No. 23-60167

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

ILLUMINA, INCORPORATED; GRAIL, INCORPORATED, now known as GRAIL, L.L.C.
Petitioners,

v.

FEDERAL TRADE COMMISSION,
Respondent.

On Petition for Review of an Order
of the Federal Trade Commission
Docket No. 9401

BRIEF OF THE FEDERAL TRADE COMMISSION (PUBLIC VERSION)

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STATEMENT REGARDING ORAL ARGUMENT

Oral argument would aid the Court in resolving the issues raised in this petition for review.

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CITATION ABBREVIATIONS

This Brief uses the same abbreviations used in Petitioners' Brief, including the following:

Conc.	Concurring Opinion of Commissioner Wilson
ID	Initial Decision of Administrative Law Judge
IDF	Initial Decision Findings of Fact
Op.	Opinion of Commission
Oral Arg. Tr.	Transcript of Oral Argument Before Commission
Prehearing Tr.	Prehearing Transcript
PX	Exhibit of Complaint Counsel
RX	Exhibit of Respondents (Petitioners here)
RFF	Proposed Findings of Fact of Respondents (Petitioners here)
Tr.	Trial Transcript

INTRODUCTION

This case involves a merger that threatens to stifle ongoing competition in the race to develop and commercialize multi-cancer early detection ("MCED") tests, which can identify several kinds of cancer in asymptomatic people by analyzing blood samples. Petitioner GRAIL, Inc., sells an MCED test called Galleri on a limited basis, but the test is not approved by the Food and Drug Administration, not covered by insurance, and costs nearly $1000. Several other companies are also developing MCED tests. Grail's ordinary-course-of-business documents show that it sees these companies as serious competitive threats, while other MCED test developers view Grail as their main rival.

All MCED tests rely on next generation sequencing ("NGS") technology to analyze DNA, and petitioner Illumina, Inc., is the only company that makes suitable NGS platforms. In 2021, Illumina purchased Grail. After thoroughly reviewing the record of a multi-week trial, the Federal Trade Commission unanimously found that this acquisition violates Section 7 of the Clayton Act, 15 U.S.C. § 18, because it may substantially lessen the existing competition among Grail and other MCED test developers. The Commission found that the merged

firm will have both the ability and a strongly increased incentive to use its dominance in NGS platforms to favor Grail and disadvantage rival test developers—*e.g.*, by raising the prices Illumina charges Grail's competitors or degrading their access to service and necessary supplies.

Illumina and Grail (collectively, "Illumina") petition for review of the Commission's order. None of their challenges has merit. The Commission correctly applied the Clayton Act, its decision is supported by substantial evidence, and there is no constitutional defect in the Commission's structure or its proceedings. At the outset, it is important to dispel one particular myth that Illumina repeats throughout its brief: the claim that the merger will save lives by somehow accelerating Grail's ability to gain FDA approval and payer acceptance for Galleri. As the Commission properly found, this claim is based on nothing more than speculation by a single Illumina executive, who could not identify a single step Illumina might actually take to expedite Galleri's approval.

The fundamental question here is whether the merger will threaten other companies' ability to develop rival MCED tests and deprive Americans of competition in this critical market. Competition

among MCED test developers will promote innovation, leading to more and better tests being made available to American consumers at lower prices. This Court should protect competition, as Congress has directed, and deny the petition.

JURISDICTIONAL STATEMENT

The Commission entered its order on March 31, 2023, pursuant to 15 U.S.C. §§ 21(b) and 45(b) . Illumina timely filed its petition on April 5, 2023. This Court has jurisdiction under 15 U.S.C. §§ 21(c) and 45(c) .

QUESTIONS PRESENTED

1. Did the Commission properly determine that the Illumina-Grail merger violates the Clayton Act?

2. Were the Commission's proceedings constitutional?

STATEMENT OF THE CASE

A. The Race To Develop MCED Tests

MCED tests are a screening tool to detect cancer at an early stage in patients with no cancer symptoms. They work by analyzing a sample of a patient's blood for minute amounts of certain "biomarkers" (such as proteins, DNA, or RNA) associated with the presence of cancers. Op. 3.

Grail and several other companies are in a race to develop and commercialize MCED tests. Op. 3. Grail started selling its Galleri test

in April 2021, but has not yet obtained FDA approval, which means the test can be sold only on a limited basis. Galleri currently costs $949 and is not covered by insurance. Op. 12, 14. Another leading competitor, Exact/Thrive, is developing a test called CancerSEEK, which received a "breakthrough" device designation from the FDA that could accelerate its review and regulatory approval. Op. 14-16. Exact/Thrive currently plans [redacted] Op. 15, 56. Other companies, including Guardant, Singlera, Freenome, Natera, and Helio Health, are at various stages of the development and commercialization process. Op. 16-19. As the Commission found (Op. 31), the market is like a racetrack where some companies are leading the pack and others are nipping at their heels, but collectively, competition is spurring the field to move faster and work harder to provide patients with many choices of MCED tests.

B. Illumina's NGS Platforms

Illumina sells NGS platforms, including the instruments used to sequence DNA and consumable supplies such as "flow cells" that hold samples and chemical reagents used in the sequencing process. Op. 4, 6. NGS platforms are a critical input for MCED tests, and only Illumina

offers products with the specific characteristics MCED test developers need: high throughput, high accuracy, low cost, and the ability to read short DNA fragments. Op. 5-7, 21, 36-40, 42. MCED test developers thus have no substitute for Illumina's NGS platforms, either now or in the near future. *Id.*

C. Illumina's Acquisition of Grail

Illumina formed Grail in 2016, but later spun it off as a separate company, retaining a 12% stake and the right to a royalty on net sales of Grail's oncology products. Op. 10-11. At the time, Illumina explained that the spinoff would "level[] the playing field" and "accelerate the liquid biopsy market for all." Op. 11, 52; PX2406-005. But in September 2020, Illumina changed its mind and decided to acquire the remainder of Grail for $8 billion. Op. 11. The Grail acquisition was part of a strategy to shift Illumina's focus away from NGS platforms and toward clinical testing, which Illumina saw as an enormous market opportunity with much greater profit potential. Op. 45-46; *see also* PX2151-005; PX2169-045; PX2488-009; PX2465-006 to -008.

D. The FTC and the Clayton Act

Congress established the FTC in 1914 and directed it to prevent "unfair methods of competition" in commerce. FTC Act, ch. 311, § 5, 38

Stat. 717, 719 (1914) (codified as amended at 15 U.S.C. § 45). A few weeks later, Congress enacted the Clayton Act to further strengthen the nation's antitrust regime and directed the FTC to enforce the Act's anti-merger provisions. Clayton Act, ch. 323, § 11, 38 Stat. 730, 734 (1914) (codified as amended at 15 U.S.C § 21).

The Commission consists of five Commissioners appointed by the President and confirmed by the Senate, no more than three of whom may be members of the same political party. 15 U.S.C. § 41. To ensure that the Commission performs its duties as an independent body, Congress provided that the President may remove Commissioners only "for inefficiency, neglect of duty, or malfeasance in office." *Id.* Commissioners also serve staggered terms of seven years, so that the composition of the Commission regularly changes. *Id.* The President selects one Commissioner as the Chair, who is the executive and administrative head of the agency, and may change that designation at any time. *Id.*; 16 C.F.R. § 0.8.

Congress directed the Commission to enforce the FTC and Clayton Acts through administrative adjudication. 15 U.S.C. §§ 21(b), 45(b). The Commission may issue an administrative complaint when it has "reason

to believe" a merger may violate the law. *Id.* The complaint is not a finding of a violation, but merely the first step in an adversarial process of review. The complaint is referred to an administrative law judge for discovery and a trial. *See* 16 C.F.R. §§ 3.31-3.46. The Commissioners are not involved in prosecuting the case; that function is performed by agency staff known as Complaint Counsel, who are walled off from the Commissioners and the ALJ and prohibited from having any *ex parte* contact with them. *See* 5 U.S.C. § 554(d)(2); 16 C.F.R. § 4.7(b). At trial, both Complaint Counsel and the respondents (*i.e.*, the merging parties) may present testimonial and documentary evidence, cross-examine witnesses, and object to the other side's evidence, much as they would in a district court proceeding. *Id.* §§ 3.41(c), 3.43. Following trial, the ALJ issues an initial decision. *Id.* § 3.51. Either side may then appeal to the full Commission, which reviews the facts and law *de novo*. *Id.* §§ 3.52, 3.54. If the Commission finds in favor of Complaint Counsel, the respondent may seek review in an appropriate court of appeals. 15 U.S.C. §§ 21(c), 45(c).

E. Proceedings in This Case.

In March 2021, the Commission voted to issue an administrative complaint alleging that the Illumina-Grail merger would violate the Clayton Act and the FTC Act. The vote was unanimous and bipartisan.[1] The Commission also sought a preliminary injunction in district court to block the merger during the pendency of the administrative case. *See* 15 U.S.C. § 53(b). Shortly afterwards, the European Commission ("EC") opened an antitrust investigation upon request from several European states. That investigation triggered a standstill obligation that barred Illumina and Grail from completing the merger. In light of the standstill, the Commission determined that interim relief was no longer needed to protect the public interest and voluntarily dismissed the preliminary injunction action. Illumina did not object, though it argued unsuccessfully that the dismissal should be with prejudice. *See FTC v. Illumina, Inc.*, No. 3:21-cv-800 (S.D. Cal), ECF Nos. 120, 124, 126.

Despite the European standstill requirement, Illumina closed its acquisition of Grail in August 2021. Op. 11. The merger was not

[1] The Commissioners at that time were Acting Chairwoman Rebecca Kelly Slaughter and Commissioners Noah Joshua Phillips, Rohit Chopra, and Christine S. Wilson, with one vacancy.

operationally implemented, however, because the EC ordered Illumina to hold Grail as a separate entity.[2] The EC later concluded that the acquisition violated European antitrust law and ordered Illumina to unwind the purchase of Grail.[3] It separately fined Illumina €432 million for knowingly and intentionally breaching the standstill obligation.[4]

Meanwhile, following a multi-week trial, the FTC's ALJ issued an initial decision in favor of Illumina. On appeal, the Commission conducted a *de novo* review and concluded that the transaction violated the Clayton Act (and therefore the FTC Act as well). Op 2, 24, 93. Although the Commission's lineup had changed, the decision was again bipartisan and unanimous.[5]

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[2] EC Press Release, *Mergers: Commission adopts interim measures to prevent harm to competition following Illumina's early acquisition of GRAIL* (Oct. 29, 2021), https://shorturl.at/iGJX4.

[3] EC Press Release, *Mergers: Commission prohibits acquisition of GRAIL by Illumina* (Sept. 6, 2022), https://shorturl.at/nozQ9.

[4] EC Press Release, *Mergers: Commission fines Illumina and GRAIL for implementing their acquisition without prior merger control approval* (July 12, 2023), https://shorturl.at/hRV58.

[5] The Commissioners at the time of decision were Chair Lina M. Khan and Commissioners Rebecca Kelly Slaughter, Christine S. Wilson, and Alvaro Bedoya, with one vacancy.

F. The Commission Decision

The Commission agreed with the ALJ that research, development, and commercialization of MCED tests in the United States is the relevant market for evaluating the acquisition. Op. 24-34. It also agreed with the ALJ that Illumina's NGS platforms are a critical and irreplaceable input for MCED test developers. Op. 35-39. To analyze the merger's effects, the Commission applied the well-established burden-shifting framework (Op. 23-24) which this Court endorsed in *Chicago Bridge & Iron Co. N.V. v. FTC*, 534 F.3d 410 (5th Cir. 2008). Under that framework, Complaint Counsel must first "establish a *prima facie* case that an acquisition is unlawful." *Id.* at 423. The merging parties may then rebut that case "by producing evidence to cast doubt on the accuracy of [Complaint Counsel's] evidence as predictive of future anti-competitive effects." *Id.* Finally, "if the respondent successfully rebuts the *prima facie* case, the burden of production shifts back to [Complaint Counsel] and merges with the ultimate burden of persuasion, which is incumbent on [Complaint Counsel] at all times." *Id.*

The Commission found that Complaint Counsel established a *prima facie* case of anticompetitive effects and that Illumina did not adequately rebut that case.

1. *Anticompetitive Effects*. The Commission analyzed the anticompetitive effects of the acquisition under two overlapping standards: one set forth by the Supreme Court in *Brown Shoe Co. v. United States*, 370 U.S. 294 (1962), and a test applied in more recent cases that examines whether a transaction will increase the ability and/or incentive of the merged firm to foreclose competition. *See, e.g.*, *United States v. AT&T Inc.*, 310 F. Supp. 3d 161, 243-45 (D.D.C. 2018), *aff'd*, 916 F.3d 1029 (D.C. Cir. 2019). Under both approaches, the Commission found that Complaint Counsel demonstrated a *prima facie* case that the merger may threaten competition.

