No. 23-60167

IN THE

United States Court of Appeals

FOR THE FIFTH CIRCUIT

ILLUMINA, INC. AND GRAIL, INC.,

Petitioners,

v.

FEDERAL TRADE COMMISSION,

Respondent.

On Petition for Review from the Federal Trade Commission (Docket Number 9401)

BRIEF OF 34 MEMBERS OF CONGRESS AS AMICI CURIAE IN SUPPORT OF PETITIONERS

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I certify that the following listed persons and entities have an interest in this case's outcome as described in Fifth Circuit Rule 28.2.1. These representations are made so that the judges of this Court may evaluate possible disqualification or recusal.

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June 12, 2023 *See Appendix for list of Amici Curiae

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INTEREST OF AMICI CURIAE¹

Amici curiae are 34 Members of Congress—2 Senators and 32 Members of the House of Representatives. (See Appendix for List of Amici.) Amici have a special interest both in ensuring that federal administrative agencies faithfully act within the scope of authority delegated to them by Congress and in protecting the physical health and safety of their constituents and all Americans.

Amici believe that the FTC's decision to block the Illumina-Grail merger flagrantly exceeds the authority delegated by Congress, and seriously threatens the health and well-being of Americans by hindering the development of potentially life-saving cancer detention technology.

Accordingly, *Amici* respectfully urge this Court to reverse the FTC's decision and render judgment for Illumina and Grail.

^{1.} This brief is submitted under Federal Rule of Appellate Procedure 29(a) with the consent of all parties. Undersigned counsel for *amici curiae* certifies that this brief was not authored in whole or part by counsel for any of the parties; no party or party's counsel contributed money for the brief; and no one other than amici and their counsel have contributed money for this brief.

INTRODUCTION

The Federal Trade Commission's power is not without limit. Section 5 of the FTC Act confines the FTC's power to stopping "unfair methods of competition." This does not include remaking a sector of the economy. The FTC Commissioners must observe the limits imposed by Congress, not act as though their "power [is] more arbitrary than that possessed by any king or potentate on earth." 51 Cong. Rec. 11,113 (1914) (Remarks of Sen. Reed).

The current FTC disregards these congressionally mandated and court defined limits, no longer evincing the regulatory humility exemplified by past commissioners. Remarks by Comm'r Maureen K. Ohlhausen, *Regulatory Humility in Practice* before the American Enterprise Institute (Apr. 1, 2015) ("recognizing the inherent limitations of regulation and acting in accordance with those limits").² Instead, the current commissioners have engaged in a pattern of unauthorized actions that bear striking resemblance to those of a potentate.

^{2.} https://www.ftc.gov/system/files/documents/public_statements/ 635811/150401aeihumilitypractice.pdf

Nor has the FTC attempted to hide its disregard of these legislative limits. In November 2022, three commissioners commenced their campaign of overreach when they replaced a bipartisan statement of enforcement principles about unfair methods of competition reflecting decades of legal precedent and economic learning with a statement that promised, according to one dissenting commissioner, "summarily to condemn essentially any business conduct [the FTC majority] finds distasteful." Comm'r Christine S. Wilson, Dissenting Statement Regarding the *Policy Statement Regarding the Scope of Unfair Methods of Competition under Section 5 of the Federal Trade Commission Act* (Nov. 10, 2022).³

Three months later, the same three-person majority followed through on that threat and launched a rulemaking to summarily ban noncompete provisions in nearly all employment contracts, a breathtaking rule that would overturn dozens of state laws, hundreds of years of legal precedent, and roughly one-fifth of all employment contracts in the United States. Comm'r Christine S. Wilson, Dissenting

^{3.} https://www.ftc.gov/legal-library/browse/cases-proceedings/publicstatements/dissenting-statement-of-commissioner-wilson-on-policystatement-regarding-section-5

Statement Concerning the Notice of Proposed Rulemaking for the Non-Compete Clause Rule (Jan. 5, 2023).⁴

Blocking the Illumina re-acquisition of Grail is simply the latest example of FTC overreach; it is industrial policymaking masquerading as an enforcement action.

Illumina created Grail years ago and then spun off most of its ownership to allow Grail the freedom to more effectively pursue its research and funding opportunities. Grail developed multicancer early detection (MCED) tests that show great promise, and it is today the only developer to even make limited sales possible without full FDA approval. But Grail cannot commercialize production and obtain the necessary full regulatory approval on its own—required steps to delivering the full benefits of these tests to the public and detecting cancer as quickly as possible. To accomplish this on any reasonable timeline, it needs to recombine with Illumina.

