United States Court of Appeals for the Fifth Circuit

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Fifth Circuit
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Lyle W. Cayce
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No. 23-60167

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

Petitioners,

versus

FEDERAL TRADE COMMISSION,

Respondent.

Appeal from the Federal Trade Commission
Agency No. 9401

Before CLEMENT, GRAVES, and HIGGINSON, *Circuit Judges*.

EDITH BROWN CLEMENT, *Circuit Judge*:

The Federal Trade Commission determined that Illumina, Inc.'s acquisition of Grail, Inc. violated Section 7 of the Clayton Act, and therefore ordered that the merger be unwound. Because the Commission applied an erroneous legal standard at the rebuttal stage of its analysis, we VACATE the Commission's order and REMAND for further proceedings.

I.

A.

Founded in 1998, Illumina is a publicly traded, for-profit corporation that specializes in the manufacture and sale of next-generation sequencing ("NGS") platforms. NGS is a method of DNA sequencing that is used in a variety of medical applications. In September 2015, Illumina founded a wholly-owned subsidiary, Grail, which was so-named because its goal was to reach the "Holy Grail" of cancer research—the creation of a multi-cancer early detection ("MCED") test that could identify the presence of multiple types of cancer from a single blood sample.

Grail was incorporated as a separate entity in January 2016. Illumina maintained a controlling stake in the company until February 2017 when, to raise the capital needed to move Grail's MCED test from concept to clinical trials, Illumina decided to bring in outside investors. This spin-off reduced Illumina's equity stake in Grail to 12%. By September 2020, Grail had raised $1.9 billion through a combination of venture capital and strategic partners. Then, on September 20, 2020, Illumina entered into an agreement to re-acquire Grail for $8 billion, with the goal of bringing Grail's now-developed MCED test to market.

The MCED-test industry had changed dramatically between February 2017—when Illumina spun Grail off—and September 2020—when Illumina agreed to re-acquire Grail. Grail's MCED test—which it named Galleri—had acquired a breakthrough device designation from the U.S. Food and Drug Administration ("FDA"), and Grail had published promising results from a clinical study concerning the initial version of Galleri and was undergoing additional clinical studies to validate its updated version. Meanwhile, Thrive Earlier Detection Corporation had announced that the initial version of its own MCED test—CancerSEEK—had also been

clinically validated. And other MCED tests—including Singlera Genomics, Inc.'s PanSeer—were in development. All of the MCED tests in development—including Galleri, CancerSEEK, and PanSeer—relied on Illumina's NGS platforms for sequencing, and there were no available alternatives.

Given their reliance on Illumina's NGS platforms, Illumina's customers—both within and without the MCED-test industry—expressed concern about whether they would be able to continue to purchase Illumina's NGS products post-merger on the same terms and conditions as pre-merger. So, Illumina developed a standardized supply contract (the "Open Offer") that it made available to all for-profit U.S. oncology customers on March 30, 2021. The Open Offer is irrevocable, may be accepted by a customer at any time until August 18, 2027, became effective as of the merger's closing, and will remain effective until August 18, 2033. Among other terms, the Open Offer requires Illumina to provide its NGS platforms at the same price and with the same access to services and products that is provided to Grail.

Grail first offered Galleri for commercial sale in April 2021 as a laboratory-developed test.[1] While Galleri is the only NGS-based MCED test currently available on the market, others expect to go to market soon and to directly compete with Galleri. Illumina's NGS platforms are still the only means of sequencing MCED tests and will remain so for the foreseeable future.

[1] The FDA does not review or validate safety or efficacy data of tests sold as laboratory-developed tests. Rather, independent labs self-certify the quality of their own product under the regulatory framework set forth under the Clinical Laboratory Improvement Amendments. For this reason, laboratory-developed tests have lower adoption rates than FDA-approved tests.

B.

On March 30, 2021—the same day Illumina released its Open Offer—the FTC's Complaint Counsel issued a complaint alleging that the Illumina-Grail merger agreement, if consummated, would violate Section 7 of the Clayton Act.[2] The merger was, in fact, consummated on August 18, 2021, but, due to ongoing regulatory review by the European Commission, Illumina held—and continues to hold—Grail as a separate company.

The FTC's Chief Administrative Law Judge ("ALJ") convened an evidentiary hearing on August 24, 2021. In the coming months, the parties developed an extensive evidentiary record consisting of over 4,500 exhibits and the live or deposition testimony of fifty-six fact witnesses and ten experts. Based on this record, the ALJ issued his initial decision on September 1, 2022. The ALJ found that Complaint Counsel failed to prove that the merger was likely to cause a substantial lessening of competition in the market for the research, development, and commercialization of MCED tests. Specifically, the ALJ concluded that Complaint Counsel had not shown a likelihood that Illumina would foreclose against Grail's rivals because Grail has no current competitors in the market to be foreclosed, the MCED tests in development would not be a good substitute for Grail's test, and any foreclosing activities would cause harm to Illumina's NGS-sales business. In any event, the ALJ determined, the Open Offer "effectively constrains Illumina from harming Grail's alleged rivals and rebuts the inference that future harm to Grail's alleged rivals, and thus future harm to competition, is likely."

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[2] For clarity, we use "FTC" when discussing the Federal Trade Commission generally, "Complaint Counsel" when describing the FTC's actions as a party to these adversary proceedings, and "Commission" when referring to the FTC's actions as an adjudicatory body.

Complaint Counsel appealed the ALJ's decision to the Commission, and, after oral argument, the Commission reversed. Upon its *de novo* review, the Commission concluded that the merger *was* likely to substantially lessen competition in the market for the research, development, and commercialization of MCED tests. The Commission found that the ALJ had factually erred in discussing the capabilities of Grail and other MCED tests in development, improperly focused on foreclosure harm to MCED tests on the market today as opposed to tests in development, and failed to recognize that any losses to Illumina's NGS sales would be more than offset by Illumina's expected gains in clinical testing. The Commission also held that the Open Offer was a remedy that should not be factored into the liability analysis. But the Commission evaluated the Open Offer as rebuttal evidence anyway, finding that the Open Offer failed to rebut Complaint Counsel's prima facie case because it would not "eliminate the effects" of the merger. Finally, the Commission rejected Illumina's constitutional defenses. The Commission therefore ordered Illumina to divest Grail. Illumina now appeals.

II.

We review the Commission's decision, not that of the ALJ. *Impax Laboratories, Inc. v. FTC*, 994 F.3d 484, 491 (5th Cir. 2021). All legal questions pertaining to the Commission's order are reviewed *de novo* while the Commission's factual findings are reviewed for "substantial evidence." *Chicago Bridge & Iron Co. N.V. v. FTC*, 534 F.3d 410, 422 (5th Cir. 2008). Under this standard, we are bound by the Commission's factual determinations so long as they are supported by "such relevant evidence as a reasonable mind might accept as adequate." *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454 (1986) (citation omitted). This is so "even if suggested alternative conclusions may be equally or even more reasonable and

persuasive." *N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346, 354 (5th Cir. 2008) (internal quotation marks and citation omitted).