Central to both analyses was the Commission's finding that a merged entity could impede or obstruct in multiple ways the efforts of Grail's rivals to develop and commercialize MCED tests—for example, by raising the prices charged for NGS platforms; withholding or degrading access to supplies, services, or new technologies; and withholding or delaying cooperation that MCED test developers need to

obtain regulatory approval for their product. Op. 43-44, 48-49. The Commission also found that the merger significantly increased Illumina's incentives to employ these foreclosure strategies. Op. 45, 49-53. As the owner of Grail, Illumina will earn much bigger profits from the sale of Grail's tests than it could by selling NGS platforms to Grail's rivals. Op. 49-50. The merged firm thus has "an enormous financial incentive to place [its] thumb on the scale" by favoring Grail over its competitors. Op. 45. The Commission found that use of these strategies would harm competition (and ultimately American consumers) by making it more difficult for Grail's rivals to develop their products, leading to reduced innovation, lower quality, and lower availability of competing MCED tests. Op. 59-61.

2. *Illumina's Defenses*. The Commission held that Illumina did not adequately rebut the *prima facie* case.[6] It rejected the claim that an "Open Offer" Illumina made to U.S. oncology customers, purporting to provide them with access to the same NGS platforms available to Grail at the same prices, would negate the merger's anticompetitive effects.

[6] The Commission majority opined that the Open Offer would more properly be addressed at the remedy stage, after a finding of liability, but because it made no difference to the outcome it analyzed the Offer on rebuttal. Op. 64-65.

Op. 65-73. The Commission likewise rejected Illumina's arguments that the merger would generate various efficiencies and procompetitive benefits that would offset the harms to competition. Op. 74-87.

3. *Constitutional Arguments*. Having found the merger unlawful, the Commission considered and rejected several constitutional challenges to its authority. Op. 87-93.

4. *Remedy*. The Commission ordered Illumina to divest Grail, except for the 12% stake it owned before the acquisition, and also imposed various interim requirements (which are stayed pending this Court's review). Op. 94-98.

G. Commissioner Wilson's Concurrence

Commissioner Christine S. Wilson authored a concurring opinion differing with some aspects of the majority's legal analysis but agreeing that the Grail acquisition "is likely to lessen competition substantially in the market for the research, development, and commercialization of MCED tests" and therefore violates the Clayton Act.[7] Conc. 1.

[7] Commissioner Wilson would have addressed anticompetitive effects solely under the ability-and-incentive test because she considered *Brown Shoe*'s focus on market share out-of-step with modern antitrust analysis. Conc. 1-3. She also disagreed with the Commission's statement that the Open Offer would more properly be addressed

Commissioner Wilson noted that "[e]ven with respect to those sections of the Opinion that I do not join, I do rely on and adopt the factual analysis contained therein." *Id.* She specifically agreed with the rejection of Illumina's Open Offer and efficiencies defenses. *Id.* at 4-5.

SUMMARY OF ARGUMENT

This case presents a textbook example of a vertical merger that threatens to stifle competition. What makes the Illumina-Grail merger especially problematic is that rival MCED test developers depend on access to Illumina's NGS platforms and have no available substitutes, now or in the near future. That gives the merged entity the ability to tilt the playing field in Grail's favor in multiple ways, and the merged firm has a strong incentive to do whatever it can to keep other MCED test developers at least one step behind Grail in the innovation race.

The Commission properly defined the relevant product market as research, development, and commercialization of MCED tests. Particularly relevant to this analysis is the overwhelming documentary evidence showing that Grail views itself as competing with other MCED

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at the remedy stage, *see supra* n.6, and did not join certain statements about efficiencies defenses. *Id.* at 3-5.

test developers in a distinct market. Illumina misses the mark with its arguments that other MCED tests are not yet being sold and may ultimately have different features from Galleri. The Commission was concerned with preserving the existing vigorous competition in research, development, and commercialization of MCED tests, not with current sales. And it found that other MCED tests in development were sufficiently similar to Galleri to give the merged firm a strong incentive to foreclose competition.

The Commission also properly found a reasonable probability that the merger will substantially lessen the existing competition among MCED test developers. Substantial evidence supports the Commission's conclusions that Complaint Counsel established a *prima facie* case of anticompetitive effects under both the ability-and-incentive test and under *Brown Shoe*. Illumina does not challenge the Commission's factual findings that the Open Offer would not offset the merger's anticompetitive effects. Its argument that the Commission should have addressed the Open Offer as part of the *prima facie* case is wrong, but in any event that does not matter because the Commission fully considered all the evidence and found the Offer fatally flawed. Further,

the Commission properly found that Illumina's claimed efficiencies were unsubstantiated, not merger-specific, and unlikely to be passed along to consumers. These findings are also supported by substantial evidence, and the Court must decline Illumina's repeated invitations to reweigh the evidence.

None of Illumina's constitutional arguments has merit. Illumina's nondelegation argument, based on *Jarkesy v. SEC*, 34 F.4th 446 (5th Cir. 2022), *cert granted,* 2023 WL 4278448 (June 30, 2023) is directed to the constitutionality of Section 13(b) of the FTC Act. That section, enacted in 1973, gave the Commission authority to sue for a permanent injunction in district court as an alternative to administrative adjudication, but the Commission has never sought a permanent injunction against Illumina under Section 13(b) so the nondelegation issue is not presented here. In any case, unlike the statute in *Jarkesy*, Section 13(b) did not give the Commission authority to determine who gets a jury trial because it authorizes only the equitable remedy of an injunction. Furthermore, Congress provided an intelligible principle to guide the Commission's choice of forum by directing it to consider the public interest in deciding whether to proceed under Section 13(b) or

administratively. The Supreme Court has long held that such directives are sufficient to avoid any nondelegation problem.

Illumina's argument that the structure of the Commission is unconstitutional because Commissioners can be removed only for cause is squarely barred by *Humphrey's Executor v. United States*, 295 U.S. 602 (1935), which is binding on this Court. But even if *Humphrey*'s *Executor* were to be overruled, that would not invalidate the Commission's decision, because it is undisputed that the Commissioners were properly appointed, and Illumina cannot show any harm traceable to the removal restriction.

Withrow v. Larkin, 421 U.S. 35 (1975), bars Illumina's argument that Commission proceedings violate due process because prosecutorial and adjudicative functions are combined in the same agency. As due process required, the agency staff responsible for prosecution were walled off from the Commissioners once the complaint was issued. Moreover, Illumina has not shown any actual bias by any of the Commissioners.

Finally, Illumina's equal protection claim fails because the allocation of merger cases between the Commission and the

Department of Justice is rationally related to legitimate government purposes. Congress gave the Commission and DOJ overlapping jurisdiction to enforce the Clayton Act, and the agencies' allocation of cases conserves resources, avoids duplicative proceedings, and allows each agency to develop industry-specific expertise. Equal protection does not give merging parties the right to enforcement in the forum of their choice.

STANDARD OF REVIEW

This Court reviews the Commission's ruling, not the ALJ's. *Impax Labs v. FTC*, 994 F.3d 484, 491 (5th Cir. 2021). The Commission's findings are "conclusive" if supported by substantial evidence, *i.e.*, "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." 15 U.S.C. §§ 21(c), 45(c); *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 454 (1986). This is a "deferential review" that is "no more searching than if [the Court] were evaluating a jury's verdict." *Impax*, 994 F.3d at 492. The Court's "task is not to reweigh the evidence." *Chicago Bridge*, 534 F.3d at 430. "The statute forbids a court to make its own appraisal of the testimony, picking and choosing for itself among uncertain and conflicting inferences." *Indiana Fed'n*, 476

U.S. at 454 (cleaned up). Rather, the Court "must accept findings supported by [substantial] evidence even if suggested alternative conclusions may be equally or even more reasonable and persuasive." *Impax*, 994 F.3d at 492 (cleaned up).

The Commission's legal conclusions are reviewed *de novo* as to both antitrust questions and constitutional issues. *Chicago Bridge*, 534 F.3d at 422; *Jarkesy*, 34 F.4th at 451.

ARGUMENT

Where a litigant raises both statutory and constitutional arguments, a court "usually should pass on the statutory claim before considering the constitutional question." *Califano v. Yamasaki*, 442 U.S. 682, 692 (1979). Accordingly, we first show that Illumina's substantive antitrust challenges to the Commission's order lack merit, and then show that Illumina's constitutional arguments also fail.

I. THE COMMISSION PROPERLY FOUND THAT ILLUMINA'S MERGER WITH GRAIL VIOLATES THE CLAYTON ACT.

The Clayton Act prohibits acquisitions the effect of which "may be substantially to lessen competition, or to tend to create a monopoly." 15 U.S.C. § 18. Congress used the words "may be" to "indicate that its concern was with probabilities, not certainties." *Brown Shoe*, 370 U.S.

at 323. Because the Act was designed to "arrest anticompetitive tendencies in their incipiency," it "requires … a prediction of [a merger's] impact upon competitive conditions in the future." *United States v. Phila. Nat'l Bank*, 374 U.S. 321, 362 (1960) (cleaned up). "[D]oubts are to be resolved against the transaction." *FTC v. Elders Grain, Inc.*, 868 F.2d 901, 906 (7th Cir. 1989). The ultimate issue is whether there is "a reasonable probability that the merger will substantially lessen competition." *Brown Shoe*, 370 U.S. at 325.

The Clayton Act applies equally to horizontal and vertical mergers.[8] *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 590-92 (1957) ("*DuPont I*") (Clayton Act always applied to vertical mergers, and 1950 amendment made that clear); *see also Heatransfer Corp. v. Volkswagenwerk, A.G.*, 553 F.2d 964, 981-82 (5th Cir. 1977) (affirming finding that vertical merger violated Clayton Act). "The primary vice of a vertical merger … is that, by foreclosing the competitors of either party from a segment of the market otherwise

[8] Illumina argues that "most vertical mergers are procompetitive" (Br. 40, 58), but it is well-recognized that a vertical merger may be anticompetitive, *e.g.*, if it "so narrow[s] the market that rivals or new entrants would have inadequate access to low-cost inputs." Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* § 1008a (Aug. 2022 update).

open to them, the arrangement may act as a clog on competition." *Brown Shoe*, 370 U.S. at 323-24 (cleaned up).

This case involves a textbook example of a vertical merger that threatens to clog competition in a developing industry. What makes Illumina and Grail's merger an especially clear statutory violation is that Grail's downstream competitors are completely dependent on Illumina's NGS platforms and have no available substitute today or in the near future. A merged entity will thus have both the ability and a strong financial incentive to disadvantage other MCED test developers—Grail's direct rivals—by raising the cost of this critical input or denying or degrading access to it. That would reduce competition among MCED test developers, leading to less innovation, higher prices, and lower quality and availability of MCED tests.

A. The Commission Properly Defined the Relevant Market.

The first step in merger analysis is definition of the relevant market, *i.e.,* the "line of commerce" and the "section of the country" where competition occurs. 15 U.S.C. § 18; *Brown Shoe*, 370 U.S. at 324. Congress "prescribed a pragmatic, factual approach to the definition of the relevant market and not a formal, legalistic one," *Brown Shoe*,

370 U.S. at 336; *see also Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2285 (2018) ("[C]ourts should combine different products or services into a single market when that combination reflects commercial realities.") (cleaned up). The Commission agreed with the ALJ that the relevant product market here is research, development, and commercialization of MCED tests. Op. 24-25; ID 164-68.[9] The evidence supporting that finding is overwhelming.[10]

The Commission defined the product market using the *Brown Shoe* methodology, which Illumina concedes is proper. Br. 34-35. Under *Brown Shoe*, the "outer boundaries of a product market are determined by the reasonable interchangeability of use" between the product and substitutes for it. 370 U.S. at 325. Within that broad market, courts examine several "practical indicia" to identify "submarkets" which "in themselves[] constitute product markets for antitrust purposes." *Id.* "[T]he presence of some [indicia], and absence of others, is not

[9] It is undisputed that the relevant geographic market is the United States.

[10] Illumina's argument that the Commission erred in not defining a "related product market" (Br. 39 n.11) is raised only in a footnote and therefore waived. *See, e.g.*, *Bridas S.A.P.I.C. v. Gov't of Turkmenistan*, 345 F.3d 347, 357 n.7 (5th Cir. 2003).

dispositive." *Se. Mo. Hosp. v. C.R. Bard, Inc.*, 642 F.3d 608, 614 (8th Cir. 2011).

The Commission focused on four of the *Brown Shoe* indicia. Op. 26-29. First, the Commission found that MCED tests have peculiar characteristics and uses that set them apart from other tests. Op. 26. The defining characteristic of MCED tests, the Commission explained, is that they can detect multiple forms of cancer at an early stage by examining DNA fragments in the bloodstream. *Id.* Illumina effectively conceded this point below. Op. 25-26; *see also* Br. 35 (characterizing whether MCEDs are a distinct product line as a "non-issue").

Second, the Commission found that MCED tests will have distinct customers from other types of tests because they are designed for use by asymptomatic adults, as opposed to patients with symptoms or a diagnosis of cancer. Op. 26-27. Again, Illumina effectively conceded this point below. Op. 27.

