No. 23-60167

IN THE

United States Court of Appeals

FOR THE FIFTH CIRCUIT

ILLUMINA, INC. AND GRAIL, INC.,

Petitioners,

v.

FEDERAL TRADE COMMISSION,

Respondent.

PETITION FOR REVIEW OF
AN ORDER OF THE FEDERAL TRADE COMMISSION

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CERTIFICATE OF INTERESTED PERSONS

Illumina, Inc. v. Federal Trade Commission, No. 23-60167

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of 5th CIR. Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

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Illumina, Inc. has outstanding securities in the hands of the public, but no parent companies, subsidiaries, affiliates, or public companies own at least 10% of Illumina, Inc.'s stock.

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STATEMENT REGARDING ORAL ARGUMENT

Petitioners respectfully request that the Court grant oral argument in this antitrust case. The issues presented are novel and/or of considerable importance. Resolution of these issues depends on a proper understanding of the disputed claims, the relevant provisions of the U.S. Constitution and case law and a voluminous record. Oral argument will aid the Court in properly evaluating the case.

TABLE OF CONTENTS

Page

CERTIFICATE OF INTERESTED PERSONS i

STATEMENT REGARDING ORAL ARGUMENT iv

TABLE OF AUTHORITIES viii

CITATION ABBREVIATIONS xiv

GLOSSARY OF TERMS xv

JURISDICTIONAL STATEMENT 1

STATEMENT OF THE ISSUES 2

STATEMENT OF THE CASE 3

A. Illumina and Grail 5

B. The Transaction 7

C. The Open Offer 8

D. FTC's Challenge 9

E. The Decision 10

SUMMARY OF ARGUMENT 12

STANDARD OF REVIEW 15

ARGUMENT 16

I. THE COMMISSION EXCEEDED ITS AUTHORITY AND INFRINGED PETITIONERS' CONSTITUTIONAL RIGHTS. 16

A. The Commission Acted Under an Improper Delegation of Legislative Power. 16

B. The Commissioners Unconstitutionally Exercised Executive Powers While Insulated from Presidential Removal. 18

C. The Commission's Acts Violated Due Process. 23

D. The Commission Followed an Uncodified, Black-box "Clearance" Process Incompatible with Equal Protection. 26

II. THE COMMISSION ERRED IN DEFINING THE RELEVANT MARKET. 28

A. The Commission's "Market" Violates the Standard of Reasonable Interchangeability of Use and Cross-Elasticity of Demand. 30

B. The Commission's "Market" Satisfies Neither the *Brown Shoe* Market Factors nor the HMT. 34

C. The Commission's R&D Market Definition Is Baseless. 37

III. THE COMMISSION ERRED IN CONCLUDING THE TRANSACTION IS LIKELY TO SUBSTANTIALLY LESSEN COMPETITION. 39

A. The Commission's "*Brown Shoe* Standard" Misstates the Law and Ignores Undisputed Evidence. 41

B. The Commission Misapplied the "Ability-and-Incentive" Test, Elevating Possibilities Over Probabilities. 46

C. The Commission Failed To Account for the Real-World Effects from the Open Offer. 55

IV. THE COMMISSION ERRED IN IGNORING EFFICIENCIES REBUTTING ANY ALLEGATION OF HARM. 58

A. The Commission Applied the Wrong Legal Standard. 60

B. The Commission's Conclusions Lack Support in Substantial Evidence 64

C. The Commission Failed to Balance Efficiencies Against Alleged Harm 70

V. THE DECISION INJURED PETITIONERS AND SHOULD BE SET ASIDE IN ITS ENTIRETY 72

CONCLUSION 74

CERTIFICATE OF SERVICE 76

CERTIFICATE OF COMPLIANCE 77

TABLE OF AUTHORITIES

Page(s)

Cases

A.L.A. Schechter Poultry Corp. v. United States,
295 U.S. 495 (1935).....43

Aransas Project v. Shaw,
775 F.3d 641 (5th Cir. 2014) 15

Axon Enter., Inc. v. FTC,
143 S. Ct. 890 (2023).....17, 24

Bankers Life & Cas. Co. v. Crenshaw,
486 U.S. 71 (1988).....26

Brown Shoe Co. v. United States,
370 U.S. 294 (1962).....passim

Carr v. Saul,
141 S. Ct. 1352 (2021).....18

City of Arlington v. FCC,
569 U.S. 290 (2013).....20

Comcast Cable Commc'ns, LLC v. FCC,
717 F.3d 982 (D.C. Cir. 2013).....40

DISH Network Corp. v. NLRB,
953 F.3d 370 (5th Cir. 2020) 47, 51

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561 U.S. 477 (2010).....21, 22

Fruehauf Corp. v. FTC,
603 F.2d 345 (2d Cir. 1979) 39, 43, 44

FTC v. Arch Coal, Inc.,
329 F. Supp. 2d 109 (D.D.C. 2004).....passim

FTC v. Ind. Fed'n of Dentists,
476 U.S. 447 (1986).....15

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211 F. Supp. 2d 34 (D.D.C. 2002).....55

FTC v. RAG-Stiftung,
436 F. Supp. 3d 278 (D.D.C. 2020).....28, 34, 36

FTC v. Tenet Health Care Corp.,
186 F.3d 1045 (8th Cir. 1999).....58, 60

FTC v. Univ. Health, Inc.,
938 F.2d 1206 (11th Cir. 1991).....60

Gibson v. Berryhill,
411 U.S. 564 (1973).....23

Golden Gate Pharmacy Servs., Inc. v. Pfizer, Inc.,
No. C-09-3854 MMC, 2010 WL 1541257 (N.D. Cal. Apr. 16, 2010),
aff'd, 433 F. App'x 598 (9th Cir. 2011).....37

Heller v. Doe,
509 U.S. 312 (1993).....27

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295 U.S. 602 (1935).....19, 20, 21

Jacob Siegel Co. v. FTC,
327 U.S. 608 (1946).....15

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34 F.4th 446 (5th Cir. 2022).....10, 16, 17, 18

Jim Walter Corp. v. FTC,
625 F.2d 676 (5th Cir. 1980).....15

Ky. Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc.,
588 F.3d 908 (6th Cir. 2009).....37

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551 U.S. 877 (2007).....42

Mercantile Tex. Corp. v. Bd. of Governors of Fed. Rsrv. Sys.,
638 F.2d 1255 (5th Cir. 1981).....38, 44

Mistretta v. United States,
488 U.S. 361 (1989).....16

In re Murchison,
349 U.S. 133 (1955).....23

Myers v. United States,
272 U.S. 52 (1926).....19, 21

New York v. Deutsche Telekom AG,
439 F. Supp. 3d 179 (S.D.N.Y. 2020) 34, 60, 62, 63

Ohio v. Am. Express Co.,
138 S. Ct. 2274 (2018).....39

Pennzoil Co. v. FERC,
789 F.2d 1128 (5th Cir. 1986) 15

PSKS, Inc. v. Leegin Creative Leather Prods., Inc.,
615 F.3d 412 (5th Cir. 2010) 30

Republic Tobacco Co. v. North Atl. Trading Co.,
381 F.3d 717 (7th Cir. 2004) 40, 58

Romer v. Evans,
517 U.S. 620 (1996).....26

SCM Corp. v. Xerox Corp.,
645 F.2d 1195 (2d Cir. 1981) 34, 38

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531 U.S. 159 (2001).....43

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975 F.3d 507 (5th Cir. 2020) 47

Tenneco, Inc. v. FTC,
689 F.2d 346 (2d Cir. 1982) 35

Tennessee v. Lane,
541 U.S. 509 (2004).....26

TRW, Inc. v. NLRB,
654 F.2d 307 (5th Cir. 1981).....51

U.S. Steel Corp. v. FTC,
426 F.2d 592 (6th Cir. 1970).....46

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855 F.3d 345 (D.C. Cir. 2017).....62

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908 F.2d 981 (D.C. Cir. 1990).....57, 61, 63, 70

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353 U.S. 586 (1957).....28

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418 U.S. 602 (1974).....40, 42

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No. 1:22-cv-0481, 2022 WL 4365867 (D.D.C. Sept. 19, 2022).....55

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340 U.S. 474 (1951).....47

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574 F.3d 685 (9th Cir. 2009).....62

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142 S. Ct. 2587 (2022).....39

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579 U.S. 1 (2016).....23

Withrow v. Larkin,
421 U.S. 35 (1975) 23

Constitutional Provisions, Statutes & Rules

16 C.F.R. § 2.7 25

16 C.F.R. § 3.42 27

16 C.F.R. § 3.43 27

16 C.F.R. § 3.54 27

5 U.S.C. § 554 23

15 U.S.C. § 18 ..... 38, 40

15 U.S.C. § 21 15

15 U.S.C. § 25 27

15 U.S.C. § 45 ..... 16, 17, 18, 27

15 U.S.C. § 53 ..... 18, 27

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CITATION ABBREVIATIONS

ABBREVIATION	MEANING
AA	Amended Answer
CCB	Appeal Brief of Complaint Counsel concerning the Initial Decision
Conc.	Concurring Opinion of Commissioner Wilson
ID	Initial Decision of the Administrative Law Judge
IDF	Initial Decision Findings of Fact
Op.	Opinion of the Commission
Order	Final Order of the Commission
PX	Exhibit of Complaint Counsel (Respondent here)
Pre-Hearing Tr.	Transcript of the Final Pretrial Hearing
RAB	Answering Appeal Brief of Respondents Below (Petitioners here)
RFF	Proposed Findings of Fact of Respondents Below (Petitioners here)
RRFF	Proposed Reply Findings of Fact of Respondents Below (Petitioners here)
RPTB	Post-Trial Brief of Respondents Below (Petitioners here)
RX	Exhibit of Respondents Below (Petitioners here)
Tr.	Trial Transcript

GLOSSARY OF TERMS

ABBREVIATION	MEANING
Acquisition	Illumina's acquisition of the shares of Grail that it did not already own by a Merger Agreement dated August 18, 2021
ALJ	Administrative Law Judge, Chief Judge Chappell
CC	Complaint Counsel of the Federal Trade Commission
CSO	Cancer Signal of Origin
Decision	The Final Order or the Opinion of the Commission dated March 31, 2023
FTC	Federal Trade Commission
Commission	Commissioners of the Federal Trade Commission
Galleri	MCED Test developed by Grail
Grail	Grail, Inc. (now known as GRAIL, LLC)
Illumina	Illumina, Inc.
LDT	Laboratory Developed Test
MCED test	Multicancer Early Detection Test
Open Offer	Illumina's offer to oncology customers dated March 30, 2021 and amended September 8, 2021
Opinion	The Opinion of the Commission dated March 31, 2023
Order	The Final Order of the Commission dated March 31, 2023
PTD	Putative MCED test in development
Transaction	Illumina's acquisition of the shares of Grail that it did not already own by a Merger Agreement dated August 18, 2021

JURISDICTIONAL STATEMENT

This is an appeal from the Decision of the FTC in *In the Matter of Illumina, Inc. and Grail, Inc.*, Docket No. 9401, on March 31, 2023, which disposes of all claims with respect to all parties. Petitioners initiated this appeal by filing a petition for review under F.R.A.P. 15 and 15 U.S.C. § 45(c) on April 4, 2023.

STATEMENT OF THE ISSUES

At issue is whether FTC erred in finding Illumina's acquisition of Grail (the "Transaction") unlawful and ordering divestiture—specifically:

1. Whether the Commission exceeded its lawful authority and violated the U.S. Constitution, including Article I, Article II and the Due Process and Equal Protection Clauses of the Fifth Amendment;
2. Whether the Commission erred in defining the relevant product market to include speculative products that do not exist, may never exist and are not interchangeable;
3. Whether in finding the Transaction anticompetitive, the Commission applied the wrong test, ignored real-world facts and cherry-picked the record;
4. Whether the Commission evaluated the Transaction's efficiencies on a mistaken legal standard; and
5. Whether the Decision should be set aside in its entirety and judgment entered for Petitioners without remand.

STATEMENT OF THE CASE

This is a case of flagrant government overreach. FTC seeks to scuttle a merger between Illumina and Grail that will accelerate the adoption of a revolutionary cancer screening test, Galleri, that will save countless lives. Under a proper application of the antitrust laws, FTC should have cleared the deal long ago. For the first time decades, FTC's own ALJ found for the merging parties after presiding over a five-week trial. Had FTC approved the merger, commercialization of Grail's award-winning test would be greatly progressed today. Instead, FTC has gone to unprecedented lengths to kill the Transaction, even colluding with European regulators to evade scrutiny from Article III courts. FTC's actions have brought longstanding constitutional defects in the agency's structure and proceedings into sharp focus. Now that the case is before an Article III court, those defects should be quickly addressed so Illumina/Grail can make Galleri available to as many people as possible.