III.

Because, as explained below, resolution of Illumina's statutory claims does not "obviate the need to consider" the constitutional issues raised, *United States v. Wells Fargo Bank*, 485 U.S. 351, 354 (1988), we begin with Illumina's four constitutional challenges. Each is foreclosed by Supreme Court authority.

A.

First, Illumina contends that the Commission proceedings were the result of an unconstitutional delegation of legislative power in violation of Article I. Specifically, Illumina claims that Congress delegated to the FTC the power to decide whether to bring antitrust enforcement actions in an administrative proceeding, pursuant to Section 5(b) of the FTC Act, 15 U.S.C. § 45(b), or to bring this same enforcement action in an Article III court pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), without providing "any guidance for purposes of deciding *between* administrative proceedings and federal court."

But as the Supreme Court recently clarified, federal-court actions under Section 13(b) are *not* the same as administrative proceedings under Section 5(b). Rather, when the FTC goes to federal court under Section 13(b), it is limited to pursuing injunctive relief; to obtain other forms of relief, such as monetary damages, the FTC must resort to administrative proceedings under Section 5(b). *AMG Cap. Mgmt., LLC v. FTC*, 141 S. Ct. 1341, 1348–49 (2021).

Moreover, to the extent that Illumina argues that Congress's directive for the FTC to commence an enforcement action when such a proceeding

would be "in the interest of the public" does not provide an "intelligible principle," we disagree. To the contrary, the Supreme 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) (collecting cases).

B.

Second, Illumina claims that the FTC unconstitutionally exercised executive powers while insulated from presidential removal in violation of Article II. But *Humphrey's Executor v. United States* held that the FTC's enabling act did not run afoul of Article II because, essentially, the FTC was vested with quasi-legislative/quasi-judicial authority rather than purely executive authority. 295 U.S. 602, 626–32 (1935). While the Supreme Court has cabined the reach of *Humphrey's Executor* in recent years, it has expressly declined to overrule it. *See Seila Law LLC v. CFPB*, 140 S. Ct. 2183, 2206 (2020); *accord Collins v. Yellin*, 141 S. Ct. 1761, 1783 (2021). Thus, although the FTC's powers may have changed since *Humphrey's Executor* was decided, the question of whether the FTC's authority has changed so fundamentally as to render *Humphrey's Executor* no longer binding is for the Supreme Court, not us, to answer. *Lefebure v. D'Aquilla*, 15 F.4th 650, 660 (5th Cir. 2021) ("[T]he only court that can overturn a Supreme Court precedent is the Supreme Court itself.").

C.

Third, Illumina argues that the FTC violated Illumina's due process rights by serving as both prosecutor and judge. But the Supreme Court has held that administrative agencies can, and often do, investigate, prosecute, and adjudicate rights without violating due process. *Withrow v. Larkin*, 421 U.S. 35, 47, 56 (1975). Of course, if there is evidence that a decisionmaker has "actual bias" against a party, that raises due process concerns. *Id.* at 47. But

courts cannot "presume bias" merely from the institutional structure of an agency. *United States v. Benitez-Villafuerte*, 186 F.3d 651, 660 (5th Cir. 1999). Moreover, this court has already rejected the argument that the FTC's structure, which combines prosecutorial and adjudicative functions, deprives parties of due process. *Gibson v. FTC*, 682 F.2d 554, 559–60 (5th Cir. 1982). Illumina points to no evidence of actual bias and instead takes issue with the FTC's structural design. Whatever merit this argument may have, it is barred by precedent.

D.

Fourth, Illumina claims an equal-protection violation because there is no rational basis for allocating certain antitrust enforcement actions to the FTC and others to the Department of Justice. But rational-basis review is a low bar that is satisfied so long as "there is any reasonably conceivable state of facts that could provide a rational basis for the classification." *FCC v. Beach Commc'ns, Inc.*, 508 U.S. 307, 313 (1993). Here, the FTC and the DOJ have an "interagency clearance process" which allocates antitrust investigations to one agency or the other based primarily on which agency has "expertise in [the] particular industry or market" of the transaction under review. U.S. Gov't Accountability Off., GAO-23-105790, DOJ and FTC Jurisdictions Overlap, but Conflicts are Infrequent (2023). This is undoubtedly a rational basis for giving one agency the lead over the other.

IV.

We turn now to Illumina's Clayton Act challenge. Section 7 of the Clayton Act prohibits mergers and acquisitions "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." 15

U.S.C. § 18.[3] To evaluate Section 7 claims, courts apply a burden-shifting framework. *See, e.g.*, *Chicago Bridge*, 534 F.3d at 423; *United States v. AT&T Inc.*, 916 F.3d 1029, 1032 (D.C. Cir. 2019) (applying burden-shifting framework to Section 7 claim concerning vertical merger).[4] Complaint Counsel bears the initial burden to "establish a prima facie case that the merger is likely to substantially lessen competition in the relevant market." *AT&T*, 916 F.3d at 1032. If a prima facie case is made, "the burden shifts to the defendant to present evidence that the prima facie case inaccurately predicts the relevant transaction's probable effect on future competition or to sufficiently discredit the evidence underlying the prima facie case." *Id.* (internal quotation marks and citations omitted). If such a rebuttal is provided, "the burden of producing additional evidence of anticompetitive effects shifts to the government, and merges with the ultimate burden of persuasion, which remains with the government at all times." *Id.* (citation omitted). This framework is applied flexibly—"in practice, evidence is often considered all at once and the burdens are often analyzed together." *Chicago Bridge*, 534 F.3d at 424.

A.

We start by reviewing Complaint Counsel's prima facie case. The Commission concluded that Complaint Counsel had carried its burden of (1) identifying the relevant product and geographic market as the market for the

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[3] The statute also prohibits mergers that would "tend to create a monopoly," 15 U.S.C. § 18, but that provision is not at issue here.

[4] We note, as did the D.C. Circuit, that "[t]here is a dearth of modern judicial precedent on vertical mergers and a multiplicity of contemporary viewpoints about how they might optimally be adjudicated and enforced." *AT&T*, 916 F.3d at 1037. Indeed, until *AT&T* in 2018, the government had not litigated a vertical merger case since the 1980s. Jonathan M. Jacobson, *Vertical Mergers: Is it Time to Move the Ball?*, 33 ANTITRUST 6, 6 (2019).

research, development, and commercialization of MCED tests in the United States, and (2) showing that the Illumina-Grail merger was likely to substantially lessen competition in this market. We find that these conclusions are supported by substantial evidence.