To address any possible competitive concerns, Illumina made an Open Offer to commit to supplying other MCED developers who use

^{4.} https://www.ftc.gov/legal-library/browse/cases-proceedings/publicstatements/dissenting-statement-commissioner-christine-s-wilsonconcerning-notice-proposed-rulemaking-non

Illumina's products and services on a nondiscriminatory basis. These developers are well behind Grail—years away even from the necessary testing—but this binding Open Offer will allow them to continue whatever competitive pressure they might provide.

Because of the FTC's actions, Illumina has been unable to fully integrate Grail and speed up these life-saving developments. Rather than focus on supplying those other developers, helping Grail commercialize, and expediting the availability of life-saving cancer detection technologies, Illumina has instead been forced to spend years fighting the FTC. After an extensive investigation and full-blown trial, Illumina's FTC's prospects were looking up when the FTC Administrative Law Judge (ALJ) ruled in its favor, the first time in history that this FTC ALJ had ruled for merging parties fighting an FTC challenge. Then, for the first time in decades, the FTC over-ruled its ALJ.⁵

^{5.} After an extensive five-week trial with comprehensive testimony from 66 witnesses and the introduction of 4,500 exhibits, in September 2022 the FTC ALJ dismissed the FTC's merger challenge—for the first time ever—finding the FTC had failed to meet its prima facie burden. The ALJ concluded that Grail's MCED test is the only currently available MCED product and other MCED products will not become available for at least five to seven years, if then. Meanwhile, he also concluded that Illumina's "Open Offer" protects against a lessening of competition.

Illumina's appeal raises many legal and constitutional issues; however, as members of Congress, *Amici* will focus on two related arguments that underscore the FTC's overreach well beyond the limits Congress placed on its authority.

First, the FTC's order is so broad and baseless that the FTC is no longer merely attending its duty to prevent unfair methods of competition. It is acting as the potentate that Congress expressly sought to avoid creating—able to arbitrarily choose winners and losers and decide the face and fate of an entire industry sector. These actions go well beyond the authority granted by Congress and implicate the Court's major questions doctrine.

The opinion effectively constrains the development of the market for early cancer detection, which is a matter of economic and political significance. Opinion of the Commission (Opinion) (Apr. 3, 2023). The major questions doctrine prevents agencies like the FTC from setting policies that decide questions of economic and political significance—and therefore the prerogative of Congress—absent clear authorization from Congress. The statutes under which the FTC claims to act do not clearly authorize these actions.

Second, the FTC's opinion misinterprets Section 7 of the Clayton Act, going well beyond the limits imposed by that statute and recognized by courts for decades. The FTC manufactures a market and market participants out of whole cloth, misuses expert testimony, and ignores facts, relying instead on credo and conjecture to conjure a "mere possibility" of future competitive harm from the transaction. The Clayton Act requires more than a theory about the "mere possibility" of a violation.

For either of these reasons, the FTC's opinion should be overturned, and this overreach stopped.

ARGUMENT

I. THE MAJOR QUESTIONS DOCTRINE PRECLUDES THE FTC FROM UNWINDING THIS TRANSACTION

Last year, the Supreme Court for the first time fully explained the "major questions doctrine." *West Virginia v. EPA*, 142 S. Ct. 2587 (2022). The doctrine itself is not new, as the Court explained: "it refers to an identifiable body of law that has developed over a series of significant cases all addressing a particular and recurring problem: agencies asserting highly consequential power beyond what Congress could reasonably be understood to have granted." *Id.* at 2609 (collecting cases). The doctrine is nothing more than the basic civics lesson taught in grade school: Congress makes policy judgments when it passes legislation and administrative agencies **administer** those policy judgments within the bounds set by the laws passed by Congress. *Id.* ("We presume that 'Congress intends to make major policy decisions itself, not leave those decisions to agencies.' "); *see also* William Eskridge Jr., *Interpreting Law: A Primer on How to Read Statutes and the Constitution* 288 (2016) ("Even if Congress has delegated an agency general rulemaking or adjudicatory power, judges presume that Congress does not delegate its authority to settle or amend major social and economic policy decisions."); U.S. Const. art. I, § 1.

