PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Lina M. Khan, Chair**
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**

RESPONDENTS ILLUMINA, INC. AND GRAIL, INC.'S COMPILATION OF MATERIALS FOR ORAL ARGUMENT

Michael G. Egge
Marguerite M. Sullivan
Anna M. Rathbun
David L. Johnson
LATHAM & WATKINS LLP
555 Eleventh Street NW
Suite 1000
Washington, D.C. 20004
Telephone: (202) 637-2200

Alfred C. Pfeiffer
505 Montgomery Street
Suite 2000
San Francisco, CA 94111-6538
Telephone: (415) 391-0600

Counsel for Respondent GRAIL, LLC

Christine A. Varney
David R. Marriott
Sharonmoyee Goswami
Jesse M. Weiss
Michael J. Zaken
CRAVATH, SWAINE & MOORE LLP
Worldwide Plaza
825 Eighth Avenue
New York, NY 10019
Telephone: (212) 474-1000

Counsel for Respondent Illumina, Inc.

Pursuant to the Commission's November 3, 2022 Order Scheduling Oral Argument, Respondents submit the following compilation of materials to facilitate its presentation during Oral Argument in this matter. The compilation of materials contains only public information that is already in the record of the proceeding. Respondents are concurrently filing an *in camera* version of these materials with the Commission.

Dated: December 6, 2022

Respectfully submitted,

/s/ *David R. Marriott*

Michael G. Egge
Marguerite M. Sullivan
Anna M. Rathbun
David L. Johnson
LATHAM & WATKINS LLP
555 Eleventh Street NW
Suite 1000
Washington, D.C. 20004
Telephone: (202) 637-2200
michael.egge@lw.com

Alfred C. Pfeiffer
505 Montgomery Street
Suite 2000
San Francisco, CA 94111-6538
Telephone: (415) 391-0600
al.pfeiffer@lw.com

Counsel for Respondent GRAIL, LLC

Christine A. Varney
David R. Marriott
Sharonmoyee Goswami
Jesse M. Weiss
Michael J. Zaken
CRAVATH, SWAINE & MOORE LLP
Worldwide Plaza
825 Eighth Avenue
New York, NY 10019
Telephone: (212) 474-1000
cvarney@cravath.com
dmarriott@cravath.com
sgoswami@cravath.com
jweiss@cravath.com
mzaken@cravath.com

Counsel for Respondent Illumina, Inc.

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Oral Argument Before the Commission

In the Matter of Illumina, Inc. and GRAIL, Inc.
Docket No. 9401

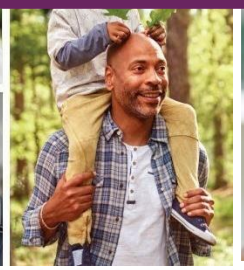
December 13, 2022

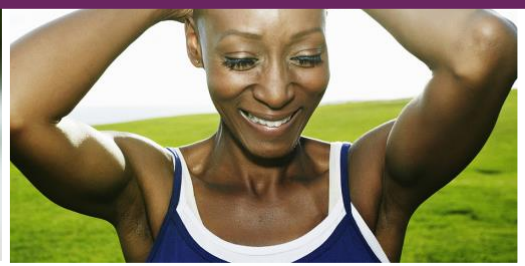
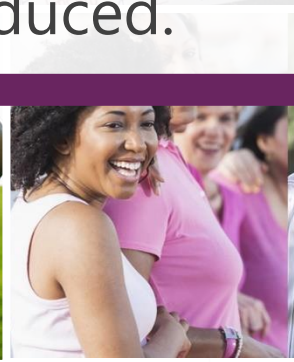
The Over-Arching Issue







Whether the Commission should unwind a **life-saving Transaction that will accelerate the adoption of a groundbreaking cancer-screening test** called Galleri, based on speculation that Illumina **might disadvantage hypothetical rival tests** many years in the future **if and when** they are introduced.

Mistaken Legal Framework

Complaint Counsel advocates a legal standard that:

1. **Presumes** vertical mergers tend to be anticompetitive
2. **Defines** the market based more on aspiration than evidence
3. **Presumes** mere ability to harm is sufficient
4. **Ignores** positive unilateral effects like EDM
5. **Disregards** real-world realities like the Open Offer
6. **Treats** unrefuted, life-saving efficiencies as **irrelevant**

Disregards Overwhelming Evidence

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Complaint Counsel has no answer for dispositive facts including that:

1. **Galleri is the only MCED test on the market today**, and there is no basis to predict (and ample evidence to doubt) that a close substitute for Galleri will launch at any point in the near future
2. There is **no model demonstrating likely harm to competition**, let alone the kind of harm needed to justify the unprecedented relief sought by Complaint Counsel
3. Foreclosing GRAIL's putative rivals would **risk an immediate reduction, and substantial future losses, in Illumina's NGS sales** without any prospect of profit from GRAIL for years—not before 2030
4. There are **significant constraints on Illumina's ability to foreclose**, including upstream competition and reputational risk, reflected in uncontested market facts such as declining NGS prices
5. Widespread access to Galleri **will save lives and billions of dollars**
6. The Open Offer **provides unprecedented protection** for Illumina oncology customers, **disabling the alleged foreclosure tools,** and **reinforcing Illumina's incentives against attempted foreclosure**
7. Illumina has always owned a substantial share of GRAIL and **never engaged in the alleged misconduct**

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Depends on Double Standards

Products in Development	Must be ***included*** in the **Relevant** Product Market	***BUT***	Must be ***excluded*** from **Related** Product Market
Actual and Imminent Competition	Should be **ignored upstream**	***BUT***	Must be **assumed** without documentation **downstream**
The Alleged Markets	Must be **defined broadly downstream** (to include unfinished tests)	***BUT***	Must be **defined narrowly upstream** (to include only Illumina products)
Determining the Number of Cancers a Test Detects	Must be **based on prospective clinical trials** as to Galleri	***BUT***	Can be **based on assertion alone as to tests in development**
Robust Proof	Is **required to support any efficiency**	***BUT***	Is **not required to prove the alleged harm**
Contractual Commitments	Must be dismissed as unimportant **in connection with the Open Offer**	***BUT***	Must be accepted as powerful enough to achieve **any efficiency absent the Transaction**

Resorts to Strawmen

Complaint Counsel distorts Respondents' position in multiple respects, claiming incorrectly that Respondents contend, e.g.,:

- Products **must be identical to fall within the same relevant market.** (CCPTRB 54.)
- The market **must be mature before it falls within the reach of the antitrust laws.** (CCRAB at 20.)
- Complaint Counsel **must disprove all aspects of a Clayton Act challenge for which defendants traditionally bear the burden.** (CCRAB at 17.)
- Differentiated products **cannot be economic substitutes.** (CCPTRB 121.)
- The Court **should treat Illumina as a benevolent dictator.** (CCPTRB 155, 167.)

Seeks Unprecedented Relief

The unwinding of a purely vertical merger where:

- The **alleged relevant market includes only one marketed product (Galleri)**
- Complaint Counsel **does not even profess to have defined a related product market**
- The supposedly-at-risk tests are **undeveloped and uncertain to launch**
- **No economic model** shows **likely harm to competition**
- The alleged foreclosure strategy **could not benefit Illumina** for years, but **would damage Illumina's** sales and reputation now
- There is **upstream competition now and imminent entry**, but **downstream competition is remote and uncertain at best**
- The Transaction will result in efficiencies that will **save lives** and **billions of dollars**
- A binding, long-term commitment **makes the alleged foreclosure unrealistic**
- The only other vertical transaction involving Illumina (Verinata) **led to more competition and more groundbreaking tests**

Roadmap

Overview

No Anti-Competitive Effect

Binding Open Offer

Extraordinary Efficiencies

Unproven Antitrust Markets

Unjustifiable Remedy

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Alleged Anticompetitive Effect

Complaint Counsel Failed to Prove Foreclosure

Foreclosing Grail's rivals would:

- **Be inconsistent with Illumina's past behavior:**
  - Prior to closing, Illumina owned 12% of GRAIL and was entitled to 7% of its net sales in perpetuity. (IDF ¶¶ 40-41.)
  - Under that structure, Illumina made **five times more** from GRAIL than other test makers. (IDF ¶ 837.)
  - There is **no evidence** of actual foreclosure. (Tr. 4613.)
- **Harm Illumina's primary business by:**
  - reducing NGS sales for MCED and non-MCED applications (IDF ¶ 807.)
  - causing **reputational damage** (IDF ¶ 1033.)
  - discouraging NGS applications on Illumina systems (ID 173; IDF ¶ 808.)
  - violating the Open Offer, subjecting Illumina to potential injunctive relief and damages. (ID 179-80.)
- **Not benefit Illumina as:**
  - Illumina will not recoup losses from Grail before 2030 (IDF ¶¶ 828-829.)
  - Foreclosure would not divert sales to Galleri in the foreseeable future (ID 175-78; IDF ¶¶ 201-14, 840-42.)
    - Galleri is the only MCED test on the market (IDF ¶¶ 201; 845.)
    - Galleri is very different from what is being developed (IDF ¶¶ 267, 842.)
    - No current alternatives (ID 177; IDF ¶¶ 201-07.)
    - Uncertain whether an alternative will emerge (ID 148, 151-153.)
    - No evidence that a "leapfrog" product will emerge in the near future (ID 176.)
  - Potential profitability of foreclosure is waning, as
    - Present and future NGS alternatives arise (RFF ¶¶ 916-23.)
    - NGS prices drop (IDF ¶¶ 809-810; RFF ¶¶ 909-10.)

No Anticompetitive Effect

1. Rests on a Mistaken Legal Standard
2. Ignores Real World Facts
3. Relies on Assumptions Contrary to the Evidence
4. Disregards Countervailing Constraints
5. Fails to Properly Model or Balance

1 Rests on Mistaken Legal Framework

CC's Contentions	Actual Burden
Ability alone is enough (*e.g.*, upstream market share sufficient) (*e.g.*, CCAB at 8.)	• Actual evidence of a probable foreclosure effect required. *Brown Shoe Co. v. United States*, 370 U.S. 294, 328, 332 (1962).
Real world facts (*e.g.*, the Open Offer) need not be considered (*e.g.*, CCAB at 29.)	• Real-world effects must be considered: in *AT&T*, the government did not meet its first-level burden because it **failed to account for real world effects**. 916 F.3d 1029, 1038 (D.C. Cir. 2019).
Unproven assumptions (*e.g.*, 100% diversion) are sufficient. (*e.g.*, CCAB at 21.)	• "[A]ntitrust theory and speculation cannot trump facts, and even Section 13(b) cases must be resolved on the basis of the record evidence relating to the market and its probable future." *FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 311 (D.D.C. 2020) (quoting *FTC v. Arch Coal*, 329 F. Supp. 2d 109, 116-17 (D.D.C. 2004)).
Harm need not be probable or imminent (*e.g.*, impact on non-existent tests) (CCAB at 12-14.)	• Alleged future harm to competition must be "sufficiently probable and imminent" to warrant relief. *United States v. Marine Bancorp.*, 418 U.S. 602, 623 n.22 (1974).
Harm and efficiencies need not be balanced (*e.g.*, efficiencies irrelevant) (CCAB at 40.)	• "[L]ower courts have since considered whether possible economies might serve not as justification for an illegal merger *but as evidence that a merger would not actually be illegal*." *New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 207 (S.D.N.Y. 2020) (emphasis added).

2 Ignores Real World Facts

- **Real world effects must be considered.**
  - In *AT&T*, the government did not meet its first-level burden because it **failed to account for real world effects.** 916 F.3d 1029, 1038 (D.C. Cir. 2019).
  - Complaint Counsel acknowledges that real world facts must be taken into account. (*See e.g.*, CCAB at 23, 26.)
- **Yet Complaint Counsel ignores important real-world facts.** (CCAB at 29.)

- The Open Offer **makes the alleged foreclosure unrealistic.**
  - **No price increases** and **significant price reductions.**
  - Requires **timely access** to products.
- **No evidence of foreclosure** while Illumina owned **12%** of GRAIL.
- Transaction will **save lives** and **billions of dollars.**
- Illumina's other vertical acquisition of a clinical test developer **led to more competition and more groundbreaking tests.**

3 Relies on Assumptions Contrary to Evidence

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Complaint Counsel:

Assumes huge near term upside

- ***When losses not recouped until at least 2030, if at all***

Assumes imminent MCED launches

- ***When no product, no sales, no certain timeline***

Assumes close substitutes

- ***When features are different or unknown***

Assumes no significant loss of upstream sales

- ***When intensifying upstream competition and NGS input small relative to projected MCED margins***

Assumes no significant harm to reputation

- ***When foreclosure would boomerang publicly***

3 Wrongly Assumes Close Substitutes Despite Unknowns

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MCED Clinical Trial

Key Unknowns About Supposed Rival Tests

- No evidence as to 5 of 7 supposed rivals (IDF ¶¶ 332-44; 365-69; 398-402, 405; 434-44; 461-71.)
- Some for 1 "rival" but only 3 of 7 categories and is 8-10 years away (IDF ¶¶ 494-96; 500-02.)
- Some for another "rival" but it is changing its test (IDF ¶¶ 289-99; 304; RFF ¶ 726.6.)

Blood CSO

Locating the cancer's origin via blood draw (IDF ¶ 155.)

Validated MCED Biomarkers

A biological sign of cancer (IDF ¶ 115.)

Detects Multiple Cancer Types

MCED Specificity

Whether test correctly generates negative result (IDF ¶ 143.)

MCED Sensitivity

Whether test correctly generates positive result (IDF ¶ 141.)

MCED PPV

Probability a patient has cancer when receiving positive result (IDF ¶ 147.)