The Transaction at the heart of this case easily passes antitrust muster. It is a vertical merger between non-competitors: Illumina transformed genomic sequencing and Grail revolutionized cancer diagnoses using Illumina's sequencing platform. There is no possibility—much less probability—that the merged parties would or could engage in foreclosure. Not only would that make no economic sense, but also it is prohibited by binding supply agreements that Illumina has with its

customers. It is also defied by real-world evidence: Illumina has had a financial stake in Grail since it founded the startup in Illumina's laboratories in 2015, and FTC concedes there has been no evidence of foreclosure in all that time.

None of this is surprising. Courts have long recognized the benefits of vertical mergers. FTC itself recognized those benefits at the time Illumina and Grail agreed to the Transaction. U.S. Dep't of Justice & Fed. Trade Comm'n, *Vertical Merger Guidelines* 12 (June 30, 2020). The evidence so heavily favors Illumina and Grail that FTC's own ALJ ruled in their favor. That almost never happens, and it is a testament to overwhelming evidence supporting the Transaction. But the Commission snatched victory from the jaws of defeat and overruled its own ALJ in a thinly reasoned decision that misapplies basic principles of antitrust law and disregards overwhelming evidence showing that the merger is pro-competitive.

To make matters worse, the FTC proceeding violated fundamental constitutional protections. It violated Article I because FTC's administrative proceedings were an unconstitutional delegation of legislative power. It violated Article II because for-cause removal protections insulated the Commissioners from critical accountability to the President—and ultimately the people. It violated due process by depriving Illumina and Grail of a fair proceeding before an impartial tribunal. And it violated equal protection by leaving the possibility of review before DOJ (and ultimately a federal district court) subject to a random, uncodified "black-

box" clearance process. Nothing in the Clayton Act gives FTC unbridled authority to block transactions based on its own *ipse dixit* or "ephemeral possibilities."

Sometimes the price of an unconstitutional agency can be measured in lost dollars. This time, the price is lost lives. This Court should reverse the Commission's decision and render judgment for Illumina and Grail, clearing the way for them to continue their life-saving work together.

A. Illumina and Grail

Illumina is a global leader in next-generation sequencing ("NGS"), a technology that involves determining the "sequence" of the base pairs in genetic material. (IDF¶¶8, 521.) NGS may be used for many downstream applications, including cancer screening. (IDF¶¶6, 522.)

Illumina has been instrumental in the development and adoption of NGS technology, dramatically reducing the cost of NGS—from $10 million to sequence a full human genome in 2007 to less than $1,000 today. (IDF¶¶809-10.) By doing so, Illumina has expanded existing NGS applications and enabled new ones. (RFF¶¶849, 857, 861.)

In 2013, Illumina acquired a company called Verinata, expanding vertically into non-invasive prenatal testing ("NIPT"). (RX3337.1.) The acquisition not only increased competition and lowered prices (RX3864¶¶164-67), but also led to Grail's

founding after Illumina scientists discovered that genetic abnormalities in blood samples of pregnant women were signals of undiagnosed cancer. (Tr. 1868-74.)

Realizing that NGS could identify cancer signals in the blood, Illumina founded Grail in 2015 to develop a multi-cancer early detection ("MCED") test: a test that can identify multiple cancer types from a single blood sample. (IDF¶21.) Grail was so named because it represents the "Holy Grail" of cancer research. (IDF¶21.) Grail would require costly studies to prove whether the idea would work, and even then the clinical utility of such a test was uncertain. (IDF¶¶30-32.)

In 2017, Illumina spun off Grail to encourage outside investment to fund the large clinical trials needed to develop and validate its test. (IDF¶¶37-40.) But Illumina has always maintained a significant economic interest in Grail, holding an equity interest of at least 12%, and, from 2017 until its reacquisition of Grail in 2021, retaining the right to a significant, perpetual royalty from Grail's future oncology revenues. (IDF¶¶40-42.)

Through extensive research, Grail compiled an "atlas" of cancer signals in the blood and developed a machine learning platform to distinguish cancer signals from non-cancer signals to create a one-of-a-kind test called Galleri. (IDF¶¶213-31.) Galleri can simultaneously detect more than 50 cancer types in asymptomatic patients from a single blood draw and accurately localize cancer in positive cases.

(IDF¶¶228, 231.) In April 2021, Grail launched Galleri in the U.S. as a laboratory developed test ("LDT"). (IDF¶52.)

But Galleri's potential was limited with Grail operating independently. Galleri costs nearly $1,000 and is not covered by most insurers, making it inaccessible for many Americans. Galleri faces many challenges to achieve wide-scale commercialization, including obtaining regulatory approvals, payor reimbursement, and production/distribution at scale. (IDF¶¶169-70, 198-99, 258; Tr.1420-21.)

B. The Transaction

In September 2020, Illumina and Grail concluded that the best way to accelerate Galleri's adoption and unlock other efficiencies was for the companies to fully reunite.[1] (IDF¶58; Tr.2341-80, 2971.) As Grail's founder and a leader in NGS, Illumina is uniquely situated to help Galleri succeed.

The companies concluded that Illumina's full reacquisition of Grail would accelerate the widespread adoption of Galleri, realizing the true "Holy Grail" by reducing the cancer burden worldwide, saving thousands of lives and avoiding billions in healthcare costs. (RFF¶¶1121-1121.9.) With the elimination of Grail's

[1] The Transaction closed in 2021, but Illumina is required to hold Grail separate pending review by the European Commission ("EC"). Illumina has challenged the EC's jurisdiction, but has not yet been able to integrate Grail or achieve the many benefits of the Transaction. (IDF¶61.)

royalty, the elimination of double marginalization ("EDM"), and Illumina's ability to make Grail's supply chain and operations more efficient, Galleri will become cheaper and more accessible. (RFF¶¶1152-67.) Accelerating Galleri's availability to underserved populations domestically and abroad will ensure that Grail's genomic dataset is more representative and diverse, improving Galleri's performance and reducing health inequities. (Tr.2375-76.)

C. The Open Offer

After the Transaction was announced, Illumina contacted its NGS customers, including companies FTC alleges are Grail rivals, to assure them that the Transaction would not adversely impact their relationships with Illumina. (IDF¶¶513-14, 875-76.) Through these discussions, Illumina developed a binding 12-year supply commitment (the "Open Offer") memorializing the protections that the customers had requested, and more. (IDF¶¶875-86.)

Illumina announced the Open Offer in March 2021, and it took effect in August 2021. (IDF¶¶876, 888.) Any customer may sign until August 2027, and any Open Offer contract lasts until August 2033 (terminable at the customer's option). (IDF¶¶880-81, 888.) The Open Offer guarantees customers, *inter alia*, the ***same access*** to Illumina's sequencing products at the ***same price*** that Grail has, with guaranteed price reductions by at least 43% in the future. (IDF¶¶890, 915-29.) It also includes robust enforcement provisions, including compliance audits and

binding arbitration. (IDF¶978.) At the close of the record, ***ten*** companies—including three of the alleged MCED developers who testified at trial for FTC—had signed the Open Offer or supply agreements incorporating its terms. (IDF¶989; RFF¶1058.) As the ALJ found, the Open Offer constrains Illumina from foreclosing Grail's purported rivals. (ID.178.)

D. FTC's Challenge

Although it is widely recognized that vertical mergers are pro-competitive and rarely harm competition, FTC commenced litigation seeking to block (and later unwind) the Transaction. It did so even though Illumina founded Grail and has always had a significant interest in its success, and—as FTC counsel conceded—there is no evidence Illumina's ownership of Grail has ever actually harmed competition.

FTC initially sued in both an Article III court and its own administrative court, while coordinating with foreign antitrust authorities. But after the EC asserted jurisdiction, FTC withdrew its Article III case (just three months before the hearing), choosing instead to try its claim exclusively in administrative court, where it had not lost a merger challenge in decades and where it could rely on evidence that would never be admissible in an Article III court (*see* Section I.C). During a five-week trial, the ALJ heard from 66 witnesses and received more than 4,500 exhibits. (ID.2-3.) Finding Illumina's witnesses credible and many of FTC's witnesses unreliable

(ID.144-45, 147 & nn.30-31, 35), the ALJ dismissed the case, concluding—for the first time in any recent merger challenge—that FTC failed to meet its *prima facie* burden. (ID.2.)

The ALJ held that FTC failed to show that the Transaction may substantially lessen competition, including because it does not incentivize Illumina to harm any downstream customer, much less supposed MCED competition. (ID.172-78.) The ALJ's findings were based in significant part on his assessment of witness credibility. (ID.174-77.) The ALJ specifically found no credible evidence that a test comparable to Galleri was likely to launch in the foreseeable future. (ID.148-49.) Thus, the ALJ found that Illumina had no incentive to foreclose Grail's rivals. (ID.177-78.) The ALJ further found that "[t]he Open Offer constrains Illumina from using virtually any of the tools that FTC asserts will raise rivals' costs or otherwise foreclose Grail's alleged rivals." (ID.179.)

E. The Decision

The Commission disregarded the ALJ's findings, cherry-picked the record, and entered an order reiterating the allegations of its discredited complaint.

Specifically, the Commission (i) disregarded multiple constitutional defects tainting its challenge and dismissed *Jarkesy v. SEC* as wrongly decided; (ii) defined the relevant market to include tests not yet on the market, whose features and functions are unknown; (iii) ruled that the Transaction will substantially lessen

competition, though there is no evidence Illumina ever disadvantaged any purported Grail rival; (iv) rejected the Open Offer as legally irrelevant; and (v) ruled the Transaction's efficiencies are of no legal consequence.

SUMMARY OF ARGUMENT

In disregarding the ALJ's conclusions, and replacing them with the discredited allegations of its own complaint, the Commission not only made a decision that will slow the adoption of a life-saving cancer test, but also committed multiple reversible legal errors.

1. Unconstitutional Proceeding/Decision. This proceeding and the Decision it produced are constitutionally defective for multiple independent reasons. FTC's unbounded discretion to initiate proceedings before an administrative tribunal or federal court violates the core limits on the delegation of Article I power. The for-cause restriction on the President's power to remove FTC Commissioners violates Article II, given the vast executive power exercised by FTC today as compared to 1935. The Commission acted as prosecutor and judge of its own case, violating fundamental principles of due process. And FTC's clearance process arbitrarily subjected Petitioners to a materially disadvantageous administrative process (as compared to a federal court proceeding), in violation of the Equal Protection Clause.

2. Flawed Market Definition. The Decision should also be reversed because the Commission failed to properly define the relevant product market, a necessary element of its case. A properly defined product market comprises only products that are reasonably interchangeable. But FTC's market includes R&D

projects that are still in development, may never become commercial products and, even if they did, would be very different from Galleri. This made-up market satisfies neither the *Brown Shoe* factors nor the Hypothetical Monopolist Test, relying entirely on speculation about theoretical future products. FTC's claim that research and development efforts suffice to establish a relevant market is mistaken.

3. No Substantial Lessening of Competition. The ALJ found that FTC failed to show that the Transaction is likely to substantially lessen competition. The ALJ was uniquely qualified to reach that conclusion, having received testimony from 56 fact and 10 expert witnesses (including three former DOJ chief economists) and having reviewed an extensive documentary record. In overturning the ALJ, the Commission applied the wrong test for evaluating vertical mergers by diluting the standard of harm, relying on possibilities rather than probabilities and ignoring the Open Offer.

4. Rebuttal Evidence Including Life-Saving Efficiencies. Even if the Transaction would otherwise have had some anticompetitive effect, the alleged harm is easily outweighed by efficiencies, including that it will save many thousands of lives. While the ALJ found it unnecessary to reach efficiencies, the unrefuted evidence showed that the Transaction will accelerate regulatory approval and market access to Galleri; eliminate double margins and a royalty Grail otherwise owed; lead to supply-chain/operational efficiencies, enabling lower prices and faster testing; and

lead to new innovations. In dismissing these benefits, the Commission imposed a mistaken, double standard, while ignoring undisputed evidence.

5. Judgment for Petitioners. Given the fundamental constitutional defects in the Commission's proceeding and the Decision, and legal and evidentiary shortcomings of FTC's case in seeking to block the merger, the Decision should be set aside and judgment entered for Petitioners without remand.

STANDARD OF REVIEW

This Court conducts *de novo* review of questions of law, *Pennzoil Co. v. FERC*, 789 F.2d 1128, 1135 (5th Cir. 1986), and mixed questions of law and fact. *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454 (1986).

The Commission's factual determinations are reviewed under the "substantial evidence" standard. 15 U.S.C. § 21(c); *Jim Walter Corp. v. FTC*, 625 F.2d 676, 681 (5th Cir. 1980). That standard is not met where a factual finding "rests on an erroneous view of the law," *Aransas Project v. Shaw*, 775 F.3d 641, 658 (5th Cir. 2014); an agency fails to "take into account whatever in the record fairly detracts from" the evidence, including "determinations by the ALJ which differ from the agency's determination," *Pennzoil*, 789 F.2d at 1135; or an agency cherry-picks facts in the record, *Jim Walter Corp.*, 625 F.2d at 683.

The standard of review for remedies is "whether the Commission abused its discretion." *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 612 (1946).

