disclosure within GRAIL is limited to the named individual and those who need it to perform their job. Disclosure of this information could have the effect of embarrassing the named individuals or impacting their careers, and personal contact information is not necessary to disclose to the public in this case. As a result, this information should remain confidential indefinitely.

15. Because disclosure of the exhibits described herein is likely to either reveal sensitive personal information or cause clearly defined, serious injury to GRAIL's financial and competitive position, GRAIL respectfully requests that the exhibits listed in Exhibit 1 be given *in camera* treatment.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct and that I executed this declaration on August 5, 2021, in Los Altos, California.



Marissa Lee Song

Exhibit 1

Filed In Camera

Exhibit 2

**Filed In Camera
via File Transfer**