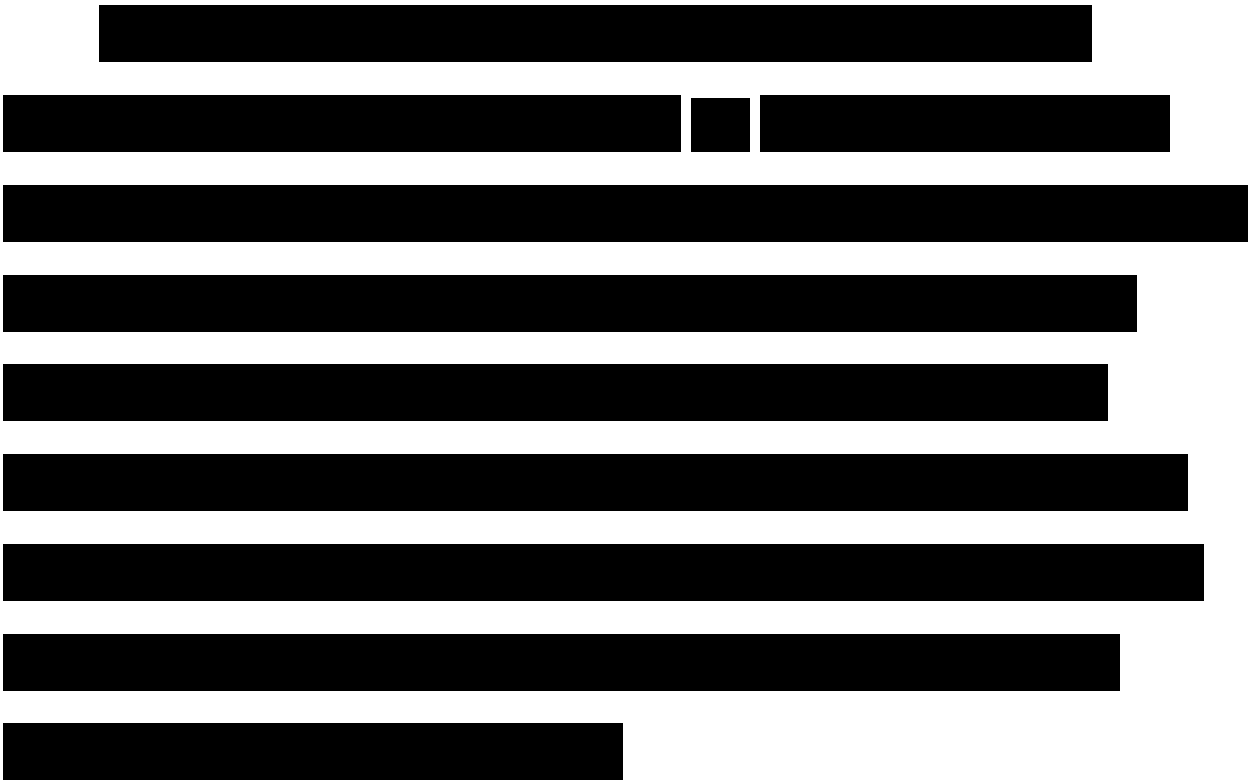
Third, the Commission found that MCED tests will have distinct prices from other types of cancer tests because of "the need to attract a unique population of asymptomatic individuals and to persuade payers to reimburse the tests at population scale." Op. 28. Illumina argues that

the exact prices for other MCED tests are unknown because they are not yet being sold (Br. 36), but that does not undermine the Commission's conclusion that the features and intended use of the tests will result in distinct prices.

Finally, the Commission focused on "industry … recognition of the []market as a separate economic entity." Op. 28; *Brown Shoe*, 370 U.S. at 325. It cited copious evidence from Grail's documents showing that Grail views itself as competing with other MCED test developers in a distinct market. Op. 28, 30-34. This evidence is particularly important because courts "assume that economic actors usually have accurate perceptions of economic realities." *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 218 n.4 (D.C. Cir. 1986).

For example, in a 2020 presentation addressing [redacted] Op. 33; PX4250-002, -009. In a 2020 SEC filing, Grail described itself as operating in an "intensely competitive" environment and identified these same companies as "competitors" that were "developing tests designed to detect cancer, including some that

will use [genetic data] analyses like ours." PX4082-036. In a 2021 presentation for a cancer research conference, Grail stated that MCED tests were "evolving into a highly competitive landscape" and identified several "[p]otential MCED direct competitor[s]." PX4616-017. Grail regularly gathered intelligence on and monitored the activities of potential competitors in the MCED space. *See* PX4048; Tr. 510-12.



Additionally, Illumina's CEO at the time of the merger acknowledged that the merged firm would be "compet[ing] with … some of our customers," including several of Grail's MCED rivals. Tr. 2222-23. And executives from other MCED test developers likewise testified

that they were directly competing with Grail and with each other. *See* [redacted] 2504-05 (Guardant); [redacted] PX7042 at 98-100 (Singlera); [redacted] This evidence leaves no doubt that Grail is currently engaged in vigorous competition with other MCED developers to win the innovation race.

Illumina wrongly suggests that the Court should ignore this real-world evidence. Br. 37. But this Court has held that materials such as "affidavits, documentary evidence, and deposition testimony"—including "marketing and competitive strategies" showing that a group of firms viewed themselves as a distinct industry and competed vigorously with each other—is probative evidence on market definition. *C.E. Servs., Inc. v. Control Data Corp.*, 759 F.2d 1241, 1246 (5th Cir. 1985). The case Illumina cites merely held that certain lay opinion testimony and internal marketing documents were not enough to support the proposed market definition in that case, not that ordinary-course documents and testimony are categorically irrelevant. *Ky. Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc.*, 588 F.3d 908, 919 (6th Cir. 2009).

Illumina's other attacks on the Commission's market definition also lack merit. First, Illumina argues that other MCED tests are not reasonably interchangeable with Galleri because they are not being sold and their precise features and performance characteristics are not yet known.[11] Br. 30-34. As the Commission explained, Illumina's arguments "miss the mark" because the issue in this case whether the *research, development, and commercialization* of MCED tests constitutes a distinct market, given all the evidence of existing vigorous competition among MCED test developers. That turns on "whether MCED tests will be sufficiently interchangeable in the future such that the merged firm has an incentive to disadvantage Grail's rivals as they pursue research, development, and commercialization." Op. 30. The Commission found that the tests would be sufficiently interchangeable because they all "share core features and functionality with Galleri"—they are "designed to detect multiple cancers by blood draw in asymptomatic patients"—and Grail "viewed rival products as potentially developing into substitutes for Galleri." *Id.*

[11] Illumina asserts that any market entry by a rival firm is five to seven years away (Br. 34), but the Commission found [redacted] Op. 15.

The fact that other tests may have some different features or performance characteristics from Galleri does not undermine the Commission's conclusion. "[P]roducts or services need not be identical to be part of the same market." *AD/SAT v. Assoc. Press*, 181 F.3d 216, 227 (2d Cir. 1999). Here, "different companies are taking different approaches" to MCED tests as one would expect in a "nascent market engaged in innovation." Op. 31. The purpose of preserving competition is to foster that innovation so that consumers have a choice. As Dr. William Cance of the American Cancer Society testified, "we don't have a depth of knowledge yet in the complex area of human cancer to know which test or tests … will be the most effective." Tr. 621.

Illumina wrongly accuses the Commission of "denigrating" Galleri. Br. 33. The portions of the Commission opinion Illumina cites (Op. 54-56) discuss anticompetitive effects, not market definition, but in any case the Commission's findings are fully supported by the record. It is undisputed that Galleri does not yet have FDA approval. Illumina's own expert acknowledged that Galleri has only been shown to detect seven types of early-stage cancer in the intended use-population of asymptomatic adults, not 50 as Illumina repeatedly claims. Op. 54; Tr.

4000-01.[12] And Grail's own website states that a positive test may require follow-up imaging for diagnostic confirmation. Op. 55; PX0063-002; *see also* Tr. 1387; PX4207-040; RX3041-003. None of the other purported facts that Illumina claims the Commission ignored have any bearing on market definition.

Illumina's argument that a product market analysis must always begin by examining the "most narrowly-defined group of products" (Br. 34-35) is also wrong. *Brown Shoe* expressly contemplates that the market analysis may start with a broad group of all reasonably interchangeable products, which can then be narrowed into distinct submarkets based upon the practical indicia. *See* 370 U.S. at 325. Indeed, the Court there rejected an argument that the market for "children's shoes" should be further subdivided based on age and sex because "[f]urther division does not aid us in analyzing the effects of this merger." *Id.* at 327. The iterative broadening process Illumina describes comes from a different method for defining markets called the hypothetical monopolist test ("HMT"), which the Commission did not

[12] As the Commission explained, the 50-cancer claim is based on a study that included patients already diagnosed with cancer. Op. 13.

apply here and which differs from the *Brown Shoe* analysis.[13] Notably, Illumina's expert agreed that it is not a requirement to begin with the smallest possible market. PX7132-029.

Illumina' remaining cases (Br. 37-38) are inapt. Illumina cites *SCM Corp. v. Xerox Corp*, 645 F.2d 1195 (2d Cir. 1981), for the proposition that the Clayton Act requires potential harm to competition in an existing market*, id.* at 1211, but here the Commission focused on the existing market for research, development, and commercialization of MCED tests. *Golden Gate Pharmacy Services, Inc. v. Pfizer*, No. C-09-3854, 2010 WL 1541257 (N.D. Cal., April 16, 2010), rejected a proposed market defined as the "pharmaceutical industry" because all pharmaceuticals are not interchangeable, *id.* at *3, but here the Commission focused on one category of medical tests sharing core features and functionality. *Mercantile Texas Corp. v. Board of*

[13] *See generally* Dep't of Justice & FTC, *Horizontal Merger Guidelines* § 4.1.1 (2010) (describing HMT). Although the HMT is often a useful way to define markets, it is not required. The Commission did not apply the HMT here because it concluded the necessary cross-elasticity data was not available given the nature of the market. Op. 29 n.12. *FTC v. Arch Coal*, 329 F. Supp. 2d 109 (D.D.C. 2004), discusses the "narrowest market" principle in the context of an HMT analysis. *Id.* at 120-21.

Governors of the Federal Reserve System, 638 F.2d 1255 (5th Cir. 1981), does not involve market definition and has no relevance to this case.[14]

B. The Commission Properly Found a *Prima Facie* Case of Anticompetitive Effects.

The Commission majority held that Complaint Counsel established a *prima facie* case of anticompetitive effects under both *Brown Shoe* and the ability-and-incentive test. The Commission properly applied both tests and substantial evidence supports its conclusions. Because all four Commissioners agreed on the ability-and-incentive test, and Illumina agrees that test is proper (Br. 46), we begin there.

1. The Commission Properly Found a *Prima Facie* Case Under the Ability-and-Incentive Framework.

The Commission properly found that Complaint Counsel established a *prima facie* case by showing that Illumina had the ability to foreclose competition among MCED test developers and that the merger substantially increases its incentive to do so. Op. 47-61.

[14] Contrary to Illumina's claims, *Mercantile Texas* did not hold that courts may not "consider market entry that will not occur within two or three years." Br. 38. It held that if a potential competitor's likely market entry were further away than that, the antitrust analysis should address whether market concentration might change in that time period. 638 F.2d at 1272.

Illumina does not dispute that it has the *ability* to foreclose competition. Its arguments focus entirely on the incentive side of the test. Br. 47-55. But substantial evidence, including Illumina and Grail's internal documents and expert economic analysis, supports the Commission's finding that the merged firm has an increased incentive to take actions that would hinder the development and commercialization of MCED tests that might compete with Galleri.[15]

Contrary to Illumina's claims (Br. 48), the Commission properly compared Illumina's incentives in a world without the Grail acquisition to Illumina's incentives as 100% owner of Grail. The Commission explained that before the merger, Illumina stood to derive only a small share of profits from Grail's sale of MCED tests, based on its 12% ownership stake in Grail and the royalty Illumina receives on sales of Grail products. Op. 49. Under those circumstances, if Illumina sought to favor Grail over rival MCED test developers, the benefit it would receive would be significantly offset by the NGS revenue it would lose if

[15] The Commission credited the testimony of Complaint Counsel's economic expert, Dr. Fiona Scott Morton, finding that she was "highly qualified to offer economic opinions for this case." Op. 47 n.31. Dr. Scott Morton is a professor at the Yale School of Organization and Management who studies and conducts research regarding competitive strategy and industrial organization. PX6090 ¶¶ 1-6.

a rival's MCED business were to shrink. *Id.*; *see* PX6090 ¶ 196. Thus Illumina had at most a small incentive to engage in a foreclosure strategy. Op. 49.

As the 100% owner of Grail, however, Illumina's incentives change dramatically. For tests sold by Grail, Illumina will earn a profit on NGS sales plus 100% of the profit on Grail's sales, whereas for tests made by other companies it will earn a profit only on NGS sales. Op. 49-50. Since Illumina now will earn substantially more profit on Grail's tests than it would on a test sold by another developer, it has a substantially increased incentive to favor Grail over other test developers. Op. 49-50; PX7138 at 57.

As the Commission found (Op. 50-51), Illumina's and Grail's internal documents bolster the conclusion that the merger will substantially increase Illumina's foreclosure incentive. The Grail acquisition was a key part of Illumina's strategy to [redacted] PX2465 at 3. Illumina saw Grail's MCED business as a [redacted], PX2151 at 5, and [redacted]

[redacted], PX2488 at 8. [redacted]

[redacted].

Post-merger, Illumina thus has "a powerful economic incentive to use its control over the NGS platform to hamstring GRAIL's competitors as they pursue commercialization and eventual FDA approval." Op. 51.