ARGUMENT

I. THE COMMISSION EXCEEDED ITS AUTHORITY AND INFRINGED PETITIONERS' CONSTITUTIONAL RIGHTS.

As a threshold matter, the FTC proceeding, from start to finish, was tainted by fundamental constitutional defects, each of which renders that proceeding unconstitutional and requires the Commission's Decision be set aside.

A. The Commission Acted Under an Improper Delegation of Legislative Power.

Article I of the Constitution provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States." U.S. Const. art. I, § 1. Congress cannot delegate that power to an executive agency unless it "provides an 'intelligible principle' by which the [agency] can exercise it." *Jarkesy v. SEC*, 34 F.4th 446, 460-61 (5th Cir. 2022) (quoting *Mistretta v. United States*, 488 U.S. 361, 372 (1989)).[2] As *Jarkesy* held, a violation of that non-delegation doctrine independently warrants vacating the agency's decision. *Id.* at 462-63.

The FTC proceeding in this case suffers from the same constitutional defect identified in *Jarkesy*. Congress delegated to FTC the power to decide whether to bring antitrust enforcement actions in administrative proceedings rather than in an Article III court. *See* 15 U.S.C. §§ 45(b), 53(b). As this Court explained in *Jarkesy*,

[2] Recognizing this Court is bound by precedent, Petitioners preserve for Supreme Court review the argument that the "intelligible principle" standard should be replaced with a more constitutionally grounded standard.

the "power to assign disputes to agency adjudication" is a "legislative power." 34 F.4th at 461. Although the Commission dismissed this Court's precedent as if it were entitled to no respect (Op.88 n.71), *Jarkesy* is controlling here.

In addition, Congress did not provide FTC with an intelligible principle by which to exercise that power. *See Jarkesy*, 34 F.4th at 462. In *Jarkesy*, the Court held that Congress failed to provide an intelligible principle by granting the SEC "exclusive authority and absolute discretion to decide whether to bring securities fraud enforcement actions within the agency instead of in an Article III court" without "indicating how the SEC should make that call in any given case." *Id.* The same is true with respect to FTC—Congress gave FTC unfettered and unguided discretion to decide whether to bring antitrust enforcement actions in administrative proceedings instead of in Article III courts. *Cf. Axon Enter., Inc. v. FTC*, 143 S. Ct. 890, 897 (2023) (equating FTC and SEC authority in this respect). Indeed, the statutes authorizing SEC and FTC administrative proceedings are materially identical. *Compare* 15 U.S.C. § 78u-3(a) (authorizing SEC to bring administrative proceedings against "any person [who] is violating, has violated, or is about to violate" the securities laws), *with* 15 U.S.C. § 45(b) (authorizing FTC to bring

administrative proceedings against "any such person, partnership, or corporation [that] has been or is using any unfair method of competition").[3]

Thus, in electing to proceed administratively in this case, FTC acted under an unconstitutional delegation of legislative power. This case illustrates how unbounded that legislative authority is: FTC initially brought suit in federal court, and later simply dropped the federal court action and continued to litigate in its home administrative court. As in *Jarkesy*, that constitutional defect alone requires vacatur of the Decision. 34 F.4th at 459 n.9, 463.[4]

B. The Commissioners Unconstitutionally Exercised Executive Powers While Insulated from Presidential Removal.

The Commission proceeding and Decision also violated Article II. Under Article II, "the 'executive Power'—all of it—is 'vested in a President.'" *Seila Law LLC v. Consumer Fin. Prot. Bureau*, 140 S. Ct. 2183, 2191 (2020). Because

[3] The Commission purported to find an "intelligible principle" in the statutory prescription that FTC may "seek administrative enforcement when it 'would be in the interest of the public.'" (Op.89 (quoting 15 U.S.C. § 45(b)). But that same prescription appears in the statute authorizing actions in federal court. *See* 15 U.S.C. § 53(b)(2). It thus does not provide any guidance for purposes of deciding *between* administrative proceedings and federal court—the key issue here.

[4] The Commission's passing suggestion that Petitioners "waived" this issue is baseless. (Op.87.) The Article I defect here concerns a structural constitutional defect that need not be exhausted before the agency. *See Carr v. Saul*, 141 S. Ct. 1352, 1360-62 (2021). Regardless, Petitioners preserved their challenge by asserting a "separation of powers" defense and raising an Article-I-non-delegation objection with the ALJ days after *Jarkesy* was decided, and with the Commission before it ruled. (AA.35; RPTB.130-31; RAB.41-42.)

principal executive officers "must remain accountable to the President, whose authority they wield," the President's executive power includes "appointing, overseeing, and controlling" such officers. *Id.* at 2197. And that power "generally includes the ability to remove" such officers on an "unrestricted" basis, as "has long been confirmed by history and precedent." *Id.* at 2197-98; *see Myers v. United States*, 272 U.S. 52, 163-64 (1926).

In 1935, the Supreme Court broke ranks with that history and precedent, and upheld the constitutionality of a provision insulating FTC Commissioners from removal by the President absent "inefficiency, neglect of duty, or malfeasance." *Humphrey's Executor v. United States*, 295 U.S. 602, 623-32 (1935). As the Supreme Court has subsequently admonished, however, that holding rested on the premise that FTC—"as it existed in 1935"—exercised "'no part of the executive power.'" *Seila Law*, 140 S. Ct. at 2198 (quoting *Humphrey's Executor*, 295 U.S. at 628). Instead, the Court reasoned, FTC in 1935 exercised *only* "quasi-legislative or quasi-judicial powers"—*i.e.*, "'making investigations and reports' to Congress" and "making recommendations to courts as a master in chancery." *Id.* at 2198-99 (quoting *Humphrey's Executor*, 295 U.S. at 628). As the Supreme Court has clarified, *Humphrey's Executor* thus established only a narrow "exception" for multimember expert agencies that "perform legislative and judicial functions" and do not exercise "any executive power." *Id.* at 2199.

But as the Court in *Seila Law* recognized, that characterization of FTC "has not withstood the test of time": "under our constitutional structure," the "activities of administrative agencies … *must be* exercises of[] the 'executive Power.'" 140 S. Ct. at 2198 n.2 (quoting *City of Arlington v. FCC*, 569 U.S. 290, 305 n.4 (2013)). Accordingly, the Court in *Seila Law* made clear that *Humphrey's Executor* represents "'the outermost constitutional limit[]'" and should not be extended beyond FTC "as it existed in 1935" and "the set of powers [*Humphrey's Executor*] considered as the basis for its decision." *Id.* at 2198, 2200 & n.4. In so holding, the Court recognized the 1935 FTC may have "possessed broader rulemaking, enforcement, and adjudicatory powers than the *Humphrey's* Court appreciated." *Id.* at 2200 n.4. But that is beside the point—"what matters is the set of powers the Court considered [in *Humphrey's Executor*] as the basis for its decision." *Id.*

The modern FTC is a different animal from the "quasi-legislative or quasi-judicial" body the Supreme Court considered in *Humphrey's Executor*. *See* Daniel A. Crane, *Debunking* Humphrey's Executor, 83 GEO. WASH. L. REV. 1835, 1859-68 (2015). As this case illustrates, FTC today operates primarily as an enforcement agency—bringing suit in both administrative proceedings and federal court for injunctive and monetary relief—that bears no resemblance to the "quasi-legislative or quasi-judicial" body described in *Humphrey's Executor*. The Commission does not deny this. Its Decision proclaimed that it exercised "[t]he federal government's

prosecutorial enforcement" powers, which fall "'exclusive[ly]'" within "the Executive Branch." (Op.87-88 (citation omitted).) Whatever powers FTC possessed in 1935, the divestiture power invoked by FTC in this case—forcing Petitioners to unwind a multi-billion dollar transaction designed to promote the widescale access to a revolutionary cancer test—was not among "the set of powers [*Humphrey's Executor*] considered." *Seila Law*, 140 S. Ct. at 2200 n.4.

Because FTC today is fundamentally different from the "quasi-legislative or quasi-judicial" body described in *Humphrey's Executor*, *Seila Law* compels the conclusion that *Humphrey's Executor* does not control the removal question presented by this case. *Seila Law*, 140 S. Ct. at 2198, 2200 & n.4. Instead, the traditional limits on restricting the President's power to remove executive officers, including the Court's decision in *Myers* invalidating a for-cause removal restriction on executive officers, 272 U.S. at 163-64, controls. *See Free Enter. Fund v. PCAOB*, 561 U.S. 477, 483, 492-93 (2010). FTC Commissioners' insulation from accountability and removal by the President today is therefore unconstitutional.[5]

That constitutional violation warrants not only striking the statutory removal protection but also vacating FTC's Decision. By limiting the President's authority

[5] To the extent the Court concludes that *Humphrey's Executor* is controlling, Petitioners preserve the argument that the Supreme Court should overrule *Humphrey's Executor*.

over members of the Commission, and thus the Commission itself, that statutory provision unconstitutionally permits FTC to act without "accountab[ility]" to the President. *Seila Law*, 140 S. Ct. at 2198 (quoting *Free Enter. Fund*, 561 U.S. at 483). While it would be difficult to prove in any case how the President may have acted if he were not restricted by an understanding rooted in a 90-year-old Supreme Court decision, the high-profile merger at issue in this case—involving a revolutionary cancer screening test that could save millions of lives—is precisely the kind of situation in which the absence of presidential accountability and oversight translates into prejudice. Unlawful removal restrictions not only restrict the President's ability to act, but also limit the political accountability that the people may exert to prompt presidential action.[6] FTC's actions here have, in fact, elicited a strong public reaction, underscoring that political—and presidential—accountability could and likely would have tipped the scales in this case.[7]

[6] Petitioners were not required to raise or develop this argument before the Commission, which lacks institutional "competence" to adjudicate the structural constitutional issue raised by Petitioners, *Free Enter. Fund*, 561 U.S. at 491, and has an inherent bias against at-will presidential removal.

[7] *E.g.*, John Tamny, *Lina Khan Blocks Cancer Cures*, WALL STREET J. (Apr. 27, 2023) ("Illumina's acquisition of Grail would save lives, and it's crazy for the FTC to call it a monopoly."); Editorial Board, *The FTC's Unholy Antitrust Grail*, WALL STREET J. (Apr. 3, 2023) ("Ms. Khan seems to be trying to make an example out of Illumina … . The tacit message to other businesses is don't dare consummate a merger that the agency challenges."); Alden Abbott, *When Bad Antitrust Costs Lives: The Illumina/GRAIL Tragedy*, TRUTH ON THE MARKET (Apr. 4, 2023); Alex

C. The Commission's Acts Violated Due Process.

The Commission also violated due process by exercising investigative, prosecutorial and adjudicative powers in the same case, in a manner that rode roughshod over Petitioners' rights. "A fair trial in a fair tribunal is a basic requirement of due process." *In re Murchison*, 349 U.S. 133, 136 (1955). This requirement applies to any adjudicative body, including administrative tribunals. *Gibson v. Berryhill*, 411 U.S. 564, 579 n.17 (1973). Not only is a biased decisionmaker constitutionally unacceptable, but our legal system has "always endeavored to prevent even the probability of unfairness." *In re Murchison*, 349 U.S. at 136. While combining investigative, prosecutorial and adjudicative functions does not necessarily violate due process, *Withrow v. Larkin*, 421 U.S. 35, 58 (1975), it does where "the probability of actual bias on the part of the judge or decision-maker is too high to be constitutionally tolerable." *Id.* at 47.[8] "[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).

Reinauer, *Secondhand Antitrust: FTC Continues to Bully Industries that Can Save Lives*, COMPETITIVE ENTER. INST. (Apr. 5, 2023).

[8] Congress recognized in the APA the general principle that the same person may not "engage[] in the performance of investigative or prosecuting functions" and also "participate or advise in the [agency] decision." 5 U.S.C. § 554(d)(2). Congress's general statutory exemption of "members of the body comprising the agency," *id.* § 554(d)(2)(C), cannot cure the constitutional due process error if (as here) FTC Commissioners combine these functions in a biased manner.

The potential for unconstitutional bias here is intolerable. The Commission voted out the complaint after investigation, directed its prosecution and then passed judgment in overruling the ALJ—playing the roles of "investigator, prosecutor, and judge." *Axon*, 143 S. Ct. at 917 (Gorsuch, J., concurring). "The numbers reveal just how tilted this game is …. [S]ome say the FTC has not lost an in-house proceeding in 25 years." *Id.*[9] And, as this case shows, when lightning does strike before an ALJ, the Commission is standing in the wings to snatch victory from the jaws of that rare FTC defeat. This patently biased and one-sided regime, constrained only by after-the-fact, appellate-style judicial review in which an agency may hide behind claims of deference, is unconstitutional. *See id.* at 909-10 (Thomas, J., concurring).