4 Disregards Countervailing Constraints

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Present & Future Alternatives

Oxford NANOPORE Technologies

SINGULAR GENOMICS

BGI

ThermoFisher SCIENTIFIC
The world leader in serving science

Roche

Element Biosciences

ULTIMA GENOMICS

OMNIOME

Make foreclosure unprofitable

Declining NGS Prices

~Cost Per Genome

- $3 Billion
- $20 Million
- $2 Million
- $200,000
- $64,000
- $9,900
- $4,500
- $1,000
- $600
- $100

Indicate limits to Illumina's influence

Declining Share of NGS Input

GRAIL

Projected COGS paid from GRAIL to Illumina, [redacted]% of GRAIL's projected revenue by 2025

Limit impact of any foreclosure

No Evidence of Diversion

- Complaint Counsel assumes foreclosing GRAIL rivals would divert sales to GRAIL
- Overwhelming evidence showed no basis for this given the difference between GRAIL and other tests in development

Limits incentive to foreclose

4 Disregards Absence of Diversion Evidence

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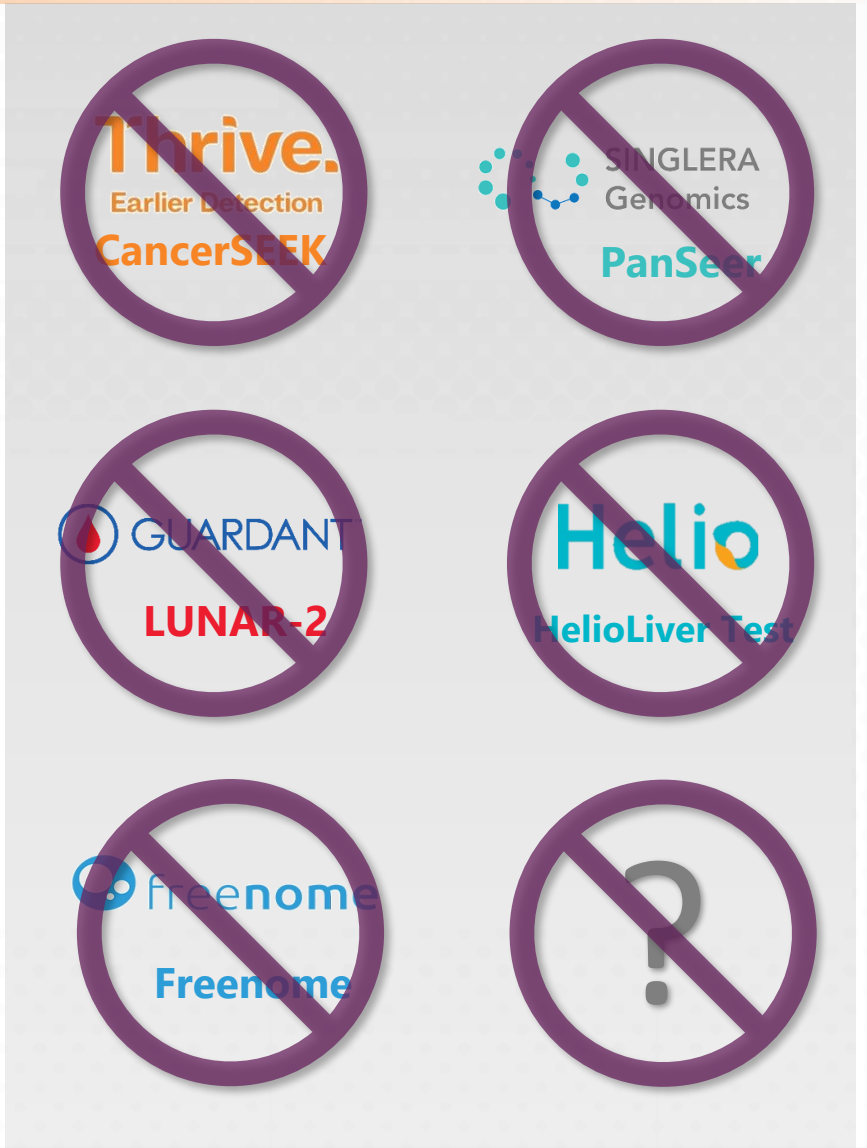
- **Only Galleri has been shown to detect 50+ cancer types with CSO in a single test**
- Complaint Counsel **failed** to show the alleged tests in development will be so similar as to be reasonable substitutes
  - **No** other test has been shown to detect 50 cancer types
  - **No** other test has been shown to detect CSO
  - **No** other test has demonstrated sensitivity, specificity & PPV across many cancers
- The alleged "closest" rival (Exact/Thrive's CancerSEEK):
  - **Is not** a single blood test (but 3 tests)
  - **Is unable** to detect CSO
  - **Is undergoing change**



5 Fails Meaningfully to Model or Balance

Incentive to Harm Competition Likely + **Resulting Harm Significant** + **Benefits of Transaction Insignificant** = **Substantial Lessening of Competition**

Depends on:

- The alleged gain:
  - Volume and timing of any diverted rival sales
  - Profit from diverted rival sales (if any)
- Balanced against how much Illumina would lose upstream:
  - Reputational harm
  - Failure to realize full potential of Illumina NGS sales to clinical markets
  - Profit from lost NGS sales

Depends on:

- What exactly Illumina would do
- Amount of competition affected
- Impact on innovation and consumer prices
- Output effects

Depends on:

- Extent of acceleration, (e.g., from accelerated market access)
- Output expansion
- Estimated number of lives saved from accelerated and expanded output
- Quality improvements (e.g., from R&D advances and additional data from international markets)
- Cost savings & lower prices (e.g., from EDM, royalty reduction, procurement savings

- Complaint Counsel modeled none of this
- It simply declared the harm enormous and dismissed the benefits as non-existent

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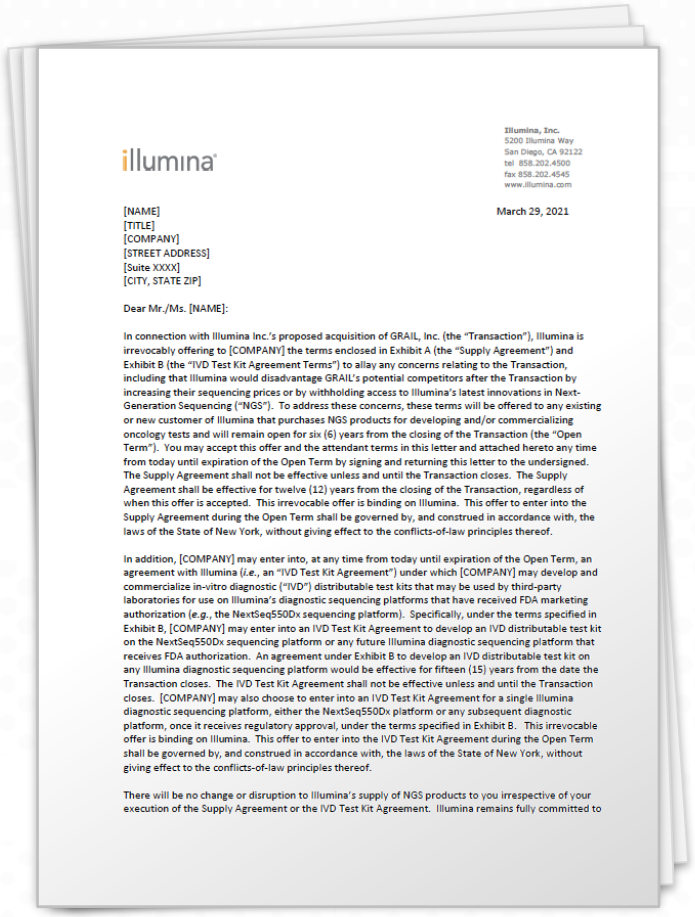
The Open Offer

The Open Offer Addresses Any Conceivable Harm

1. Comprehensive Protections
2. Disables Alleged Levers
3. Accepted by Numerous Customers
4. Complaints Not Credible
5. Successful in Other Matters
6. No Reason to Doubt Compliance
7. Criticisms Fall Flat

1 Sets Forth Comprehensive Protections



illumina

Illumina, Inc.
5200 Illumina Way
San Diego, CA 92122
tel 858.202.4500
fax 858.202.4545
www.illumina.com

March 29, 2021

[NAME]
[TITLE]
[COMPANY]
[STREET ADDRESS]
[Suite XXXX]
[CITY, STATE ZIP]

Dear Mr./Ms. [NAME]:

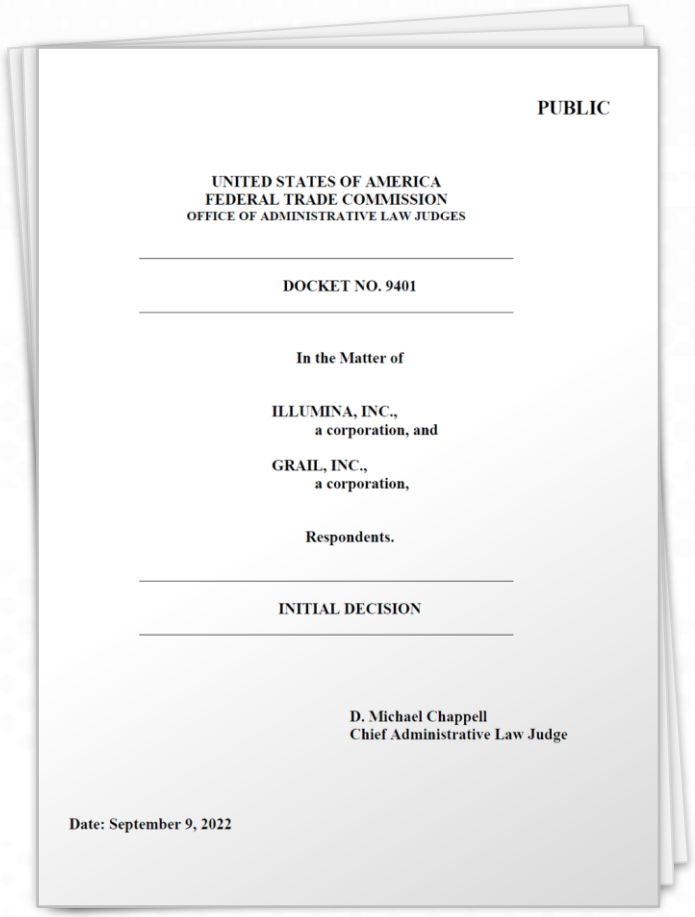
In connection with Illumina Inc.'s proposed acquisition of GRAIL, Inc. (the "Transaction"), Illumina is irrevocably offering to [COMPANY] the terms enclosed in Exhibit A (the "Supply Agreement") and Exhibit B (the "IVD Test Kit Agreement Terms") to allay any concerns relating to the Transaction, including that Illumina would disadvantage GRAIL's potential competitors after the Transaction by increasing their sequencing prices or by withholding access to Illumina's latest innovations in Next-Generation Sequencing ("NGS"). To address these concerns, these terms will be offered to any existing or new customer of Illumina that purchases NGS products for developing and/or commercializing oncology tests and will remain open for six (6) years from the closing of the Transaction (the "Open Term"). You may accept this offer and the attendant terms in this letter and attached hereto any time from today until expiration of the Open Term by signing and returning this letter to the undersigned. The Supply Agreement shall not be effective unless and until the Transaction closes. The Supply Agreement shall be effective for twelve (12) years from the closing of the Transaction, regardless of when this offer is accepted. This irrevocable offer is binding on Illumina. This offer to enter into the Supply Agreement during the Open Term shall be governed by, and construed in accordance with, the laws of the State of New York, without giving effect to the conflicts-of-law principles thereof.

In addition, [COMPANY] may enter into, at any time from today until expiration of the Open Term, an agreement with Illumina (*i.e.*, an "IVD Test Kit Agreement") under which [COMPANY] may develop and commercialize in-vitro diagnostic ("IVD") distributable test kits that may be used by third-party laboratories for use on Illumina's diagnostic sequencing platforms that have received FDA marketing authorization (*e.g.*, the NextSeq550Dx sequencing platform). Specifically, under the terms specified in Exhibit B, [COMPANY] may enter into an IVD Test Kit Agreement to develop an IVD distributable test kit on the NextSeq550Dx sequencing platform or any future Illumina diagnostic sequencing platform that receives FDA authorization. An agreement under Exhibit B to develop an IVD distributable test kit on any Illumina diagnostic sequencing platform would be effective for fifteen (15) years from the date the Transaction closes. The IVD Test Kit Agreement shall not be effective unless and until the Transaction closes. [COMPANY] may also choose to enter into an IVD Test Kit Agreement for a single Illumina diagnostic sequencing platform, either the NextSeq550Dx platform or any subsequent diagnostic platform, once it receives regulatory approval, under the terms specified in Exhibit B. This irrevocable offer is binding on Illumina. This offer to enter into the IVD Test Kit Agreement during the Open Term shall be governed by, and construed in accordance with, the laws of the State of New York, without giving effect to the conflicts-of-law principles thereof.

There will be no change or disruption to Illumina's supply of NGS products to you irrespective of your execution of the Supply Agreement or the IVD Test Kit Agreement. Illumina remains fully committed to

- A **12-year supply contract** for products. (IDF ¶ 888.)
- **Guaranteed access** to the latest sequencing products as GRAIL at the same time. (IDF ¶¶ 896-901.)
- **No price increases** for sequencing products. (IDF ¶¶ 926, 929.)
- **Guaranteed lower pricing -** at least **43% lower** on highest throughput products by 2025. (IDF ¶¶ 926, 929.)
- **No obsolescence** of the sequencing products. (IDF ¶ 905.)
- **Audit rights** and an **arbitration option**. (IDF ¶¶ 978-88.)

2 Disables Alleged Levers



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

DOCKET NO. 9401

In the Matter of

ILLUMINA, INC.,
a corporation, and

GRAIL, INC.,
a corporation,

Respondents.