The Commission found that Illumina's past conduct bolsters the conclusion that the Grail acquisition heightened Illumina's incentive to foreclose. When Illumina was Grail's sole owner, it gave Grail deep discounts on pricing and other benefits that were not available to other firms. When Illumina reduced its ownership to a minority stake, it eliminated these benefits to "level[] the playing field" and "accelerate the liquid biopsy market for all." Op. 11, 52; PX2406-005. As the Commission found, these statements acknowledge the existence of competition and raise concerns that Illumina's reacquisition of Grail will "re-tilt" the playing field. Op. 52-53.

Additionally, when Illumina vertically expanded into therapy selection tests (used to help clinicians choose the appropriate treatment for cancer patients), it began to see some NGS customers in that market as competitive threats, and took that into account in deciding whether to support their efforts to obtain FDA approval. Op. 53; *see* PX2095-002 (arguing [redacted]); Tr. 2085 (discussing "cannibalization" of Illumina's business). The Commission found that this "real-world evidence" showed that Illumina "rationally acted on its incentives in determining the amount of cooperation it would provide to downstream competitors," and that Illumina "can be expected to similarly limit support for MCED rivals after the Acquisition." Op. 53.

Illumina's arguments (Br. 48-55) essentially ask the Court to reweigh the evidence, which is improper under the substantial evidence standard. For example, Illumina argues that other MCED tests are not reasonable substitutes for Galleri and hence will not divert sales. Br. 49-50. But the Commission cited extensive evidence that other tests are sufficiently close substitutes to Galleri that they could divert sales—making it economically advantageous for Illumina to try to slow or halt

their development. *See* Op. 54-57. And as noted above (at 27-28) the fact that other tests may not be identical to Galleri does not mean they will not meaningfully compete with it. *See AD/SAT*, 181 F.3d at 227.

Substantial evidence likewise supports the Commission finding that concerns about reputational harm will not constrain Illumina from engaging in foreclosure strategies. The record showed that Illumina has the ability to target MCED customers specifically. Op. 57-58 (citing IDF ¶¶ 746-759, 766-778). Moreover, Illumina could undercut MCED test developers' access to NGS platforms in subtle ways that would not be apparent to other customers and thus would not cause reputational harm. Op. 58 (citing PX7105 at 69-71; PX7113 at 277; PX7058 at 174-77). And the fact that MCED customers have no alternative to Illumina's NGS platforms limits Illumina's potential losses. Op. 58. Illumina claims there is evidence of actual and potential competition in the NGS market (Br. 51-52), but the Commission carefully analyzed the evidence and concluded (in agreement with the ALJ) that Illumina's NGS platforms are the only ones suitable for use in MCED testing now or in the near future. Op. 7-9, 36-40; *see also* ID 151-52.

Illumina is mistaken in asserting (Br. 54-55) that the Commission "ignored" its 2013 acquisition of Verinata, which makes noninvasive prenatal tests ("NIPT"). Although Illumina contends that the Verinata merger had procompetitive effects, that acquisition involved a very different market situation because—as Illumina acknowledges—there were already four NIPT providers on the market and Verinata was not the first to market. *See* RFF ¶ 953. But the Commission raised concerns about Illumina's conduct with respect to Verinata, [redacted] Op. 33 (citing [redacted]). Other evidence raises additional concerns about Illumina's tactics, including a presentation showing that Illumina wanted to "[c]reate a cost structure for Natera that they can't sustain or introduce[] a reasonable price floor" and to "[l]ock in" another NIPT competitor "in order to ensure … [m]arket price floor." PX2076-003.

Finally, Illumina's assertion that it does not expect to earn a profit on the purchase of Grail until 2026 or fully recoup the cost of purchase until 2030 (Br. 52) does not undercut the Commission's findings.

Presumably Illumina would not have invested $8 billion to purchase Grail if it did not think the transaction would be profitable in the long term.

2. The Commission Properly Found a *Prima Facie* Case Under *Brown Shoe*.

The Commission majority also properly found a *prima facie* case of anticompetitive effects under *Brown Shoe* and its progeny. That approach begins by examining the "share of the market foreclosed," which is an "important" but not necessarily "determinative" consideration in determining whether a vertical merger may substantially lessen competition. *Brown Shoe* 370 U.S. at 328. "[I]f the share of the market foreclosed is so large that it approaches monopoly proportions, the Clayton Act will, of course, have been violated," but otherwise courts must examine other "economic and historical factors" to determine whether the transaction may have an anticompetitive effect. *Id.* at 328-29.

In keeping with this approach, the Commission first found that the share of the market foreclosed was "very substantial" because NGS platforms are a critical input for MCED test developers and Illumina is the only viable supplier of that technology. Op. 42-45. Illumina could

exploit its dominance to gain a competitive advantage over Grail's MCED rivals, including by raising prices for NGS platforms, withholding or degrading access to service or supplies or new products, and delaying or withholding cooperation necessary to obtain regulatory approval. Op. 43-45.

The Commission then turned to other factors discussed in *Brown Shoe* and its progeny, starting with the "nature and purpose" of the acquisition. *Brown Shoe*, 370 U.S. at 329. That factor supported a finding of likely anticompetitive effects, since Illumina's stated purpose for the merger was to shift the balance of its revenues away from NGS platforms and toward clinical testing, which Illumina saw as an enormous profit opportunity. Op. 45-46. Another relevant factor is "the degree of market power … possessed by the merged enterprise." *Fruehauf Corp. v. FTC*, 603 F.2d 345, 353 (2d Cir. 1979). That factor also supported a *prima facie* case, since Grail is the only current seller of MCED tests and will directly benefit from the merged firm's use of foreclosure strategies against its competitors. Op. 46. "[B]arriers to entry" are also a relevant factor. *Ford Motor Co. v. United States*, 405 U.S. 562, 571 (1972); *see also Fruehoff*, 603 F.2d at 353 ("capital cost"

and "market share needed … to achieve a profitable level of production" are relevant factors). The Commission found that the merger will likely raise entry barriers, because developing an MCED test is an extremely costly and time-consuming process, and companies are less likely to make the necessary investments to enter the market if they are completely dependent on a sole-source supplier that is also a competitor. Op. 47-48.

There is no merit to Illumina's arguments that the Commission misapplied *Brown Shoe*. Br. 41-46. Contrary to Illumina's claim (Br. 41-42), the Commission did not rely on mere "possibilities." The Commission found a "reasonable likelihood" that the merger will substantially lessen competition (Op. 41-42), which is the proper standard. *See Brown Shoe*, 370 U.S. at 323 n.39, 324; *Chicago Bridge*, 534 F.3d at 423. The Clayton Act does not require proof of more because its purpose is to "arrest restraints of trade in their incipiency and before they develop into full-fledged restraints." *Id.*

Nor did the Commission apply a *per se* rule or rely solely on market share, as Illumina claims. Br. 42-43. The Commission considered the share of the market foreclosed, as instructed by *Brown*

Shoe, and then proceeded to analyze other factors. Illumina faults the Commission for not addressing all of the *Brown Shoe* factors (Br. 43), but as the Commission noted, the Supreme Court has found mergers unlawful where only some of the factors were satisfied. Op. 42 n.27 (citing *Ford Motor*, 405 U.S. at 566-70); *see also Fruehoff*, 603 F.2d at 353 ("[T]here are no precise formulas for determining whether a vertical merger may probably lessen competition."). Illumina makes no showing that the omitted factors were relevant to this case or that consideration of them might have changed the analysis.

Illumina's argument that "the merger will cause no actual foreclosure today" because Galleri is the only MCED currently being sold (Br. 44) focuses on the wrong market. The Commission properly found a reasonable likelihood that the merger will foreclose the competition existing today between Grail and other firms *to develop and commercialize* MCED tests.[16] Op. 40-41.

Illumina's challenges to the *Brown Shoe*-related factual findings (Br. 43-46) of the Commission likewise fail. Although Illumina argues

[16] Illumina's citation to *Mercantile Texas* again misstates that case's holding, and Illumina again ignores [redacted] *See supra* nn.11, 14

that the purpose of the merger was simply to "accelerate Galleri and save lives" (Br. 44), ample evidence showed that the Grail acquisition was part of a long-term strategy by Illumina to shift its profit center away from NGS platforms and toward clinical testing. PX2151-005; PX2169-045; PX2465-006 to -008; PX2488-009. And as discussed below (at 56), the Commission found that Illumina offered only unsupported speculation to support its claims of market acceleration and potential lives saved. Given this record, the Commission was not required to credit self-serving testimony from Illumina and Grail executives that they acted out of altruism.[17]

Illumina is also off base in arguing that the merger will not change the merged firm's market power. Br. 45. As the Commission explained, Illumina already has the power to foreclose competition among MCED test developers and the merger will give it an increased *incentive* to foreclose because it will be directly competing with Grail's rivals. Op. 52-53; *cf. Ford Motor Co.*, 405 U.S. at 571 (vertical

[17] Illumina is not aided by its reference to Professors Areeda and Hovenkamp's discussion of the "antitrust injury" a private plaintiff must demonstrate to have standing to sue. Br. 45. That requirement does not apply to the United States government. *See* Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* § 335a (May 2023 update).

acquisition violated § 7 where the merged firm had "every incentive" to foreclose rivals).

Finally, although Illumina contends that the merger will not increase barriers to entry (Br. 45), the Commission cited ample evidence that the merger will disincentivize firms from undertaking the large investments necessary to develop an MCED test, including testimony from several of Grail's leading competitors, *see* Op. 47; [redacted]. Illumina argues that the ALJ gave scant weight to this evidence (Br. 45-46), but Congress gave the ultimate authority to weigh evidence to the Commission, not the ALJ. *See Impax*, 994 F.3d at 491.

C. The Commission Properly Held That the Open Offer Does Not Offset the Merger's Anticompetitive Effects.

The Commission carefully analyzed the evidence concerning Illumina's "Open Offer" and properly concluded that the Offer does not "eliminate Illumina's ability to favor GRAIL and harm GRAIL's rivals" or "fundamentally alter its incentive to do so." Op. 73.[18] Illumina does

[18] Commissioner Wilson agreed that "the Open Offer does not prevent Illumina from advantaging GRAIL relative to GRAIL's rivals" or "eliminate the predicted anticompetitive effects of the transaction," and that "even after considering the

not contend that any of these findings are unsupported by substantial evidence and has shown no basis for overturning them.

As the Commission explained, the flaws in the Open Offer are legion. First, Illumina's offer to provide price parity to Grail's rivals is illusory because after the merger, the "prices" charged to Grail are internal transfer prices that can be adjusted at will. Op. 67-68. Illumina's own expert conceded that "GRAIL doesn't technically pay a price" and that any "price" charged by Illumina would be a made-up scenario. Op. 68; RX6000-36. Second, the offer to provide comparable service to Grail's competitors would be easy to evade. Op. 68-69. The Open Offer allows Illumina to give Grail advance access to information about new products still in development or to design NGS sequencers specifically to optimize performance for Grail. Op. 69-70. And the Offer's firewall to protect MCED rivals' competitive information is "unusually porous and inherently flawed." Op. 70. Finally, enforcement of the Offer's terms would be difficult and of limited effect. Op. 71-72.

effects of the Open Offer, anticompetitive effects are likely and the transaction is likely to lessen competition substantially." Conc. 4-5.

Illumina's argument that the Commission erred by not addressing the Open Offer as part of Complaint Counsel's *prima facie* case (Br. 57-58) is a red herring. As this Court held in *Chicago Bridge* (which Illumina does not reference), burden-shifting is "a flexible framework rather than an air-tight rule," and "in practice, evidence is often considered all at once and the burdens are often analyzed together." 534 F.3d at 424. Here, Complaint Counsel produced evidence in its case-in-chief that the Open Offer was ineffective, *see, e.g.*, PX6090 ¶¶ 305-315, and Illumina attempted to produce contrary evidence in the defense case. Although the Commission addressed this evidence at the rebuttal stage of the analysis, the result would have been no different if it had been considered at the *prima facie* stage, given the Commission's findings that the Offer is full of holes and would not offset the anticompetitive effects of the merger.

In any case, the Commission did not err by addressing the Open Offer at the rebuttal stage. Illumina's argument is a variation on one this Court rejected in *Chicago Bridge*, where the merging parties claimed that the Commission improperly shifted the burden of persuasion on their market entry defense. 534 F. 3d at 425. The Court

held that the Commission had properly imposed the burden of *production* on the merging parties, *i.e.*, "the obligation to come forward with evidence" to support their defense. *Id.* Once such evidence is introduced, the Court explained, the Commission must "judge whether the nexus between the rebuttal arguments and the proffered evidence is plausible so as to satisfy the burden of production as a matter of law." *Id.* While the Commission cannot impose "too exacting a standard," it "has some discretion to decide if the [merging parties'] proffered evidence justifies [their] arguments in rebuttal." *Id.* at 425-26. Where Complaint Counsel has anticipated and addressed the rebuttal evidence in its prima facie case, as in both *Chicago Bridge* and this case, the merging parties' "burden of production on rebuttal is also heightened." *Id.* at 426. Here, the Commission properly determined that the Illumina did not meet its burden of production because the evidence did not show that the Open Offer would significantly counteract the merger's anticompetitive effects.