1.

The first step of the prima facie case requires defining the relevant market—that is, the "line of commerce" and the "section of the country" where the relevant competition occurs. 15 U.S.C. § 18; *see also United States v. Marine Bancorporation, Inc.*, 418 U.S. 602, 618 (1974) ("Determination of the relevant product and geographic markets is a necessary predicate to deciding whether a merger contravenes the Clayton Act." (internal quotation marks and citation omitted)). The parties agree with the Commission's finding that the relevant geographic market is the United States but disagree as to its determination that the relevant product market is "the research, development, and commercialization of MCED tests."[5]

In antitrust law, the relevant product market is "the area of effective competition," which is typically the "arena within which significant substitution in consumption or production occurs." *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2285 (2018) (internal quotation marks and citation omitted). However, the relevant product market must "correspond to the commercial realities of the industry." *Brown Shoe Co. v. United States*, 370 U.S. 294, 336 (1962) (internal quotation marks and citation omitted). So, "courts should combine different products or services into a single market" when necessary to reflect these realities. *Ohio*, 138 S. Ct. at 2285 (alteration adopted) (internal quotation marks and citation omitted).

[5] The ALJ defined the relevant product market the same way.

To determine the boundaries of the relevant product market, the Commission relied on what is known as the "*Brown Shoe*" methodology, which looks to certain "practical indicia" of market demarcation, such as "industry or public recognition of the [market] as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." *Brown Shoe*, 370 U.S. at 325.

First, the Commission found that MCED tests have "peculiar characteristics and uses" as compared to other current standard-of-care cancer-screening tests. As the Commission explained, cancer is traditionally detected through more invasive procedures, like a tissue biopsy, colonoscopy, or mammography, which often screen for only one type of cancer and only at a later stage of cancer development.[6]

Second, the Commission found that MCED tests are designed for distinct customers—asymptomatic patients as opposed to those with symptoms or a history of cancer. And, as the Commission noted, MCED test developers expect to market their tests to primary care physicians and, in Illumina's case, directly to patients, as opposed to marketing plans for other oncology tests, which focus on sales to oncologists and other cancer specialists.

Third, the Commission found that MCED tests, which will be targeted toward a more general population than traditional cancer-screening tests, will likely have their own distinct pricing strategy. Specifically, MCED tests will need to have particularly low out-of-pocket costs to patients in order to achieve wide acceptance. Other MCED-test developers testified that they

[6] As the ALJ noted, "[t]he conclusion that MCED tests are a distinct product from other oncology tests borders on the obvious."

anticipated competing with Grail on price, and evidence in the record showed that Grail understood that lower-priced MCED tests would pose a competitive threat. Finally, the Commission found that "MCED developers, including Grail, see themselves as competing in a distinct market and view each other as key competitors."

Critically, because the Commission viewed the relevant product market as one for the research, development, and commercialization of MCED tests—not the *existing* commercial market for MCED tests—it based its market definition on what MCED-test developers reasonably sought to achieve, not what they currently had to offer. Each of Illumina's proposed bases for why the Commission's market definition fails springs from the presumption that the Commission should have defined the market based on the products that currently exist, not those that are anticipated or expected. We disagree.[7]

First, Illumina argues that there is no evidence of reasonable interchangeability of use or cross-elasticity of demand between Galleri and other MCED tests in development because the other tests either will not match Galleri's "performance characteristics" or "are years from coming to market." But as the Commission noted, record evidence suggested otherwise—CancerSEEK has been shown to detect eight types of cancer in an asymptomatic screening population while Galleri has only been shown to detect seven. And even if Illumina was correct in its claim that the other

[7] In any event, the leading antitrust commentators have noted that "the difference between actual and potential competition" for purposes of antitrust enforcement is often "exaggerate[d]": "[P]otential competition is competition 'for' the market, while 'actual' competition is said to be competition 'in' the market. But insofar as antitrust policy is concerned, both kinds of competition can be equally 'actual.'" 4 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 907 (4th ed. 2016).

MCED tests in development would only be able to detect a subset of the fifty cancer types that Galleri can detect, two products need not be identical to be in the same market; rather, the question is merely whether they are "similar in character or use." *United States v. Anthem, Inc.*, 236 F. Supp. 3d 171, 194 (D.D.C.) (quoting *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1074 (D.D.C. 1997)), *aff'd*, 855 F.3d 345 (D.C. Cir. 2017). And the Commission correctly noted that these other tests could *still* take sales from Galleri (*i.e.*, be substitutes, albeit not *perfect* substitutes) if they were priced lower.

Nor was the Commission required to mathematically demonstrate cross-elasticity of demand. Indeed, requiring such hard metrics to prove the bounds of a market where only one product has been commercialized but there is indisputably ongoing competition to bring additional products to market would, in effect, prevent research-and-development markets from ever being recognized for antitrust purposes. This, in turn, would directly contravene the purpose of Section 7—"to arrest anticompetitive tendencies in their incipiency." *United States v. Phila. Nat'l Bank*, 374 U.S. 321, 362 (1963) (internal quotation marks and citation omitted).[8]

To be sure, simply labeling a market as one for "research and development" does not relieve Complaint Counsel of its burden to delineate the bounds of a relevant product market. In some circumstances, there may be no firms which can fairly be said to be "competing" in a space. And the mere fact that some company, someday may innovate a competing product in a given market would be too speculative to support a Section 7 claim, lest

[8] For similar reasons, the Commission was not required to use the hypothetical monopolist test to define the relevant product market. In a research-and-development market where most products have yet to reach the consumer marketplace, there are no prices from which to build a data set, and thus no way to run a hypothetical monopolist test analysis.

every acquisition be presumptively unlawful. *Cf. FTC v. Elders Grain, Inc.*, 868 F.2d 901, 906 (7th Cir. 1989) ("Section 7 forbids mergers and other acquisitions the effect of which 'may' be to lessen competition substantially. . . . Of course the word 'may' should not be taken literally, for if it were, every acquisition would be unlawful."). But that is not the case here. While Grail may have the most advanced MCED test, competing tests—particularly CancerSEEK—have been clinically validated, and other developers have concrete plans to begin the trials necessary for FDA approval. Indeed, Grail's own internal documents show that the company viewed itself as being in active competition with these other MCED-test developers.