INITIAL DECISION

D. Michael Chappell
Chief Administrative Law Judge

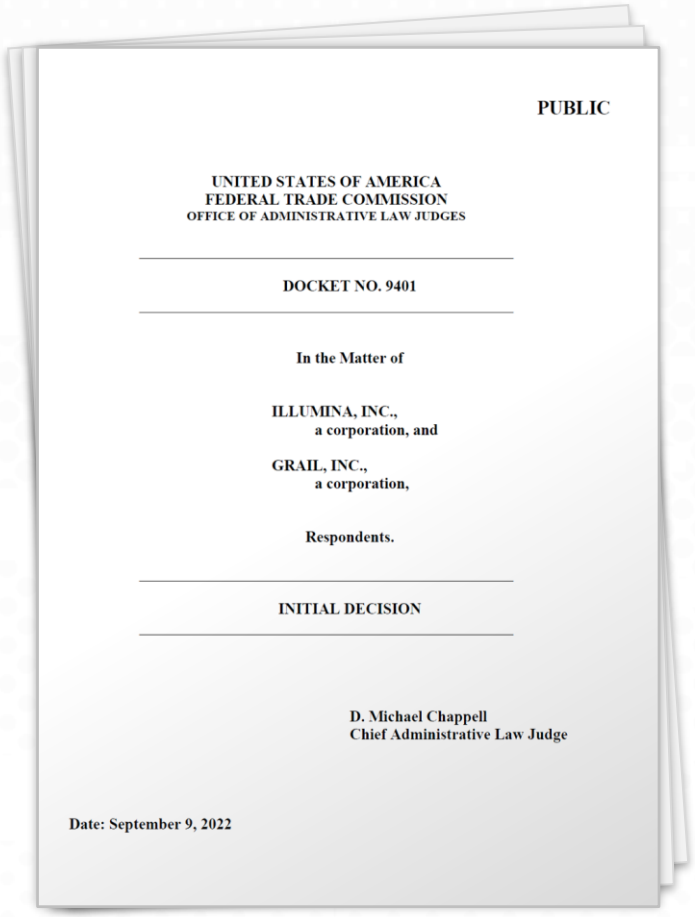
Date: September 9, 2022

"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.)

2 Disables Alleged Levers

Alleged Lever	Open Offer Constraint
Illumina can impact supply (CCPTB § II.E.1.a, c.)	Illumina must supply all sequencing instruments and core consumables ordered by the customer in a timely manner. (*See* IDF ¶¶ 905, 908, 968.)
Illumina can increase prices (CCPTB § II.E.1.b.)	Illumina cannot increase prices except for inflation and cost of goods sold for the entire 12-year term of the Open Offer, until August 18, 2033. (IDF ¶ 926.) Customers can keep pricing available to them at the close of the Transaction for the entire 12-year term. (IDF ¶¶ 915-17.) Illumina must lower sequencing prices by at least 43% by 2025. (IDF ¶ 929.)
Illumina can diminish service and support (CCPTB § II.E.1.d.)	Illumina must supply the same levels of service and support to the customer as it provided pre-merger and as it makes available to GRAIL. (IDF ¶ 890.)
Illumina can delay or deny access to new technology (CCPTB § II.E.1.e.)	Illumina must provide customers access to new technology at the same time—within five days—as it provides that technology to GRAIL. (IDF ¶¶ 899-901.)
Illumina can develop products specifically for GRAIL (CCPTB § II.E.1.f; CCRAB at 34.)	Illumina must agree to design or modify sequencing products to optimize interoperability with a customer's tests. (IDF ¶ 910.)
Illumina can deny access to information for FDA approval (CCPTB § II.E.1.g.)	Illumina must enter into IVD agreements and provide all information reasonably required by FDA. (IDF ¶¶ 945, 948-49.)

3 Accepted by Numerous Customers



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- Several of Grail's purported rivals (including all but two of Complaint Counsel's own witnesses) have signed the Open Offer or amended supply agreements reflecting the Open Offer's terms. (ID 181.)
- Five additional Illumina oncology customers have signed. (RFF ¶ 1058.)

"[T]he 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 to prevent harm to Grail's alleged rivals." (ID 181.)

4 Complaints Not Credible

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Company	Lack of Credibility	Evidence Shows Open Offer Terms Are Appealing
EXACT SCIENCES	• Exact's CEO, Mr. Conroy, had not read the Open Offer. (IDF ¶ 994.) • Mr. Conroy did not know (beyond what counsel described to him) what the Open Offer requires Illumina to do. (IDF ¶ 994.) • [redacted] (RFF ¶ 1717.)	• [redacted] • [redacted] • [redacted]
[redacted]	• [redacted] was unaware of terms in [redacted] own supply agreement. (RFF ¶ 1075.2.) • [redacted] admitted that he does not participate in [redacted] supply agreement negotiations. [redacted]	• [redacted] signed an agreement that is similar to the Open Offer. (IDF ¶ 989.) • [redacted] General Counsel who negotiated the agreement, found [redacted] supply agreement sufficient for [redacted] needs. (RFF ¶ 1075.)
[redacted]	• [redacted], admitted that [redacted] did not have a supply agreement before the fall of 2020. (IDF ¶ 995.) • [redacted] admitted that he felt that the time during the FTC investigation was a good time to start negotiating. (IDF ¶ 996.)	• [redacted] backed out of a supply agreement that included certain Open Offer terms in an attempt to obtain GRAIL's IP. (RRFF ¶¶ 4189, 4276.) • [redacted] wanted a 2 or 3-year agreement with MFN pricing, uninterrupted supply and the ability to terminate for convenience. The Open Offer is a *12-year* agreement with each of these and more. (RRFF ¶ 4189.) • [redacted] admitted that an annual audit addressed his concerns, provided that possible breaches in the interim could be addressed. (RFF ¶ 1047.4.)
[redacted]	• [redacted], admitted that "[t]here are probably certain aspects of the open offer that we do want and we don't currently have." [redacted]	• [redacted] • [redacted] admitted that [redacted] has never agreed not to raise its prices over a 12-year agreement. (RFF ¶ 1025.3.)
SINGLERA Genomics	• Dr. Gao of Singlera testified that he was "not even aware of the first open [...] offer until [his] lawyer told [him]", let alone the amended version. (RFF ¶ 1895.) • Dr. Gao admitted that Illumina provided a draft supply agreement to Singlera and that Singlera never responded. (RRFF ¶ 2642.)	• Dr. Gao admitted that the revenue share term in the Open Offer's standardized template IVD agreements was "a step in the right direction". (PX7102 (Gao (Singlera) Dep. at 128).)

5 Successful When Used In Other Matters

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U.S. v. AT&T Inc.,
916 F.3d 1029, 1042–43
(D.C. Cir. 2019)

Holding, in a vertical merger case, that "Turner Broadcasting's irrevocable offers of no-blackout arbitration agreements" made the merger "unlikely to afford Turner Broadcasting increased bargaining leverage", the government's primary theory of harm.

FTC v. Butterworth,
946 F. Supp. 1285, 1298
(W.D. Mich. 1996)

Holding that merging hospitals had successfully rebutted FTC's prima facie case and evidence in light of the hospitals' proposed "Community Commitment", which served as an "additional assurance that the merged entity would not exercise its market power to raise prices or otherwise injure the community".

5 Complaint Counsel Misreads *AT&T* & *Butterworth*

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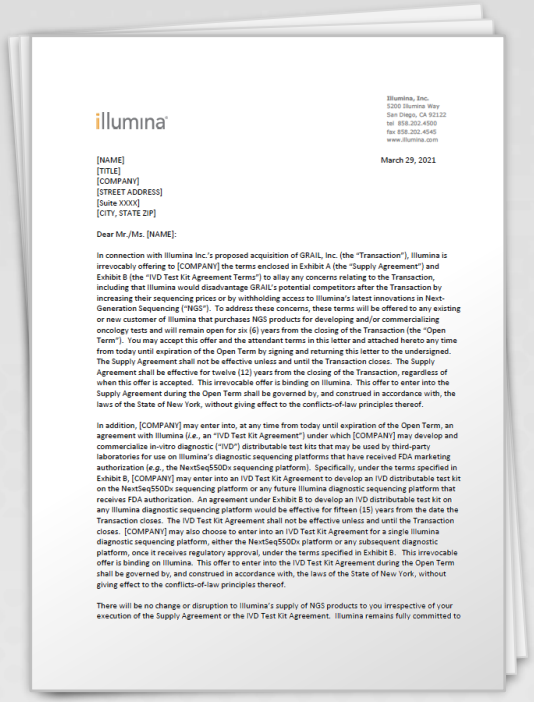
Complaint Counsel's Argument		Fact
Unlike *AT&T* agreements, Open Offer is novel and there is no "real world evidence" to support its efficacy. (CCAB at 32.)	**BUT**	FTC and DOJ have used consents similar to the Open Offer for decades. (RFF ¶ 1078.1; IDF ¶¶ 1003, 1017.)
Illumina customers would not know of a potential breach. (CCAB at 31.)	**BUT**	The Open Offer requires that customers are **notified of a potential breach within 10 days**. (IDF ¶ 983.)
AT&T arbitration triggers "ban on any blackout"; harm during arbitration with Illumina would not be "stayed". (CCAB at 31.)	**BUT**	The arbitrator is empowered to order **any relief necessary to restore the status quo**, including monetary and/or injunctive relief. (IDF ¶ 987.)
Butterworth relied on the non-profit status of the hospital defendants. (CCAB at 32.)	**BUT**	The hospitals' public promises "besp[oke] a **serious commitment by defendants** . . . to which they can be held accountable to refrain from exercising market power in ways injurious to the consuming public", ***separate from*** any additional safeguards offered by their non-profit status. 946 F. Supp. at 1298.

6 No Reason to Doubt Compliance

illumina GRAIL

- Complaint Counsel's own witness testified that:
  - "Illumina took **every contract that we put in place very seriously** . . . [and] took reasonable efforts with which to enforce all aspects of contracts." (RRFF ¶ 4746.)
  - "[Illumina] always dealt with our customers on an **aboveboard and honest** basis." (RRFF ¶ 4746.)
  - Illumina "provided the **best [customer] service in the industry, bar none**." (RRFF ¶ 4985.)
- The Open Offer's audit and arbitration provisions require and incentivize compliance.
  - The Arbitrator is required to "take into account, and the **Arbitrator's decision shall reflect, that the purpose of the [Open Offer] is to allay any concerns relating to the Transaction**, including that Illumina would disadvantage GRAIL's potential competitors after the Transaction by increasing their sequencing prices or by withholding access to Illumina's latest innovations in NGS." (IDF ¶ 988.)

6 Ordering Compliance Would Remove All Doubt


illumina

Illumina, Inc.
5200 Illumina Way
San Diego, CA 92122
tel. 858.202.4500
fax 858.202.4545
www.illumina.com

March 29, 2021

[NAME]
[TITLE]
[COMPANY]
[STREET ADDRESS]
[Suite XXXX]
[CITY, STATE ZIP]

Dear Mr./Ms. [NAME]:

In connection with Illumina Inc.'s proposed acquisition of GRAIL, Inc. (the "Transaction"), Illumina is irrevocably offering to [COMPANY] the terms enclosed in Exhibit A (the "Supply Agreement") and Exhibit B (the "IVD Test Kit Agreement Terms") to allay any concerns relating to the Transaction, including that Illumina would disadvantage GRAIL's potential competitors after the Transaction by increasing their sequencing prices or by withholding access to Illumina's latest innovations in Next-Generation Sequencing ("NGS"). To address these concerns, these terms will be offered to any existing or new customer of Illumina that purchases NGS products for developing and/or commercializing oncology tests and will remain open for six (6) years from the closing of the Transaction (the "Open Term"). You may accept this offer and the attendant terms in this letter and attached hereto any time from today until expiration of the Open Term by signing and returning this letter to the undersigned. The Supply Agreement shall not be effective unless and until the Transaction closes. The Supply Agreement shall be effective for twelve (12) years from the closing of the Transaction, regardless of when this offer is accepted. This irrevocable offer is binding on Illumina. This offer to enter into the Supply Agreement during the Open Term shall be governed by, and construed in accordance with, the laws of the State of New York, without giving effect to the conflicts-of-law principles thereof.

In addition, [COMPANY] may enter into, at any time from today until expiration of the Open Term, an agreement with Illumina (*i.e.*, an "IVD Test Kit Agreement") under which [COMPANY] may develop and commercialize in-vitro diagnostic ("IVD") distributable test kits that may be used by third-party laboratories for use on Illumina's diagnostic sequencing platforms that have received FDA marketing authorization (*e.g.*, the NextSeq550Dx sequencing platform). Specifically, under the terms specified in Exhibit B, [COMPANY] may enter into an IVD Test Kit Agreement to develop an IVD distributable test kit on the NextSeq550Dx sequencing platform or any future Illumina diagnostic sequencing platform that receives FDA authorization. An agreement under Exhibit B to develop an IVD distributable test kit on any Illumina diagnostic sequencing platform would be effective for fifteen (15) years from the date the Transaction closes. The IVD Test Kit Agreement shall not be effective unless and until the Transaction closes. [COMPANY] may also choose to enter into an IVD Test Kit Agreement for a single Illumina diagnostic sequencing platform, either the NextSeq550Dx platform or any subsequent diagnostic platform, once it receives regulatory approval, under the terms specified in Exhibit B. This irrevocable offer is binding on Illumina. This offer to enter into the IVD Test Kit Agreement during the Open Term shall be governed by, and construed in accordance with, the laws of the State of New York, without giving effect to the conflicts-of-law principles thereof.

There will be no change or disruption to Illumina's supply of NGS products to you irrespective of your execution of the Supply Agreement or the IVD Test Kit Agreement. Illumina remains fully committed to

- Illumina has agreed to be bound by an order **incorporating the provisions of the Open Offer**. (IDF ¶ 990.)
- Illumina's proposed order adds **a monitor provision to further ensure compliance**. (IDF ¶ 990.)
- The proposed order **fully resolves** any lingering concerns about monitoring or enforcement of the Open Offer.
- Any violation of the Open Offer would therefore also be **a violation of a court order**, subjecting Illumina to penalties and further dis-incenting any favoritism.