The major questions doctrine counsels judicial skepticism toward agency action with substantial "economic and political significance"—i.e., action that strays into the arena preserved for legislators. *West Virginia*, 142 S. Ct. at 2608. When confronted with such cases, courts must assure themselves that Congress made an unmistakable delegation of authority for such agency action. Only then may the agency "implement and enforce the laws" Congress enacted. *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019). Absent such a clear statement from Congress, there is an unacceptable risk that the administrative agency is not administering the law, but instead "attempting to 'work around' the legislative process to resolve for itself a question of great political significance." *West Virginia*, 142 S. Ct. at 2621 (Gorsuch, J., concurring) (citation omitted).

Courts presume "Congress intends to make major policy decisions itself, not leave those decisions to agencies." *Id.* at 2609. An agency's assertion of "unheralded" regulatory power over "a significant portion of the American economy" also presents a major question. *Id.* at 2608. And to take such regulatory action, an agency must point to clear congressional authorization. *See Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2489 (2021).

The FTC's obstruction of Illumina's re-acquisition of Grail is a textbook example of agency action that meets both prongs of the major questions doctrine. First, the agency action is one of "economic and political significance" as it hinders the development, regulatory approval, and commercialization of an entire market for a revolutionary method to detect multiple forms of cancer—literally, a matter of life and death. Second, the FTC went well beyond any authority granted by Congress under the Clayton and FTC Acts by becoming a sector planner and

substituting its judgment for that of the marketplace by selecting the number and identity of competitors in a nascent market.

A. The FTC's Obstruction of the Illumina-Grail Merger Is an Action of Economic and Political Significance Triggering the Major Questions Doctrine

Cancer risk and its early detection obviously are matters of "economic and political significance." The disease killed over 600,000 Americans in 2021, the second leading cause of death.⁶ Congress has made many policy decisions to fight it. In the Centers for Disease Control and Prevention Consolidated Appropriations Act in 2023, Congress allocated \$7.3 billion to the National Cancer Institute (NCI), a \$408 million increase year over year.⁷

Of that money, \$216 million was allocated for the NCI component of the Cancer Moonshot, the Biden Administration's plan to "end cancer as we know it." While there are many elements of the Cancer Moonshot,

^{6.} Centers for Disease Control and Prevention, National Center for Health Statistics, FastStats, Leading Causes of Death, https://www.cdc. gov/nchs/faststats/leading-causes-of-death.htm

^{7.} Fact Sheet: President Biden Reignites Cancer Moonshot to End Cancer as We Know It (Feb. 2, 2022), https://www. whitehouse.gov/briefing-room/statements-releases/2022/02/02/factsheet-president-biden-reignites-cancer-moonshot-to-end-cancer-as-weknow-it/

one is for the NCI to "study and evaluate multicancer detection tests," like Grail's test. The point is that cancer detection is a matter of economic and political significance and Congress has treated it as such.

Grail is poised to play a large role in improving cancer detection. From a single blood draw, its test can simultaneously screen for more than fifty types of cancer in asymptomatic patients. FTC Initial Decision ¶¶ 228, 231 (Sept. 9, 2022) (Initial Decision). Grail's test is the only such MCED test for sale now, though in limited quantities without full FDA approval. Grail's small size and scale means it needs to combine with Illumina to achieve wide-scale commercialization, timely regulatory approvals, payor reimbursement, and production and distribution at scale. The FTC has chosen to insert itself and its own speculative judgments into this matter of "economic and political significance."

B. The FTC Exceeded the Limited Authority Granted to It by Congress Under the FTC and Clayton Acts

Yet Congress did not clearly authorize the FTC in either the FTC Act or the Clayton Act to make the policy decisions it effectively made in blocking this transaction. Under the FTC Act, the FTC may prohibit "unfair methods of competition." 15 U.S.C. § 45. While broad, that charge is not boundless.

Congress intended the FTC to use Section 5, like other laws aimed at prohibiting anticompetitive conduct, to protect competition, not competitors. *See Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977) (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962) (the antitrust laws were enacted for "the protection of *competition*, not *competitors*")).