For similar reasons, Illumina's other arguments—that the Commission misapplied the *Brown Shoe* factors and "baseless[ly]" defined the market to include products in development—also fail. Specifically, Illumina contends that the Commission assessed the *Brown Shoe* "practical indicia" too broadly, examining whether MCED tests were different from other oncology tests rather than whether Galleri was different from other MCED tests in development. But Illumina's proposed approach assesses the indicia far too narrowly. Indeed, under the narrower application urged by Illumina, the relevant market would consist of only one product—Galleri. Antitrust law does not countenance such a cramped view of competition, particularly in a research-and-development market.[9]

[9] Because the relevant "line of commerce" is the research and development of MCED tests, Illumina's reliance on *Mercantile Texas Corp. v. Board of Governors of Federal Reserve System*, 638 F.2d 1255, 1272 (5th Cir. Unit A 1981) for the proposition that market entry needs to occur within two to three years is misplaced. Although other MCED test developers have not yet entered the *consumer* market, they *have* entered the *research-and-development* market.

2.

With the relevant market established, we next turn to whether Complaint Counsel carried its initial burden of showing that "the proposed merger is likely to substantially lessen competition." *AT&T*, 916 F.3d at 1032 (emphasis omitted). As the Commission recognized, courts have used "two different but overlapping standards for evaluating the likely effect of a vertical transaction": (1) the *Brown Shoe* standard, which requires courts to look (again) at the factors first enunciated in *Brown Shoe* and carried on through its progeny, including *Fruehauf Corp. v. FTC*, 603 F.2d 345, 353 (2d Cir. 1979); and (2) the "ability-and-incentive" standard, which asks whether the merged firm will have both the ability and the incentive to foreclose its rivals, either from sources of supply or from distribution outlets. Commissioner Wilson, concurring in the Commission's decision, argued that there is no *Brown Shoe* standard—only the "ability-and-incentive" test—for vertical mergers in modern antitrust analysis. But we need not resolve this issue because we find that, under either standard, Complaint Counsel established a prima facie case supported by substantial evidence.

a.

We begin by addressing the test upon which all Commissioners agreed—the ability-and-incentive test. Under this framework, courts consider whether the merged firm will have the ability and incentive to foreclose rivals from sources of supply or distribution to determine whether the merger is likely to substantially lessen competition in the relevant market.

Illumina concedes that it would have the ability to foreclose Grail's rivals post-merger. But, in its reply brief, Illumina claims that merely *having* the ability to foreclose is not enough; rather, the merger must have "*increased* Illumina's ability to foreclose." But we do not consider arguments raised for the first time on reply. *MDK Sociedad De Responsabilidad Limitada v. Proplant*

Inc., 25 F.4th 360, 367 (5th Cir. 2022). And, in any event, we disagree with Illumina's assertion. As the Commission astutely observed, Illumina was already established as the monopoly supplier of a key input—NGS platforms—to MCED-test developers pre-merger. So, it would have been impossible for Complaint Counsel to show that the merger would *increase* Illumina's ability to foreclose. Thus, as the Commission explained, requiring such a showing would effectively "*per se* exempt from the Clayton Act's purview any transaction that involves the acquisition of a monopoly provider of inputs to adjacent markets." We decline to adopt a rule that would have such perverse results.[10]

That leaves *incentive* to foreclose as the determining factor in evaluating the Illumina-Grail merger under the ability-and-incentive test. As the Commission explained, the degree to which Illumina has an incentive to foreclose Grail's rivals depends upon the balance of two competing interests: Illumina's interest in maximizing its profits in the downstream market for MCED tests vis-à-vis its ownership interest in Grail versus Illumina's interest in maximizing its profits in the upstream market for NGS platforms vis-à-vis its sales to *all* MCED-test developers. Foreclosing Grail's rivals would increase the former (by diverting MCED-test sales from competitors to Grail) but decrease the latter (by reducing the total number of MCED tests in the marketplace). So, the Commission reasoned, the greater Illumina's ownership stake in Grail, the more its interest in maximizing downstream

[10] Contrary to Illumina's assertion, we do not read the Northern District of California's *Microsoft* decision as reaching a different conclusion. Indeed, that court's ultimate formulation of the ability-and-incentive test stated that Complaint Counsel was required to show that "the combined firm (1) *has* the ability to" and "(2) *has* the incentive to" foreclose. *FTC v. Microsoft Corp.*, No. 23-cv-02880, 2023 WL 4443412, at *13 (N.D. Cal. July 10, 2023) (emphases added). The decision does not require a showing that the merger "provides" the combined firm with both, as Illumina wrongly claims.

profits will outweigh its interest in preserving upstream profits, and thus the more incentive it will have to foreclose. And since the merger would increase Illumina's ownership stake in Grail from 12% to 100%, Illumina would "now earn much more from the sale of a [Grail] test than from the sale of a rival's test" and would therefore "have a significantly greater incentive to foreclose [Grail's] rivals rather than to keep them on a level playing field."

Illumina challenges this conclusion on two bases. First, Illumina argues that, even if the merger would result in Illumina earning larger profits from the sale of a Grail test than the sale of a rival MCED test, that profit differential means nothing without proof of diversion, *i.e.*, Grail's capture of sales lost by rival MCED-test developers. Illumina is correct that diversion is necessary for a vertical merger to give rise to foreclosure incentives. If Illumina forecloses Grail's rivals, preventing them from entering the MCED-test market or lowering their sales, Illumina's NGS-sales revenue generated from those rivals will suffer. Therefore, a foreclosure strategy is only economically rational if Grail can pick up enough of its competitors' lost MCED-test sales to offset the losses to Illumina's NGS-sales revenue. But, Illumina argues, "[b]ecause Galleri is the only test on the market today, there are no sales to divert," so foreclosing Grail's rivals would only harm Illumina's NGS revenue without any concomitant benefit to Grail's MCED-test-sales revenue.

This contention suffers from the same fatal flaw as Illumina's arguments concerning the Commission's market definition—it insists that the Commission must consider only the MCED tests on the market *right now*, not those likely to be on the market in the future. But the relevant market is not "MCED tests commercialized today," it is the "research, development, and commercialization of MCED tests." And as explained earlier, there is substantial evidence in the record showing that other MCED-test developers are, right now, working on creating tests that will rival Grail's capabilities and

that are expected to make it to the market in the near future. And when they do, they would divert sales from Grail—or vice versa, should a foreclosure strategy be pursued.

Illumina's second argument—that harm to Illumina's NGS business from foreclosure of Grail's rivals would outweigh any benefit to Grail's MCED-testing business—is more compelling. Pre-merger, the vast majority of Illumina's revenue—nearly 90% in 2020—was earned through its core business of selling NGS products. And Illumina is right that pursuing a foreclosure strategy threatens material harm to this business in two ways: first, by loss of NGS sales to the foreclosed MCED-test developers, and second, by loss of NGS business in areas outside of cancer detection as a result of reputational damage. But, as the Commission identified, there are two reasons why the risk of such harm is not as great as Illumina claims. First, there are myriad ways in which Illumina could engage in foreclosing behavior *without* triggering suspicion in other customers, such as by making late deliveries or subtly reducing the level of support services. And second, and more importantly, Illumina's monopoly power in the NGS-platform market means that, even if other customers *did* learn about Illumina's foreclosing behavior and therefore *wanted* to take their business elsewhere, they would have nowhere else to turn.