7 Criticisms Fall Flat

illumina® GRAIL

CC's Contentions	The Truth
The Open Offer's preamble indicates it is a proposed remedy. (CCAB at 30.)	• The Open Offer should not be treated as a proposed remedy merely because its purpose was to resolve concerns with the Transaction. It is a binding contractual commitment with real-world effects that must be accounted for in assessing Illumina's alleged ability to foreclose. (*See* ID 181, 183.)
The Open Offer has not been "implemented across the market". (CCAB at 30.)	• Open Offer should be considered part of CC's prima facie case where the merger and fix become operative together and where the fix was advanced at same time as complaint. *In re Otto Bock HealthCare N. Am., Inc.*, 2019 WL 5957363, at *43 (F.T.C. Nov. 1, 2019). • Open Offer is implemented across the market: every putative GRAIL rival has the option of entering into the Open Offer and all but two have. (*See* IDF ¶ 989.)
The Open Offer was not negotiated and was "unilateral". (CCRAB at 15.)	• The Open Offer was created based on multiple negotiations with Illumina customers. (ID 153-54.) • The Open Offer includes provisions not previously included in supply agreements because customers negotiated for these provisions. (*See, e.g.*, RFF ¶¶ 989.6-7.)
Open Offer is not operationalized. (CCPTRB at 4.)	• Illumina has a contract with Deloitte to operationalize the terms of the Open Offer in a customer-friendly manner and shows Illumina is taking its obligations seriously. (IDF ¶ 992.)
The terms of the Open Offer are too flexible to provide protection. (CCPTRB at 4.)	• Flexibility is pro-customer. (RFF ¶¶ 1083-1083.3.) • For example, the FDA provision requires Illumina to provide whatever documentation is needed, which ensures customer protection even if FDA requirements change. (RFF ¶ 1083.2.)
The Open Offer does not cover library preparation. (CCPTRB at 156.)	• Customers generally do not buy library preparation materials from Illumina and instead create it on their own as it is the "secret sauce" of a test developer's test. (RRFF ¶ 4547.)

7 Criticisms Fall Flat

illumina GRAIL

CC's Contentions	The Truth
The Open Offer does not prevent GRAIL from having advance knowledge of new technology. (CCAB at 33-34.)	• The Open Offer provides information about final product specifications (IDF ¶¶ 896-901), and non-final product specifications are not relevant, because GRAIL could not use them. (Aravanis (Illumina) Tr. 1930-31.)
The Open Offer does not license application-specific IP. (CCPTRB at 156.)	• There is no sound antitrust basis to require Illumina to license application specific IP. Such IP is GRAIL's secret sauce, which no rival to GRAIL would have access to in the absence of the transaction, so no rival to GRAIL can expect just because of the transaction. (RRFF ¶ 4719.) • Customers conceded that their test development efforts would not rely on Illumina or GRAIL's application-specific IP. (*See, e.g.*, RRFF ¶ 3068.)
The IP protections are inadequate because they are excluded from the arbitration provision. (CCPTRB at 171.)	• Customers agreed that Illumina and GRAIL are entitled to enforce their valid IP, both before and after the GRAIL acquisition. (*See, e.g.*, RFF ¶ 1789.) • Illumina is not allowed to cease shipments of products based on an allegation of IP infringement. (RFF ¶ 1037.) Illumina can cease supplying products on the basis of infringement only if a court has found that infringement has in fact occurred. (RFF ¶ 1037.2.)
The Open Offer excludes discretionary discounts, which allows Illumina to favor GRAIL and makes customers' pricing worse than before the Transaction. (CCPTRB at 168.)	• Illumina cannot provide more favorable pricing to GRAIL or to any other MCED developer using discretionary discounts because the MFNs would require that such discounts be extended to other customers. (IDF ¶ 925.) • The elimination of discretionary discounts makes pricing standardized and transparent, which helps ensure equitable treatment. (IDF ¶¶ 918-25.)
The promise to decrease prices is per gigabase, not per read. (CCAB at 34.)	• By reducing price per gigabase of the highest throughput S4 flow cell, Illumina will also reduce price per read because the number of reads in a given flow cell kit is constant. (IDF ¶¶ 930-31.) • Open Offer's protections not limited to highest throughput instrument. (RRFF ¶¶ 1017-19; 2001.1.)

7 Criticisms Fall Flat

CC's Contentions	The Truth
The Open Offer cannot be effectively audited and Illumina decides if customers have a good-faith basis for additional audits. (CCAB at 36.)	• The Open Offer's provisions can be audited effectively according to the only audit expert in the case. (IDF ¶¶ 1024-31.) • Customers automatically have access to bi-annual audits (regardless of claims of good-faith basis) and customers must be notified of any potential noncompliance within 10 days. (IDF ¶¶ 979-80, 982-83.)
The theory of incomplete contracting does not save the Open Offer. (CCPTRB at 180.)	• Contracts can be incomplete and still function effectively over time. (IDF ¶ 1004.) • Customers have acknowledged that no contract is perfect, but they enter into contracts all the time. (RFF ¶ 1083.3.)
The Open Offer does not change Illumina's incentives. (CCAB at 35.)	• The Open Offer disables Illumina's ability and reinforces its incentives against foreclosure. (RFF ¶ 1082.4.) • Foreclosure would subject Illumina to potentially enormous arbitration penalties and hurt its reputation. (RFF ¶¶ 1082.2-3.)
Illumina can surreptitiously evade the Open Offer and any breach would be confidential. (CCAB at 35.)	• Customers must be notified of any potential breach within 10 days. (IDF ¶¶ 982-83.)
Illumina's reputation with its customers is poor, [redacted] (CCAB at 37.)	• [redacted] testified that [redacted] had "no proof to validate" these allegations (RRFF ¶ 4767), and testified that Illumina works hard to maintain a positive reputation, including that Illumina "took every contract that we put in place very seriously . . . [and] took reasonable efforts with which to enforce all aspects of contracts." (RRFF ¶ 4746.) • Illumina measures its reputation using Net Promoter Scores and has very high scores relative to industry benchmarks. (RFF ¶ 856.3; Berry (Illumina) Tr. 837–38.)

7 Criticisms Fall Flat

illumina

Illumina, Inc.
5200 Illumina Way
San Diego, CA 92122
tel: 858.202.4500
fax 858.202.4545
www.illumina.com

September 8, 2021

[NAME]
[TITLE]
[COMPANY]
[STREET ADDRESS]
[Suite XXXX]
[CITY, STATE ZIP]

Re: Additional Terms – Addendum to Supply Agreement

Dear Mr./Ms. [NAME]:

With reference to the standard contract terms Illumina, Inc. ("Illumina") made available to any U.S. oncology customer on March 30, 2021, specifically, Exhibit A to Illumina's letter dated March 29, 2021 ("Exhibit A"), Illumina is irrevocably offering additional terms to further allay any concerns relating to Illumina's August 18, 2021 acquisition (the "Transaction") of GRAIL, Inc. (now, GRAIL, LLC, referred to hereafter as "GRAIL").

Any terms used but not otherwise defined herein shall have the meanings ascribed to them in the March 29, 2021 Letter, including Exhibit A. The terms of this addendum may be accepted any time from today until expiration of the Open Term for Exhibit A. The terms of this addendum shall become effective immediately upon Customer's acceptance of these terms, and shall remain in effect during the Term for as long as GRAIL is an Affiliate of Illumina.

Under this addendum, each of the terms and conditions set forth in the Exhibit A shall continue to apply, in addition to or as modified by the supplemental terms provided in Exhibit C to this letter (together with Exhibit A, the "Supply Agreement").

Sincerely,

Francis deSouza
Chief Executive Officer

Accepted and Agreed:

[COMPANY]

Name:
Title:
Date:

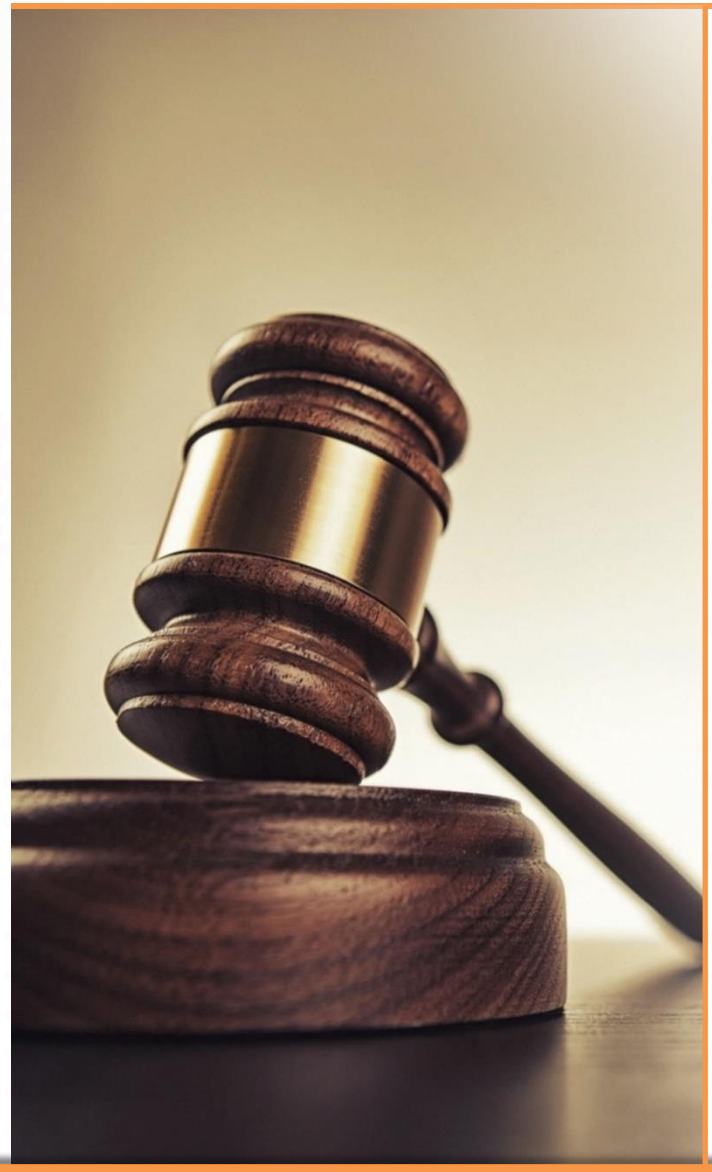
- All NovaSeq and NextSeq products fall under the Open Offer's protections.

- "The price for a **new Supplied Product** or a new version of a materially improved Supplied Product must be commercially reasonable. For any materially improved Supplied Product, the price of the new version must take into account the value of the improvement. For avoidance of doubt, in any arbitration in which the price of a new version of a Supplied Product or a new Supplied Product is disputed, the arbitrator is empowered to determine the reasonableness of the price, including the value of the any improvement in performance or capability, and to require that Illumina charge a price that is commensurate with the improvement, as well as require any associated refunds to Customer." (RFF ¶ 1022.2; *see* IDF ¶ 928.)

illumina®
GRAIL

The Efficiencies

The Efficiencies Matter



"One way defendants may [contest the government's case] is to offer evidence that post-merger efficiencies outweigh the merger's anticompetitive effects."

United States v. AT&T Inc., 310 F. Supp. 3d 161 (D.D.C. 2018) (internal citations omitted)

Efficiencies may not be "a defense" to an illegal merger, but may indicate a merger is not illegal.

New York v. Deutsche Telekom AG, 439 F. Supp. 3d 179, 207 (S.D.N.Y. 2020)

"[A] defendant can rebut a prima facie case with evidence that the proposed merger will create a more efficient combined entity and thus increase competition."

Saint Alphonsus Med. Ctr.-Nampa Inc. v. St. Luke's Health Sys., Ltd., 778 F.3d 775, 790 (9th Cir. 2015)

Supported By Extensive Evidence

Efficiency						
Saves Lives	**Accelerates Market Access**	**R&D Innovations**	**Accelerated Fruits of International Expansion**	**Reduced Royalty Burden**	**Eliminated Double Margin**	**Supply Chain & Operational Efficiencies**
Witness: • Aravanis • deSouza • Febbo • Flatley • Bishop • Freidin • Jamshidi • Ofman • Conroy • Chahine • Fiedler • Nolan • Rabinowitz • Carlton • Deverka	**Witness:** • Aravanis • deSouza • Febbo • Flatley • Qadan • Bishop • Della Porta • Freidin • Ofman • Conroy • Gao • Nolan • Rabinowitz • Carlton • Deverka	**Witness:** • Aravanis • deSouza, • Febbo • Flatley • Bishop • Jamshidi • Klausner • Carlton	**Witness:** • Aravanis • deSouza • Febbo • Flatley • Bishop • Freidin	**Witness:** • Aravanis • deSouza • Freidin • Strom • Carlton	**Witness:** • Aravanis • deSouza • Carlton	**Witness:** • Aravanis • deSouza • Flatley • Bishop • Carlton
RFF ¶¶ 1117, 1119–26	RFF ¶¶ 1127–35	RFF ¶¶ 1136–45	RFF ¶¶ 1168–73	RFF ¶¶ 1146–51	RFF ¶¶ 1152–55	RFF ¶¶ 1156–67

Endorsed by a Highly Qualified Illumina Board

Board of Directors

illumina®

Q. And was the board's decision to reacquire GRAIL a unanimous decision?

A. It was unanimous, yes.

Q. And why did the board of Illumina decide to have Illumina reacquire GRAIL?

A. Well, there were a whole host of reasons, but if you think about it first at 50,000 feet, it was -- we considered that it was a great deal for our shareholders, number one, but also and probably most importantly **that the deal had the ability to accelerate the adoption of the Galleri test that GRAIL was about to launch into the market. This is a very, very important clinical test, and anything we believed that we could do to accelerate that adoption rate was going to be very important in saving lives.**

(RFF ¶ 1110; Flatley (Illumina) Tr. 4081-82)

Endorsed by a Highly Qualified GRAIL Board

Board of Directors

GRAIL

Q. [W]hat do you recall about the discussions [regarding GRAIL being acquired by Illumina?

A. I recall that there were multiple discussions. I recall that they were very involved and detailed with a board that had deep experience in contemplating the different paths ahead of us, that had done so multiple times with different companies they had been involved in, and that they involved also expert outside advisors. So, yeah, they were very detailed discussions and very thorough discussions.