FTC now disregards Congress' direction to focus on The competition-not the number of competitors-and instead appointed itself health care sector planner when it found that more potential (i.e., hypothetical) developers of MCED tests necessarily will improve competition. Instead of focusing on competition and its results for the American public, the FTC's opinion attempts to revive long-discredited analyses of vertical mergers that focus on "the number and strength of and purchasers." Opinion at suppliers 41. competing 46. As Commissioner Wilson's concurring opinion notes, the cases relied on by the majority are more than forty years old and have been ignored by the

FTC and the courts in numerous more recent cases. Comm'r Wilson Concurrence at 2 (Apr. 3, 2023).⁸

And for good reason. As the concurrence notes, those old cases relied on a discredited economic paradigm—Structure-Conduct-Performance that focused more on counting competitors than economic realities (quoting Herbert J. Hovenkamp, *Competitive Harm from Vertical Mergers*, Fac. Scholarship at Penn Carey L. at 5 (Oct. 24, 2020)⁹ ("The economic writings since the 1980's has largely repudiated the *Brown Shoe* view of vertical mergers.")). Comm'r Wilson Concurrence at 2. The FTC's focus on individual potential rivals—and blithe assumption that more of them will necessarily lead to better outcomes for consumers—is contrary to the direction Congress set when it passed Section 5 of the FTC Act. The FTC is seeking to help hypothetical potential competitors not competition, and certainly not the public.

In short, the FTC is punishing the more efficient Grail by slowing down its commercialization and allowing the other developers of MCED

^{8.} https://www.ftc.gov/system/files/ftc_gov/pdf/d09401wilsoncon curringopinion.pdf.

^{9.} https://scholarship.law.upenn.edu/faculty_scholarship/2218/

tests a chance to catch up. Everyone agrees Grail is ahead of other developers. It is the only developer selling an MCED test. Allowing Grail to combine with Illumina through the transaction will speed regulatory approval and commercialization of Grail's test, saving countless lives. With the Open Offer, other developers will continue to have the opportunity to develop MCED tests alongside Grail's, perhaps even bettering it. By blocking the transaction, the FTC is slowing down the most efficient developer to date in an effort to protect hypothetical future competitors, thereby exceeding the authority granted to it by Congress.

C. The FTC Botched the Necessary Market Analysis Required Under the Clayton Act

The FTC also exceeded the authority granted by Congress to prohibit anticompetitive mergers under the Clayton Act by confidently conjuring a market definition and list of participants before anyone is sure any market exists. 15 U.S.C. § 18.

Section 7 of the Clayton Act requires the FTC to show a substantial lessening of competition "in any line of commerce in any section of the country." *Id.* The Court has long held that this language means that "[d]etermination of the relevant market is a necessary predicate" to a Section 7 claim. *United States v. E.I. duPont de Nemours & Co.*, 353 U.S. 586, 594 (1957). The Court has also held that such a determination requires a reasoned analysis of real-world facts, not a commissioner's theoretical musings on competition. *See United States v. Gen. Dynamics Corp.*, 415 U.S. 486, 498 (1974) ("Congress indicated plainly that a merger had to be functionally viewed, in the context of its particular industry.") (quoting *Brown Shoe*, 370 U.S. at 321–22).

Here, the FTC defines a "nascent" market for MCED tests despite having few if any of the functional facts necessary for such a determination. The FTC does not know key attributes of the products in the alleged market, such as how many cancers an MCED must detectis it two, fifty, or something in between? The FTC does not know how those cancers will be detected—a single blood draw or some different or additional procedures? Who are the participants in the market? Grail is the only one selling these kinds of tests now, though in limited quantities prior to full regulatory approval. The FTC considered seven other developers-are some, or none, or all of them participants in "the market?" All known rivals are years away from commercial launch and full regulatory approval-when, if ever, will any of them obtain such approvals? Even before then, to what extent will each of them engage in

the years-long studies to even gather the data to begin the regulatory process?

Congress required the FTC and judges to identify a "line of commerce" and "section of the country" under Section 7 using real-world facts to rein in any temptation to go beyond protecting competition by inventing markets and shaping an industry as the FTC thinks it should be shaped. 15 U.S.C. § 18. Congress gave the FTC broad powers to stop anticompetitive practices. But that delegation did not include the power to decide all major policy questions by shaping a market's structure and naming and numbering competitors before anyone knows if a product or market even exists.

The FTC lacks the clear congressional authority to make the major policy decision it has made here.

II. THE FTC IS NOT ACTING CONSISTENTLY WITH THE DIRECTIVES OF THE CLAYTON ACT

The Clayton Act, as amended, prohibits mergers whose effect "may be substantially to lessen competition, or to tend to create a monopoly." *Id.* This standard does not require the FTC to show that the merger will have the proscribed competitive effect with *certainty*, but it must establish that the competitive effect is more than a *mere possibility*.