The Commission did not err by placing the burden on Illumina to produce evidence that the Open Offer would be effective. "Where the facts with regard to an issue lie peculiarly in the knowledge of a party,

that party is best situated to bear the burden…." *Smith v. United States*, 568 U.S. 106, 112 (2013) (cleaned up). Here, Illumina crafted the Open Offer and continued to modify it even while trial was proceeding. Because the facts regarding the Offer were peculiarly within Illumina's knowledge and control, Illumina bore the burden to produce evidence that the Offer would remedy the merger's anticompetitive effects. As the Commission explained, placing the burden on Complaint Counsel would "create a perverse incentive for merging parties to propose so-called fixes that leave some portion of competitive harm unremedied, requiring the government to keep up with shifting proposals that change, as this one did, in the midst of litigation, and forcing the public to live with partial remedies that do not fully restore competition." Op. 64; *see also* Conc. 4 (agreeing that "the burden of showing the competitive effects of the Open Offer falls on [Illumina]").

United States v. E.I. du Pont de Nemours & Co., 366 U.S. 316 (1961) ("*DuPont II*"), supports the Commission's conclusion that Illumina bore the burden of production here. In that case the Supreme Court held that "[t]he burden is not on the Government" to show that a proposed remedy for a Clayton Act violation would itself violate § 7, and

that complete divestiture is the appropriate remedy if there is a "substantial likelihood" that the proposed alternative remedy would not "satisfactorily eliminate[]" the anticompetitive effects. *Id.* at 331-32 (cleaned up). Although *Du Pont* involved a remedy that was proposed after a finding of liability, as an alternative to complete divestiture, the Commission majority and Commissioner Wilson, writing separately, both noted that lower courts have applied the same principles when considering proposed remedies at the liability stage. *See, e.g.*, *United States v. Aetna Inc.*, 240 F. Supp. 3d 1, 60 (D.D.C. 2017) ("In rebuttal, a defendant may introduce evidence that a proposed divestiture would restore the competition lost by the merger counteracting the anticompetitive effects of the merger.") (cleaned up); *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016) (merging parties "bear the burden of showing that any proposed remedy would negate any anticompetitive effects of the merger"); *FTC v. Sysco Corp*, 113 F. Supp. 3d 1, 72-73 (D.D.C. 2015) (placing burden on merging parties to show partial divestiture would replace competitive intensity lost by the merger.)

As the Commission noted (Op. 63-64), the cases cited by Illumina (Br. 55) are not to the contrary. In *United States v. AT&T, Inc.*, 916 F.3d 1029 (D.C. Cir. 2019), the district court held that the government failed to establish a *prima facie* case under the ability-and-incentive test, and described evidence of certain arbitration agreement offers as "extra icing on a cake already frosted." *Id.* at 1038. It did not hold that the government had the burden of producing evidence concerning those agreements. In *United States v. UnitedHealth Group, Inc.*, 630 F. Supp. 3d 118 (D.D.C. 2022), the court held that even applying the government's proposed standard, the defendants' evidence that a proposed divestiture would offset a merger's anticompetitive effects was sufficient to rebut the government's *prima facie* case. *Id.* at 134-35, 140. Although the court expressed its view that the government should bear the initial burden of showing the merger would substantially lessen competition with the proposed divestiture in place, that discussion is merely dicta and, as the court acknowledged, contrary to cases such as *Aetna* and *Sysco*. *Id.* at 132-33. *United States v. Libbey, Inc.*, 211 F. Supp. 2d 34 (D.D.C. 2002), merely held that where the original merger

agreement was superseded by an amended agreement, review should focus on the amended agreement. *Id.* at 46.

Finally, the Commission properly rejected Illumina's argument (renewed here at Br. 57) that the Open Offer should not be treated as a proposed remedy because it is supposedly a "market reality." Op. 62-63. As the Commission noted, the Offer was not "some preexisting market condition or 'economic reality' but a remedial effort crafted in anticipation of legal concerns about the Acquisition." Op. 62. The Offer was conditioned on Illumina's purchase of Grail; its terms are subject to ongoing modification; and it only applies to customers who sign the agreement (which not all MCED test developers have done). *Id.* The Commission properly held that the Open Offer should be analyzed the same way as other proposed remedies.

D. The Commission Properly Found That Illumina's Claimed Efficiencies Did Not Rebut the Showing of Anticompetitive Effects.

The Commission properly rejected Illumina's claims that various purported efficiencies could justify the merger. Op. 74-87. No court has ever held that efficiencies immunized an otherwise unlawful transaction, and several courts have expressed skepticism that an

efficiencies defense is even cognizable. *E.g.*, *FTC v. Hackensack Meridian Health, Inc.*, 30 F.4th 160, 176 (3d Cir. 2022); *United States v. Anthem, Inc.*, 855 F.3d 345, 353-54 (D.C. Cir. 2017); *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 347-48 (3d Cir. 2016); *St. Alphonsus Med. Ctr.-Nampa, Inc. v. St. Luke's Health Sys.*, 778 F.3d 775, 789-90 (9th Cir. 2015).

At a minimum, though, a party asserting the defense must meet several strict requirements. First, because "the language of the Clayton Act must be the linchpin of any efficiencies defense," the evidence must be sufficient to show that the merger is not anticompetitive. *St. Alphonsus*, 778 F.3d at 790. Second, the efficiencies must be "merger-specific," meaning they "cannot be achieved by either company alone" or by other means "without the concomitant loss of a competitor." *Id.* at 790-91; *Penn State Hershey*, 838 F.3d at 348. Third, the efficiencies must be "verifiable, not speculative." and "must be shown in what economists label 'real' terms." *Id.* at 348-49 (cleaned up). Fourth, the efficiencies "must not arise from anticompetitive reductions in output or service." *Id.* at 349. Finally, the benefits from the efficiencies must actually be passed through to consumers. *Anthem*, 855 F.3d at 362; *FTC*

v. University Health, Inc., 938 F.2d 1206, 1223 (11th Cir. 1991). The Commission properly considered these requirements and concluded that Illumina's claimed efficiencies were "unverified, not merger-specific, and to the extent they might somehow come to pass, not likely to benefit the public." Op. 76.[19]

Illumina's claims of legal error (Br. 60-64) mischaracterize the Commission's decision. The Commission did not shift the burden of persuasion to Illumina. It recognized that the burden of persuasion "remains with the government at all times" (Op. 24), but found Illumina's evidentiary showing insufficient to rebut Complaint Counsel's *prima facie* case. Nor did the Commission conclude that testimony of Illumina's business executives was "legally irrelevant," as Illumina claims. Br. 61. The Commission found that much of the specific testimony offered by Illumina consisted of unsupported speculation and was not independently verifiable. The legal standards applied by the Commission are correct and consistent with governing case law discussed above.

[19] Commissioner Wilson agreed that Illumina "failed adequately to substantiate [its] claims." Conc. 5.

Illumina's claims that the Commission's specific findings are not supported by substantial evidence also fall flat.

Grail Royalty: The Commission found that Illumina failed to show that elimination of the royalty paid by Grail to Illumina was merger-specific, pointing to [redacted]. Illumina asserts (Br. 65) that these scenarios were not viable, but as the Commission noted, the undisputed evidence is that [redacted], so there is no way to tell whether they might have been accepted. Op. 84; Tr. 3086-87.

In any event, even if this could be characterized as a merger-specific benefit, the Commission found no evidence that the royalty reduction (or any of the other claimed efficiencies) would be passed through to consumers, given "the current absence of a commercial alternative to Galleri and the corresponding absence of a competitive pressure to pass through." Op. 86. Illumina's expert merely assumed 100% pass-through and conceded that he could not model the effects of a reduction in Grail's royalty. Op. 86-87; RX3864 at 73 n.270; RX6000 at 125-26. Illumina argues that some portion of a reduced cost would be

passed through to consumers (Br. 67), but it was Illumina's burden to demonstrate that through economic analysis of this specific market (*e.g.*, by showing what portion of the costs will be passed through), and it failed to do so. Op. 87.

EDM: The Commission concluded that Illumina's evidence of efficiencies resulting from the elimination of double marginalization ("EDM") were not adequately substantiated and that there was no evidence any savings would be passed through to consumers. Op. 84, 87.[20] Illumina's economic expert conceded that he could not reliably quantify the value of EDM, and that his calculations were "intended only to be illustrative," and relied on "assumptions" about cost passthrough. Op. 84.

Illumina does not dispute these findings but argues that EDM should have been addressed as part of Complaint Counsel's *prima facie* case. Br. 66. Yet Illumina's expert agreed that EDM is an efficiency. RX3864 ¶ 101. As the Commission found, courts have uniformly held that the merging parties bear the burden of production as to

[20] Illumina's counsel conceded at oral argument before the Commission that EDM "is not one of the more significant efficiencies." Oral Arg. Tr. 56.

efficiencies. *See*, *e.g.*, *St. Alphonsus*, 778 F.3d at 791; *see also* Steven C. Salop, *Invigorating Vertical Merger Enforcement*, 127 Yale L.J. 1962, 1981 (2018) (in vertical mergers, "[b]ecause the merging parties have better access to the relevant information, they also bear the burden of producing evidence of efficiency benefits, just as they do elsewhere in antitrust").[21]

Supply Chain/Operational Efficiencies: Illumina is wrong in claiming that the Commission rejected claimed supply chain and operational efficiencies "principally because Grail had made some operational improvements on its own." Br. 66. The Commission rejected the claimed efficiencies primarily because they were speculative and unsupported; they were based on a single spreadsheet with no explanation of how the numbers were generated or the assumptions underlying the cost savings. Op. 84. The fact that Grail was improving operations on its own (which Illumina does not dispute) was an additional factor that made it "difficult to tell what incremental value, if any, the Acquisition will provide." Op. 85.

[21] Commissioner Wilson's 2020 remarks, which Illumina cites, did not argue that Complaint Counsel should bear the burden of demonstrating efficiencies, and Commissioner Wilson agreed that Illumina's efficiencies claims failed here.

R&D Efficiencies: Contrary to Illumina's assertion (Br. 67), the Commission rejected Illumina's claimed research and development efficiencies because they were not adequately verified, not because they were based on testimony by company executives. Illumina "failed to identify the nature or timing of specific, concrete research advances; to quantify their value; or to account for the likely costs of or barriers to achieving them." Op. 77.

Market Access Acceleration: The Commission had multiple reasons for rejecting Illumina's claim that the merger would save lives by accelerating FDA approval and payer acceptance for Galleri. First, the claim was based on vague and unsupported speculation. Illumina's economic expert assumed that the merger would accelerate Galleri's market acceptance by one year, but the only evidence to support that claim came from Illumina's chief medical officer ("CMO"), who testified as to the company's "feel[ing]" but provided no supporting analysis. Op. 78-79, Tr. 4360-61. The Commission also noted that Illumina did not account for any market acceleration in its financial modeling for the Grail acquisition, which "gives reason to question whether it will actually occur." Op. 79. Illumina claims that it was being "conservative"

(Br. 69), but the Commission credited expert testimony that this explanation was implausible given the [redacted]. Op. 79; PX6092 ¶48, PX7140 at 25-27. Illumina also failed to quantify the costs it would incur to achieve the purported market acceleration. Op. 79.

Furthermore, Illumina failed to produce any credible evidence as to how the claimed acceleration might occur. Illumina's CMO testified that "[redacted]. Op. 79. Despite Illumina's claim of superior FDA experience, it has obtained only one approval in the relevant area, and that was not for a liquid biopsy test. [redacted]. Op. 80-81; PX2593-001.

Illumina also failed to show that any regulatory acceleration would be merger-specific. Op. 80-81. The Commission found that Grail already had significant FDA experience. Given the enormous profits Illumina says are anticipated from Galleri, a stand-alone Grail would have a "massive financial incentive to accelerate market acceptance," either by expanding its own capabilities or by partnering with another firm. Op. 81.

The Commission likewise found that Illumina's claims that the merger would accelerate payer acceptance of Galleri amounted to "vague aspirations" and lacked the "verifiable, analytical plan needed to support an efficiency claim." Op. 81-82. These claims were also not merger-specific because the evidence showed that Illumina's experience was limited and not impossible to replicate, and that Grail was capable of working to obtain market access on its own.

All of these conclusions are supported by substantial evidence, as shown by the Commission's extensive citations to the record. Stripped to its essence, Illumina's argument (Br. 68-70) is that the Commission should simply have credited the say-so of its company executives. But the Commission reasonably and unanimously concluded that this

evidence was not sufficient to establish a verifiable, merger-specific efficiency that would benefit consumers.

International Expansion: Illumina also claims that the merger will accelerate international expansion of Galleri, but as the Commission found, a merger cannot be justified based on asserted efficiencies outside the relevant market (here, the United States). Op. 86 (citing *Phila. Nat'l Bank*, 374 U.S. at 370). In addition, the Commission found that any claimed benefits from international expansion were not verified or merger-specific. Illumina failed to produce concrete, verifiable evidence that international expansion would produce merger-specific benefits that would be passed on to American consumers.

II. ILLUMINA'S CONSTITUTIONAL CHALLENGES LACK MERIT.

Illumina also raises several constitutional challenges. None has merit.[22]

[22] Several *amici* also raise constitutional arguments, but all arguments not made by Illumina are waived. *See, e.g.*, *United States v. Fernandez*, 48 F.4th 405, 412 (5th Cir. 2022).

A. Illumina's Nondelegation Argument Is Waived, Not Properly Presented, and Wrong.

The Commission correctly found that Illumina waived its nondelegation argument by failing to raise that argument before trial. Op. 87.[23] Even if the nondelegation argument is not waived, it is not properly presented here. Illumina relies on this Court's decision in *Jarkesy*, where the petitioner was subject to an administrative penalty under a statute that gave the SEC "unfettered discretion" to impose penalties administratively rather than by suing in court. 34 F.4th at 459-63.[24] Illumina argues that Congress gave the FTC analogous discretion in 1973 by enacting Section 13(b) of the FTC Act, 15 U.S.C.