Q. Why did the board decide to be acquired by Illumina?

A. Because they concluded that it was -- it would result in, by far, the best outcome for patients, and it would reduce the risks associated with the challenges ahead of us.

(RFF ¶ 1113; Bishop (GRAIL) Tr. 1422-23)

The Transaction Will Generate Enormous Efficiencies

1. Saves Lives
2. Accelerates Market Access
3. R&D Efficiencies
4. Accelerates the International Expansion of Galleri
5. Reduces Royalty Burden
6. Eliminates Double Marginalization
7. Supply Chain and Operational Efficiencies

1 Saves Lives

- **All agree** cancer screening saves lives.
  (RFF ¶¶ 1117–19.)
- **All agree** accelerating the adoption of an MCED test will save even more lives.
  (RFF ¶ 1122.)
- **Only question is:**
  Will further uniting Illumina and GRAIL accelerate the adoption of the Galleri test?
  (RFF ¶ 1117.)

How Could It Not?

- Illumina is the world's foremost expert in NGS technology. (RFF ¶ 1.)
- Illumina has deep relationships and credibility with regulators, payors and labs. (RFF ¶¶ 1131.5, 1131.7.)
- Illumina is a sophisticated, global operator of NGS clinical testing at scale. (RFF ¶ 1141.1.)
- It founded GRAIL. (RFF ¶ 44.)
- Its brand is synonymous with innovative and low-cost sequencing. (RFF ¶ 855.)
- Illumina innovations have allowed for the development of entire industries. (RFF ¶ 855.)
- Illumina has been repeatedly recognized as an innovator, earning recognition as one of the world's smartest and most influential companies. (RFF ¶ 1139.)

1 Ample Evidentiary Support

illumina GRAIL

Francis de Souza

"[T]his transaction has the potential to fundamentally dent the mortality curve in cancer and save many, many thousands of lives..." (RFF ¶ 1121.2.)

Alex Aravanis

The transaction "will lead to millions of more tests performed, tens of thousands of additional lives saved..." (RFF ¶ 1121.3.)

Phil Febbo

"[E]arlier detection has the opportunity to save a lot of lives..."

The reunion of Illumina and GRAIL "could accelerate the speed with which patients would have access to that test..." (RFF ¶ 1121.4.)

Jay Flatley

"[T]his would have a dramatic impact on the rate with which we could deploy the Galleri test and, therefore, save the lives of cancer patients who don't know they have cancer." (RFF ¶ 1121.5.)

Hans Bishop

"[T]hey'll help us globalize and reach more patients around the world more quickly."

"[T]hey'll help us accelerate the speed at which we can reduce the price of our test and thereby make it more affordable for many." (RFF ¶ 1121.6.)

Josh Ofman

"[P]artnering with Illumina would really enable our mission and our vision to be accelerated in terms of our ability to achieve it". (RFF ¶ 1121.7.)

Aaron Freidin

"[A]cceleration of Galleri by Illumina means that GRAIL "will do it faster. We will save more lives". (RFF 1121.8.)

Dr. Dennis Carlton

"[E]stimates in the literature about how Galleri testing will save lives" and arrived at a "range . . . from 7,429 to 10,441" lives saved from the acceleration. (RFF ¶ 1123.3.)

2 Accelerates Market Access

Accelerating FDA, Medicare & Payor Approval

- **Galleri Has Limited Availability Today**
  (RFF ¶ 1128.)
- **FDA, CMS and Payor Approval Are Necessary for Widespread Adoption**
  (RFF ¶ 1129.)
- **GRAIL Has Little Experience With FDA, CMS or Payor Approval**
  (RFF ¶ 1130.)
- **Illumina Has Significant Experience and Expertise Obtaining FDA Approval and Market Access for NGS-based Tests**
  (RFF ¶ 1131-32.)
- **Reuniting Illumina and GRAIL Will Accelerate FDA, CMS and Payor Coverage of Galleri** (RFF ¶ 1133.)

2 Unrefuted Witness Testimony of Acceleration

Jay Flatley

Illumina "has the ability to accelerate the adoption of this test or the approval of the test through the FDA. We also have the ability, because of the size and scope of the company, to establish reimbursement much more quickly than GRAIL would have the ability to do". (RFF ¶ 1133.5.)

Alex Aravanis

"Those benefits will be conferred to GRAIL as part of the acquisition...apply the same approaches that Illumina used in other areas where it's increased market access and reimbursement" (RFF ¶ 1133.2.)

Phil Febbo

"We determined that, in aggregate, these efficiencies will accelerate the adoption and availability of the Galleri test by approximately at least one year". (RFF ¶ 1133.3.)

Francis de Souza

"[W]e can just plug the GRAIL, you know, work into and accelerate the adoption of GRAIL, so there's a lot of work we can do on market access..." (RFF ¶ 1133.1.)

Hans Bishop

"Illumina will help us accelerate the speed at which we can drop the price of our tests". (RFF ¶ 1133.6.)

Josh Ofman

"Illumina's resources and experience will help us get FDA approval faster".

"[E]xpertise in the genomics space would be invaluable for us". (RFF ¶ 1133.7.)

Chris Della Porta

"Expect regulatory market access, sales, people and expertise to be the driving – some of the driving factors" that the Transaction would speed up. (RFF ¶ 1133.9.)

Ammar Qadan

"[W]e will be able to accelerate the development, for example, with commercial payers in the U.S.". (RFF ¶ 1133.4.)

2 Acceleration in Multiple Dimensions

Capability	GRAIL	Illumina	Expected Efficiencies
Experience With Private And Public Payors	Experience to date with Galleri is all pre-market (RFF ¶ 1130.)	Extensive and international. Established coverage track record for multiple NGS test categories (RFF ¶ 1131.)	Will open doors to payors that may be early adopters of Galleri. Will help GRAIL identify innovative payors for pilots and real-world evidence generation. Increases patient access to novel cancer screening approach (RFF ¶ 1133.)
Health System Partnerships	Limited to date (RRFF ¶ 5499.)	Extensive and international. Track record of success with NIPT, CGP and RUGD (RFF ¶¶ 1451-58.)	GRAIL more likely to gain adoption of LDT Galleri with real-world evidence collection with Illumina's relationships and implementation resources. Illumina collaborations with ex-US health systems can also support real-world evidence generation that can build evidence quicker than GRAIL can do alone (RFF ¶ 1132-33; 1171.)
De-risking Of Reimbursement Challenges	[redacted] (RRFF ¶ 5593-95.)	Harvard Pilgrim/NIPT case Harvard Pilgrim/WGS case Queensland Australia WGS for RUGD case (RFF ¶ 1131.12, 14; 1133.1.)	Risk sharing arrangements between GRAIL and payors will accelerate clinical integration of Galleri and enable real-world evidence collection (RFF ¶ 1133.)
Value assessment methods development	[redacted] (RFF ¶ 1133.)	Experience with funding methods research for value assessments of NGS-based tests (GEECS) (RFF ¶ 1133.)	Will help to support the conduct and dissemination of credible Real-World Evidence and cost-effectiveness studies for Galleri (RFF ¶ 1133.)

2 Acceleration in Multiple Dimensions

Capability	GRAIL	Illumina	Expected Efficiencies
Regulatory experience with PMA	Limited (RFF ¶ 1130.1.)	Extensive (RFF ¶ 1131.6.)	FDA approval will be a significant factor for payor coverage, so if Illumina's resources and prior experience dealing with FDA can accelerate regulatory approval for Galleri, this could further accelerate payor and Medicare coverage (RFF ¶ 1129; 1133.)
Global presence and expertise	Only in UK (RFF ¶ 1169.)	Extensive (RFF ¶ 1170.)	Will enable GRAIL to leverage Illumina's international footprint and support earlier adoption of Galleri, which also helps accelerate evidence needed for PMA approval (RFF ¶ 1170-72.)
Resources to support appropriate real-world use of Galleri, fit into clinical workflow	Limited (RFF ¶ 1130.)	Experience with educating patients and providers through pre-competitive collaborations (CAPS). Existing partnership with Genome Medical providing education to individuals, health care providers, and employers nationwide (RFF ¶ 1131-32.)	Increases likelihood that Galleri will be used appropriately in clinical practice (*e.g.*, in addition to current SOC screenings, appropriate referrals for positive tests, management of FPs and FNs, etc.) (RFF ¶ 1133.)

3 R&D Efficiencies

R&D Efficiencies

- **GRAIL Has Limited R&D Resources** (RFF ¶ 1138.)
- **Illumina's R&D Resources and Capabilities Are Advanced** (RFF ¶ 1139.)
- **The Transaction Will Lead to R&D Efficiencies** (RFF ¶ 1141-5.)
  - Related to Galleri
  - Unrelated to Galleri
- **Evidence of R&D Efficiencies Is Unrefuted** (RFF ¶ 1141.)

3 Unrefuted Witness Testimony of R&D Efficiencies

Francis de Souza

"[O]ur teams are very good at creating lower-cost, high-throughput workflows to process samples, and that will benefit Galleri." (RFF ¶ 1141.2.)

Alex Aravanis

"[I]nnovations that we're making in those other areas we will be able to apply also to future versions of the Galleri test, improving the performance and, therefore, increasing the clinical value of the test." (RFF ¶ 1141.2.)

Phil Febbo

"As you "scale testing... you end up getting data that really helps you understand the test [and] improve the test itself, improve the performance, improve the efficiency." (RFF ¶ 1141.3.)

Jay Flatley

"[T]ake advantage of the data that's coming from the international expansion, integrate that data, and use the deep learning algorithms to improve the accuracy of the Galleri test." (RFF ¶ 1141.4.)

Arash Jamshidi

With "access to additional high-quality data, we'll be able to bring that earlier and capture those benefits earlier and actually incorporate them in earlier versions of our product." (RFF ¶ 1141.6.)

4 Accelerates the International Expansion of Galleri

Accelerating International Expansion

- **Illumina Has International Presence and Capabilities.** (RFF ¶ 1168.)
- **GRAIL Lacks International Reach.** (RFF ¶ 1169.)
- **The Transaction Will Accelerate International Expansion.** (RFF ¶ 1170.)
- **International Expansion Will Have a Positive Effect in the US.** (RFF ¶ 1171-2.)
- **Complaint Counsel Did Not Present Any Fact Witnesses or Evidence to Rebut the Testimony of Respondents' Fact Witnesses on this Efficiency.** (RFF ¶ 1168.1.)

4 Unrefuted Witness Testimony

Francis de Souza

"[T]he GRAIL test will become more and more accurate..."

"...accessing larger sample sets will improve the GRAIL test for people here in the U.S." (RFF ¶ 1170.2.)

Alex Aravanis

"[T]he test will be available worldwide, much faster than GRAIL could given that it has no operations in those countries..."

"...data will be useful in discussions with the FDA around FDA approval." (RFF ¶ 1170.3.)

Jay Flatley

"[I]nfrastructure that Illumina has in place would dramatically accelerate GRAIL's ability to bring Galleri to other markets of the world and to do that quite quickly." (RFF ¶ 1170.4.)

Hans Bishop

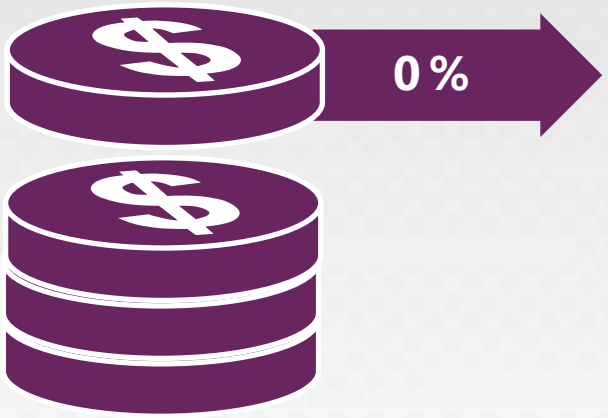
"[S]elling Galleri more broadly, you know, outside the United States will have a series of country-specific regulatory approvals. We don't have a team today that has any experience of that. Illumina already has those people. (RFF ¶ 1170.5.)

Chris Della Porta

"[O]ur long-range plan for the next ten years, you know, really ignores anything international."

"[I]t's pretty obvious to me that they could accelerate us internationally if they have the infrastructure already." (RFF ¶ 1170.6.)

5 Reduces Royalty Burden



Elimination of Royalties

- Under a 2017 supply agreement stemming from Illumina's creation of GRAIL, **GRAIL (unlike other Illumina customers) was obligated to pay Illumina a royalty of 7% of all oncology revenues until GRAIL had paid cumulative royalties of $1 billion, at which point the royalty rate would decline to 5%.** (RFF ¶ 1147.)
- **The Transaction eliminated the royalty obligation**. (RFF ¶ 1146, 1148.)
- Dr. Carlton computed the U.S. consumer surplus from the elimination of these royalties during the years 2022-2030 at **$136.9 million**. (RFF ¶ 1150.)
- At least some (if not all) of that reduction in royalties will be passed on to consumers in the form of lower prices. (RFF ¶ 1146,1149.)
- Complaint Counsel presented no contrary evidence. (RFF ¶ 1148.5.)
- Complaint Counsel's argument that the efficiency is not merger specific is rebutted by fact witness testimony that GRAIL tried and failed to eliminate the royalty. (RFF ¶ 1148.)

5 Unrefuted Witness Testimony of Royalty Burden

Francis de Souza

"Once the deal closed, no royalty is owed..."

(RFF ¶ 1148.3.)

Alex Aravanis

"It is Illumina's plan to pass 100% of those efficiency savings on to payers of the test".

(RFF ¶ 1149.4.)