The FTC misused expert testimony, ignored real world facts, and relied on theory and conjecture to summon up, at most only a "mere possibility" of competitive harm from the transaction. *Id*.

Congress used the "may be" language in the original Clayton Act. When amending the Act in 1950, Congress maintained that language.

While Congress did not intend to require certainty to condemn mergers as anticompetitive, it did intend to require something more than a theoretical possibility of such harm. "The use of these words means that [the amended Clayton Act] would not apply to the *mere possibility* but only to the reasonable probability of the prescribed effect." S. Rep. No. 1775, 81st Cong., 2d Sess. 6, *Amending an Act entitled: An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes*, approved October 15, 1914 (38 Stat. 730) (emphasis added).

Courts, beginning with the Supreme Court, have subsequently interpreted and applied Congress' direction. For example, the Court in *Brown Shoe* clearly drew the "certainties/probabilities/possibilities" distinction:

Congress used the words '*may be* substantially to lessen competition' (emphasis supplied), to indicate that its concern

was with probabilities, not certainties. Statutes existed for dealing with clear-cut menaces to competition; no statute was sought for dealing with ephemeral possibilities. Mergers with a probable anticompetitive effect were to be proscribed by this Act.

370 U.S. at 323.

Similarly, two years later in *Penn-Olin*, the Court recited its earlier discussion of certainties and probabilities but also quoted a warning from its earlier *Philadelphia National Bank* opinion that any prediction by a court "is sound only if it is based upon a firm understanding of the relevant market; yet the relevant economic data are both complex and elusive." *United States v. Penn-Olin Chem. Co.*, 378 U.S. 158, 171 (1964) (quoting *United States v. Phila. Nat'l Bank*, 374 U.S. 321, 362 (1963)).

Lower courts have applied the same standard. See, e.g., FTC v. HJ Heinz, Co., 246 F.3d 708, 713 (D.C. Cir. 2001) (reasonable likelihood of substantial lessening of competition); FTC v. Whole Foods Mkt., Inc., 548 F.3d 1028, 1042 (D.C. Cir. 2008) (probabilities, not certainties). They have also heeded the warning to base their predictions of future probabilities on real-world facts. See, e.g., FTC v. Arch Coal, Inc., 329 F. Supp. 2d 109, 116–17 (D.D.C. 2004) ("Hence, antitrust theory and

speculation cannot trump facts [and cases] must be resolved on the basis of the record evidence relating to the market and its probable future.").

A comparison of this case with the courts' review of AT&T's acquisition of TimeWarner in 2018 illustrates the extent of the FTC's overreach and disregard of the Clayton Act's requirements. *See United States v. AT&T*, 310 F. Supp. 3d 161, 189–92 (D.D.C. 2018).

Like this case, the AT&T transaction was a vertical merger case, with AT&T, a distributor of video content, acquiring TimeWarner, a producer of video content. Like this case, the government attempted to block the transaction on antitrust grounds, claiming that the transaction would allow AT&T to block or hinder the distribution of video content by TimeWarner competitors. Like the ALJ in this case, the *AT&T* District Court found that the government had not shown anything more than a "mere possibility" of substantial lessening of competition. *Id.* at 189. That assessment was affirmed on appeal. *United States v. AT&T, Inc.*, 916 F.3d 1029 (D.C. Cir. 2019).

Unlike this case, the challenge in AT&T involved an evaluation of a well-established market properly assisted by economic experts who considered all relevant real-world conditions. Yet even those factors were insufficient to meet the standard set by Congress in the Clayton Act. A comparison with the far weaker evidence in this case illustrates why the Commissioners' decision here was incorrect.

