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.

OPPOSITION OF THE FEDERAL TRADE COMMISSION TO PETITIONERS' MOTION TO EXPEDITE APPEAL

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Petitioners Illumina, Inc. and GRAIL, Inc. (collectively, "Illumina") have moved to expedite this case, in which they seek review of an order of the Federal Trade Commission requiring Illumina to unwind its 2021 acquisition of Grail. That requirement does not take effect until judicial review is complete; in the meantime, the Commission has ordered Illumina to continue operating Grail as a separate company. Expedition should be denied because Illumina fails to show that the hold-separate order presents any good cause to expedite this case. *See* 5th Cir. R. 27.5. To the contrary, Illumina's motion makes clear that there is no urgency here. The European Commission, which conducted its own antitrust review and found that the transaction violated European competition laws, has independently ordered Illumina to hold Grail as a separate company pending further proceedings. That order bars Illumina and Grail from combining operations regardless of what happens in this case, and Illumina concedes that the European order will remain in effect at least through the end of 2023 (and it will likely be even longer given the anticipated timing of the European proceedings). That gives the parties plenty of time to complete briefing in the ordinary course.

Furthermore, given the number and complexity of the issues that Illumina intends to raise (including both substantive antitrust issues and multiple constitutional challenges), an expedited briefing schedule would be highly prejudicial to the FTC. That is especially true of the lopsided and unfair schedule

proposed by Illumina, which would give the company 66 days from when it received the decision to prepare its opening brief and require the FTC to respond in a mere 21 days. Even if Illumina were not independently barred from combining operations with Grail, that schedule would be manifestly unfair on its face.

The Court should give no weight to Illumina's speculative arguments that allowing the companies to combine operations will save lives by accelerating Grail's ability to gain regulatory approval for its medical tests. As the company admits, the FDA has not yet even approved Grail's test, insurance companies will not reimburse for it, and its cost is prohibitive for most Americans. The Commission found that Illumina's argument that the merger would somehow speed up regulatory approval or commercial acceptance of the test were based on nothing more than vague and unsupported speculation by Illumina executives. And it further found that keeping the companies separate would likely save more lives than the merger could because it would encourage competition in the development of early-stage cancer detection tests. The Commission's findings are amply supported by the record evidence and are entitled to conclusive weight in this Court. The motion should be denied.

BACKGROUND

A. Procedural History

This case involves an emerging class of innovative blood tests known as multi-cancer early detection ("MCED") tests, which can detect multiple forms of cancer in asymptomatic people. Grail developed one such test, called Galleri, which has been clinically shown to detect seven types of early-stage cancer in asymptomatic populations.[1] Commission Opinion ("Op.") 13.[2] Several other companies are competing to research, develop, and commercialize other innovative MCED tests. Op. 14-18. All of these tests rely on next-generation gene sequencing ("NGS") platforms manufactured by Illumina; there is currently no viable substitute for Illumina's NGS technology. Op. 7.

Illumina originally formed Grail in 2016 but spun it off as a separate company in February 2017, with Illumina ultimately retaining a 12% stake. Op. 10-11. In September 2020, Illumina changed its mind and decided to acquire the remainder of Grail for $8 billion. Op. 11. Although Illumina and Grail do not compete with each other, the acquisition raised antitrust concerns because Grail's competitors rely on Illumina's technology, and Illumina would have the ability and

[1] Illumina states that Galleri can detect 50 types of cancer, but as the Commission found, that has not been shown to be true with regard to screening for early-stage cancers in asymptomatic populations, which is the purpose of an MCED test. Op. 13.

[2] The public version of the Commission's decision is attached as Exhibit A. It has been redacted to protect confidential business information.

incentive to favor Grail over its rivals if the companies were combined. Accordingly, both the FTC and the European Commission's Directorate General for Competition carefully reviewed the proposed transaction.

In March 2021, the FTC issued an administrative complaint alleging that the combination of Illumina and Grail may substantially lessen competition in the market for research, development, and commercialization of MCED tests, leading to diminished innovation, higher prices, and reduced choice and quality of MCED tests available to consumers. As a result, the complaint alleged, the transaction would violate Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45. Under the Administrative Procedure Act and the FTC's rules, such complaints are prosecuted by agency staff known as "Complaint Counsel," who are walled off from the Commission itself. Discovery and trial are conducted before an administrative law judge, whose factual findings and legal conclusions are subject to *de novo* review by the Commission. *See* 5 U.S.C. § 554(d)(2); 16 C.F.R. Pt. 3.