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[23] *Carr v. Saul*, 141 S. Ct. 1352 (2021), reiterated the general rule that litigants must raise issues before the agency to preserve their right to judicial review when the agency proceeding is adversarial. *Id.* at 1358. Contrary to Illumina's argument (Br. 18 n.4), *Carr* did not categorically exempt structural constitutional issues; it held that in the "specific context" of Social Security ALJ hearings, which have many inquisitorial features, the fact that a structural constitutional issue was involved "tipp[ed] the scales" against treating the matter as adversarial. *Id.* at 1360. Unlike Social Security proceedings, FTC adjudications are adversarial, and this Court has held that failure to properly raise an issue before the Commission generally precludes judicial review. *Cotherman v. FTC*, 417 F.2d 587, 591-92 (5th Cir. 1969); *see also Cmty. Fin. Servs. Ass'n of Am. v. CFPB*, 51 F.4th 616, 633 n.6 (5th Cir. 2022) (nondelegation argument not raised below was forfeited), *cert. granted on other grounds*, 143 S. Ct. 978 (2023).

[24] The Supreme Court granted certiorari in *Jarkesy* on June 30. The FTC respectfully preserves for future review the issue of whether Congress's decision to give an agency discretion to choose between judicial and administrative enforcement is a delegation of legislative power.

§ 53(b), which authorizes the Commission to sue in court for a permanent injunction as an alternative to administrative adjudication.[25] Br. 16-17. But since the Commission has not sought a permanent injunction against Illumina under Section 13(b), the Court has no occasion to address whether Congress violated the nondelegation doctrine by enacting that section.

If the Court nonetheless reaches this issue, it should hold that Section 13(b) does not unconstitutionally delegate legislative authority. The nondelegation issue in *Jarkesy* turned on Congress's having given the SEC "the ability to determine which subjects of its enforcement actions are entitled to Article III proceedings *with a jury trial*, and which are not." 34 F.4th at 461 (emphasis added). The FTC statutory scheme, by contrast, does not implicate jury trial rights because the only relief available under Section 13(b) is an "injunction"—an equitable remedy that does not trigger Seventh Amendment jury trial rights. *See, e.g.*, *Baum v. Blue Moon Ventures, LLC*, 513 F.3d 181, 193

[25] Section 13(b) also authorizes the Commission to sue in court for a *preliminary* injunction in aid of administrative proceedings, *e.g.,* to block a merger while the Commission considers its legality. As discussed above (at 8), the Commission filed a preliminary injunction action in this case but then voluntarily dismissed it after the EC's investigation triggered a standstill obligation.

(5th Cir. 2008). Because there is no right to a jury trial either under Section 13(b) or in an administrative adjudication, giving the Commission a choice between those forums is not a delegation of legislative power under the reasoning of *Jarkesy*.

Furthermore, the statute in *Jarkesy* said "nothing at all" about how the SEC should choose between seeking penalties in court or administratively. 34 F.4th at 462. Here, Congress provided an intelligible principle to guide the FTC's exercise of discretion by directing the Commission to consider "the interest of the public" in deciding whether to institute administrative or judicial proceedings. 15 U.S.C. §§ 45(b), 53(b).[26]

The "intelligible principle" standard is "not demanding." *Gundy v. United States*, 139 S. Ct. 2116, 2129 (2019). The Supreme Court has only found delegations excessive in two cases—both instances where "Congress had failed to articulate *any* policy or standard to confine

[26] Illumina argues (Br. 18 n.3) that the public interest does not provide guidance for deciding between administrative and judicial proceedings because that language appears in both Section 5 and Section 13(b), but the most natural reading of the two provisions is that where the Commission has a choice between judicial and administrative enforcement, it must determine which forum would better serve the public interest.

discretion"—and the Court has "over and over upheld even very broad delegations." *Id.* (cleaned up). Of particular relevance here, the Court has repeatedly "found an 'intelligible principle' in various statutes authorizing regulation in the 'public interest.'" *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 474 (2001). The public interest is "not a concept without ascertainable criteria," *N.Y. Cent. Sec. Corp. v. United States*, 287 U.S. 12, 25 (1932), or "so indefinite as to confer an unlimited power," *Nat'l Broad. Co. v. United States*, 319 U.S. 190, 216 (1943)*; see also id.* at 225-26 (rejecting nondelegation argument). Just last year, the First Circuit held that a criminal statute authorizing prosecutions in the "public interest" "indisputably satisfies the lax 'intelligible principle' standard under our precedents and those of the Supreme Court." *United States v. Diggins*, 36 F.4th 302, 319 n. 19 (1st Cir. 2022). Congress's directive to act in the "interests of the public" likewise satisfies the intelligible principle standard here.

In Clayton Act merger cases, the "interests of the public" often weigh in favor of administrative adjudication. That was the only means of enforcement available to the Commission from 1914 to 1973, and there is no indication that Congress intended the enactment of Section

13(b) to significantly alter that practice in merger cases. The legislative history of Section 13(b) indicates that Congress wanted to give the Commission flexibility to bypass the administrative process in situations where it "does not desire to further expand upon the provisions of the Federal Trade Commission Act through the issuance of a cease-and-desist order," as for example "in the routine fraud case." S. Rep. No. 93-151, at 31 (1973). Congress reasoned that giving the Commission the option of seeking a permanent injunction would enable "Commission resources [to] be better utilized, and cases [to] be disposed of more efficiently." *Id.*

Clayton Act merger cases, however, are well-suited for administrative adjudication. Congress created the Commission as an expert body that would be "specially competent" to deal with complex antitrust issues "by reason of information, experience and careful study of the business and economic conditions of the industr[ies] affected." *FTC v. R.F. Keppel & Bro., Inc.*, 291 U.S. 304, 314 (1934) (quoting S. Rep. No. 63-597 at 9, 11 (1914)); *see also Humphrey's Executor*, 295 U.S. at 624 (Commissioners "are called upon to exercise the trained judgment of a body of experts appointed by law and informed by

experience.") (cleaned up). Administrative adjudication in Clayton Act cases benefits the public because it allows the Commission to apply that specialized expertise and experience to the novel and complex questions that frequently arise in these cases. Thus the Commission has most commonly enforced Section 7 of the Clayton Act through administrative adjudication using the process that Congress prescribed in 1914.[27]

B. Illumina's Article II Challenge Is Barred by Supreme Court Precedent and Provides No Basis for Invalidating the Commission's Order.

Humphrey's Executor squarely bars Illumina's argument that the structure of the Commission violates Article II of the Constitution because the President cannot remove Commissioners at will.[28] In that case, President Roosevelt sought to remove a Commissioner without cause. The Supreme Court held that the FTC Act authorized removal of Commissioners only on the grounds specified in the statute

[27] There are exceptions, such as where the Commission seeks to enforce the Clayton Act jointly with a State *See, e.g.*, *St. Alphonsus*, 778 F.3d at 782 (joint suit with Idaho). In such instances, the public interest may favor district court enforcement because the State cannot participate as a plaintiff in an administrative proceeding.

[28] Arguments concerning the constitutionality of removal restrictions on FTC Commissioners and the combination of prosecutorial and adjudicative functions within the same agency were also raised in *Traffic Jam Events, LLC v. FTC*, No. 21-60947, which was argued on May 3, 2023.

("inefficiency, neglect of duty, or malfeasance in office") and that this limitation on the President's removal power was constitutional given the "character of the structure and functions of the Commission." 295 U.S. at 626-32.

In recent cases addressing the President's removal power, the Supreme Court has repeatedly declined to overrule *Humphrey's Executor*. For instance, *Seila Law LLC v. CFPB*, 140 S. Ct. 2183 (2020), held that Congress cannot restrict the President's power to remove a *single* head of department, but the Supreme Court expressly stated that "we need not and do not revisit our prior decisions allowing certain limitations on the President's removal power" in other contexts, including *Humphrey's Executor*. *Id.* at 2192; *accord Collins v. Yellin*, 141 S. Ct. 1761, 1783 (2021). Because the Supreme Court has not revisited *Humphrey's Executor*, that case is binding here. The Supreme Court's instructions on this point are clear: if one of its precedents "has direct application in a case, yet appears to rest on reasons rejected in some other line of decisions, the Court of Appeals should follow the case which directly controls, leaving to this Court the prerogative of overruling its own decisions." *Agostini v. Felton*, 521 U.S. 203, 237

(1997); *accord Lefebure v. D'Aquila*, 15 F.4th 650, 660-61 (5th Cir. 2021).

None of Illumina's arguments for disregarding *Humphrey's Executor* (Br. 20-21) withstands scrutiny. Although Congress has expanded the Commission's powers since *Humphrey's Executor* was decided, *e.g.*, by enacting Section 13(b), that does not make the Supreme Court's decision any less binding. *See FTC v. Am. Nat'l Cellular, Inc.*, 810 F.2d 1511, 1513-14 (9th Cir. 1987) (enactment of Section 13(b) did not render *Humphrey's Executor* inapposite). And *this* case does not involve any of those additional powers. The Commission is exercising the very authority that Congress granted in 1914: the power to conduct administrative adjudications to determine whether a transaction violates the Clayton Act. Illumina's assertion that the Commission lacked authority to order divestiture when *Humphrey's Executor* was decided (Br. 21) is incorrect. The Clayton Act has expressly authorized divestiture of stock from 1914 on (though it was later amended to authorize divestiture of assets as well). *See* ch. 323, § 11, 38 Stat. 730, 734 (1914) (codified as amended at 15 U.S.C. § 21(b)).

Furthermore, the key policy rationale underlying *Humphrey's Executor* remains valid today. Commissioners act as an adjudicatory body, and the for-cause removal standard ensures that they are free from "suspicion of partisan direction" or "political domination or control." *Humphrey's Executor*, 295 U.S. at 625. Congress has similarly provided for-cause removal standards for the members of many other non-Article III tribunals composed of multiple members who perform adjudicatory functions as an expert body within a specific area of the law.[29] *See Collins*, 141 S. Ct. at 1783 n.18; *Wiener v. United States*, 357 U. S. 349, 353 (1958).

In any event, even if *Humphrey's Executor* were overruled, that would not invalidate the Commission's decision. In *Collins*, the Court held that so long as agency officials were "properly *appointed*"—*i.e.*, there was "no constitutional defect in the statutorily prescribed method of appointment to [the] office"—then an unconstitutional restriction on the President's *removal* power does not void the agency's actions unless

[29] *See* 10 U.S.C. § 942(f) (United States Court of Appeals for the Armed Forces); 15 U.S.C. § 2053(a) (Consumer Product Safety Commission); 26 U.S.C. § 7443(f) (Tax Court); 28 U.S.C. § 176 (Court of Federal Claims); 29 U.S.C. § 153(a) (National Labor Relations Board); 38 U.S.C. § 7253(f) (Court of Appeals for Veterans Claims). 42 U.S.C. § 7171(b) (Federal Energy Regulatory Commission).

the restriction actually caused harm. 141 S. Ct. at 1787-88. Harm might be shown if the President "had attempted to remove [an agency official] but was prevented from doing so by a lower court decision holding that he did not have 'cause' for removal," or "had made a public statement expressing displeasure with actions taken by [an agency official] and asserted that he would remove [the official] if the statute did not stand in the way." *Id.* at 1789. Based on that analysis, this Court recently held that "harm" under *Collins* requires "(1) a substantiated desire by the President to remove the unconstitutionally insulated actor, (2) a perceived inability to remove the actor due to the infirm provision, and (3) a nexus between the desire to remove and the challenged actions taken by the insulated actor." *Cmty. Fin. Servs. Ass'n of Am. v. CFPB*, 51 F.4th 616, 632 (5th Cir. 2022), *cert. granted on other grounds*, 143 S. Ct. 978 (2023).

Illumina does not dispute that all of the Commissioners who voted out the administrative complaint or issued the Commission's decision were properly appointed. Illumina therefore cannot obtain relief from the Commission's order unless it shows harm traceable to the President's inability to remove Commissioners at will. It cannot do so.

Illumina's brief does not even reference the *Collins* and *Community Financial* standard for harm, let alone try to satisfy it. Illumina merely cites two *Wall Street Journal* editorials and two blog posts criticizing the Commission's decision (Br. 22). This does not come close to demonstrating a "substantiated desire by the President" to remove any of the Commissioners, let alone the other requisites set forth in *Community Financial*.

C. The Commission's Procedures Do Not Violate Due Process.

Binding precedent also squarely bars Illumina's argument that the Commission's procedures violated due process. As Illumina concedes, the Supreme Court has rejected "[t]he contention that the combination of investigative and adjudicative functions necessarily creates an unconstitutional risk of bias in administrative adjudication." *Withrow*, 421 U.S. at 47. It is "very typical for the members of administrative agencies to receive the results of investigations, to approve the filing of charges or formal complaints instituting enforcement proceedings, and then to participate in the ensuing hearings," and "[t]his mode of procedure … does not violate due process of law." *Id.* at 56. This Court has previously observed that the FTC Act

specifically authorizes the Commission "to issue administrative complaints and subsequently sit as an adjudicative body," and that "[t]he combination of investigative and judicial functions within an agency has been upheld against due process challenges." *Gibson v. FTC*, 682 F.2d 554, 560 (5th Cir. 1982).