First, the judge in AT&T appreciated the difficulty of the "uncertain task" of "making a prediction about the future" of a market: "To say the least: that is no easy assignment!" 310 F. Supp. 3d at 190. But at least the market whose future he was predicting—the market of multichannel video distribution, such as through cable, streaming, and over-the-air distributors—had existed for decades. Numerous fact witnesses, some with decades of experience in the businesses, helped with that "uncertain task" by testifying as to how the businesses currently operated and offered their own predictions about how the transaction would affect those practices. *Id.*

In this case, Grail first offered for sale its MCED test in April 2021 on a limited basis and by later that year had sold about 3,000 tests. Initial Decision at 11–12. Going beyond limited commercialization will require Grail to seek FDA approval, which in turn will require "multi-year largescale clinical studies." *Id.* at 26. Still, Grail's test is the only such product currently for sale at all, and most of the other researchers do not even expect to launch a screening test for years. *Id.* at 27–28. Finally, the tests of those other researchers might work differently than Grail's test and detect many fewer cancer types. *Id.* And yet, the FTC believes it can confidently describe the contours of a market that includes Grail and many other researchers and predict the effects of this transaction on that alleged market now and in the near and distant future, despite that this market does not exist.

Second, in AT&T, the defendants "irrevocably" offered an arbitration agreement commitment to competitive distributors of video content to ease their fears that, post-transaction, the merged entity would use its leverage over popular content to harm those distributors with blackouts of popular content. 310 F. Supp. 3d at 184. The government urged the judge to "ignore" the commitment or view it as an admission that the transaction would lead to the competitively harmful effects of leveraging asserted by the government. *Id.* at nn.31, 51. The judge decided to consider the commitment because its mere presence in the market "will have real-world effects." *Id.* at n.51. After consideration, the judge found the commitment yet another reason to be "skeptical of the Government's increased-leverage theory of competitive harm." *Id.*

Similarly, in one of the few real-world facts in the alleged market. Illumina also made a commitment, an Open Offer, to the current customers of its gene-sequencing products and services that would ease any fears of post-transaction leveraging by locking Illumina's contractual terms in place for years. Initial Decision at 98. Several such customers have agreed to the Open Offer. Id. at 154. Just as in AT&T, the government (here, FTC complaint counsel) urged that the Open Offer be ignored as "made for litigation." Initial Decision at 153. Just as in AT&T, the judge (here, the FTC ALJ) rejected that argument, considered the Open Offer as part of his evaluation of the potential real-world effects of the transaction. and found that it helped alleviate fears of anticompetitive effects post-transaction. Id. at 178–88.

Unfortunately, the Commissioners rejected that approach and found a way to ensure that the real-world fact of the Open Offer did not thwart their desired theoretical outcome. Instead of requiring FTC complaint counsel to deal with the often-accepted Open Offer as a fact in their prima facie case, the majority opinion relegated consideration of the Open Offer to rebuttal and assigned the burden of proof to Illumina and Grail. Opinion at 61–65. There, the opinion followed "antitrust theory

and speculation" and imagined several ways in which the Open Offer *might* not remedy complaint counsel's anticompetitive harm thesis: "But it *could* easily give plausible-sounding explanations for missed deadlines or service failures" (id. at 68); "Illumina could also . . . say simple things like, you know, 'We can't get a technician out to your sequencers until next Friday'" (id. at 69); "As a combined firm, Illumina could adapt its new technology to give Grail a competitive edge." Id. (all emphases added). Congress intended the FTC to grapple with probabilities, not "ephemeral possibilities" and other musings of events that "could" happen.

Third, the AT&T court properly used economic experts to assist in its "uncertain task" by having them opine on subjects where they had real expertise. Both parties used economic witnesses (Shapiro and Carlton) with decades of study and experience in industrial organization economics in general and predicted responses to economic incentives in particular. See, e.g., AT&T, 310 F. Supp. 3d at 187. While crediting both witnesses, the court ended up siding with the defense's expert witness. Id. In this case, FTC complaint counsel called an industrial organization economic witness, Dr. Fiona Scott Morton, to opine on various questions, including speculation about the possibility that other researchers of MCED tests might improve on or even leapfrog Grail's test. She speculated that "one of those approaches *might* turn out to be superior in the future. A rival *might* make a discovery or advancement at any time, and leapfrog ahead of Grail." Initial Decision at 147–48 (quoting Scott Morton Expert Report ¶¶ 159, 222 (emphasis added)).

The FTC ALJ recognized that Scott Morton's qualifications to render such speculative opinions were "minimal" because she is "not an expert . . . in any field of chemistry or biological studies [and] does not have medical training or direct experience with cancer screening [and] lacks scientific expertise to compare and contrast . . . tests in development." Initial Decision at 147 n.35. As a result, the ALJ rejected such speculation as "unsupported." *Id.* at 148.