In any event, there is a more fundamental reason why any harm to Illumina's NGS business may not disincentivize Illumina from pursuing a foreclosure strategy against Grail's rivals—the Illumina-Grail merger was the cornerstone of a foundational change in Illumina's business model through which Illumina planned to "transform [itself] into a clinical testing and data driven healthcare company" as opposed to its current iteration as a "life sciences tools & diagnostics company focused on genomics." In other words, Illumina was willing to suffer losses to its NGS-platform sales in order to accelerate the growth of its MCED-test sales because it now viewed the

latter, not the former, as its primary (and far more profitable) business. Illumina's own internal projections bear this out, predicting that, although Illumina would *lose* money in the short term as a result of the merger, by 2035, its "net margin profit pool" for clinical testing services would be nearly eight times the projected profit pool for its NGS-related sales.

In light of the foregoing, the Commission had substantial evidence to support its conclusion that Complaint Counsel made a prima facie showing that, post-merger, Illumina had a significantly increased incentive to crowd out Grail's competitors from the market. MCED testing is a nascent field in which, although only one firm—Grail—has begun to commercialize its product, numerous firms are researching and developing their own products with the end goal of commercialization. And all of the players expect the field to one day generate tens of billions of dollars in yearly revenue. To create and eventually sell this product, each developer will need access to one critical input—NGS platforms. Now, the sole supplier of that input—Illumina—has purchased the first mover in this nascent industry. Given Illumina's monopoly power and shifting business priorities, it was reasonable for the Commission to conclude that Illumina would likely foreclose against Grail's competitors—even at the expense of some short-term profits—to pursue its long-term goal of establishing itself (via Grail) as the market leader in clinical testing.[11]

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[11] We give the evidence about Illumina's past behavior little weight in this analysis. The MCED-test market today, in which multiple firms are racing to develop their own tests and earn a share of what is predicted to be a significant market, is very different from the market that existed when Illumina last owned Grail, when the use of liquid biopsies for cancer screening was highly experimental and not sure to succeed. It is therefore speculative at best to draw conclusions about Illumina's future actions from its past behavior as the owner of Grail. Nor can we draw many insights concerning Illumina's potential post-vertical-merger actions in the MCED-test market by looking at its post-vertical-merger actions in the noninvasive-prenatal-tests market, which already had

b.

The Commission also applied the factors first identified in *Brown Shoe*, and later reiterated in *Fruehauf*, to determine whether the Illumina-Grail merger was likely to substantially lessen competition. These factors include:

> [T]he nature and economic purpose of the [transaction], the likelihood and size of any market foreclosure, the extent of concentration of sellers and buyers in the industry, the capital cost required to enter the market, the market share needed by a buyer or seller to achieve a profitable level of production (sometimes referred to as "scale economy"), the existence of a trend toward vertical concentration or oligopoly in the industry, and whether the merger will eliminate potential competition by one of the merging parties. To these factors may be added the degree of market power that would be possessed by the merged enterprise and the number and strength of competing suppliers and purchasers, which might indicate whether the merger would increase the risk that prices or terms would cease to be competitive.

Fruehauf, 603 F.2d at 353. The Commission found that at least four of the factors—likely foreclosure, the nature and purpose of the transaction, the degree of market power possessed by the merged firm, and entry barriers—supported a finding of a probable Section 7 violation. We conclude that the Commission's *Brown Shoe* determination was supported by substantial evidence.

The first factor the Commission relied upon—likelihood of foreclosure—weighs in favor of Complaint Counsel for the reasons set forth

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multiple competing products on the market at the time of Illumina's acquisition and where the company Illumina acquired was not the first mover in the market.

in our ability-and-incentive analysis. The second factor—nature and purpose of the transaction—also overlaps significantly with our prior discussion and supports Complaint Counsel: The "nature" of the transaction is the acquisition of a downstream customer by a sole-source supplier, and the "purpose" is to fundamentally transform Illumina's business model such that it would be competing most intensely in the downstream market, *i.e.*, the same market in which it has the ability to foreclose.

As for the third factor—degree of market power—the parties' arguments reflect a broader debate about how to view the potential anticompetitive impact of the merger, which we have now already addressed twice: whether the Commission was required to look at the *immediate* effect of the merger (in which case, Illumina would be correct to say that the acquisition does not change Grail's share of the MCED-test market because its Galleri test is the only product on the market) or could consider the merger's long-term impact. And as we have already explained, the Commission properly considered the longer-term impact of the merger and found that the merger was likely to lead to a concentration of market power in the merged firm. This factor thus favors Complaint Counsel as well.

Finally, the Commission found that the merger would increase barriers to entry in the relevant market. Specifically, based on testimony from other MCED-test developers and Complaint Counsel's expert witness, the Commission found that rival firms would be disincentivized from investing in MCED-test development post-merger. Illumina suggests that the Commission gave too much weight to this self-interested testimony and too little weight to other record evidence. But even if we would have found a different conclusion to be "more reasonable and persuasive" had we weighed the evidence ourselves, that would not be enough to set aside the Commission's finding on this factor under our deferential "substantial evidence" review. *See Impax*, 994 F.3d at 491–92.

Nor did the Commission commit legal error by omitting three of the *Brown Shoe* factors from its analysis. There is "no precise formula[]" when it comes to applying these factors. *Fruehauf*, 603 F.2d at 353. Indeed, the Supreme Court has found a vertical merger unlawful by examining only three of the *Brown Shoe* factors. *Ford Motor Co. v. United States*, 405 U.S. 562, 566 (1972) (considering the nature and purpose of the transaction, increased barriers to entry, and increased concentration).

At bottom, the record supports the Commission's findings that the merger will result in the potential foreclosure of a key input by the sole supplier, that it was intended to transform Illumina's business model by shifting its focus from NGS products to clinical testing, and that investment by other MCED-test developers may be chilled, especially given the deferential nature of our review. This was sufficient to support a determination that Complaint Counsel had made a prima facie showing that the merger was likely to substantially lessen competition under the *Brown Shoe* test.

B.

Next, we address the Open Offer—the long-term supply agreement that Illumina offered to rival MCED-test developers. First, we consider *where* in the Section 7 analysis the Open Offer should be evaluated, and second, we turn to *how* it should be evaluated.

1.