While due process requires an unbiased decisionmaker, *Withrow*, 421 F.3d at 46-47, courts cannot "presume bias from the mere institutional structure" of an agency." *United States v. Benitez-Villafuerte*, 186 F.3d 651, 660 (5th Cir. 1999). Agency adjudicators are presumed to be unbiased, absent some showing of "conflict of interest or some other specific reason for disqualification." *Schweiker v. McClure*, 456 U.S. 188, 195 (1982); *see also Withrow,* 421 U.S. at 55 (adjudicators are presumed to be people of "conscience and intellectual discipline, capable of judging a particular controversy fairly on the basis of its own circumstances"). To establish a due process violation, a party must show that the decisionmakers' minds were "irrevocably closed" to its position. *FTC v. Cement Inst.*, 333 U.S. 683, 701 (1948); *Benitez-Villafuerte*, 186 F.3d at 660.

Illumina does not even attempt to make this showing. Instead, it relies on misrepresentations and outright falsehoods. First, Illumina asserts that the Commission "directed [the complaint's] prosecution." Br. 24. That is untrue. The Commission complied fully with the requirements of the APA and its own regulations, both of which require that the agency staff responsible for prosecuting the complaint be walled off from the Commission and the ALJ. *See* 5 U.S.C. § 554(d)(2); 16 C.F.R. § 4.7(b). Next, Illumina falsely asserts that the Commission "colluded with the European Commission" to "deprive the parties of a hearing before an Article III judge," citing a letter from four Senators as purported support. Br. 24-25. The letter is not part of the administrative record and therefore is not properly before this Court, *see, e.g.*, *Sierra Club v. United States Dep't of Interior*, 990 F.3d 898, 907 (5th Cir. 2021), but in any event the letter does not show that FTC "colluded" with European officials. Each agency conducted an independent assessment of the merger consistent with the facts and its governing law.[30]

[30] FTC staff communicated with their EC counterparts as part of their routine duties, but as both the Commission majority and Commissioner Wilson noted, that

Illumina's citation to the individual concurring opinions of Justice Thomas and Justice Gorsuch in *Axon Enterprises, Inc. v. FTC*, 143 S. Ct. 890 (2023) (Br. 24), do not advance its argument. Justice Thomas's opinion acknowledges that existing Supreme Court law allows for administrative adjudication, but calls for a reevaluation of those precedents. *Id.* at 906-11 (Thomas, J., concurring). This Court, however, is bound by existing Supreme Court precedent. Justice Gorsuch asserted that "some say the FTC has not lost an in-house proceeding in 25 years," though he acknowledged statistics showing the Complaint Counsel's success rate is closer to 90%. *Id.* at 917-18 (Gorsuch, J., concurring). But even a "demonstrated tendency to rule any particular way" does not prove unconstitutional bias. *Phillips v. Jt. Legis. Comm. on Performance & Expenditure Review*, 637 F.2d 1014, 1020 (5th Cir. 1981).[31] The most comprehensive analysis of Commission

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kind of coordination is explicitly authorized by Congress and international agreements. Op. 91-02 n.75; Conc. 5-6. Communications at the staff level also do not show any bias by the Commissioners. The only Commissioner-level communications with foreign authorities that Illumina cited below were with officials of the United Kingdom, which is no longer part of the European Union and never opened an investigation into the merger.

[31] *See also So. Pac. Commc'n Co. v AT&T Co.*, 740 F.2d 980, 995 (D.C. Cir. 1994) ("Statistical one-sidedness" of rulings "cannot be used to support an inference of

decisionmaking, conducted by former Commissioner Maureen Ohlhausen and published in a peer-reviewed economics journal, found no evidence of systemic bias.[32] As a point of comparison, more than 90% of federal criminal cases are resolved with guilty pleas, and fewer than 1% of federal criminal defendants go to trial and are acquitted.[33] That is not because federal judges are biased against criminal defendants, but because the Government does not bring cases without strong evidence of illegality.

Illumina's complaint that the Commission considered some evidence that might not have been admissible under the Federal Rules of Evidence (Br. 25-26) likewise does not show bias.[34] The same rules of

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judicial bias."); *In re IBM Corp.*, 618 F.2d 923, 930 (2nd Cir. 1980) ("[S]tatistics alone, no matter how computed, cannot establish extrajudicial bias.")

[32] Maureen K. Ohlhausen, *Administrative Litigation at the FTC: Effective Tool for Developing the Law or Rubber Stamp*, 12 J. Comp. L. & Econ. 623, 634-35, 651 (2016).

[33] John Gramlich, Pew Research Center, *Only 2% of federal criminal defendants go to trial, and most who do are found guilty* (June 11, 2019), at https://shorturl.at/AILMT.

[34] Illumina's specific examples are spurious. Illumina complains about the Commission's reliance on testimony from investigational hearings (Br. 25), but Illumina's proposed findings cited the same hearing transcripts. See, e.g., RFF ¶¶ 296, 627, 629, 631, 785, 792, 948. Illumina did not object to the admission of the deposition transcripts and exhibits that it now complains about. Br. 25-26. Illumina's assertion that the Commission "refused to consider evidence" that

evidence applied to both sides. And although the Commission's evidentiary rules are not identical to the Federal Rules, they are very similar, *see* 16 C.F.R. § 3.43, and an agency's "relaxation of the ordinary rules of procedure and evidence does not invalidate the proceedings, provided the substantial rights of the parties are preserved." *Avondale Shipyards, Inc. v. Vinson*, 623 F.2d 1117, 1121 (5th Cir. 1980). In practice, the ALJ adheres closely to the Federal Rules. *See* Prehearing Tr. at 41 ("[I]f you have an objection to that type of testimony, don't be afraid to cite to the Rules of Evidence…. [Y]ou'll find I go by the book.").

The fact that the Commission ruled in Illumina's favor on several important issues further shows that it was not biased. For example, the Commission rejected Complaint Counsel's argument that Illumina waived its challenge to the ALJ's market determination by failing to file a cross-appeal. Op. 24 n.12. The Commission also rejected a provision of Complaint Counsel's proposed remedy that Illumina characterized as "disgorgement." Op. 97. And the Commission ultimately granted

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contradicted Complaint Counsel's theory of the case (Br. 26) is untrue. Illumina is referring to its request to reopen the record more than a month after oral argument to admit two new exhibits. The Commission rejected this evidence because it was untimely and Complaint Counsel would not have an opportunity for cross-examination, but also found that even if considered, "the statements at issue would not change our analysis." Op. 56 n.38.

Illumina's request for a stay of the final order over Complaint Counsel's objection. As these and other rulings illustrate, the Commission decided this matter based on the relevant facts and law.

D. Illumina Was Not Denied Equal Protection.

Illumina's equal protection argument also fails. The allocation of Clayton Act cases between the Commission and the Department of Justice neither proceeds along suspect lines nor infringes fundamental constitutional rights. Thus, as Illumina concedes (Br. 26), that allocation is subject only to rational basis review. It "must be upheld … if there is any reasonably conceivable state of facts that could provide a rational basis for the classification." *FCC v. Beach Commc'ns*, 508 U.S. 307, 313 (1993); *see also Heller v. Doe*, 509 U.S. 312, 320 (1993) (there need only be "a rational relationship between the disparity of treatment and some legitimate governmental purpose"). The government has "no obligation to produce evidence to sustain [its] rationality," and the justification for the classification "may be based on rational speculation unsupported by evidence or empirical data." *Id.* at 320 (cleaned up). The allocation of cases between the FTC and DOJ easily satisfies this standard.

When Congress passed the Clayton Act in 1914, it gave the Commission and the Attorney General overlapping enforcement authority. Congress directed the Commission to enforce certain sections of the Act (including the merger provisions) through administrative adjudication. 15 U.S.C. § 21(b). Congress chose this mode of enforcement because it "thought the assistance of an administrative body would be helpful in resolving [antitrust] questions and indeed expected the FTC to take the leading role in enforcing the Clayton Act." *Hospital Corp. of Am. v. FTC*, 807 F.2d 1381, 1386 (7th Cir. 1986). But Congress also authorized the Attorney General to sue in equity to restrain violations of the Act. 15 U.S.C. § 25. As the Supreme Court has explained, Congress wanted to "provide the Government with cumulative remedies against activity detrimental to competition," and to "permit the simultaneous use of both types of proceedings" rather than "confin[ing] [them] within narrow, mutually exclusive limits." *Cement Institute*, 383 U.S. at 694-95.

Congress reconfirmed its intention that the FTC and DOJ would share enforcement authority over mergers when it enacted the 1976 Hart-Scott-Rodino Antitrust Improvements Act, which requires the

parties to most large mergers to submit detailed filings to both the Commission and DOJ before the merger can close. 15 U.S.C. § 18a. This premerger notification gives the agencies an opportunity to investigate the proposed transaction for antitrust issues and, if necessary, to take action to block the merger. To conserve resources and avoid duplicative proceedings, the FTC and DOJ have agreed that any antitrust investigation will be assigned to one agency or the other, depending on which has the most experience in the relevant industry and which has available resources or capacity.[35]

This allocation of shared authority does not violate the Constitution's equal protection guarantee. Rational basis review "is not a license for courts to judge the wisdom, fairness, or logic of legislative choices." *Beach Commc'ns*, 508 U.S. at 313. Here, Congress reasonably determined that in the realm of antitrust, two enforcement agencies were better than one. And because Congress gave the FTC and DOJ overlapping authority, the agencies had a rational basis for deciding to assign responsibility for any given merger to the agency with the most

[35] *See* GAO, *DOJ and FTC Jurisdictions Overlap, but Conflicts are Infrequent* 9-12 (Jan. 2023), https://www.gao.gov/assets/820/814486.pdf.

relevant experience and best current capacity. Allocating cases in this way conserves government resources, prevents parties from being subjected to duplicative investigations, and allows each agency to develop and utilize industry-specific expertise. These are all legitimate governmental purposes.

Illumina errs in claiming that procedural differences between the administrative and a judicial forum caused it to be denied equal protection. Equal protection does not guarantee the subject of government enforcement action a right to the forum it deems most advantageous, even when substantive rights are at issue. For example, in *United States v. Lopez-Velaquez*, 526 F.3d 804 (5th Cir. 2008), this Court rejected a criminal defendant's claim that he was denied equal protection because he was prosecuted in a judicial district without a "fast-track" early disposition program, and thus was not eligible for a sentencing reduction that might have been available if he was prosecuted in another district. The Court applied rational basis review, holding that the Attorney General's decision to implement a fast-track program in some districts but not others was "a function of Congressional policy," and that the structure of the program was

rationally related to the goals of "promoting judicial efficiency" and "preserving prosecutorial discretion." *Id.* at 808. Similarly, in this case, the FTC and DOJ's overlapping authority to enforce the Clayton Act is a function of longstanding Congressional policy and the decision to allocate cases between the two agencies is rationally related to legitimate government purposes.

Illumina also exaggerates the procedural differences between the Commission's administrative proceedings and court proceedings. The two are fundamentally very similar.[36] The same substantive legal standard—the Clayton Act—applies in both forums. Procedurally, in both forums the parties have substantially the same rights to take discovery, present evidence at trial, and cross-examine the other side's witnesses. *See* 16 C.F.R. §§ 3.31-3.38, 3.41, 3.43. In both types of proceedings, the ultimate decisionmaker—an Article III judge in a trial, and the Commissioners in an FTC adjudication—are appointed by the

[36] In some respects, administrative adjudication affords procedural advantages to merging parties as compared to federal court. For example, when DOJ brings an action in district court, it chooses the forum, but in FTC adjudications the merging parties may seek review in any circuit where they reside or carry on business. 15 U.S.C. §§ 21(c), 45(c). And while DOJ may appeal an adverse district court decision, Complaint Counsel cannot appeal from a Commission decision.

President, confirmed by the Senate, and protected from arbitrary removal to ensure that politics does not influence their decisions. Decisions in both types of proceedings are subject to review in the courts of appeals. Illumina has not shown any differences between the forums materially affected the outcome of this case.

CONCLUSION

The petition should be denied.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that the foregoing brief complies with the volume limitations of Fed. R. App. P. 32(a)(7)(B), as modified by the Court's order of June 23, 2023, because it contains 15,901 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii), and that it complies with the typeface and type style requirements of Fed. R. App. P. 32(a)(5) and (a)(6) and 5th Cir. R. 32.1 because it was prepared in a proportionally spaced typeface using Microsoft® Word for Microsoft 365 MSO. The text is in 14 point Century Schoolbook type and the footnotes are in 12-point Century Schoolbook type.

July 26, 2023

/s/ Matthew M. Hoffman
Matthew M. Hoffman

ADDENDUM OF RELEVANT STATUTES

United States Code, 2021 Edition
Title 15 - COMMERCE AND TRADE
CHAPTER 1 - MONOPOLIES AND COMBINATIONS IN RESTRAINT OF TRADE
Sec. 18 - Acquisition by one corporation of stock of another
From the U.S. Government Publishing Office, www.gpo.gov

§ 18: Acquisition by one corporation of stock of another

No person engaged in commerce or in any activity affecting commerce shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no person subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or any part of the assets of another person engaged also in commerce or in any activity affecting commerce, where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly.