Unfortunately, the FTC commissioners embraced Scott Morton's report and her speculation. The opinion described Scott Morton as "highly qualified to offer *economic* opinions" and listed her lengthy academic and enforcement accomplishments in economics. Opinion at 47 n.31 (emphasis added). Left unexplained was how that experience in economics qualified her as an expert in the possible development of cancer testing many years in the future. But the FTC commissioners went even further and dropped Scott Morton's caution about developments that "might" happen to assert that they knew what "would" happen: "lower availability of competing MCED tests *would* harm U.S. patients;" "Consumers *would* lose the benefit of multiple competitors pursuing diverse scientific approaches." *Id.* at 59 (emphasis added).

The FTC ALJ recognized the

substantial uncertainty around the MCED tests in development . . . when clinical trials for many of the MCED tests in development might be started . . . whether any of [the tests] will get FDA approval . . . if the . . . tests . . . will launch . . . how many cancers [the tests] will screen for . . . and . . . what features the . . . tests may have.

Initial Decision at 148. The FTC ALJ did not find speculation from an economist helpful in clearing up this uncertainty and rejected it. Id. (quoting AT & T, 310 F. Supp. 3d at 221) ("To be probative in a particular case, expert testimony must incorporate assumptions that are 'reasonable' in light of the record evidence."). The FTC commissioners ignored such uncertainty, accepted speculation by an unqualified expert, and confidently asserted that they could correctly predict scientific

developments years into the future. Such misuse of antitrust theory and conjecture to trump facts and divine ephemeral possibilities about an uncertain future conflicts with the Clayton Act as written by Congress and interpreted by courts and must be rejected.

CONCLUSION

Amici request that the Court hold that, in blocking this Illumina/Grail transaction, the FTC exceeded the scope of its authority granted by Congress and that the Court overturn the FTC's action in this case.

Respectfully submitted,

Date: June 12, 2023

BONA LAW PC

<u>/s/ Luke Hasskamp</u> LUKE HASSKAMP

Counsel for Amici Curiae

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), I certify that:

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 4,914 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionately spaced typeface using Word 2016, Century Schoolbook 14-point font.

Date: June 12, 2023

BONA LAW PC

<u>/s/ Luke Hasskamp</u> LUKE HASSKAMP

Counsel for Amici Curiae*

*See Appendix for list of Amici Curiae

CERTIFICATE OF SERVICE

I hereby certify that on June 12, 2023, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system.

Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

Date: June 12, 2023

BONA LAW PC

<u>/s/ Luke Hasskamp</u> LUKE HASSKAMP

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*See Appendix for list of Amici Curiae

APPENDIX

List of Amici Curiae

MEMBERS OF CONGRESS

2 United States Senators

Sen. Bill Hagerty

Sen. John Kennedy

32 Members of the United States House of Representatives

Lead Representatives:

Rep. Gus M. Bilirakis (FL-12) and Rep. Darrell Issa (CA-48)

Rep. Rick W. Allen (GA-12)

Rep. Mark E. Amodei (NV-02)

Rep. Larry Bucshon, M.D. (IN-08)

Rep. Vern Buchanan (FL-16)

Rep. Michael C. Burgess, M.D. (TX-26)

Rep. Kat Cammack (FL-03)

Rep. Earl L. "Buddy" Carter (GA-01)

Rep. Lori Chavez-DeRemer (OR-05)

Rep. Ben Cline (VA-06)

Rep. Jeff Duncan (SC-03)

Rep. Neal P. Dunn, M.D. (FL-02) Rep. Mike Ezell (MS-04) Rep. A. Drew Ferguson, IV D.M.D. (GA-03) Rep. Andrew R. Garbarino (NY-02) Rep. Lance Gooden (TX-05) Rep. Diana Harshbarger (TN-01) Rep. Erin Houchin (IN-09) Rep. Richard Hudson (NC-09) Rep. John Joyce, M.D. (PA-13) Rep. Mike Kelly (PA-18) Rep. Nicholas A. Langworthy (NY-23) Rep. Debbie Lesko (AZ-08) Rep. Nancy Mace (SC-01) Rep. Mariannette J. Miller-Meeks, M.D. (IA-01) Rep. Barry Moore (AL-02) Rep. Greg Pence (IN-06) Rep. Guy Reschenthaler (PA-14) Rep. Keith Self (TX-03) Rep. Pete Sessions (TX-17)

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Rep. Steve Womack (AR-03)