The proceeding here (including the black-box clearance process describe below) epitomizes the constitutional flaws of this biased scheme. Throughout its investigation and legal proceedings, FTC comported itself in procedurally irregular ways to deprive the parties of a fair hearing before a neutral judge. For example, in what four U.S. Senators described as "outsourcing of U.S. competition policy to foreign entities," FTC colluded with the European Commission to undermine the

[9] An analysis of FTC merger challenges from 1956 to 1992 found: the "ability of commissioners to act as both prosecutor and judge in a particular matter can significantly increase the likelihood of a merger order." (RFF¶1197.2.) A former FTC Commissioner described FTC's remarkable win record as "a strong sign of an unhealthy and biased institutional process." (RFF¶1197.5.)

normal process of U.S. merger enforcement and deprive the parties of a hearing before an Article III judge. Letter from Senator Bill Hagerty et al. to Secretary Antony Blinken et al. (Oct. 20, 2022), https://shorturl.at/adEF3.

FTC then pursued its own protracted administrative proceedings where it had home-court advantage and presumably assumed it would prevail. Instead, in an unprecedented decision showing the fundamental flaws in FTC's case, FTC's ALJ rejected the Commission's merger challenge following a month-long trial in which he heard the testimony of numerous witnesses firsthand. But that did not stop the Commission. In nevertheless reversing the ALJ, the Commission disregarded the ordinary rules of evidence and belied any appearance of a neutral factfinder.

As the ALJ acknowledged, the Commission rules were designed to prevent him from applying the Federal Rules of Evidence. (Pre-Hearing Tr.66 ("[T]he rules were changed after I came to the [FTC] because of rulings I continually made applying [the] Federal Rule[s] of Evidence.").) And the Commission took full advantage of that on appeal. For example, the Commission: relied on nonparty testimony given in proceedings that neither Petitioners nor their counsel were permitted to attend (*e.g.*, Op.30 (citing PX7051, PX7043)), 16 C.F.R. § 2.7(f)(3), and would be inadmissible in Article III proceedings, Fed. R. Civ. P. 32(a)(1)(A); relied on deposition testimony even when the witness testified in the administrative trial or was otherwise available to testify (Op.70 (citing PX7109, PX7110,

PX7113)), which would not be permitted in an Article III court, Fed. R. Civ. P. 32(a)(4); relied on documents even if no witness testified about them (*e.g.*, Op.14, 30 (citing PX4018, PX4450); RRFF¶¶3438, 3295-96); relied on an economist (Op.59) who was found unqualified by the ALJ who heard her testimony (ID.147 n.35); refused to consider evidence from FTC's own witnesses when it contradicted FTC's theory of the case (Op.56-57 n.38); and eliminated the only independent check on its bias by overriding the findings of its own ALJ, who has more than twenty years' experience in merger cases. Rather than respect his detailed findings, the Commission reversed them, without observing a single trial witness firsthand. Due process requires more.

D. The Commission Followed an Uncodified, Black-box "Clearance" Process Incompatible with Equal Protection.

The assignment of the review of this merger to FTC, rather than DOJ, lacks any rational basis and therefore violates Petitioners' equal protection rights, too. Under the Equal Protection Clause, "[t]he guaranty of equal protection of the laws is a pledge of the protection of equal laws." *Romer v. Evans*, 517 U.S. 620, 633-34 (1996) (citations omitted). Thus, the Equal Protection Clause protects against "arbitrary and irrational discrimination" by the Government, *Bankers Life & Cas. Co. v. Crenshaw*, 486 U.S. 71, 83 (1988), and demands that "all persons similarly situated should be treated alike," *Tennessee v. Lane*, 541 U.S. 509, 522 (2004) (citation omitted). Differential 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." *Heller v. Doe*, 509 U.S. 312, 320 (1993). The record demonstrates precisely such a disconnect here.

The review of this merger was arbitrarily assigned to FTC, which treated Petitioners very differently than if their merger had been reviewed by DOJ. For example, FTC may challenge a merger in an administrative forum, enjoying adjudication by the same body that voted to bring the complaint and directed its prosecution, which can then reverse an ALJ's decision and demand deference to its supposed "findings" when that reversal reaches Article III appellate review. 15 U.S.C. §§ 45(b), 53(b); 16 C.F.R. §§ 3.42(a), 3.54(b). By contrast, DOJ can only challenge a merger in federal court, where fact findings are made *de novo* by an Article III judge, and those findings cannot simply be discarded by another body that did not observe a single witness, as here. 15 U.S.C. § 25. Additionally, FTC's administrative tribunal applies its own evidentiary rules, 16 C.F.R. § 3.43, whereas the Federal Rules of Evidence apply in litigation by DOJ, *see* 15 U.S.C. § 25. All this can dramatically change the nature—and outcome—of a proceeding based solely on which agency brings it.

There is no rational basis for these stark, potentially outcome-determinative differences. Yet the choice of whether a merger review (and any subsequent challenge) is conducted by DOJ or FTC is decided by the agencies through an

informal, non-public, unwritten "clearance" process. (RFF¶1210.) At times, this is accomplished by a mere coin flip. (RFF¶1211.) The agencies generally allocate mergers between them by industry based on past practice, which is entirely arbitrary (RFF¶1214) and provides no rational basis for why particular industries (such as healthcare, here) receive lesser procedural protections than others. The arbitrary assignment of the Illumina-Grail merger to FTC had no rational basis and therefore violated Petitioners' equal protection and due process rights.

II. THE COMMISSION ERRED IN DEFINING THE RELEVANT MARKET.

In addition to suffering from constitutional defects, the Decision fails because it lacks any legally sustainable market definition. To prove a *prima facie* case, 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). If FTC fails to carry this burden, judgment must be entered for Petitioners. *See FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 291 (D.D.C. 2020). Because it is impossible to assess properly whether a transaction is likely to result in harm to competition without defining the market, the Clayton Act proscribes only mergers that will substantially lessen competition "within the area of effective competition." *United States v. E.I. DuPont de Nemours & Co.*, 353 U.S. 586, 593 (1957).

Faced with the reality that Galleri is the *only* test on the market that detects multiple cancers through a single blood draw, the Commission defined an

unprecedentedly broad and speculative market: the supposed market for the "research, development, and commercialization of MCED tests." (Op.34.) The Commission's market includes any test that purports to detect more than one cancer, regardless of the test's features, regardless of whether the test is in concept or has been validated by clinical studies (the sequential life cycle phases of a medical diagnostic are concept, feasibility, analytical validation, clinical validation, and commercialization, and many products fall off between steps) (ID.144-45; RFF¶¶707.1-707.3), and regardless of how close the test is to being on the market or whether it even makes it to the market. The Commission identified Galleri and a handful of putative tests in development ("PTDs")—none of which is commercially available—as market participants. (Op.3.)

The Commission's market definition fails to satisfy the government's burden for three reasons. *First*, the Commission discarded the foundational market definition rules announced by the Supreme Court in *Brown Shoe*, namely that the outer bounds of the market must be based on reasonable interchangeability. *Second*, the Commission failed to properly apply the market definition tests adopted by the courts and ignored key evidence that contradicted its market definition. *Third*, the Commission used invented market definition principles to define an R&D market that is inconsistent with precedent and designed for only one purpose—to ensure the Commission can block almost any merger. The Commission's errors result in an

overbroad market that does not properly analyze the impact of the Transaction. Accordingly, the Commission's market definition should be rejected and the Decision reversed.

A. The Commission's "Market" Violates the Standard of Reasonable Interchangeability of Use and Cross-Elasticity of Demand.

"The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962). An overbroad market that contains products that are not reasonably interchangeable is legally erroneous and must be rejected. *See PSKS, Inc. v. Leegin Creative Leather Prods., Inc.*, 615 F.3d 412, 418 (5th Cir. 2010). Speculation about future substitutability cannot prove a relevant market. *See Arch Coal*, 329 F. Supp. 2d at 116 ("[A]ntitrust theory and speculation cannot trump facts[.]"). The Commission's supposed market violates these principles and should be rejected.

The reasonable interchangeability inquiry requires a careful comparison of Galleri and its supposed substitutes in the proposed market. The Commission did no such thing. Instead, the Commission cherry-picked the evidence and relied on the testimony of an economist with no experience in the relevant industries to assert that *any* test (or test in development) that purports to detect more than one cancer through a blood draw is in the same market. (Op.3, 29-30.) In doing so, the

Commission ignored fundamental differences between Galleri and tests in development that—if they are ever launched—would do very different things.

Contrary to the Decision—and as the ALJ found—there is no evidence of reasonable interchangeability of use, currently or in the foreseeable future, between Galleri and the PTDs. (ID.145.) Galleri is on the market and has been since April 2021. (IDF¶¶52, 201.) Its features are known, and its performance tested and validated in clinical studies and in the real world: its operative biomarkers, its sensitivity and specificity, the number of cancer types it detects (more than 50), and its ability to localize the identified cancer. (IDF¶¶209, 231.) These performance characteristics drive physicians' decisions to order a test. (IDF¶¶206-07.)

By contrast, the record provides no evidence of the above performance characteristics, which would drive physician decisions, for five of the seven PTDs. (IDF¶¶338-41, 361-67, 398-402, 434-44, 468-71.) For the other two, Exact and Singlera, there is record evidence for only a subset of these attributes. (ID.146.) However, these two PTDs are years from coming to market (if they ever do): Singlera acknowledged it is 7-10 years away from launch (ID.143-44), and Exact's CEO stated publicly in January 2023 that the launch timeline for its PTD was "unknown" and it would be "a number of years" before any market developed (RX4067.9)—facts the Commission refused to consider (Op.56-57 n.38), in violation of Petitioners' due process rights (*see supra* Part I.C).

It is undisputed that the Commission's market would include tests that share none of Galleri's features and would never be interchangeable with it. For example, Galleri tests for cancer with a blood test alone, whereas others require a full body scan after receiving at least one positive test result. Under the Commission's market, a test that detects only two cancer types, and cannot localize the cancer, would be interchangeable with a test that detects 50 cancer types and can pinpoint where in the body the cancer is located to help direct physicians' follow-up care, as Galleri does. (Op.29-30.)

There is no evidence in the record to show that the PTDs and Galleri are reasonably interchangeable. The only qualified experts to testify on the subject, Drs. Cote and Abrams, explained that Galleri is very different from the PTDs and no reasonable substitute to Galleri is expected in the foreseeable future. (ID.144-45.) The ALJ found these experts qualified and agreed with their conclusions. (ID.144-45 & nn.30-31.) FTC could have called medical or scientific experts to address these issues. It could have developed evidence about the preferences and likely switching behavior of clinicians related to the products it includes and excludes from its alleged market. It did neither. Instead, it relied on its economics expert and witnesses affiliated with the PTDs. But as the ALJ found, "Dr. Fiona Scott Morton's qualifications to give opinions for this case are minimal. … [She] is not an expert in MCED tests, clinical trials, any field of chemistry or biological studies, or cancer

screening technologies; nor is she a biochemist, molecular biologist, pathologist or medical doctor." (ID.147 n.35.) As for the PTDs, although it was said some had a test in development that would be commercialized in a matter of months (Tr.1625; Tr.354-55), none of Grail's potential rivals has released a test in the two years since trial (Op.25) (noting no Galleri rivals have launched).

Without evidence that the PTDs are reasonable substitutes with Galleri, the Commission resorts to denigrating Galleri, stating it lacks certain regulatory approvals and can identify only seven cancer types and may require a follow-up scan. (Op.54-56.) Even if all this were true (and it is not) none of it changes the fact that Galleri is not a substitute for the other PTDs. The Commission disregarded the undisputed evidence that Galleri is the only cancer test that has demonstrated the ability to detect more than 50 types of cancer in clinical trials, with a highly accurate feature to localize cancer. (IDF¶231.) It ignored that Galleri is the only MCED test with approval from the New York State Department of Health, considered the highest state regulatory bar for an LDT, and was reviewed by the FDA as part of multiple investigational device exemption applications, in which the FDA allowed Grail to report out all cancer type information that Galleri generated. (Tr.3306, 3318, 3440.) And it distorted the record to conclude that Galleri's results require diagnostic confirmation. Unlike Exact's PTD, which requires a ***full-body*** PET-CT scan for every positive case, and even beyond that, may require additional biopsies

to further characterize the cancer (IDF¶¶294-95), Galleri generally does not require a full-body scan, and only requires a targeted workup for a particular organ/region (Tr.1387-88).

Even if (hypothetically) a PTD were to become a substitute for Galleri, there is no dispute that such an event is, at least, years in the future, rendering the Decision unduly speculative. Developing an MCED test is challenging, requiring many years of development and validation, and even then, virtually all efforts to develop MCED tests have been unsuccessful. (ID.144-45.) As the ALJ found, even if the putative Grail rivals were among the rare MCED developers who are ultimately successful, commercial PTDs are at least five to seven years away from launching any MCED test. (ID.144-45.) Accordingly, the alleged harm is neither probable nor imminent. *See SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1211 (2d Cir. 1981).