No person shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no person subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or any part of the assets of one or more persons engaged in commerce or in any activity affecting commerce, where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition, of such stocks or assets, or of the use of such stock by the voting or granting of proxies or otherwise, may be substantially to lessen competition, or to tend to create a monopoly.

* * *

United States Code, 2021 Edition
Title 15 - COMMERCE AND TRADE
CHAPTER 1 - MONOPOLIES AND COMBINATIONS IN RESTRAINT OF TRADE
Sec. 21 - Enforcement provisions
From the U.S. Government Publishing Office, www.gpo.gov

§ 21. Enforcement provisions

(a) Commission, Board, or Secretary authorized to enforce compliance

Authority to enforce compliance with sections 13, 14, 18, and 19 of this title by the persons respectively subject thereto is vested in the Surface Transportation Board where applicable to common carriers subject to jurisdiction under subtitle IV of title 49; in the Federal Communications Commission where applicable to common carriers engaged in wire or radio communication or radio transmission of energy; in the Secretary of Transportation where applicable to air carriers and foreign air carriers subject to part A of subtitle VII of title 49; in the Board of Governors of the Federal Reserve System where applicable to banks, banking associations, and trust companies; and in the Federal Trade Commission where applicable to all other character of commerce to be exercised as follows:

(b) Issuance of complaints for violations; hearing; intervention; filing of testimony; report; cease and desist orders; reopening and alteration of reports or orders

Whenever the Commission, Board, or Secretary vested with jurisdiction thereof shall have reason to believe that any person is violating or has violated any of the provisions of sections 13, 14, 18, and 19 of this title, it shall issue and serve upon such person and the Attorney General a complaint stating its charges in that respect, and containing a notice of a hearing upon a day and at a place therein fixed at least thirty days after the service of said complaint. The person so complained of shall have the right to appear at the place and time so fixed and show cause why an order should not be entered by the Commission, Board, or Secretary requiring such person to cease and desist from the violation of the law so charged in said complaint. The

Attorney General shall have the right to intervene and appear in said proceeding and any person may make application, and upon good cause shown may be allowed by the Commission, Board, or Secretary, to intervene and appear in said proceeding by counsel or in person. The testimony in any such proceeding shall be reduced to writing and filed in the office of the Commission, Board, or Secretary. If upon such hearing the Commission, Board, or Secretary, as the case may be, shall be of the opinion that any of the provisions of said sections have been or are being violated, it shall make a report in writing, in which it shall state its findings as to the facts, and shall issue and cause to be served on such person an order requiring such person to cease and desist from such violations, and divest itself of the stock, or other share capital, or assets, held or rid itself of the directors chosen contrary to the provisions of sections 18 and 19 of this title, if any there be, in the manner and within the time fixed by said order. Until the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time, or, if a petition for review has been filed within such time then until the record in the proceeding has been filed in a court of appeals of the United States, as hereinafter provided, the Commission, Board, or Secretary may at any time, upon such notice and in such manner as it shall deem proper, modify or set aside, in whole or in part, any report or any order made or issued by it under this section. After the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time, the Commission, Board, or Secretary may at any time, after notice and opportunity for hearing, reopen and alter, modify, or set aside, in whole or in part, any report or order made or issued by it under this section, whenever in the opinion of the Commission, Board, or Secretary conditions of fact or of law have so changed as to require such action or if the public interest shall so require: *Provided, however*, That the said person may, within sixty days after service upon him or it of said report or order entered after such a reopening, obtain a review thereof in the appropriate court of appeals of the United States, in the manner provided in subsection (c) of this section.

(c) Review of orders; jurisdiction; filing of petition and record of proceeding; conclusiveness of findings; additional evidence; modification of findings; finality of judgment and decree

Any person required by such order of the commission, board, or Secretary to cease and desist from any such violation may obtain a review of such order in the court of appeals of the United States for any circuit within which such violation occurred or within which such person resides or carries on business, by filing in the court, within sixty days after the date of the service of such order, a written petition praying that the order of the commission, board, or Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the commission, board, or Secretary, and thereupon the commission, board, or Secretary shall file in the court the record in the proceeding, as provided in section 2112 of title 28. Upon such filing of the petition the court shall have jurisdiction of the proceeding and of the question determined therein concurrently with the commission, board, or Secretary until the filing of the record, and shall have power to make and enter a decree affirming, modifying, or setting aside the order of the commission, board, or Secretary, and enforcing the same to the extent that such order is affirmed, and to issue such writs as are ancillary to its jurisdiction or are necessary in its judgment to prevent injury to the public or to competitors pendente lite. The findings of the commission, board, or Secretary as to the facts, if supported by substantial evidence, shall be conclusive. To the extent that the order of the commission, board, or Secretary is affirmed, the court shall issue its own order commanding obedience to the terms of such order of the commission, board, or Secretary. If either party shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the commission, board, or Secretary, the court may order such additional evidence to be taken before the commission, board, or Secretary, and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The commission, board, or Secretary may modify its

findings as to the facts, or make new findings, by reason of the additional evidence so taken, and shall file such modified or new findings, which if supported by substantial evidence, shall be conclusive, and its recommendation, if any, for the modification or setting aside of its original order, with the return of such additional evidence. The judgment and decree of the court shall be final, except that the same shall be subject to review by the Supreme Court upon certiorari, as provided in section 1254 of title 28.

United States Code, 2021 Edition
Title 15 - COMMERCE AND TRADE
CHAPTER 2 - FEDERAL TRADE COMMISSION; PROMOTION OF EXPORT TRADE AND PREVENTION OF UNFAIR METHODS OF COMPETITION
SUBCHAPTER I - FEDERAL TRADE COMMISSION
Sec. 41 - Federal Trade Commission established; membership; vacancies; seal
From the U.S. Government Publishing Office, www.gpo.gov

§ 41. Federal Trade Commission established; membership; vacancies; seal

A commission is created and established, to be known as the Federal Trade Commission (hereinafter referred to as the Commission), which shall be composed of five Commissioners, who shall be appointed by the President, by and with the advice and consent of the Senate. Not more than three of the Commissioners shall be members of the same political party. The first Commissioners appointed shall continue in office for terms of three, four, five, six, and seven years, respectively, from September 26, 1914, the term of each to be designated by the President, but their successors shall be appointed for terms of seven years, except that any person chosen to fill a vacancy shall be appointed only for the unexpired term of the Commissioner whom he shall succeed: *Provided, however*, That upon the expiration of his term of office a Commissioner shall continue to serve until his successor shall have been appointed and shall have qualified. The President shall choose a chairman from the Commission's membership. No Commissioner shall engage in any other business, vocation, or employment. Any Commissioner may be removed by the President for inefficiency, neglect of duty, or malfeasance in office. A vacancy in the Commission shall not impair the right of the remaining Commissioners to exercise all the powers of the Commission. The Commission shall have an official seal, which shall be judicially noticed.

United States Code, 2021 Edition
Title 15 - COMMERCE AND TRADE
CHAPTER 2 - FEDERAL TRADE COMMISSION; PROMOTION OF EXPORT TRADE AND PREVENTION OF UNFAIR METHODS OF COMPETITION
SUBCHAPTER I - FEDERAL TRADE COMMISSION
Sec. 45 - Unfair methods of competition unlawful; prevention by Commission
From the U.S. Government Publishing Office, www.gpo.gov

§ 45. Unfair methods of competition unlawful; prevention by Commission

(a) Declaration of unlawfulness; power to prohibit unfair practices; inapplicability to foreign trade

(1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.

(2) The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations, except banks, savings and loan institutions described in section 57a(f)(3) of this title, Federal credit unions described in section 57a(f)(4) of this title, common carriers subject to the Acts to regulate commerce, air carriers and foreign air carriers subject to part A of subtitle VII of title 49, and persons, partnerships, or corporations insofar as they are subject to the Packers and Stockyards Act, 1921, as amended [7 U.S.C. 181 et seq.], except as provided in section 406(b) of said Act [7 U.S.C. 227(b)], from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.

* * *

(b) Proceeding by Commission; modifying and setting aside orders

Whenever the Commission shall have reason to believe that any such person, partnership, or corporation has been or is using any unfair method of competition or unfair or deceptive act or practice in or affecting commerce, and if it shall appear to the Commission that a proceeding by it in respect thereof would be to the interest of the public, it shall issue and serve upon such person, partnership, or corporation a

complaint stating its charges in that respect and containing a notice of a hearing upon a day and at a place therein fixed at least thirty days after the service of said complaint. The person, partnership, or corporation so complained of shall have the right to appear at the place and time so fixed and show cause why an order should not be entered by the Commission requiring such person, partnership, or corporation to cease and desist from the violation of the law so charged in said complaint. Any person, partnership, or corporation may make application, and upon good cause shown may be allowed by the Commission to intervene and appear in said proceeding by counsel or in person. The testimony in any such proceeding shall be reduced to writing and filed in the office of the Commission. If upon such hearing the Commission shall be of the opinion that the method of competition or the act or practice in question is prohibited by this subchapter, it shall make a report in writing in which it shall state its findings as to the facts and shall issue and cause to be served on such person, partnership, or corporation an order requiring such person, partnership, or corporation to cease and desist from using such method of competition or such act or practice. Until the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time, or, if a petition for review has been filed within such time then until the record in the proceeding has been filed in a court of appeals of the United States, as hereinafter provided, the Commission may at any time, upon such notice and in such manner as it shall deem proper, modify or set aside, in whole or in part, any report or any order made or issued by it under this section. After the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time, the Commission may at any time, after notice and opportunity for hearing, reopen and alter, modify, or set aside, in whole or in part any report or order made or issued by it under this section, whenever in the opinion of the Commission conditions of fact or of law have so changed as to require such action or if the public interest shall so require, except that (1) the said person, partnership, or corporation may, within sixty days after service upon him or it of said report or order entered after such a

reopening, obtain a review thereof in the appropriate court of appeals of the United States, in the manner provided in subsection (c) of this section; and (2) in the case of an order, the Commission shall reopen any such order to consider whether such order (including any affirmative relief provision contained in such order) should be altered, modified, or set aside, in whole or in part, if the person, partnership, or corporation involved files a request with the Commission which makes a satisfactory showing that changed conditions of law or fact require such order to be altered, modified, or set aside, in whole or in part. The Commission shall determine whether to alter, modify, or set aside any order of the Commission in response to a request made by a person, partnership, or corporation under paragraph1 (2) not later than 120 days after the date of the filing of such request.

(c) Review of order; rehearing

Any person, partnership, or corporation required by an order of the Commission to cease and desist from using any method of competition or act or practice may obtain a review of such order in the court of appeals of the United States, within any circuit where the method of competition or the act or practice in question was used or where such person, partnership, or corporation resides or carries on business, by filing in the court, within sixty days from the date of the service of such order, a written petition praying that the order of the Commission be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Commission, and thereupon the Commission shall file in the court the record in the proceeding, as provided in section 2112 of title 28. Upon such filing of the petition the court shall have jurisdiction of the proceeding and of the question determined therein concurrently with the Commission until the filing of the record and shall have power to make and enter a decree affirming, modifying, or setting aside the order of the Commission, and enforcing the same to the extent that such order is affirmed and to issue such writs as are ancillary to its jurisdiction or are necessary in its judgement to prevent injury to the public or to competitors pendente lite. The findings of the Commission as to the facts, if supported by evidence, shall be

conclusive. To the extent that the order of the Commission is affirmed, the court shall thereupon issue its own order commanding obedience to the terms of such order of the Commission. If either party shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Commission, the court may order such additional evidence to be taken before the Commission and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Commission may modify its findings as to the facts, or make new findings, by reason of the additional evidence so taken, and it shall file such modified or new findings, which, if supported by evidence, shall be conclusive, and its recommendation, if any, for the modification or setting aside of its original order, with the return of such additional evidence. The judgment and decree of the court shall be final, except that the same shall be subject to review by the Supreme Court upon certiorari, as provided in section 1254 of title 28.

United States Code, 2021 Edition
Title 15 - COMMERCE AND TRADE
CHAPTER 2 - FEDERAL TRADE COMMISSION; PROMOTION OF EXPORT TRADE AND PREVENTION OF UNFAIR METHODS OF COMPETITION
SUBCHAPTER I - FEDERAL TRADE COMMISSION
Sec. 53 - False advertisements; injunctions and restraining orders
From the U.S. Government Publishing Office, www.gpo.gov

§ 53. False advertisements; injunctions and restraining orders

* * *

(b) Temporary restraining orders; preliminary injunctions

Whenever the Commission has reason to believe—

(1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and

(2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the interest of the public,

the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond: *Provided, however*, That if a complaint is not filed within such period (not exceeding 20 days) as may be specified by the court after issuance of the temporary restraining order or preliminary injunction, the order or injunction shall be dissolved by the court and be of no further force and effect: *Provided further*, That in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction. Any suit may be brought where such person, partnership, or corporation resides or transacts business, or wherever venue is proper under section 1391 of

title 28. In addition, the court may, if the court determines that the interests of justice require that any other person, partnership, or corporation should be a party in such suit, cause such other person, partnership, or corporation to be added as a party without regard to whether venue is otherwise proper in the district in which the suit is brought. In any suit under this section, process may be served on any person, partnership, or corporation wherever it may be found.

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