Based on the record, the parties' arguments, and applicable case law, we see three different options for the point in the Section 7 analysis at which the Open Offer could come into play. The first option—pressed by Illumina—is to require Complaint Counsel to account for the Open Offer as part of its prima facie case. The second option—adhered to by the Commission's majority opinion—is to only consider the Open Offer at the

remedy stage following a finding of liability. The third option—suggested by Commissioner Wilson in her concurring opinion—is to place the burden of showing the Open Offer's competitive effects on Illumina as part of its rebuttal to the prima facie case. As explained below, we agree with Commissioner Wilson.

a.

The parties' divergent views on this issue appear to stem from a disagreement over whether the Open Offer should be treated as a "market reality"—as Illumina contends—or a remedy—as the Commission found. But we do not think that the Open Offer fits neatly into either bucket, and we decline to force it into one.

On the one hand, it is evident that the Open Offer is not just a normal commercial supply agreement but instead a direct response to anticompetitive concerns over the Illumina-Grail merger. The opening sentence of the Open Offer makes this plain; it explains that the Open Offer was made "[i]n connection with Illumina's proposed acquisition of Grail . . . to allay any concerns relating to the [merger], including that Illumina would disadvantage Grail's potential competitors." So, to treat the Open Offer as just another fact of the marketplace seems to miss the forest for the trees.

But, on the other hand, the Open Offer is different in kind from a Commission- or court-ordered "remedy," which, as the Commission itself noted, can be imposed "only on the basis of a violation of the law," *i.e.*, after a finding of liability. *See Gen. Bldg. Contractors Ass'n, Inc. v. Pennsylvania*, 458 U.S. 375, 399 (1982). Indeed, the Open Offer became effective before the evidentiary hearing in this case had even begun and nineteen months before the Commission's liability determination. Thus, the Commission majority's

reliance on cases like *Ford Motor Co.*[12] and *du Pont*[13]—which concerned *court-ordered* divestitures *after* a finding of Section 7 liability—to support its position that the Open Offer is a remedy is misplaced. So too is its reliance on *United States v. Aetna Inc.*, 240 F. Supp. 3d 1 (D.D.C. 2017), and *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1 (D.D.C. 2015). To be sure, both *Aetna* and *Sysco*—like this case—involved proposals by the parties, not decrees by the Commission or court. But in both cases, the proposed divestitures were conditional upon the court's liability determination, coming into effect in *Aetna* only if the court found such divestiture "necessary to counteract the merger's anticompetitive effects," 240 F. Supp. 3d at 17, and in *Sysco* "if the merger received regulatory approval," 113 F. Supp. 3d at 15. No such conditions accompanied the Open Offer.

In this sense, the Open Offer is somewhere in between a fact and a remedy—a post-signing, pre-closing adjustment to the status quo implemented by the merging parties to stave off concerns about potential anticompetitive conduct. Take, for example, the arbitration agreement at issue in *United States v. AT&T, Inc.*, 310 F. Supp. 3d 161 (D.D.C. 2018), *aff'd*, 916 F.3d 1029 (D.C. Cir. 2019). That case concerned a Section 7 challenge to the vertical merger between AT&T (which distributes television content via its cable platform DirecTV) and Time Warner (which packages television content via its networks such as TNT, TBS, CNN, and HBO and licenses such networks to distributors). *Id.* at 167. Shortly after the government filed suit, and in an effort to assuage concerns that it would price-discriminate against distributors other than AT&T post-merger, Time Warner made an irrevocable offer to distributors to engage in "baseball style" arbitration

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[12] 405 U.S. at 571.

[13] *United States v. E. I. du Pont de Nemours & Co.*, 366 U.S. 316, 334 (1961).

when it came time to renew their licensing agreements. *Id.* at 184.[14] The government argued that the arbitration agreements should be "ignored" until the remedy stage, but the court disagreed, holding that the agreements would have "real-world effect[s]" that should be considered prior to any liability determination. *Id.* at 217 n.30.

The Northern District of California reached a similar determination in *FTC v. Microsoft Corp.*, where the court considered a "binding offer" by Microsoft (the details of which are redacted from the opinion) designed to assuage the government's concerns that Microsoft (the manufacturer of the popular Xbox gaming console) would pull certain videogames from competing consoles following its vertical merger with videogame publisher Activision. No. 23-cv-02880-JSC, 2023 WL 4443412, at *15 (N.D. Cal. July 10, 2023). The court rejected the government's argument that, under *du Pont*, Microsoft's offer was merely a "proposed remedy" to be considered after a finding of liability and explained that "offered and executed agreements made before any liability trial, let alone liability finding," should be considered at the liability phase. *Id.*

The Open Offer is akin to the remedial agreements at issue in *AT&T* and *Microsoft*. And we agree with those courts that such agreements should be addressed at the liability—not remedy—stage of the Section 7 proceedings.

b.

Having determined that the Open Offer should be considered at the liability stage, the question remains: where does it fit within the burden-

[14] In "baseball style" arbitration, "each party puts forward a final offer before knowing about its counterparty's offer, and the arbitrator chooses between those two." *AT&T*, 310 F. Supp. 3d at 217.

shifting framework for determining liability? Illumina urges that Complaint Counsel was required to incorporate the Open Offer into its prima facie case. Commissioner Wilson says that the Open Offer only comes into play as part of Illumina's *rebuttal* to Complaint Counsel's prima facie case. We find the latter approach most compatible with the "flexible framework" at play. *See Chicago Bridge*, 534 F.3d at 424.

As we and our sister circuits have recognized, the burden-shifting framework is "somewhat artificial." *FTC v. Butterworth Health Corp.*, No. 96-2440, 1997 WL 420543, at *1 (6th Cir. July 8, 1997); *accord Chicago Bridge*, 534 F.3d at 424–25. "Conceptually, this shifting of the burdens of production, with the ultimate burden of persuasion remaining always with the government, conjures up images of a tennis match, where the government serves up its prima facie case, the defendant returns with evidence undermining the government's case, and then the government must respond to win the point." *FTC v. Univ. Health, Inc.*, 938 F.2d 1206, 1219 n.25 (11th Cir. 1991). "In practice, however, the government usually introduces all of its evidence at one time, and the defendant responds in kind." *Id.* Thus, the "evidence is often considered all at once and the burdens are often analyzed together." *Chicago Bridge*, 534 F.3d at 425. This is particularly true in vertical merger cases. In horizontal merger cases, the government can "use a short cut to establish [its prima facie case] through statistics about the change in market concentration." *AT&T*, 916 F.3d at 1032. No such "short cut" exists in vertical merger cases, and the government "must make a 'fact-specific' showing" even at the prima facie stage. *Id.*

That is precisely what happened in this case. As the government's brief explains, "[h]ere, Complaint Counsel produced evidence in its case-in-chief that the Open Offer was ineffective, and Illumina attempted to produce contrary evidence in the defense case." The Commission then siloed all of

this Open-Offer-related evidence into the rebuttal stage of its analysis.[15] Had the Commission applied the correct standard at the rebuttal stage, there would have been no error in this approach. Indeed, we approved such a methodology in *Chicago Bridge*.