B. The Commission's "Market" Satisfies Neither the *Brown Shoe* Market Factors nor the HMT.

Courts use two approaches to define a relevant product market. *First*, many courts have looked to the "practical indicia" of *Brown Shoe*, 370 U.S. at 325, to determine whether a proposed market is accurate. In addition, typically in horizontal mergers, courts apply the hypothetical monopolist test ("HMT"). *See RAG-Stiftung*, 436 F. Supp. 3d at 293; *New York v. Deutsche Telekom AG*, 439 F. Supp. 3d 179, 204 (S.D.N.Y. 2020). Under either test, "[t]he analysis begins by examining the most narrowly-defined product or group of products," and if that narrow grouping

does not constitute a relevant product market, the analysis shifts "to the next broadest product grouping." *Arch Coal*, 329 F. Supp. 2d at 120. In reviewing the Commission's application of these tests, this Court need not defer to these findings where they are the result of ignoring and cherry-picking the evidence in the record. *See Tenneco, Inc. v. FTC*, 689 F.2d 346, 357 (2d Cir. 1982). As explained below, FTC failed to meet the requirements for either test.

Brown Shoe: Under the Supreme Court decision in *Brown Shoe*, a court must assess the following factors to determine whether a proposed market is sound: "industry or public recognition of the [market] as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." 370 U.S. at 325. While paying lip service to them, the Commission did not properly apply the *Brown Shoe* "practical indicia."

As a threshold matter, the Commission failed to start with "the most narrowly-defined product or group of products." *Arch Coal*, 329 F. Supp. 2d at 120. Instead, it focused on a non-issue: whether MCEDs are distinct from single-cancer screening or non-screening oncology tests. (Op.26.) The question is not whether MCEDs are different from single-cancer screening or non-screening oncology tests, but rather whether Galleri is different from other purported MCEDs. By failing to conduct that analysis, the Commission failed to meet its burden to define the

narrowest market. *Arch Coal*, 329 F. Supp. 2d at 120. That alone is a basis to reject the Decision.

Even if the Commission had started in the appropriate place, it still failed to properly analyze the *Brown Shoe* factors. It mentioned two factors, "peculiar characteristics and uses" and "distinct customers," only to differentiate MCED tests from single-cancer and non-screening oncology tests (Op.26-27), not (as the Commission was required to do) to show that Galleri and the PTDs are in the same market. It suggested all MCED tests share "distinct prices" and similar "sensitivity to price changes" (effectively one factor) because MCED tests must be priced low enough to achieve adoption and other MCED test developers "expect" their tests to compete on price with Galleri (Op.27-28), yet it ignored the ALJ's finding that "the prices of yet-to-be marketed MCED tests have not yet been determined." (IDF¶205.) It claimed the "industry recognition" factor is met because Grail has described other MCED developers as "key competitors" (Op.28-29), ignoring that there is a high degree of uncertainty as to what these PTDs will look like if they ever launch. (RX6004.21-22.)

HMT: The HMT asks whether a hypothetical monopolist of the alleged product market could "profitably impose … a small but significant and non-transitory increase in price" ("SSNIP"). *RAG-Stiftung*, 436 F. Supp. 3d at 293. The Commission found that FTC did not marshal the data necessary to conduct a HMT

and did not apply the HMT in its Decision. (Op.29 n.15.) Accordingly, the Commission's market definition cannot be justified under the HMT.

C. The Commission's R&D Market Definition Is Baseless.

Unable to justify its "market" based on *Brown Shoe* or the HMT, the Commission attempted to sidestep these requirements by claiming it is sufficient that a number of companies are exploring the development of MCED tests and have described one another as competitors. (Op.30-34.) But describing other firms as competitors does not "provide a sound economic basis for assessing the market … the way that a proper interchangeability test would." *Ky. Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc.*, 588 F.3d 908, 919 (6th Cir. 2009). That is especially true here, where there is such a "high degree of uncertainty" as to what these putative tests will look like, such that identifying other firms as competitors is "not really enough … to reliably tell us what the market boundaries are going to be." (RX6004.21-22.)

Regardless, the law does not set a different standard for establishing an R&D market. *See Golden Gate Pharmacy Servs., Inc. v. Pfizer, Inc.*, No. C-09-3854 MMC, 2010 WL 1541257, at *1, *3 (N.D. Cal. Apr. 16, 2010) (rejecting proposed market definition that failed to sufficiently allege interchangeability "both in the pharmaceutical product markets and in the innovation market for pharmaceutical products"), *aff'd*, 433 F. App'x 598 (9th Cir. 2011). Nor is there any basis to define

a relevant antitrust market based on the fact that firms are working toward a general objective (*e.g.*, developing a cancer screening test). *First*, the Clayton Act was "intended to allow courts to appreciate immediately the potential consequences that a particular acquisition might have upon an *existing line of commerce*[]," *SCM Corp.*, 645 F.2d at 1211 (citing *Brown Shoe*, 370 U.S. at 323-25) (emphasis added). *Second*, to assess competitive effects of a merger, courts do not consider entry that will not occur within two to three years.[10] *Mercantile Tex. Corp. v. Bd. of Governors of Fed. Rsrv. Sys.*, 638 F.2d 1255, 1272 (5th Cir. 1981). The Commission's market definition contravenes these well-settled principles, resulting in a grossly overbroad market.

In defining the market as it does, the Commission exceeded its clearly delegated powers. The Clayton Act prohibits mergers that, among other things, affect "any line of commerce" or "activity affecting commerce," in accordance with the market definition principles developed by the courts. 15 U.S.C. § 18. The Commission may not seek to block a merger where it has not defined the market based on principles of reasonable interchangeability. *Brown Shoe*, 370 U.S. at 325. By failing to do so here, and instead inventing a legally erroneous R&D market, FTC

[10] None of the alleged Grail rivals has entered in the nearly two years since trial. (Op.25.)

exceeded its mandate and exercised transformational regulatory power without Congressional authority. *See West Virginia v. EPA*, 142 S. Ct. 2587, 2608 (2022).[11]

III. THE COMMISSION ERRED IN CONCLUDING THE TRANSACTION IS LIKELY TO SUBSTANTIALLY LESSEN COMPETITION.

In addition to failing to define a legally cognizable antitrust market, the Commission erred in reversing the ALJ's decision that FTC failed to prove that the Transaction is anticompetitive. The Commission claims the Transaction is unlawful under "two different but overlapping standards": what it calls the *Brown Shoe* "share of the market foreclosed" standard, and the "ability and incentive framework." (Op.40-41.) But neither standard applied by the Commission reflects the law or finds support in substantial evidence.

Antitrust law makes a fundamental distinction between vertical mergers, such as the Transaction, and horizontal mergers. A horizontal merger eliminates a competitor from the market, and therefore, by definition, increases concentration. *Fruehauf Corp. v. FTC*, 603 F.2d 345, 351 (2d Cir. 1979). In contrast, a vertical merger between a supplier (here, Illumina) and a customer (here, Grail) does not eliminate a competitor from either the upstream or downstream market. *Id.* To the

[11] In addition to mis-defining the "relevant product market," the Commission erred in not defining a "related product market." While the Commission says it was unnecessary to do so (Op.35-36), determining market power necessarily requires defining a related product market based on the principles of substitution. *See Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2285 (2018).

contrary, vertical mergers tend to "encourage product innovation, lower costs for businesses, and create efficiencies—and thus reduce prices and lead to better goods and services for consumers." *Comcast Cable Commc'ns, LLC v. FCC*, 717 F.3d 982, 990 (D.C. Cir. 2013) (Kavanaugh, J., concurring). For this reason, antitrust policymakers believe "most vertical mergers are procompetitive," 4A Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ch. 10A-1 (5th ed. 2021); government enforcers have concluded that "non-horizontal mergers are less likely than horizontal mergers to create competitive problems," U.S. Dep't of Justice, *Non-Horizontal Merger Guidelines* § 4.0 (June 14, 1984); and courts have "cautio[ned] about importing relaxed standards of proof from horizontal agreement cases into vertical agreement cases. To do so might harm competition and frustrate the very goals that antitrust law seeks to achieve." *Republic Tobacco Co. v. North Atl. Trading Co.*, 381 F.3d 717, 737 (7th Cir. 2004).

Because the Transaction is purely vertical, the Commission "cannot use a short cut to establish a presumption of anticompetitive effect." *United States v. AT&T, Inc.* (*AT&T II*), 916 F.3d 1029, 1032 (D.C. Cir. 2019). On the contrary, to block the Transaction, FTC was required to prove that it is *likely* to cause *imminent* and *substantial* harm to competition in a relevant market. 15 U.S.C. § 18; *see Brown Shoe*, 370 U.S. at 325 (FTC must show there is a "reasonable probability that the merger will substantially lessen competition"); *United States v. Marine Bancorp.*,

418 U.S. 602, 623 n.22 (1974) ("[R]emote possibilities are not sufficient[.] … Rather, the loss of competition which is sufficiently probable and imminent is the concern of § 7." (citations omitted)).

Yet, the Commission based its decision on possibilities instead of probabilities, disregarding the plain language of the statute, the great weight of authority and the overwhelming evidence. The Commission's "*Brown Shoe* standard" is legally wrong, and an appropriate *Brown Shoe* analysis supports the Transaction. (§ III.A.) While the "ability-and-incentive" test may be the right legal standard, the Commission misapplied the test, and the ALJ's factual findings demonstrate why the Transaction does not harm competition. (§ III.B.) The Commission then committed an additional legal error in finding substantial harm to competition without accounting for the Open Offer as part of its *prima facie* case. (§ III.C.)

A. The Commission's "*Brown Shoe* Standard" Misstates the Law and Ignores Undisputed Evidence.

Citing *Brown Shoe* and its progeny, FTC argued that it met its prima facie burden merely by showing that Illumina controls an important input (its NGS products) to MCED development—that is, that Illumina has the *ability* (even without the incentive) to harm putative Grail rivals. (CCB.8.) Although the Commission purported to apply certain factors identified in *Brown Shoe*, it improperly reduced the burden on FTC by permitting speculation about the mere possibility of

theoretical harm, rather than requiring evidence of probable, substantial and imminent harm. (Op.42.)

Nothing in *Brown Shoe* supports the standard the Commission ascribes to it. There, the Supreme Court considered a horizontal and vertical merger between a leading shoe manufacturer and the largest independent shoe retailer. 370 U.S. at 331-35. While the Court held the government met its burden in that instance, the Court made clear that vertical mergers may stimulate competition and must be viewed in the context of the particular industry. *Id*. at 319, 321-22. Contrary to the Commission's characterization, *Brown Shoe* is clear that the Clayton Act is not concerned with "ephemeral possibilities." *Id*. at 323. Rather, it requires examining the "*probable effects* of the merger upon the economics of the particular markets affected." *Id.* at 333 (emphasis added). Thus, to prove a merger unlawful, FTC was required to show a reasonable *probability* that the Transaction may substantially lessen imminent competition. *Id*. at 325; *Marine Bancorp.*, 418 U.S. at 623 n.22. *Possibilities* are insufficient.

By focusing on possibilities alone, the Commission violated well-settled law that the government *cannot* use a "short cut" to presume anticompetitive effects from vertical mergers. *AT&T II*, 916 F.3d at 1032. It flouted modern precedent eschewing *per se* rules against vertical restraints, *e.g.*, *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 888 (2007), including *per se* rules against vertical mergers

based on share of the market foreclosed. *Fruehauf*, 603 F.2d at 352. And it ignored the principle of constitutional avoidance that is triggered because interpreting the Clayton Act as the Commission does would grant it an extraordinary social and economic power—the power to block a vertical merger merely on the basis of "ephemeral possibilities"—that Congress did not clearly delegate. *See Brown Shoe*, 370 U.S. at 323; *Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 172-73 (2001).[12]

Under a proper interpretation of *Brown Shoe*, the Transaction is plainly lawful. The Commission conceded three *Brown Shoe* factors by making no attempt to establish them. (Op.42.)[13] But in reducing *Brown Shoe* to possibilities, the Commission not only omits three factors, but also distorts the four it purports to apply.

First, as Commissioner Wilson observed (Conc.2-3), the Commission erred as a matter of law in assuming foreclosure from Illumina's upstream market share. (Op.42.) *Brown Shoe* does not permit the Commission to conclude, without an

[12] If the Clayton Act permitted FTC to block any transaction it wished based on "ephemeral possibilities," that would pose an independent non-delegation problem. *See A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 541 (1935).