Aaron Freidin

"[I]f the royalty did not exist we could price the test lower and increase access."

(RFF ¶ 1147.)

Dr. Dennis Carlton

"U.S. consumer surplus from the elimination of these royalties during the years 2022-2030 is estimated conservatively at $136.9 million."

(RFF ¶ 1150.)

6 Eliminates Double Marginalization

Elimination of Double Marginalization

- EDM is a well-documented efficiency from a vertical transaction (RFF ¶ 1152), as Complaint Counsel's own expert acknowledged. (RFF ¶ 1152.1.)
- Before the Transaction closed, **Illumina charged a margin to GRAIL on sales of its NGS products, and GRAIL projected a margin on its products**. (RFF ¶ 1153.1.)
- Dr. Carlton estimated that the consumer surplus likely to result from the Transaction for the period from 2022 to 2030 is **$627.9 million**. (RFF ¶ 1154.)
- Complaint Counsel did not present any factual testimony or other evidence suggesting that there were not two margins before the Transaction or that EDM will not be achieved. (RFF ¶ 1155.1.)

6 Unrefuted Witness Testimony of EDM

Francis de Souza
President and CEO
Illumina, Inc.

There is "double marginalization of having these two companies as separate companies. And by bringing them together, we believe you can eliminate those costs, too"). (RFF ¶ 1154.)

Alex Aravanis
Chief Technology Officer
Illumina, Inc.

"We'll be able to eliminate the double-marginalization and pass the savings on to payers of the test and patients." (RFF ¶ 1154.)

Dr. Dennis Carlton
Respondents' Expert

"If you just do the calculation, you can see that the number over, you know, an approximate eight-year period is around $630 million". (RFF ¶ 1154.)

7 Supply Chain and Operational Efficiencies

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Supply Chain Efficiencies

- Illumina has relationships with suppliers that allow Illumina to purchase inputs at a significant discount. (RFF ¶¶ 1159-60.)
- By contrast, GRAIL is a young company that has only one product on the market with very limited sales. (RFF ¶ 1161.)
- The Transaction will allow GRAIL to benefit from Illumina's prices and relationships in areas of common procurement. (RFF ¶ 1162.)

Lab Efficiencies

- Illumina also has significant experience managing laboratories that operate NGS tests at scale and has optimized its workflow from a cost and safety perspective. (RFF ¶ 1163.3.)
- GRAIL, in contrast, only has one laboratory and limited experience operating that lab. (RFF ¶ 1164.)
- Combining Illumina and GRAIL will allow GRAIL to benefit from Illumina's lab operations capabilities. (RFF ¶ 1165.)

- Illumina estimates savings of **least $140M over a 10-year period**. (RFF ¶ 1166.)
- Complaint Counsel offered no evidence to the contrary. (RFF ¶ 1166.)

Supply Chain & Operational Efficiencies

7 Unrefuted Witness Testimony of Supply & Lab Efficiencies

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Francis deSouza

Alex Aravanis

Jay Flatley

Hans Bishop

Supply Efficiencies

"[C]onsolidating purchasing for these materials between GRAIL and Illumina, GRAIL would enjoy bigger discounts than it gets today for a lot of the materials that it has..." (RFF ¶ 1162.2.)

"The cost reductions associated with volume that Illumina benefits from could be shared with GRAIL as part of an integrated company. Therefore, the cost of goods for the Galleri test would decrease." (RFF ¶ 1162.3.)

"[W]e'd have the ability to combine volumes and, therefore, reduce the prices..."

"We also would have the ability to have increased purchasing power." (RFF ¶ 1162.4.)

"As part of Illumina, I think we'll scale faster, and scale brings cost benefits." (RFF ¶ 1162.5.)

Lab Efficiencies

"[O]perational capabilities are benefits that GRAIL will enjoy, and it will take GRAIL years to develop that capability themselves." (RFF ¶ 1165.2.)

"[W]ill lower the facilities costs that GRAIL will incur, and those, again, costs can be passed on to people purchasing the test." (RFF ¶ 1165.3.)

"In a combined company, we would have the ability to integrate that in a very important way and leverage the data across multiple tests for a given patient and have much more unified software structures and reporting." (RFF ¶ 1165.4.)

"Illumina has established operations and the relevant teams of experts and laboratories in certain instances in many countries around the world" that will help GRAIL scale. (RFF ¶ 1165.5.)

Courts Have Credited Lesser Efficiencies Based on Lesser Proof

No.	Case Name	Outcome	Credited Efficiency	Evidence Relied On
1	***FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, 1302 (W.D. Mich. 1996)**	Injunction Denied	• Enabling world-class health facilities • Efficiencies of scale, capital expenditure avoidance and operations	• Expert and witness testimony
2	***United States v. Long Island Jewish Med. Ctr.*, 983 F. Supp. 121, 147 (E.D.N.Y. 1997)**	Injunction Denied	• Cost savings used to provide high quality health care • Reduction in personnel and some reduction in the cost of lab services and medical supplies	• Expert testimony
3	***United States v. Carilion Health Sys.*, 707 F. Supp. 840, 845 (W.D. Va. 1989)**	Injunction Denied	• Improving the quality of health care • Capital avoidance and other clinical and administrative efficiencies	• Testimony at trial
4	***New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 208–09; 216-17 (S.D.N.Y. 2020)**	Injunction Denied	• Meeting projected market growth with no loss in quality and accelerate provision of 5G service • Supporting additional subscribers at lower cost • $4.2 billion in operating costs per year and savings from streamlining and reducing redundancies	• T-Mobile's successful past acquisition of MetroPCS in 2013
5	***FTC v. Lab'y Corp. of Am.*, No. SACV 10-1873 AG MLGX, 2011 WL 3100372, at *10-11 (C.D. Cal. 2011)**	Injunction Denied	• Over $22 million annually from consolidating redundant facilities and employees and taking advantage of LabCorp's lower costs	• Expert testimony

Complaint Counsel Seeks to Impose an Impossible Standard

Complaint Counsel Dismissed Assured Efficiencies on the Ground that:

➢ Some are based on Illumina / GRAIL witness testimony (CCAB at 41.)	YET	Accepts claims of MCED developers based on testimony of companies without corroboration
➢ Some are based on expert opinions (CCAB at 41.)	YET	Relies on less qualified experts to rebut the same efficiency
➢ Some depend on high level predictions (CCAB at 41.)	YET	Depends on even higher level predictions to justify alleged relevant market
➢ Consumer benefits have not been quantified for some (CCAB at 40.)	YET	Posits harm that is not measured at all and far more speculative
➢ Some are forward-looking (CCPTRB at 203.)	YET	Accepts claim of entry that are far more remote and speculative
➢ Magnitude has not been fully assessed for some (though quantified) (CCAB at 40.)	YET	Accepts harm with no quantification

Complaint Counsel Seeks to Impose Impossible Standard

Dismisses Proven Efficiencies On the Ground:	This Standard Would:
• Illumina is not the only company that could help. (CCPTRB 221-22.)	• Foreclose an efficiency defense any time an alternative acquirer could be imagined. *Deutsche Telekom*, 439 F. Supp. 3d at 213.
• R&D breakthroughs are by definition unverifiable. (CCPTRB 216; CCRAB 19-20.)	• Mean no R&D efficiencies are ever verifiable. *Deutsche Telekom*, 439 F. Supp. 3d at 216.
• Witnesses could not answer specific questions / did not have all the facts on a given topic. (e.g., CCPTRB 200.)	• Doom efficiencies where a transaction is not fully consummated and integration has not yet occurred.
• There has been little integration planning. (CCPTRB 192.)	• Mean efficiencies cannot be credited where government litigation prevents integration planning.
• The costs of achieving the efficiency have not been itemized. (CCPTRB 199.)	• Foreclose efficiencies that are certain but not capable of being itemized or have not been itemized.

Complaint Counsel's Criticisms Are Misplaced

CC's Contentions	The Truth
Efficiencies Are Respondents' Burden	• In a vertical merger, Complaint Counsel must prove that the transaction is anticompetitive when balanced against any efficiencies that will be generated by the transaction. (CCCoL ¶ 7.)
Efficiencies Are Not Cognizable, Verifiable or Substantiated by Ordinary Course Documents	• Numerous unrebutted witnesses testified to the efficiencies that the merger will generate and their current plans to achieve those efficiencies. (RFF ¶ 1106-77.) • Efficiencies are borne out by analogous past experience (NIPT). (RFF ¶ 1145); *Deutsche Telekom*, 439 F. Supp. 3d at 216 ("efficiency claims may be verifiable if substantiated by analogous past experience"). • Efficiencies are consistent with ordinary course documents produced prior to the deal. (RRFF ¶¶ 5061.) • If this is insufficient, no defendant could ever prove efficiencies.
Efficiencies Insufficiently Quantified	• Numerous witnesses (fact and expert) testified to the scale of the efficiencies. (*e.g.* RFF ¶ 1154.) • Dr. Carlton has rigorously, yet conservatively, analyzed consumer surplus arising from the efficiencies. (*e.g.* RFF ¶ 1154 (over $600 million in EDM for 2022 to 2030); RFF ¶ 1123 (at least $37 billion in acceleration efficiencies from 2022 to 2030).) • If this is insufficient, no defendant could ever prove efficiencies.
Illumina Has Not Begun Enacting the Efficiencies	• Illumina has been prevented from integration planning. (RRFF ¶¶ 5073, 5088.)

Complaint Counsel's Criticisms Are Misplaced

CC's Contentions	The Truth
Efficiencies Not Merger Specific	• The efficiencies have not been achieved when Illumina and GRAIL were separate companies. (RFF ¶¶ 1173-79.) • Every single fact witness to address the issue testified—without exception—that it would take GRAIL years to develop the capabilities Illumina has today. (RFF ¶ 1176.1.) • A number of the efficiencies would require sharing confidential information and close planning that are impossible in an arm's length transaction. (RFF ¶ 1176.) • GRAIL tried and failed to achieve elimination of royalties outside of this Transaction. (RFF ¶ 1177.) • Illumina and GRAIL currently have two margins (because of the Hold Separate), which shows that EDM efficiencies have yet to be achieved. (RFF ¶ 1177.)
Efficiencies Could Be Achieved by Contract	• Numerous fact witnesses testified the efficiencies could not be created by contract. (RFF ¶¶ 1400, 1177.4.) • Illumina has never offered such services to third parties. (RFF ¶ 1176.2.) • Collaborating outside the transaction would require GRAIL to share its "secret sauce" with a third party. (RFF ¶ 1176.)
Efficiencies Could Be Achieved by Consultants	• Illumina has unparalleled expertise and experience in efficiently scaling clinical NGS testing and working with regulators and payors to understand and adopt NGS-based clinical testing. (RFF ¶ 1175.) • Numerous fact witnesses testified consultants cannot be used to do the work necessary to achieve the efficiencies. (RRFF ¶ 2693.)

Complaint Counsel's Criticisms Are Misplaced

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CC's Contentions	The Truth
GRAIL Can Achieve Efficiencies on Its Own	• GRAIL has made great progress with Galleri, but that does not repudiate the efficiencies the transaction will bring. • Numerous GRAIL witnesses have testified that GRAIL needs Illumina's help in specific ways (FDA, market access, R&D, cost savings, funding, international expansion). (*e.g.* RFF ¶¶ 1115, 1121.6-9; 1132.5-7, 1133.6-9.)
Illumina Has an Imperfect Record	• NGS is a novel technology for the FDA that presents unique, unprecedented challenges for anyone seeking FDA approval of an NGS-based clinical diagnostic test. (RRFF ¶¶ 5158, 5240.) • Illumina has been at the vanguard of these efforts, guiding the FDA through educational sessions and as it seeks to achieve the most challenging of approvals. (RRFF ¶ 5293.) • [redacted] • [redacted]
Benefits Will Not Be Passed On	• The evidence and economic theory support that Illumina will pass on some portion of EDM and the royalty reduction to consumers. (RFF ¶¶ 1146.2, 1155.5.) • Illumina witnesses have testified that "it is Illumina's plan to pass 100% of those efficiency savings on to payers". (RFF ¶ 1149, 1151.) • Everything known about the market says lower prices will be essential to expanding demand and payor adoption, creating powerful incentives to pass on any cost reductions.
International Efficiencies Out of Market	• International acceleration benefits U.S. consumers by improving performance of MCED tests in the U.S. (RFF ¶ 1172.)

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Failure to Prove Requisite Markets

The Proposed Relevant Market

- **Galleri + any test in development that screens for at least 2 cancers (of any kind)**

"The FTC bears the burden of proof and persuasion in defining the relevant market." *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 119 (D.D.C. 2004)

Flaws In the Proposed Relevant Market

1. Impermissibly Speculative
2. Unsupported by *Brown Shoe*
3. No Hypothetical Monopolist Test Showing
4. Insufficient Evidence of Interchangeability
5. Misplaced Reliance on Innovation Principles

1 Impermissibly Speculative

- **Galleri is the only MCED test on the market**
- The pre-commercial tests Complaint Counsel cites **are too unknown or underdeveloped to be included**
  - Most have **not even started clinical trials for multiple cancer types**
  - Exact/Thrive is **not making the test used in its trials**
  - Singlera says they are **8-10 years away**

Bringing MCED Test to Market is Inherently Risky & Uncertain:

- Developing new or improved cancer tests is a **speculative and risky endeavor**
- A test developer may need to explore a number of **different biomarker combinations**
- A test developer may need to **alter its candidate products and platform technologies** accordingly
- Product development is **expensive**, may take **years to complete** and can have **uncertain outcomes**
- **Failure can occur** at any stage of development
- Tests that may initially show promise **may fail** to achieve the desired results in large clinical trials

(RFF ¶¶ 1694, 1695, 1698 (Conroy Tr. 1709, 1711-12, 1716-19).)