As we explained there, in many Section 7 cases, the "[g]overnment's *prima facie* case anticipates and addresses the respondent's rebuttal evidence." *Chicago Bridge*, 534 F.3d at 426. In such a situation, the Commission need only "assess[] the rebuttal evidence in light of the *prima facie* case" rather than switch the burden of production back-and-forth. *Id.* at 424.

2.

At the rebuttal stage of the Section 7 analysis, Illumina bore the burden "to present evidence that the *prima facie* case inaccurately predicts the relevant transaction's probable effect on future competition." *AT&T*, 916 F.3d at 1032 (internal quotation marks and citation omitted). Because Complaint Counsel preemptively addressed the Open Offer as part of its case-in-chief, Illumina's burden on rebuttal was "heightened." *Chicago Bridge*, 534 F.3d at 426. To be sure, Illumina's burden was only one of production, not persuasion; the burden of persuasion remained with Complaint Counsel at all times. *AT&T*, 916 F.3d at 1032. But to satisfy its burden of production, Illumina was required to do more than simply put forward the terms of the Open Offer; it needed to "*affirmatively show*[]" why

[15] As explained above, the Commission majority erroneously viewed the Open Offer as a remedy to be properly considered only "at the remedy stage, following a finding of liability." Nonetheless, it examined the Open Offer "at the rebuttal stage" because it found that doing so made no difference to "the ultimate analysis or outcome." But the Commission applied the wrong rebuttal-stage standard. We express no view on whether the application of the proper standard will change "the ultimate analysis or outcome" in this instance.

the Open Offer undermined Complaint Counsel's prima facie showing to such an extent that there was no longer a probability that the Illumina-Grail merger would "substantially lessen competition." *See United States v. Baker Hughes Inc.*, 908 F.2d 981, 991 (D.C. Cir. 1990) (emphasis added).

This is where the Commission erred. The Commission held Illumina to a rebuttal standard that was incompatible with the plain language of Section 7 of the Clayton Act, which only prohibits transactions that will "substantially" lessen competition. 15 U.S.C. § 18. And this error pervaded the Commission's analysis of the Open Offer, as the Commission invoked the wrong standard in five separate instances. Specifically, the Commission held that Illumina was required to "show that the Open Offer would restore the pre-[merger] level of competition," *i.e.*, "*eliminate* Illumina's ability to favor Grail and harm Grail's rivals." In effect, Illumina could only rebut Complaint Counsel's showing of a likelihood of a *substantial* reduction in competition with a showing that, due to the Open Offer, the merger would not lessen competition *at all*. This was legal error.

The Commission's standard stems from its mistaken belief that the Open Offer is a remedy. Indeed, the source of this total-negation standard is the Supreme Court's holding in *Ford Motor Co.* that "[t]he relief in an antitrust case must be 'effective to redress the violations' and 'to restore competition.'" 405 U.S. at 573 (quoting *du Pont*, 366 U.S. at 326). The District of Columbia applied this remedy-stage standard in its liability-stage analysis in a string of cases, beginning with *Sysco*, 113 F. Supp. 3d at 72, continuing in *Aetna*, 240 F. Supp. 3d at 60, and then again in *FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 304 (D.D.C. 2020).[16] But in its most recent

[16] We express no view as to whether a total-negation standard is appropriate at the remedy stage of the Section 7 analysis.

case, the District of Columbia reversed course, recognizing that the total-negation standard "contradicts the text of Section 7." *United States v. UnitedHealth Grp. Inc.*, 630 F. Supp. 3d 118, 132 (D.D.C. 2022). As that court explained, "the text of Section 7 is concerned only with mergers that '*substantially* . . . lessen competition,'" and by requiring on rebuttal a showing that the merger will "preserve exactly the same level of competition that existed before the merger, the Government's proposed standard would effectively erase the word 'substantially' from Section 7." *Id.* at 133 (quoting 15 U.S.C. § 18).

The Northern District of California agreed with this assessment. *See Microsoft*, 2023 WL 4443412, at *13 ("It is not enough that a merger might lessen competition—the FTC must show the merger will probably *substantially* lessen competition." (citing *UnitedHealth*, 630 F. Supp. 3d at 133)). And so do we. To rebut Complaint Counsel's prima facie case, Illumina was only required to show that the Open Offer sufficiently *mitigated* the merger's effect such that it was no longer likely to *substantially* lessen competition. Illumina was not required to show that the Open Offer would negate the anticompetitive effects of the merger entirely.

C.

Finally, we turn to Illumina's other proffered rebuttal evidence—efficiencies. As it did before the Commission, Illumina contends on appeal that the Illumina-Grail merger would have "result[ed] in significant efficiencies" which would have "easily offset[] the supposed [anticompetitive] harm."[17] To be cognizable as rebuttal evidence, an

[17] The Commission stated that, to rebut the prima facie case, any substantiated efficiencies needed "to offset and reverse the likely anticompetitive effects" of the merger. This standard gives us pause for the same reasons discussed with respect to the standard used to evaluate the Open Offer. But we need not decide whether such a standard is

efficiency must be (1) merger specific, (2) verifiable in its existence and magnitude, and (3) likely to be passed through, at least in part, to consumers. *See FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 348–49, 351 (3d Cir. 2016); *Anthem*, 855 F.3d at 362. The Commission determined that none of Illumina's proposed efficiencies were cognizable. We find that this conclusion was supported by substantial evidence.

First, Illumina claimed that the merger would reduce (if not eliminate entirely) Grail's obligation to pay Illumina a royalty, which would have generated a significant consumer surplus. The Commission found that this claimed efficiency was neither merger specific nor likely to be passed through to consumers. We find that the former determination was not supported by substantial evidence, but the latter was. The Commission's finding that the royalty reduction was not merger specific was based on evidence demonstrating that Grail had considered other ways to reduce or eliminate the royalty without merging with Illumina, such as a buyout or longer-term supply agreement. But the Commission did not fairly consider evidence that Grail—in coordination with its bankers at Morgan Stanley—had determined that it lacked the leverage necessary to bring Illumina to the table on these alternative proposals, leaving merger as the only realistic option. We

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appropriate for evaluating efficiencies because the Commission did not rely on it. Instead, the Commission found that Illumina had failed to substantiate its claimed efficiencies in the first place.