[13] The three omitted factors are: (1) the extent of concentration of sellers and buyers in the industry, (2) the existence of a trend toward vertical concentration or oligopoly in the industry and (3) whether the merger will eliminate potential competition by one of the merging parties. *Fruehauf*, 603 F.2d at 353.

evidentiary basis, that it is probable that Illumina would have the ability and incentive to use its market share in the upstream NGS market to foreclose rivals in the downstream MCED test market. *See AT&T II*, 916 F.3d at 1032; *Fruehauf*, 603 F.2d at 352. It is undisputed that, as the ALJ found, the merger will cause no actual foreclosure today because Galleri is still the only commercialized MCED. (ID.143, 191.) And the ALJ properly found that—given the lack of evidence of past foreclosure when Illumina owned 12% of Grail, the lack of diversion between Galleri and other PTDs, and the protections of the Open Offer (ID.172-81)—the "evidence fails to prove that a likelihood of harm to Grail's alleged rivals is probable or imminent, and therefore the evidence cannot properly support a finding that a resulting substantial lessening of competition is probable or imminent." (ID.193.) Faced with the lack of evidence of actual or imminent foreclosure, the Commission asserts "harms to current, ongoing innovation competition in nascent markets" and simply declares that such harm is "sufficiently 'probable and imminent'" under the Clayton Act. (Op.61.) But in assessing imminence, courts have looked to a period of two to three years in the future. *See Mercantile Tex. Corp.*, 638 F.2d at 1272. There is no evidence here of harm within any such timeframe.

Second, the "nature and purpose" of the Transaction is not foreclosure of potential rivals. As Illumina and Grail executives unanimously testified, the Transaction was motivated by a desire to accelerate Galleri and save lives. (Tr. 1512,

2334-45, 4081-82; PX2465.12.) The Commission ignores this, and instead cites evidence that Illumina believed in the prospect of large future profits in the MCED test market (Op.45-46), which does not show competitive harm, *cf.* 4A Areeda & Hovenkamp, *Antitrust Law* ¶ 1004d n.16 ("[A] complaint about lost profits resulting from increased competition is not one of 'antitrust injury.'"). Illumina put its money where its mouth is: the Open Offer prevents Illumina from engaging in foreclosure. (ID.178-79.)

Third, the Transaction will not change the market shares of the merged firm in either the upstream or downstream markets. The Decision simply asserts that, pre-merger, Illumina is the only NGS supplier and Grail the only seller of MCED tests. (Op.46.) This proves nothing, as the Transaction does not change the merged firm's market power.[14]

Fourth, the Transaction will not result in barriers to entry to the MCED market. To the contrary, the evidence shows that the Transaction has *lowered* entry barriers: after the Transaction was announced, one of the alleged Grail rivals first decided to pursue MCED development (IDF¶339) and Exact acquired Thrive (Op.14; IDF¶272), confirming analysts' prediction that the Transaction would accelerate investment and innovation in MCED test development (RFF¶928). The

[14] There are NGS alternatives to Illumina on the market today and additional entry is imminent. (RFF¶¶777-88.)

Commission ignored this, and instead relied on trial testimony from aspirational competitors (Op.46-47) to which the ALJ assigned "scant probative weight." (ID.192.) This evidence does not amount to the type of "formidable" and "stiffened" barriers to entry required to fulfill this factor. *See, e.g.*, *U.S. Steel Corp. v. FTC*, 426 F.2d 592, 604-05 (6th Cir. 1970). While Illumina has had every opportunity to take advantage of its supposed market position (IDF¶837), the Decision cites no evidence that it ever has. On the contrary, companies have invested hundreds of millions of dollars in developing cancer screening tests on Illumina's (and other) platforms (Op.30; RFF¶¶927-42), showing that innovation has flourished.

Thus, a proper application of the *Brown Shoe* factors shows no imminent and substantial harm to competition.

B. The Commission Misapplied the "Ability-and-Incentive" Test, Elevating Possibilities Over Probabilities.

As an alternative to its "*Brown Shoe* standard," the Commission purported to apply the "ability-and-incentive" framework described in cases like *AT&T*. That test, properly applied, may be used to evaluate whether a vertical merger is likely to substantially lessen competition. *United States v. AT&T Inc. (AT&T I)*, 310 F. Supp. 3d 161, 242-46 (D.D.C. 2018); *AT&T II*, 916 F.3d at 1032. But the Commission misapplied the test.

In overruling the ALJ, the Commission conducted a three-part analysis purportedly focused on Illumina's pre-acquisition incentive, its post-acquisition

incentive and its past behavior. The Commission disregarded the ALJ's findings without adequate explanation; relied upon cherry-picked facts at odds with substantial evidence; and continued to elevate possibilities over probabilities. The Commission's "ability-and-incentive" analysis is not supported by substantial evidence. *See Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951) (remanding where agency failed to "take into account whatever in the record fairly detracts from its weight"); *STP Nuclear Operating Co. v. NLRB*, 975 F.3d 507, 515 (5th Cir. 2020) (reversing where agency "ignored substantial parts of the record"); *DISH Network Corp. v. NLRB*, 953 F.3d 370, 378 (5th Cir. 2020) (reversing where the agency's determination relied on "[s]uspicion, conjecture, and theoretical speculation [which] register no weight on the substantial evidence scale" (citation omitted)).

1. Alleged Pre-Acquisition Incentive

The Commission reasons that the Transaction increased Illumina's incentive to foreclose Grail's rivals because it increased Illumina's stake in Grail. But that does not give rise to probable, substantial and imminent harm to competition. Any assessment of potential harm must account for the undisputed historical record. Before closing, Illumina already owned 12% of Grail and was entitled to a 7% royalty of its sales in perpetuity. (Op.10-11.) Under that structure, Illumina was making five times more from Grail than any other test developer. (IDF¶837.) Yet,

there is no evidence—none—that Illumina attempted to foreclose any putative Grail rival—not initially when Illumina owned all of Grail, not when it owned only part of Grail, and not now that it owns all of Grail again. FTC conceded as much before the ALJ. (Tr.4613 ("[FTC]: I am not aware of any evidence of clogging [competition] with the 12 percent ownership prior to this. No.").)

To demonstrate "the probable anticompetitive effect of the merger," FTC was required to show that Illumina's likely incentives absent the Transaction would be different, or else there could be no merger-specific "effect" as required by law. *AT&T I*, 310 F. Supp. 3d at 190. But the Commission did no analysis comparing the but-for future world without the Transaction—including existing incentives from Illumina's 12% ownership and royalty rights—versus the post-Transaction future with Illumina fully owning Grail. Thus, the Commission had no basis to conclude that Illumina going from partial owner (with royalty rights) to full owner lessened competition *substantially*.

2. Alleged Post-Transaction Incentive

The Commission next asserts that upon fully reacquiring Grail, Illumina "stands to profit substantially more from the sale of a GRAIL MCED test," purportedly giving it more reason to disadvantage Grail rivals. (Op.49-50.) But in so doing, the Commission cherry-picks the record, substitutes speculation for the ALJ's well-supported findings, and elevates possibilities over probabilities.

Whether the Transaction is likely to create an ability and incentive to harm competition depends on the alleged gain, which is a function of the volume and timing of any diverted sales and increased MCED test profits downstream, balanced against how much Illumina would lose upstream (such as from lost NGS sales, reputational harm and lost opportunities in clinical markets). Yet FTC's economist acknowledged that she failed to model post-Transaction downstream profits versus upstream losses. (RFF¶¶808-14.) Instead, the Commission assumes foreclosing Grail's supposed rivals would (1) divert significant sales to Galleri, (2) result in little material harm to Illumina's core NGS business and (3) generate significant profits for Illumina (Op.54-59)—without supporting evidence and notwithstanding substantial evidence to the contrary.

No Diversion. Material diversion is necessary for a vertical merger to give rise to foreclosure incentives. It is basic economics that "if there's no diversion, then there's no incentive to engage in [a foreclosure] strategy" because "the vertically integrated firm would just lose sales" and therefore "you need significant diversion for the strategy to make sense." (RX6000.22.) FTC's economist agreed that one cannot "put aside diversion" in a foreclosure analysis because if there is no likelihood of "recaptur[ing] sales, then yes, raising price above the optimal level will harm Illumina." (PX7138.227.)

As the ALJ found, FTC failed to show that the Transaction will cause diversion of sales from Grail's purported rivals to Grail. (ID.175-77.) Diversion depends on substitutability: foreclosure of one product is unlikely to divert sales to a product that is not a close substitute. (IDF¶840.) As discussed (§ II.A), there is no substantial evidence that any PTD is or soon will be a reasonable substitute for Galleri. Because Galleri is the only test on the market today, there are no sales to divert. Regardless of whether R&D competition is sufficient to place the PTDs in the same market as Galleri, "[t]he lower the substitutability there is among the MCED tests, the lower the diversion will be between rivals and Grail." (ID.177.) And there is no basis to conclude (and FTC has provided none) that there will be any material volume of rival sales to divert in the foreseeable future, because there is no basis to predict that any tests that physicians and patients would consider close substitutes for Galleri will launch in the foreseeable future. (ID.145-47; RFF¶¶825-29.) The Commission's finding about substitutability is rank speculation, which is insufficient to support the conclusion of a violation of the Clayton Act.

Harm to Illumina. The Decision also assumes, without evidence, that Illumina could foreclose Grail's putative rivals *without* materially harming its profitable NGS business. (Op.57-58.) That assumption is not only unsupported, but also contrary to undisputed evidence. Disfavoring Grail's alleged rivals would undisputedly harm Illumina's primary business by reducing its NGS sales, causing

reputational damage, discouraging development of new applications on Illumina's NGS systems, and subjecting Illumina to liability for violating the Open Offer. (IDF¶¶807-08, 998-1000.) The Commission dismissed these harms by claiming that Illumina could target *only* MCED developers and pursue "a campaign of 'death by a thousand cuts.'" (Op.58.) But that assertion is speculation unsupported by the record, which receives "'no weight on the substantial evidence scale.'" *DISH Network*, 953 F.3d at 378 (citation omitted); *see also TRW, Inc. v. NLRB*, 654 F.2d 307, 312 (5th Cir. 1981).

For a diversion strategy to succeed, Illumina would have to correctly predict which customers are likely to develop tests that would be close substitutes for Galleri in the future, and be certain that such attempted foreclosure of those customers would not result in lost business in other areas outside of cancer detection, or business from other customers. There is no evidence that Illumina could successfully target customers this way.

Even if Illumina could successfully target customers, it would be unable to profit from foreclosure for the independent reason that foreclosure would cause Illumina to lose business to NGS alternatives. The Commission predicts that foreclosing MCED customers would result in no lost business for Illumina because there are supposedly no alternatives to Illumina's NGS products. (Op.36-40.) But the record is replete with evidence of actual and potential upstream entry rivaling

Illumina and providing alternatives were Illumina to foreclose the PTDs in the future. (RFF¶¶777-88.) The Commission applied a double standard, requiring an impossibly high burden to prove entry by NGS competitors upstream (Op.36-40), but crediting the unsupported assertions of entry by Grail's alleged rivals downstream (Op.30). Such double-standard logic is entitled to no deference under the substantial evidence standard of review.

Uncertain, Future Profits. The Commission's theory further depends on the proposition that Illumina would make more money than it would lose from foreclosing its MCED customers. But, as the ALJ found, Illumina's first dollar of profit on the Transaction is not expected until about 2026, and Illumina does not expect to recoup its losses from Grail until 2030. (ID.173.) The Commission does not dispute this finding but disregards it because of "the scale of the projected profits available to the winner of the competitive race." (Op.58.) Essentially, the Commission says Illumina's near-term, years-long losses are immaterial because it may make back the losses in 10 years. But this theory is both speculative and ignores the record. Grail has commercialized an MCED test. There is nothing in Illumina's deal model suggesting that the expected profits from Grail depend on the foreclosure of any putative rival. (*See generally* PX5042.) And the Open Offer and resulting supply agreements prevent any such foreclosure. (ID.178-81.) The Commission grapples with none of this.

3. Alleged Past Behavior

Finally, the Commission contends Illumina's past behavior illustrates and confirms its anticompetitive incentives. (Op.52-53.) However, that contention ignores the only other vertical transaction Illumina has undertaken—its acquisition of an NIPT company called Verinata—and mischaracterizes the record evidence about Grail.

The Commission asserts that "Illumina gave GRAIL special pricing and other benefits" shortly after it was founded (while wholly owned by Illumina). (Op.52-53.) While true, this does not support FTC's case. Illumina's support of Grail, six years ago, was the only way Grail could survive as an independent company and develop the Galleri test. (IDF¶¶34-35.) Rather than a sign of anticompetitive effects, Illumina's assistance supports the Transaction's procompetitive nature, *i.e.*, Illumina's assistance allowed development of a life-saving test. Since then, Grail has matured and launched Galleri (IDF¶52), the costs of sequencing have fallen dramatically (IDF¶809), and Illumina is bound by the Open Offer, which forbids preferential pricing or access to Grail. (ID.178.) Even the Commission's allegations about special pricing do not show that Illumina *foreclosed* any putative Grail competitor, of which there were none when Grail was founded (and are still none today). In criticizing Illumina's early support of Grail, the Commission attacks the very thing that sparked industry interest in MCED development and ignores that

Illumina has always owned part of Grail and had a stake in its future revenues. The Decision does not cite a single instance when Illumina has hampered the competitiveness or development of any supposed Grail rival, despite Illumina's past ownership of Grail.