2 Unsupported By *Brown Shoe*

	Brown Shoe Factors	Complaint Counsel Post-Trial Brief	What Sets Galleri Apart
1	Unique Production Facilities	Not argued	• Uses proprietary methods requiring **unique production facilities**
2	Specialized Vendors	Not argued	• Consists of a **single test requiring a single vendor,** whereas Exact/Thrive's only tested product consists of 3 tests and requires multiple vendors
3	Sensitivity to Price Changes	Not argued	• **Only MCED test on the market**, thus no evidence of price sensitivity
4	Peculiar Characteristics and Uses	Argued as to a non-issue	• **Only test able to detect 50+ cancers and CSO**
5	Distinct Customers	Argued as to a non-issue	• **Only MCED test with customers**
6	Industry and Public Recognition	Argued but incorrectly	• **Only MCED test whose features and parameters are known**
7	Distinct Prices	Argued but incorrectly	• **Only MCED test with a price**

Misplaced Reliance on Ordinary Course Documents

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- **Complaint Counsel purports to rely on "ordinary course" documents referring to MCED "markets" and "competitors".**
- However, lay references to such terms **do not define an antitrust market:**
  - ***FTC v. Sysco Corp.***, 113 F. Supp 3d. 1, 26 (D.D.C. 2015) ("mere fact that a firm may be termed a competitor" does not require inclusion in relevant market)
  - ***FTC v. Lundbeck, Inc.***, 2010 WL 3810015, at *20 (D. Minn. Aug. 31, 2010), *aff'd*, 650 F.3d 1236 (8th Cir. 2011) (rejecting FTC's proposed market despite internal company documents that refer to such a market)
  - ***Ky. Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc.***, 588 F.3d 908, 919 (6th Cir. 2009) (lay testimony and marketing documents do not provide "sound economic basis" for assessing the market)

What the Ordinary Course Documents Actually Show:

No MCED test developer is close to developing a test for even 10+ cancers:

[redacted]

3 Fails the Hypothetical Monopolist Test

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No Quantitative Analysis

- Complaint Counsel relies entirely on Dr. Scott Morton
- Dr. Scott Morton did not do a quantitative SSNIP test:

> **Q.** You have not conducted a SSNIP analysis on any subset of MCED tests within your relevant product market; correct?
>
> **[. . .]**
>
> **A.** Yes. That's the quantitative version of the SSNIP. **I have definitely not done that**.

(RFF ¶ 765; PX7138 (Scott Morton Tr. 102-03).)

Insufficient Qualitative Analysis

- Dr. Scott Morton purports to have done a **qualitative** SSNIP test. But
  - Her analysis is merely a thought exercise that does not track *Brown Shoe*.
  - She is not qualified to offer any technical opinions and her narration of the evidence is improper.
  - She did not account for all the evidence or fill holes in the proof.
  - She relies on a series of unsupported assertions, e.g., 100% diversion, no upstream competition.

4 Insufficient Evidence of Interchangeability

- **Only Galleri has been shown to detect 50+ cancer types with CSO in a single test**
- Complaint Counsel **failed** to show the alleged tests in development will be so similar as to be reasonable substitutes
  - **No** other test has been shown to detect 50 cancer types
  - **No** other test has been shown to detect CSO
  - **No** other test has demonstrated sensitivity, specificity & PPV across many cancers
- The alleged "closest" rival (Exact/Thrive's CancerSEEK):
  - **Is not** a single blood test (but 3 tests)
  - **Is unable** to detect CSO
  - **Is undergoing change**

Complaint Counsel's Attack on Galleri Is Misplaced

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7-Cancer Claim

- Numerous witnesses testified **Galleri can detect 50 cancer types** (RFF ¶¶ 698, 1296,1918.)

> Q. Do you know how many cancer types GRAIL's test can detect?
>
> **A. 50.**
>
> (Cance (ACS) Tr. 633.)

- Trial data shows that Galleri **detects 50+ cancers** (RFF ¶¶ 61-62.5.)
- **Multiple health authorities** have reviewed Galleri and **none has objected** to GRAIL reporting 50 cancer types (RRFF ¶¶ 6272, 6288.)
- Galleri has been **analytically validated under CLIA and clinically validated under CAP** (RRFF ¶ 6272.)
- That PATHFINDER has not detected 50+ cancer types is immaterial – it only has 6600 patients and was not designed to do so (RFF ¶¶ 398.4, 399.)

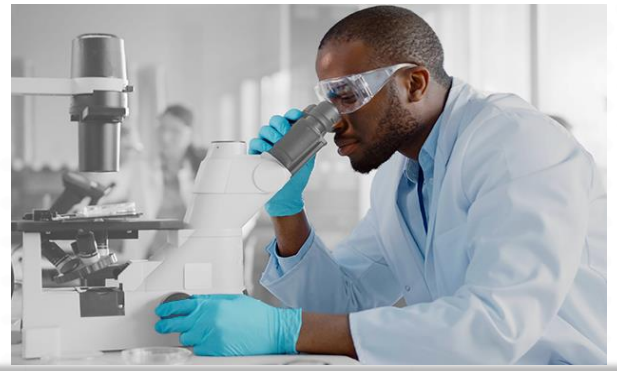
CSO Claim

- Galleri is the **only test** that has demonstrated the capability to detect cancer signal of origin. (RFF ¶¶ 684.2, 724.)
- Galleri has demonstrated a cancer signal of origin prediction accuracy of 96%. (RFF ¶ 62.1.)
- That Galleri's "CSO classifier includes 20 cancer categories, not 50+" is **immaterial** (CCPTRB at 47 n.30.)
  1. It does not mean Galleri detects only 20 cancer types.
  2. The CSO allows for **targeted follow-up** and **reduces the need** for unnecessary work-ups. (RRFF ¶ 3567.)
  3. If Complaint Counsel were correct, then it would have no basis to say Thrive's test detects 8 cancer types, because it does not report CSO at all.

5 Misplaced Reliance on Innovation Principles

- Allegations of R&D **do not lighten** Complaint Counsel's **burden to prove the relevant market**
- **Complaint Counsel failed to prove an innovation R&D market:**
  - No application of *Brown Shoe* at the R&D stage
  - No analysis of whether the hypothetical monopolist test would be met in an R&D market
- **No case says evidence of R&D meets Complaint Counsel's burden:**
  - Under Complaint Counsel's approach, the market definition requirement would have no limiting principle



Unsupported by Precedent

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None of CC's cases include early-stage products in the relevant market:

Case	
Actavis	No dispute about what the "pre-commercial" product is; it is ***bioequivalent to the product on the market***.
Altitude Sports	Denying motion to dismiss based on plausible allegation Comcast could "rapidly" enter Regional Sports Programming Market. ***Relevant market not disputed.***
Ford Motor Co.	Assessed barriers to entry to **mature, defined** spark plug aftermarket.
Bazaarvoice	Assigning market share to firms that could "rapidly and easily" enter in response to a SSNIP. No dispute over whether all "Ratings and Reviews" platforms are interchangeable.
Town Sound & Custom Tops	Assessed potential new entry in the market for automobiles.
SmithKline	No dispute about what the "pre-commercial" product is; it is ***bioequivalent to the product on the market***.

Courts have declined to include early-stage products in the relevant market:

Case	
OrthoAccel	Requiring "precise" description of "relatively new" market with "nascent products."
Golden Gate Pharmacy	Rejecting alleged interchangeability in pharmaceutical product and innovation markets.
Apartment Source	Finding for defendants because alleged market was "emerging" rather than well-defined.
Epic Games	Excluding games that are "too new" from the relevant submarket.
SCM Corp.	Overturning jury verdict because product market did not exist at time of acquisition.
Fraser	Finding '[w]here there is no existing market, there can be no reduction in . . . competition."

"Generally, principles of market definition applicable to cases arising under Sherman Two are also applicable . . . to merger cases arising under [section] 7 of the Clayton Act". *Kaplan v. Burroughs Corp.*, 611 F.2d 286, 292 n.2 (9th Cir. 1979).

The Proposed Related Market

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SINGULAR GENOMICS

ULTIMA GENOMICS

Element BIOSCIENCES

Oxford NANOPORE Technologies

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BGI

ThermoFisher SCIENTIFIC
The world leader in serving science

OMNIOME

Roche

Complaint Counsel Bears the Burden of Proof

- "[P]laintiffs have the burden on every element of their Section 7 challenge, and a failure of proof in any respect will mean the transaction should not be enjoined." *Arch Coal*, 329 F. Supp. 2d at 116
- Complaint Counsel's case depends on the proposition that Illumina has market power as to its NGS products.
  - If it does not, then it could not successfully foreclose.
- Determining whether Illumina has market power requires definition of the related product market.
  - "Vertical restraints often pose no risk to competition unless the entity imposing them has **market power**, **which cannot be evaluated unless the Court first defines the relevant market**."

    Ohio v. Am. Express Co., 138 S. Ct. 2274, 2285, n.7 (2018)
  - "Where substantial market power is absent at any one product or distribution level, vertical integration will not have an anticompetitive effect."

    Auburn News Co. v. Providence J. Co., 659 F.2d 273, 278 (1st Cir. 1981)

Complaint Counsel's Cases Are Inapposite

- **None of the cases** cited by Complaint Counsel holds that the related product needs only to be *identified*, not proven. (CCPTRB at 68.)
- Complaint Counsel itself admits that the Part 3 rules **require it to prove** any proposition on which it relies. (CCPTRB at 48.)
  - Complaint Counsel's case depends on the proposition that Illumina's NGS products are a critical input to any MCED test. (CCPTRB at 49.)
  - It also depends on the proposition that there are no alternatives to Illumina NGS products
  - Both propositions effectively require proof that Illumina's products are in a market of their own.
  - **Thus, Complaint Counsel bears the burden to prove the Related Product Market.**

Complaint Counsel's Arguments Depend on a Double Standard

Superior Performance	Means Illumina instruments have no rivals	**BUT**	Does not mean GRAIL has no rivals
Developer Product Expectations	Should be disregarded as to NGS manufacturers	**BUT**	Should be taken at face value as to MCED developers
Expert Testimony	Cannot be credited from a qualified technical expert and a practicing physician re NGS issues	**BUT**	Must be credited by economic expert with no MCED expertise re MCED issues
Absence of Precise Launch Timeline	Should preclude considering an NGS system to be in the market	**BUT**	Does not preclude considering an MCED to be in the market
Lack of Customers	Justifies excluding an NGS instrument	**BUT**	Does not justify excluding an MCED test
Launched Products	Can be excluded from the market for NGS instruments	**BUT**	Should be included in the market as to MCED tests
The Challenges of Launching a New Product	Require exclusion of unlaunched NGS alternatives to Illumina	**BUT**	Do not require exclusion of unlaunched MCED alternatives to Galleri
The Expenditure of Time and Money	Does not merit inclusion of NGS alternatives in development	**BUT**	Requires inclusion of MCED tests in early development
Missing a Launch Date	Precludes crediting an NGS entrant [redacted]	**BUT**	Does not require exclusion of MCED tests in early development
Company Testimony	Should be disregarded as self-serving regarding NGS entry	**BUT**	Should be credited re MCED entry

Unjustifiable Remedy

No Basis For the Requested Remedy

1. **No Violation, No Remedy**
2. **Divestiture Would Be Extreme and Unnecessary**
3. **Any Remedy Here Would Be Unconstitutional**

- **Violates Article I**
  - Congress gave FTC no intelligible principle by which to bring agency actions rather than federal actions
- **Violates Article II**
  - FTC Commissioners exercise executive power and should be subject to at-will removal
- **Violates Due Process Clause**
  - Risk of unfair hearing when Commission is both accuser and adjudicator
- **Violates Equal Protection**
  - FTC/DOJ system of assigning cases subjects parties to disparity without a rational basis

1 No Violation, No Remedy

Bacon v. City of Richmond,
475 F.3d 633, 638 (4th Cir. 2007)

"Remedies . . . are the consequence of some wrong. At its most basic, this principle limits the reach of judicial decrees to parties found liable for a legal violation."

Breaux Bros. Farms v. Teche Sugar Co.,
21 F.3d 83, 89 (5th Cir. 1994)

"[C]ompetition has not been injured and [thus] the antitrust laws offer them no relief."

Jacob Siegel v. FTC,
327 U.S. 608, 611–13 (1946)

The remedy must bear "reasonable relation to [any] unlawful practices".

2 Divestiture Would Be Extreme and Unnecessary

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- Even if a remedy were required here (which it is not), less extreme remedies than the proposed divestiture would be more than sufficient to address the alleged harm – **including an order embodying the terms of the Open Offer**.
- The purpose of antitrust remedies is to **restore competition**.
  United States v. E.I. du Pont de Nemours & Co., 366 U.S. 316, 326 (1961).
- A divestiture order would be disproportionate in this case as it would:
  - Eliminate the Transaction's life-saving benefits;
  - Harm the interest of the general public; and
  - Address concerns that are already eliminated by the Open Offer
- Illumina has committed to a **consent order formalizing the Open Offer's terms**: this would be the most effective and appropriate remedy in this case.

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3 Any Remedy Will Be Unconstitutional

Jarkesy v. SEC, 2022 WL 1563613 (5th Cir. 2022)

- The SEC brought an enforcement action against Petitioners for securities fraud.
- An SEC administrative law judge adjudged Petitioners liable and ordered various remedies.
- The SEC affirmed the decision on appeal over several constitutional arguments raised by Petitioners.
- Petitioners raised the same constitutional arguments before the Fifth Circuit.