We also note that our court has never addressed the threshold question of whether it is proper for a court to take account of a merger's efficiencies as a defense in a Section 7 case. *But see Anthem*, 855 F.3d at 355 (holding that proof of post-merger efficiencies can rebut a Section 7 prima facie case); *FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1054 (8th Cir. 1999) (same); *Univ. Health*, 938 F.2d at 1222 (same). We do not reach that question here, either. Instead, we assume arguendo that such a defense can be properly considered. *Cf. FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 348 (3d Cir. 2016) (assuming, without deciding, that efficiencies defense was valid); *Saint Alphonsus Med. Ctr.-Nampa Inc. v. St. Luke's Health Sys., Ltd.*, 778 F.3d 775, 790 (9th Cir. 2015) (same).

therefore cannot conclude that substantial evidence supported this finding. *See Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951) ("The substantiality of evidence must take into account whatever in the record fairly detracts from its weight.").

With respect to pass-through, however, there was substantial evidence to support the Commission's finding that, while Grail *could* decrease the price of Galleri (*i.e.*, pass some of the benefit through to consumers) following reduction of the royalty, Illumina had not shown a likelihood that Grail *would* do so. Indeed, as explained earlier, substantial evidence supported the Commission's finding that the merger would increase Illumina's incentive to foreclose against Grail's rivals such that competing MCED tests either never make it to market or the costs of bringing such tests to market increase. In other words, Grail had no reason to pass its royalty-reduction savings through to Galleri's customers because, if any of Grail's competitors actually made it to market, Grail could force those competitors to pass through *extra* costs to *their* customers.

Second, Illumina argued that the merger would eliminate double marginalization—*i.e.*, Illumina would no longer charge Grail a margin, as it did before the merger—leading to additional consumer surplus. But Illumina never put forward a proposed model for calculating this benefit, only an "illustrative" one. Illumina does not contest this fact. Rather, Illumina contends that it was Complaint Counsel's burden to model these benefits. But when it comes to efficiencies, "much of the information relating to efficiencies is uniquely in the possession of the merging firms." 4A AREEDA & HOVENKAMP, ANTITRUST LAW ¶ 970f (citation omitted). It is therefore Illumina—not Complaint Counsel—that "must demonstrate that the intended acquisition would result in significant economies." *Univ. Health*, 938 F.2d at 1223; *see also* Steven C. Salop, *Invigorating Vertical Merger Enforcement*, 127 YALE L.J. 1962, 1981 (2018) ("Because the merging

parties have better access to the relevant information, they also bear the burden of producing evidence of efficiency benefits . . . ."). And because Illumina failed to demonstrate that this proposed efficiency was verifiable, the Commission had substantial evidence in support of its decision not to recognize it.

Third, Illumina contended that the merger would lead to "significant supply chain and operational efficiencies" of approximately $140 million over a ten-year period. But, again, it presented no model by which it calculated this number. And without an underlying model, including the assumptions upon which it was based, the Commission had a sound basis to conclude that Illumina had failed to carry its burden of showing this efficiency was verifiable. *See United States v. H & R Block, Inc.*, 833 F. Supp. 2d 36, 91 (D.D.C. 2011) ("[T]he lack of a verifiable method of factual analysis resulting in the cost estimates renders [the proposed efficiency] not cognizable by the Court."). Plus, record evidence showed that Grail was in the process of improving its operations pre-merger, and Illumina had not shown any method of quantifying the incremental value, if any, the merger would provide with respect to these operational efficiencies. Thus, there was not only a verification issue, but a merger-specificity issue as well.

Fourth, Illumina claimed that the merger would result in significant research-and-development efficiencies. But Illumina made no attempt to quantify these claimed efficiencies, instead relying on testimony of its executives that such efficiencies would be achieved. But "[w]hile reliance on the estimation and judgment of experienced executives about costs [or innovation] may be perfectly sensible as a business matter, the lack of a verifiable method of factual analysis . . . renders [the efficiency] not cognizable." *H & R Block*, 833 F. Supp. 2d at 91.

Fifth, Illumina argued that due to its "regulatory and market-access expertise," the merger would "accelerate" FDA approval and payer coverage for Galleri. But the Commission, again supported by substantial evidence, found that Illumina had not established that such acceleration would actually occur, much less shown how it would be achieved. For instance, Illumina's own financial modeling of the merger did not assume that Galleri's widespread commercialization would be accelerated. Nor did it account for the costs that would be associated with achieving any such acceleration, such as diverting Illumina personnel to work on Grail projects. And in any event, Illumina had failed to demonstrate that its claimed "regulatory expertise" was superior to that which Grail already possessed. Indeed, Grail had already obtained breakthrough device designation for Galleri on its own. Illumina, on the other hand, had only ever obtained pre-market approval for one Class III NGS-based diagnostic test, and in that instance, a third party sponsored the clinical study upon which approval was granted.

Sixth, Illumina pointed to "international efficiencies," *i.e.*, that the merger would "accelerate the international expansion of Galleri." But as the Commission explained, Illumina "offered no concrete plans regarding countries in which international expansion would occur, how much more quickly the international expansion would occur, how much additional data the international expansion would generate, how much the international efforts would cost, or why such international expansion could only be achieved through a merger."[18]

[18] Because we find that substantial evidence supported the Commission's conclusion that Illumina had failed to substantiate its claimed international efficiencies, we do not address the question of whether it is proper to consider efficiencies outside of the relevant geographic market. *But see Phila. Nat'l Bank*, 374 U.S. at 370 (rejecting contention

At bottom, an efficiency defense is very difficult to establish. *See* 4A AREEDA & HOVENKAMP, ANTITRUST LAW ¶ 970a ("[W]hile efficiencies are commonly asserted as a defense, they are rarely found sufficient to undermine a prima facie case against a merger.") And substantial evidence supported the Commission's determination that Illumina failed to establish cognizable efficiencies here.

V.

To sum up, Illumina's constitutional challenges to the FTC's authority are foreclosed by binding Supreme Court precedent, and substantial evidence supported the Commission's conclusions that (1) the relevant market is the market for the research, development, and commercialization of MCED tests in the United States; (2) Complaint Counsel carried its initial burden of showing that the Illumina-Grail merger is likely to substantially lessen competition in that market under either the ability-and-incentive test or looking to the *Brown Shoe* factors; and (3) Illumina had not identified cognizable efficiencies to rebut the anticompetitive effects of the merger. However, in considering the Open Offer, the Commission used a standard that was incompatible with the plain language of the Clayton Act. We therefore VACATE the Commission's order and REMAND the case for reconsideration of the effect of the Open Offer under the proper standard.

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that "anticompetitive effects in one market could be justified by procompetitive consequences in another").