The Commission also argues that "[w]hen Illumina vertically integrated into therapy selection tests [which are different from, and not in the same market as, MCED tests] …, it considered the competitive threat posed by its customers." (Op.53.) But FTC does not even claim to have examined whether there has been foreclosure or a loss of consumer welfare due to Illumina having its own therapy selection test. If FTC had performed any such analysis, it would have seen unrefuted evidence in the record that there was no foreclosure in therapy selection. (RFF¶¶966-73.)

While seizing on cherry-picked and falsely characterized anecdotes, the Commission ignored the most relevant past transaction—Illumina's acquisition of Verinata. It is unsurprising that the Commission ignores Illumina's vertical entry into NIPT in discussing Illumina's past conduct, as the Verinata acquisition was decidedly procompetitive. (RFF¶¶963.1-63.4.) Following the acquisition, between 2015 and 2019, the number of NIPT tests conducted by Verinata's rivals on Illumina's platforms in the U.S. more than doubled, and, critically, Verinata's share of NIPT sales decreased while rival sales increased—the opposite of foreclosure.

(RX3864¶¶162-67.) Since the Verinata acquisition, there have been many new entrants and substantial investment in NIPT, with a dramatic decline in test pricing. (RFF¶¶962-63.4.) Illumina has played a major role in expanding payor coverage for NIPT, resulting in broader market access. (Tr.2343, 4123-26.) The idea for Grail actually came out of the work that Illumina and Verinata scientists did after that acquisition. (Tr.1868-74; RFF¶¶40-44.) The Commission imagines a parade of horribles while ignoring the parade of benefits that resulted from Illumina's only other vertical acquisition of a clinical test developer.

Accordingly, the Commission's "ability-and-incentive" analysis is not supported by substantial evidence, and should be reversed.

C. The Commission Failed To Account for the Real-World Effects from the Open Offer.

The Commission further erred in considering an artificial case without the Open Offer, rather than requiring FTC to take the Open Offer into account as part of its liability case. Any assessment of a merger under the Clayton Act must take account of real-world effects. Thus, courts require the government to consider post-merger announcement, binding contractual commitments as part of its liability case. *See AT&T II*, 916 F.3d at 1038, 1041; *AT&T I*, 310 F. Supp. 3d at 241 n.51; *United States v. UnitedHealth Grp. Inc.*, No. 1:22-cv-0481, 2022 WL 4365867, at *9 (D.D.C. Sept. 19, 2022); *FTC v. Libbey, Inc.*, 211 F. Supp. 2d 34, 46 (D.D.C. 2002).

Yet, in finding the Transaction unlawful, the Commission disregarded the Open Offer, which is an undisputed part of the economic realities.

When Illumina decided to acquire Grail, it reached out to its major clinical customers, including those that had publicly stated that they were developing cancer tests, to offer supply agreements that would guarantee customers access to the same products and pricing that the customer enjoyed pre-Transaction. (ID.153-54.) These conversations resulted in the Open Offer. During its twelve-year term, customers who sign the Open Offer will benefit from significant protections (Op.65-66), including:

- uninterrupted access to Illumina's current and future NGS products, including guaranteed access to the same products as Grail (IDF¶¶896-902);
- a guarantee that customers will pay the *same* for NGS products as they did pre-Transaction, including guaranteed access to the same most-favored-nation pricing available to other Open Offer customers and Grail (IDF¶¶915-29);
- knowledge of the products and pricing for NGS products for Grail, which shall be published on the Illumina website (IDF¶977);
- a guarantee that NGS prices will not *increase* (beyond inflation) for the entire twelve-year term, and in fact will *decrease* by at least 43% by 2025 (IDF¶¶926, 929);
- rights, under Illumina's core intellectual property, to use Illumina products (IDF¶¶965-68); and
- a guarantee that customers' information provided to Illumina will be firewalled and protected. (IDF¶¶969-70.)

The provisions of the Open Offer are subject to robust enforcement provisions, including biannual and customer-requested audits, and binding arbitration if any dispute arises. (IDF¶¶978-88.)

The Commission dismissed the Open Offer as merely a "remedy," immaterial to whether a transaction is unlawful. (Op.61-65.) But the Commission relied on cases where the proposed remedy was an unconsummated divestiture proposal, which was conditional and whose impact was unknown. (*Id.*) By contrast, the Open Offer's terms have been operative since Illumina acquired Grail. They are self-executing and, as the ALJ found, have present, real-world effects (ID.181); they are an intrinsic aspect of the economic reality of the Transaction, like any operative contract; and the contracts that have been signed will remain in place even if Grail is divested. These facts are fundamentally different from *DuPont* (cited by the Commission), where the Court held that the government did not need to disprove an alternative proposed remedy (conditional on the defendant otherwise losing the case) as part of its liability case, rendering the Commission's reliance on that case misplaced (Op.61). Neither the timing of the Open Offer, nor the fact Illumina created it to address customer concerns, transforms the Open Offer from market reality into a remedy.

This threshold legal error fatally infected the Commission's analysis of the Open Offer as a remedy. Under the burden-shifting framework, *see United States v.*

Baker Hughes Inc., 908 F.2d 981, 982-83 (D.C. Cir. 1990), there was a profound difference between requiring Petitioners to rebut FTC's artificial case without the Open Offer (Op.66-73) and requiring FTC instead to prove a substantial lessening of competition in the real world with the Open Offer in place.

IV. THE COMMISSION ERRED IN IGNORING EFFICIENCIES REBUTTING ANY ALLEGATION OF HARM.

Even if there were evidence of probable, substantial and imminent harm to competition, the Decision should be reversed because it failed to account for efficiencies easily offsetting the supposed harm. Evidence of efficiencies can rebut a presumption that a merger will have anticompetitive effect. *E.g.*, *FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1054-55 (8th Cir. 1999). It is widely recognized that "most vertical mergers are procompetitive," in part because they often result in significant efficiencies. 4A Areeda & Hovenkamp, *Antitrust Law* ch. 10A-1; *see Republic Tobacco Co.*, 381 F.3d at 737.

Petitioners tendered extensive, unrebutted evidence that the Transaction will result in numerous merger-specific benefits. Chief among them is that it will save tens of thousands of lives by accelerating access to Galleri. The merger will also lead to innovations from R&D synergies; reduce costs by eliminating a royalty Grail would otherwise owe and EDM; and lead to supply-chain and operational efficiencies—all of which will lower prices and otherwise benefit patients. (RFF¶¶1106-79.)

The record evidence supporting these efficiencies included: (i) unrefuted testimony from numerous Illumina and Grail executives, each intimately familiar with the relevant facts (RFF¶¶1107-08); (ii) unrefuted testimony that Illumina's Board—at the time comprising a Nobel Laureate, a former FDA commissioner, financial experts, and veterans of the biotech industry—unanimously concluded the Transaction will generate substantial efficiencies (RFF¶¶1110-11); (iii) "analogous past experience," U.S. Dep't of Justice & Fed. Trade Comm'n, *Horizontal Merger Guidelines* § 10 (Aug. 19, 2010), including Illumina's vertical acquisition of Verinata, which resulted in expanded access to NIPT testing and the discovery that spawned Grail (Tr.1868-74, 2343, 4123-26); and (iv) testimony from highly qualified economic experts (RFF¶1121.10).

FTC did not offer any fact evidence demonstrating these efficiencies are unlikely, and the Commission made no such findings. Nor did the Commission find that if these efficiencies were supported, the Transaction would be anticompetitive. Instead, the Commission relied on the unsupported assertions of an economist (Op.79-84), that Petitioners did not meet an impossibly high and mistaken legal standard. In so doing, the Commission dismissed the testimony of more than 15 witnesses, all deeply knowledgeable, as somehow "vague" and "speculative" (Op.81, 87), while substituting its own non-expert, unsupported judgment on the

likelihood of these efficiencies coming to pass and whether Grail could achieve them on its own (though Grail's executives said otherwise). (Tr.1513, 3004, 3371, 3378.)

A. The Commission Applied the Wrong Legal Standard.

The Decision understates the role efficiencies play in evaluating a merger's competitive effects. While efficiencies cannot justify an illegal merger, they can demonstrate that a merger is not illegal in the first place. The Clayton Act forbids only those mergers that are anticompetitive after any pro- and anti-competitive effects are weighed, as numerous courts have held. *E.g.*, *Tenet Health Care Corp.*, 186 F.3d at 1054-55; *FTC v. Univ. Health, Inc.*, 938 F.2d 1206, 1222 (11th Cir. 1991); *Deutsche Telekom*, 439 F. Supp. 3d at 207. Although the Commission purported to evaluate each efficiency identified by Petitioners, it did so using a legal standard that would effectively eliminate the role of efficiencies in merger analysis, upending decades of precedent and economic understanding. The Decision committed three over-arching legal errors in its approach to efficiencies: (i) it placed on Petitioners the burden of balancing the Transaction's efficiencies against the alleged harms, (ii) it rejected the efficiencies evidence proffered by Petitioners as legally irrelevant and (iii) it imposed on Petitioners an impossibly high, double standard that has no support in the law.

First, the Commission erroneously placed on Petitioners the burden of balancing efficiencies against the alleged harms. For example, in rejecting the EDM

efficiencies and the evidence that cost savings will be passed to consumers (as lower prices), the Commission faulted Petitioners' economic expert for not proffering a "full vertical model" of the Transaction's likely effects. (Op.84.) While Petitioners bear the burden of *production* to put forward evidence of efficiencies, it was FTC's burden to model the full effects of the Transaction, including its efficiencies, since the "ultimate burden of persuasion … remains with the government at all times." *Baker Hughes*, 908 F.2d at 983; *AT&T I*, 310 F. Supp. 3d at 192, 194-95; *Arch Coal*, 329 F. Supp. 2d at 116-17. It was FTC that was required to do such balancing, and its economist did not attempt to do so. (RFF¶¶1078.1-78.3.) By shifting the burden of balancing efficiencies to Petitioners, and thereby overlooking FTC's failure of proof, the Decision committed reversible error.

Second, the Decision erred by dismissing Petitioners' efficiencies evidence as legally irrelevant. The Commission treated the testimony of company executives as necessarily unreliable and ignored the evidence showing Illumina had achieved similar efficiencies in prior vertical transactions, including R&D efficiencies from the acquisition that led to the formation of Grail. (Op.75-78.) The Commission did not find the testimony of Petitioners' executives insincere; nor did it identify any grounds to doubt their credibility. (Op.87 & n.70.) Rather, the Commission effectively determined that executive testimony alone can never establish a merger's efficiencies, no matter how credible, even if corroborated by historical experience.

(Op.75-78.) The Commission's assumption that executive testimony alone can never constitute reliable evidence constitutes legal error. *See, e.g.*, *Valentine v. Comm'r Soc. Sec. Admin.*, 574 F.3d 685, 694 (9th Cir. 2009); *Deutsche Telekom*, 439 F. Supp. 3d at 216-17.

Third, the Commission erred in holding FTC to a dramatically lowered standard of proof for competitive harm (§§ II-III above), while imposing on Petitioners an impossibly heightened standard for establishing that efficiencies are merger-specific and verifiable.

The Commission effectively ruled that efficiencies are not merger-specific (and thus not cognizable), if it is theoretically possible that they could be achieved by contract or in some other way. That is not the law. An efficiency is merger-specific if it "cannot be achieved by either company alone." *United States v. Anthem, Inc.*, 855 F.3d 345, 356 (D.C. Cir. 2017); *Deutsche Telekom*, 439 F. Supp. 3d at 212-13. In keeping with its erroneous view that company testimony can never establish efficiencies, the Commission ignored the testimony of numerous fact witnesses with personal knowledge explaining why the Transaction's efficiencies could not be achieved by other means (*e.g.*, with consultants/contracts). (RFF¶¶1175-77.5.)

Additionally, "[c]ourts consider efficiencies verifiable if they are not speculative and shown in what economists label 'real' terms." *Deutsche Telekom*,

439 F. Supp. 3d at 213 (citations omitted). "[E]fficiency claims substantiated by analogous past experience are those most likely to be credited." *Id.* Here, the Commission disregarded unrefuted evidence that Illumina achieved similar efficiencies in a prior vertical merger and ignored consistent witness testimony concerning the likely benefits of the merger. The Commission deemed the Transaction's efficiencies speculative and thus not verified, by applying an impossible and baseless double standard. In particular, the Commission:

- dismissed the Transaction's efficiencies as speculative though they are well supported and some (royalty elimination) have been achieved already (Op.76-86), while accepting speculative claims regarding the projected future launch of PTDs (Op.14-19);

- disregarded EDM as unsupported by a model (Op.84), while not requiring FTC to proffer any reliable model of the Transaction's likely effects though FTC bears the ultimate burden of persuasion, *Baker Hughes*, 908 F.2d at 983;

- accepted the speculative claim of FTC's economist, who has no expertise in NGS or cancer testing, that the Transaction might cost lives (Op.83), while ignoring the testimony of numerous fact witnesses with ample experience/expertise in NGS and cancer testing, that the Transaction will save lives (RFF¶1117);

- rejected the testimony of company witnesses as necessarily self-serving (Op.75-86), while blindly accepting the testimony of interested third parties and unqualified experts (*e.g.*, Op.47);

- found the testimony of a dozen-plus Illumina and Grail executives corroborating the Transaction's efficiencies insufficient (Op.75-78), while basing its determination of Illumina's supposed foreclosure incentives on the testimony of third-party executives (Op.52) with an incentive to slow down Grail (ID.189);

- dismissed efficiencies as unquantified (Op.77) (though they had been quantified), while not requiring any quantification of the alleged harms (Op.49-60); and

- refused to recognize efficiencies because they were not reflected in detailed planning documents that could not have been created (because regulators have not permitted Illumina and Grail to integrate) (Op.80), while crediting the claims of supposed MCED developers with no documentary support (*e.g.*, Op.30).