- **The Fifth Circuit held that the proceeding violated Article I, Article II, and the Seventh Amendment, because:**
  - Congress gave the SEC (as it did with the FTC) unfettered discretion over whether to bring a suit in an administrative or federal district court. *See id.* at *8–11.
  - SEC ALJs, like FTC ALJs, exercise executive functions, yet enjoy dual-layer protections of removal from the President. *See id.* at *11–13.
  - The SEC, like the FTC in this case, sought a civil penalty and thus made a claim arising at common law. *See id.* at *2–7.
- **Thus, there is no constitutional difference between that case and this one.**

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Violates Article I

- Article I provides that **"[a]ll legislative Powers herein granted shall be vested in a Congress of the United States".** U.S. Const. art. I, § 1 (emphasis added).
- Determining which cases are assigned to administrative tribunals is an exercise of legislative power. *See Crowell v. Benson*, 285 U.S. 22, 50 (1932) (quoting *Ex parte Bakelite Corp.*, 279 U.S. 438, 451 (1929)).
- Congress can delegate that power to another entity only if it provides an "intelligible principle" by which that entity can exercise it. *Mistretta v. United States*, 488 U.S. 361, 372 (1989).
- Congress gave the FTC the power to bring antitrust actions within the agency instead of in an Article III court. *See* 15 U.S.C. §§ 45(b).
- But Congress gave the FTC no intelligible principle by which the FTC was to exercise that power. *See* 15 U.S.C. §§ 45(b), 53(b).
- **Thus, Complaint Counsel's remedy is unconstitutional as a product of FTC's improperly delegated legislative power.**

Complaint Counsel's Article I Arguments Miss the Mark

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CC's Contentions	The Truth
Respondents waived this defense by failing to argue it in their pre- or post-trial briefs	• Respondents asserted their Article I defense promptly after it was recognized in *Jarkesy*. • Until *Jarkesy* there was no "known right" to waive. *U.S. v. Alkhafaji* 754 F.2d 641, 660 n.8 (6th Cir. 1985) (Krupansky, J., concurring) (quoting *Curtis Publishing Co. v. Butts*, 388 U.S. 130, 143 (1967)). • Respondents reserved the right to assert any other available defenses. • Respondents had no notice of the proposed disgorgement of profits until receiving Complaint Counsel's post-trial brief. • Defenses that challenge the constitutional sufficiency of a tribunal and its power to adjudicate "can never be forfeited or waived," *U.S. v. Cotton*, 535 U.S. 625, 630 (2002).
The Commission's choice to pursue an action in federal or administrative court is an exercise of executive, not legislative, power.	• The choice among Article III courts is an exercise of prosecutorial discretion. The choice between an Article III court and an administrative court is an exercise of legislative power. *Crowell v. Benson*, 285 U.S. 22, 50 (1932). • That choice would be an exercise of executive power only if Congress gave the FTC an intelligible principle. *Mistretta v. United States*, 488 U.S. 361, 372 (1989). Congress gave no such principle. *See* 15 U.S.C. §§ 45(b), 53(b).

Runs Counter to Article II

- Article II vests **"[t]he executive Power . . . in a President of the United States of America"**, who must "**take care that the laws be faithfully executed".**
  U.S. Const. art II, § 1, cl. 1, § 3.

- The President cannot "be restricted in his ability to remove a principal officer". *Free Enterprise Fund v. Public Co. Accounting Oversight Bd.*, 561 U.S. 477, 483-84 (2010).

- But the FTC Act restricts the President's ability to remove an FTC Commissioner, except for cause. 15 U.S.C. § 41.

- In *Humphrey's Executor*, the Supreme Court recognized a narrow exception to the President's unrestricted removal power over principal officers. *Humphrey's Executor v. United States*, 295 U.S. 602, 632 (1935); *Seila Law LLC v. Consumer Fin. Prot. Bureau*, 140 S. Ct. 2183, 2198 (2020).

  – Congress may grant for-cause removal protection to multi-member agency heads if the agency mirrors the FTC "as it existed in 1935," when it "was said not to exercise any executive power." *Seila*, 140 S. Ct. at 2198-99.

- That conclusion "has not withstood the test of time." *Seila*, 140 S. Ct. at 2198-99, n.2.

  – Commissioners today exercise vast enforcement, investigative, and prosecutorial authority.

- **Thus, Complaint Counsel's remedy violates Article II.**

Complaint Counsel's Article II Argument Misses the Mark

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CC's Contentions	The Truth
The Commission rejected Article II challenges in *1-800 Contracts*, *Otto Bock* and *LabMD*.	• The Commission's decisions are inconsistent with *Jarkesy* and *Lucia v. SEC*.
***Decker Coal* rejected an Article II challenge as to DOL ALJs**	• *Decker Coal* expressly limited its holding to *Department of Labor* ALJs. *See Decker Coal*, 8 F.4th 1123, 1126 ("[w]e must decide whether the statute is constitutional with respect to DOL ALJs")
***Jarkesy* Is Inapposite:** ➢ **The Commission has rejected its rationale**	• *Jarkesy* is well reasoned.
➢ **Unlike SEC ALJs, FTC ALJs serve "a purely adjudicatory function"**	• FTC ALJs perform substantial executive functions: they control the presentation and admission of evidence, 16 C.F.R. § 3.42(c); they can punish contemptuous conduct, 16 C.F.R. § 3.24(d); and their decisions can be final, 16 C.F.R. § 3.52(a)(1).
➢ **Decisions of FTC ALJs are "purely recommendatory"**	• ALJ decisions are final when Commission decides not to review the decisions at all. 16 C.F.R. § 3.52. • The FTC has never reversed a decision in which an FTC ALJ found liability in the past 26 years. (RFF ¶ 1188.)

Disregards Due Process Clause

- **"A fair trial in a fair tribunal is a basic requirement of due process."**
  In re Murchison, 349 U.S. 133, 136 (1955).
- The combination of investigative and adjudicative functions can constitute a due process violation, where **"the probability of actual bias on the part of the judge or decision-maker is too high to be constitutionally tolerable".**
  Withrow v. Larkin, 421 U.S. 35, 47, 58 (1975).
- **"[A]n unconstitutional potential for bias exists when the same person serves as both accuser and adjudicator in a case".**
  Williams v. Pennsylvania, 579 U.S. 1, 8 (2016).

- **The final administrative decision will be decided by Commissioners who**:
  - Voted out the complaint (RFF ¶ 1191);
  - Interviewed witnesses (RFF ¶ 1195);
  - Rejected Illumina's efforts to resolve the case;
  - Insisted on proceeding to trial (RFF ¶ 1195.3);
  - Withdrew their federal case, reserving the right to decide the case to themselves. (RFF ¶ 1196.)
- **Thus, Complaint Counsel's remedy violates the Due Process Clause.**

Complaint Counsel's Due Process Argument Fails

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CC's Contentions	The Truth
An administrative agency can combine "investigative and adjudicatory functions" and any doubts about this were resolved in *Withrow*.	• In *Williams v. Pennsylvania*, the Supreme Court held that "an unconstitutional potential for bias exists when the same person serves as both accuser and adjudicator in a case". 579 U.S. 1, 8 (2016). • *Withrow v. Larkin* clearly carved out situations where "the probability of actual bias . . . is too high to be constitutionally tolerable", as here. *Withrow,* 421 U.S. 35, 47 (1975).
Nothing in Section 5(b) of the FTC Act requires the Commission to prejudge the outcome.	• Whether or not the statute requires it, the risk of prejudgment is considerable. • Once the Commission votes out a complaint, it finds in favor of itself 100% of the time. Regardless, acting as a prosecutor and judge in the same case is enough to violate due process.
***Williams v. Pennsylvania* is inapposite.**	• Commissioners do act as prosecutors by issuing a complaint and directing its prosecution, thereby serving as advocates and having a direct personal role in the conduct of Complaint Counsel. (RFF ¶¶ 1195-95.6.) • Three of the five sitting Commissioners participated in the prosecution of this case by interviewing witnesses and rejecting settlement offers by Respondents. • This dual prosecutor / adjudicator role results in an unconstitutional risk of bias under *Williams*.
There is no evidence any Commissioner has prejudged the outcome.	• Voting out a complaint, putting reputation at stake, and spending resources reflect some prejudgment of the merits. • Once the Commission votes out a complaint, it finds in favor of itself 100% of the time. • Complaint Counsel dismissed its own complaint to move to the friendlier forum of the Office of Administrative Law Judges. (RFF ¶ 1198.2.) The FTC also withdrew the 2020 Vertical Merger Guidelines mid-trial, further slanting the playing field in Complaint Counsel's favor. (RFF ¶ 1198.5.)

Elides Equal Protection

- The Equal Protection Clause commands that the government shall not **"deny to any person within its jurisdiction the equal protection of the laws".**

U.S. Const. amend. XIV, § 1; *U.S. v. Windsor*, 570 U.S. 744, 774 (2013)

- Any difference in treatment "run[s] afoul of the Equal Protection Clause" when there is **no "rational relationship between the disparity of treatment and some legitimate governmental purpose".**

Montgomery v. Louisiana, 577 U.S. 190, 231 (2016) (Thomas, J., dissenting) (quoting *Armour v. Indianapolis*, 566 U.S. 673, 680 (2012)).

- The FTC/DOJ system of assigning cases subjects parties to disparity without a rational basis

	DOJ	FTC
Forum	• Federal Court	• Administrative Proceeding or Federal Court (FTC chooses)
PI Standard	• Traditional 4-Part Showing	• Lesser 2-Part Showing
Substantive Legal Standard/ Policy	• Vertical Merger Guidelines	• No Vertical Merger Guidelines
Rules if District Court Rules Against	• Only Single Proceeding	• Risks Two Tracks
Independence of Fact Finder	• Article III Judge	• FTC can replace and review de novo
PI Forum	• Federal Court Alone	• Administrative Proceeding
Ability to Change Merits Decision Before Circuit Court Appeal	• None	• FTC can and does change anything it wants
Circuit Court Appellate Standards	• Clearly Erroneous Standard	• Lesser Substandard Evidence Standard

Complaint Counsel's Equal Protection Argument Lacks Merit

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CC's Contentions	The Truth
An FTC action does not preclude a DOJ action in parallel.	• Complaint Counsel admits that the agencies do not in fact bring same claims in parallel to "avoid[] duplicative efforts". Regardless, the potential difference in treatment alone violates the EP Clause.
Any difference in procedural rules is inconsequential and not outcome determinative.	• Parties to a merger challenged by DOJ are treated very differently from the parties to a merger challenged by the FTC. (*See* table on previous slide; *see* RFF ¶¶ 1200-09.) • The procedural and substantive differences can be outcome-determinative: the parties to a merger challenge in the FTC's administrative proceedings run the significant risk that the FTC will change a merits decision, including a decision that is adverse to the FTC, prior to appeal to the circuit court. 15 U.S.C. § 45(c); 16 C.F.R. § 3.54(b). The Commission takes the view it is empowered to ignore an ALJ's determinations in their entirety and substitute the Commission's own legal and factual findings prior to appeal. 16 C.F.R. § 3.54. In the past 20 years, the FTC has reversed all but one decision in which this Court ruled in favor of a defendant. (RFF ¶ 1208.)
Any difference in rules is rationally related to a legitimate governmental purpose.	• No such showing made.
Respondents cannot point to any prejudice they have experienced as a result of the administrative litigation process being followed.	• Respondents are not required to make such a showing; the potential difference in treatment (which is substantial) is sufficient to violate the EP Clause. • Respondents were deprived of a timely decision on the merits in federal court • Complaint Counsel's case would never have served summary judgment in an Article III court, especially in the Fifth Circuit following *Jarkesy*.

Violates the Seventh Amendment

- The Seventh Amendment protects **the right to a civil jury trial.** U.S. Const. amend. VII.
- The Seventh Amendment applies as to claims that arise "at common law", *see Tull v. United States*, 481 U.S. 412, 417 (1987), and do not center on "public rights", *see Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 54 (1989).
- An action seeking a civil penalty arose "at common law". *Tull*, 481 U.S. at 422.
- Disgorgement is a civil penalty and not an equitable remedy. *Retractable Techs., Inc. v. Becton Dickinson & Co.*, 919 F.3d 869, 883–84 (5th Cir. 2019).
- Complaint Counsel seeks to disgorge from Illumina its naturally earned profits.
  - Proposed Order II.D: "Illumina shall return to GRAIL any proceeds from the divestiture of the Hold Separate Business that is greater than the Investment Amount."
- **The Seventh Amendment applies here**.
- Complaint Counsel argues that a proceeding to enjoin an allegedly anticompetitive merger does not "arise at common law".
- In fact, a proceeding that seeks a civil penalty, like disgorgement, is akin to common law debt proceedings, which arose "at common law". *Tull*, 481 U.S. 412, 418-19 (1987); *Retractable Techs., Inc. v. Becton Dickinson & Co.*, 919 F.3d 869, 883-84 (5th Cir. 2019).)

Requiring Divestiture Will Harm Patients and Consumers

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Lifesaving Certainty

- Cancer screening **SAVES LIVES NOW**.
- The Galleri test **SAVES LIVES NOW**.
- Accelerated adoption of tests will **SAVE LIVES**.
- Merging Illumina and GRAIL will accelerate the development of other test that will **SAVE LIVES**.

CERTIFICATE OF SERVICE

I hereby certify that on December 6, 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
ElectronicFilings@ftc.gov

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-110
Washington, DC 20580

I also certify that I caused the foregoing document to be served via email to:

Complaint Counsel
U.S. Federal Trade Commission
Susan Musser
Stephen A. Mohr
Jordan S. Andrew
Sarah Wohl
Stephanie Bovee
Peter Colwell
Eric Edmondson
Paul Frangie
Samuel Fulliton
Lauren Gaskin
David Gonen
James Wells Harrell
Matthew Joseph
Wade D. Lippard
Sebastian Lorigo
Dylan P. Naegele
Joseph Neely
Brian O'Dea
Nicolas Stebinger
Nicholas Widnell

Counsel for Respondent Illumina, Inc.
Cravath, Swaine & Moore LLP
Christine A. Varney
David R. Marriott
Sharonmoyee Goswami
Jesse M. Weiss
Michael J. Zaken

Counsel for Respondent GRAIL, LLC
Latham & Watkins LLP
Michael G. Egge
Marguerite M. Sullivan
Alfred C. Pfeiffer, Jr.
Anna M. Rathbun
David L. Johnson

December 6, 2022

/s/ Sharonmoyee Goswami
Sharonmoyee Goswami

Counsel for Respondent Illumina, Inc.