In short, the Commission imposed an erroneously high standard on Petitioners to show efficiencies, while imposing an equally erroneous permissive standard on its staff to show harm. Such an approach might align with the current Commissioners' antipathy toward merger efficiencies, but it has no place in the Clayton Act.

B. The Commission's Conclusions Lack Support in Substantial Evidence.

In addition to applying the wrong legal standard, the Commission ignored substantial evidence that the Transaction's efficiencies are merger-specific and likely to occur. None of the Commission's critiques of the Transaction's efficiencies survives scrutiny.

1. Cost-Saving Efficiencies

Petitioners amassed substantial evidence that the Transaction will eliminate substantial costs for Grail and that the savings will be passed on to consumers. The

Commission's rejection of this evidence is not only unfounded but also contrary to its own theory of harm.

Grail royalty: The Transaction eliminated Grail's obligation to pay Illumina a royalty of 7% of its oncology revenues up to a cumulative royalty of $1 billion, at which point the rate would decline to 5%. (RFF¶1147.2.) Petitioners' expert estimated that elimination of the royalty would result in $136.9 million in consumer surplus. (RFF¶¶1150, 1151.5.) The Commission does not dispute the royalty has been eliminated, but claims this efficiency is not merger-specific because Grail evaluated other options to reduce the royalty before deciding to fully re-unite with Illumina. (Op.83-84.) However, every witness called on this topic, including the banker hired to help Grail evaluate its options, testified that none of the other options was viable. (RFF¶¶1148, 1151.5.) The Commission is not entitled to deference when it merely substitutes its own judgment for that of witnesses with personal knowledge.

EDM: The Transaction also resulted in EDM benefits. (RFF¶¶1153-55.5.) EDM benefits arise when an upstream firm acquires a downstream firm to which it supplies inputs. (RX3864¶102.) As separate entities, each firm maximizes its profits by setting its price such that the marginal revenue from an additional sale equals the marginal cost of an additional sale; a merger leads a profit-maximizing firm to eliminate the upstream margin from its downstream pricing decision and to

reduce the price of the downstream good. (*Id.*) Petitioners estimated the EDM benefit resulting from the Transaction is likely to create $627.9 million in consumer surplus between 2022-30. (RFF¶1154.) Although EDM is a widely recognized consequence of vertical integration, e.*g.*, *AT&T I*, 310 F. Supp. 3d at 193, the Commission rejected the EDM evidence here because Petitioners' expert did not model the full effects of the transaction. (Op.84.) But, as noted (§ IV.A), it was FTC's burden (not Petitioners') to model the full effects of the transaction and it failed to do so. In fact, EDM is a unilateral price effect relevant to whether FTC can establish its *prima facie* case. Bruce H. Kobayashi & Timothy J. Muris, *Screening Out Innovation—Vertical Merger Principles and the FTC's Misapplication in the Illumina-GRAIL Case*, COMPETITIVE ENTER. INST. (2021); Christine Wilson, *Reflections on the 2020 Draft Vertical Merger Guidelines and Comments from Stakeholders*, Remarks at the DOJ Workshop on Draft Vertical Mergers 6 (March 11, 2020).

Supply-Chain/Operational Efficiencies: Illumina has vastly superior operational capabilities that can be made available to Grail for Galleri's scaled distribution. (RFF¶¶1157-67.) Petitioners quantified the savings from these efficiencies at approximately $140 million over 10 years. (RFF¶1166.) The Commission rejected this evidence principally because Grail had made some operational improvements on its own. (Op.85.) No one ever claimed Grail has no

operational capabilities or was not seeking to improve. But the evidence showed that Illumina can accelerate those efforts at a lower cost. (RFF¶¶1165.2-65.5.) There is an obvious difference between building vast laboratory and operational infrastructure from the bottom up, as Grail would have to do on its own, and being part of a global organization that has those capabilities already and has considerable experience running them at scale. (*Id*.)

Pass-through: As Petitioners' economist explained, economic theory demonstrates that the cost savings derived from EDM, eliminating the royalty and supply-chain/operational efficiencies will be passed through to consumers by lowering Galleri's price: "if your costs go down, your marginal costs go down, all else equal, you will lower price, not because you're a good person, but because you want to make more money." (RX6000.69; *see also* RFF¶¶1149.1-49.5.) The Commission ignored this evidence and instead determined—without citing any economic authority—that passthrough was unlikely because Grail has no rivals (and so, supposedly, no incentive to lower Galleri's price). (Op.86-87.) In addition to contravening economic theory, this rationale is irreconcilable with the finding that other MCED developers expect "to compete with Galleri on price" (Op.27) and upends the foundation of the Commission's case: that Grail faces robust competition giving rise to a purported foreclosure incentive (Op.54-57).

2. R&D Efficiencies

Unrefuted evidence, including witness testimony and analogous past experience, established that the Transaction will lead to significant R&D efficiencies—both related to Galleri (making the test more accurate and cheaper, just as Illumina did for NIPT after acquiring Verinata) and other technologies (using Galleri samples to discover genomic biomarkers in the blood, just as Illumina discovered the insights leading to Grail's formation by studying patient samples from Verinata's NIPT test). (RFF¶¶1136-45.) The Commission identified no basis to question the evidence of these efficiencies—it merely took issue with the fact they were established, in part, by company testimony. In characterizing the evidence as the "mere expectations of corporate executives" (Op.78), the Commission *completely* ignored that both forms of R&D efficiency were substantiated by analogous past experience, exactly the type that the agencies' guidelines describe as "most likely to be credited." *Horizontal Merger Guidelines* § 10.

3. Market Access Acceleration

Petitioners proffered ample evidence the Transaction will accelerate widespread access to Galleri, saving thousands of lives and billions of dollars, as Illumina's regulatory and market-access expertise and resources will accelerate FDA approval and payer coverage. (RFF¶¶1127-35.) The Commission rejected this evidence because Illumina's executives did not detail every step in the regulatory

process that will be accelerated and by precisely how much. (Op.79-80.) The law, however, does not demand such specificity, and the Commission cited no evidence that the *overall* FDA process is unlikely to be accelerated. The Commission also determined that these efficiencies are not merger specific on the theory Grail could have partnered with another company to achieve FDA and payer acceleration. There is no evidence supporting that assumption (Op.81-82) and ample evidence to the contrary (RRFF¶¶5388, 5646). The Commission pointed only to the unremarkable fact that Grail has a "massive" incentive to accelerate Galleri (Op.81), while ignoring that every Grail executive to address the subject testified that re-uniting with Illumina was a more effective way to achieve that objective (Tr. 538, 1417, 2980, 3371). The Commission's speculation that Grail could do as well without the merger deserves no deference.

The Commission discounted the evidence of market-access acceleration largely because Illumina purportedly did not take acceleration into account in its deal model. (Op.79.) That claim distorts the record and warrants no deference. The unrefuted evidence showed Illumina's board took acceleration into account (RFF¶1121.5); the deal model was created to determine the acquisition price and was therefore necessarily conservative. (RFF¶1379; RRFF¶5043.) Further distorting the record, the Commission cited testimony that Illumina did not model the *probability* that acceleration will occur, (Op.79), while ignoring undisputed

evidence that Illumina was confident that acceleration was *highly* probable. (RRFF¶¶5060-64.) That confidence is a reason to credit the evidence on acceleration, not ignore it.

4. International Expansion

Finally, the Commission rejected robust evidence of international efficiencies on the ground ex-U.S. efficiencies are irrelevant, only to acknowledge that international acceleration will improve the test for U.S. patients. (Op.86.) The Commission speculated Grail could achieve the same degree of international acceleration by partnering with other global companies, or could do so on its own. (Op.86.) It cited no supporting evidence and ignored unrefuted evidence to the contrary. (RFF¶¶1168-73.)

C. The Commission Failed to Balance Efficiencies Against Alleged Harm.

Even if some of the Transaction's efficiencies were disregarded, the Commission erred in failing to balance proven efficiencies against the alleged harm. That alone is fatal to FTC's case.

Given the potential benefits that come from a vertical merger, the government was required to weigh the alleged harm against proven efficiencies. *See* 4A Areeda & Hovenkamp, *Antitrust Law* ¶ 1020; *Baker Hughes*, 908 F.2d at 984 (holding that the Clayton Act requires "a totality-of-the-circumstances approach … weighing a variety of factors to determine the effects of particular transactions on competition").

"If you don't take account of the efficiencies or, more broadly, the incentive to lower price, you risk preventing a merger that would bring large benefits to society because you've failed to balance the benefits against the possible harms." (RFF ¶ 803.1.) To properly determine whether competitive harm is probable depends on the extent of acceleration, output expansion, the estimated number of lives saved from accelerated and expanded output, quality improvements (*e.g.*, from R&D advances and additional data from international markets), and cost savings and lower prices (*e.g.*, EDM savings, royalty reductions, procurement savings), as compared to the timing and magnitude of potential harm.

Yet the Commission failed to do the required balancing. Instead, it simply assumed the Transaction will generate no efficiencies at all and thus gave them no weight on the scale (Op.77), while ascribing insurmountable weight to alleged harms the Commission made no effort to quantify (Op.49-60). The Commission's approach is especially ill-conceived as the Commission offered no evidence refuting any of the efficiencies, most have been quantified (RFF¶¶1150, 1154, 1166) and the Grail royalty has already been eliminated, resulting in more than $136.9 million in consumer surplus (RFF¶1150).

V. THE DECISION INJURED PETITIONERS AND SHOULD BE SET ASIDE IN ITS ENTIRETY.

Individually and collectively, the errors described above require reversal of the Commission's Decision.

The Decision rests not on vertical merger precedent—under which FTC's case fails, as its own ALJ found—but on the current Commission's policy goals, grounded in antipathy to mergers. The Commission relied on possibilities instead of probabilities and embraced a series of double standards unrecognized in the law. For example, the Decision:

- defined a broad downstream market to include unfinished research for possible tests years from launch that may never compete with Galleri (Op.24-34), but defined the upstream market narrowly to include only Illumina products, ignoring NGS products both on the market and poised to launch (Op.35-40);

- concluded that FTC need not provide robust proof of harm as the future is unknown (Op.49-60), but required Respondents to precisely quantify the Transaction's future efficiencies (Op.77);

- relied on self-interested third parties FTC lined up to speculate on issues relating to Illumina's incentives (Op.52), while disregarding testimony from Illumina executives about Illumina's own incentives (IDF¶895);

- ignored concrete evidence of actual and imminent NGS competition with Illumina upstream (RFF¶¶777-80), while assuming imminent MCED competition with Grail downstream based only on aspirational, undocumented claims not credited by the ALJ (Op.30);

- found the Open Offer inadequate because contracts supposedly cannot constrain Illumina's conduct (Op.73), but concluded that Grail could realize efficiencies through contract (Op.81); and

- allowed FTC to enter evidence into the record after trial regarding BGI (an Illumina rival) (Op.38 n.21), while refusing to re-open the record for Petitioners' evidence that further discredited claims by PDTs about the timing and status of their MCED development (Op.56-57 n.38).

A decision so steeped in double standards is better suited to judgment as a matter of law than to remand.

Judgment should also be entered for Petitioners because there is no basis for remand, even on corrected legal standards. The overwhelming weight of the evidence demonstrates that the Transaction is procompetitive and remand would only result in further and unwarranted delay. Entering judgment for Petitioners is the only available remedy given the constitutional defects in FTC's administrative scheme.

CONCLUSION

The Commission's Decision should be reversed, allowing Petitioners to get about the business of revolutionizing cancer care.

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CERTIFICATE OF SERVICE

This is to certify that the foregoing instrument has been served via the Court's ECF filing system in compliance with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure, on June 5, 2023, on all registered counsel of record, and has been transmitted to the Clerk of the Court.

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CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limit requested in Petitioners' timely-filed motion to file a single brief of 16,000 words (rather than two briefs of 13,000 words each), which is pending before the Court, because, excluding the parts of the document exempted by FED. R. APP. P. 32(f) and 5th CIR. R. 32.1:

this document contains 15,920 out of the requested 16,000 words.

2. This document complies with the typeface requirements of FED. R. APP. P. 32(a)(5), and 5th CIR. R. 32.1 and the type-style requirements of FED. R. APP. P. 32(a)(6) because:

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