In April 2021, the European Commission opened its own investigation into the proposed merger upon referral from several member states.[3] Illumina challenged the EC's jurisdiction to review the merger in the European General

[3] EC Press Release, *Mergers: Commission opens in-depth investigation into proposed acquisition of GRAIL by Illumina* (July 22, 2021), https://ec.europa.eu/commission/presscorner/detail/en/IP_21_3844.

Court.[4] The EC's investigation, which continued despite the jurisdictional challenge, triggered a standstill obligation under European law, but in August 2021 Illumina closed on the sale anyway.[5] To allay concerns about the closing, Illumina committed to the EC that it would hold Grail as a separate entity until either the General Court ruled that the EC lacked jurisdiction or the EC approved the merger. *See* Ex. B. The EC thereafter imposed its own binding hold-separate obligation on Illumina and Grail while it continued its review.[6] In July 2022, the General Court rejected Illumina's challenge to the EC's jurisdiction. Illumina appealed this decision to the European Court of Justice ("ECJ"), which is effectively the European Union's Supreme Court.

Meanwhile, the FTC case went to trial before the ALJ. The trial lasted several weeks and yielded an extensive factual record, including testimony from 56 fact witnesses and 10 expert witnesses and more than 4,500 exhibits. In September 2022, the ALJ issued an Initial Decision in favor of Illumina, holding that

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[4] Illumina Press Release, *Illumina Files Action for Annulment of European Commission's Decision Asserting Jurisdiction to Review GRAIL Transaction* (Apr. 29, 2021), https://investor.illumina.com/news/press-release-details/2021/Illumina-Files-Action-for-Annulment-of-European-Commissions-Decision-Asserting-Jurisdiction-to-Review-GRAIL-Acquisition/default.aspx

[5] EC Press Release, *Mergers: Commission alleges Illumina and GRAIL breached EU merger rules by early implementation of their acquisition* (July 19, 2022), https://ec.europa.eu/commission/presscorner/detail/en/ip_22_4604.

[6] EC Press Release, Mergers: *Commission adopts interim measures to prevent harm to competition following Illumina's early acquisition of GRAIL* (Oct. 29, 2021), https://ec.europa.eu/commission/presscorner/detail/en/ip_21_5661.

Complaint Counsel had not shown that a likelihood of harm to Grail's rivals was sufficiently probable or imminent to warrant relief. Op. 21-22.

The EC, however, reached the opposite conclusion in its review. It barred the transaction, finding that if the merger were completed, "Illumina would have had the ability and the incentive to engage in foreclosure strategies against GRAIL's rivals"—for example, by refusing to supply them with NGS systems, increasing prices, degrading quality, or delaying supplies—and that this would have a "significant detrimental effect" on competition in the emerging MCED test market.[7] Illumina sought review of the EC's merits determination in the General Court. The EC subsequently indicated that it intends to require Illumina to unwind the acquisition of Grail; the hold-separate obligation remains in place in the meantime.[8]

In the FTC proceeding, the Commission conducted a *de novo* review of the record, and on March 31, 2023, issued the Opinion and Final Order under review in this case. *See* Ex. A. By a 4-0 vote, the Commission concluded that the merger

[7] EC Press Release, *Mergers: Commission prohibits acquisition of GRAIL by Illumina* (Sept. 6, 2022), https://ec.europa.eu/commission/presscorner/detail/en/IP_22_5364.

[8] *See* EC Press Release, *Mergers: The Commission adopts a Statement of Objections outlining measures to unwind Illumina's blocked acquisition of GRAIL* (Dec. 5, 2022), https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7403; EC Daily News, *Commission renews interim measures to ensure Illumina and GRAIL continue to be kept separate following the prohibition decision* (Oct. 28, 2022), https://ec.europa.eu/commission/presscorner/detail/en/mex_22_6467.

may substantially lessen competition in the United States market for the research, development, and commercialization of MCED tests. To remedy the violation, the Commission ordered Illumina to divest Grail, but that provision does not become final and take effect under the FTC Act until the conclusion of judicial review. *See* 15 U.S.C. § 45(g)(4); 16 C.F.R. § 3.56(a). In the meantime, the Commission ordered Illumina to continue holding Grail as a separate entity—essentially the same requirement the EC has already imposed.[9]

B. The Commission Decision

Although it disagreed with the ALJ's ultimate legal conclusions, the Commission agreed with and adopted many of the ALJ's factual findings. In particular, it agreed with the ALJ that the research, development, and commercialization of MCED tests constitutes a relevant product market, and that currently and in the near future, Illumina is the only viable supplier of NGS platforms that are a critical input for MCED test developers. Op. 21, 24-34, 36-40. The Commission concluded that a fully merged Illumina-Grail combination would have both the ability and an increased incentive to foreclose competition in the

[9] On April 4, 2023, Petitioners moved the Commission to stay the Final Order, including the hold-separate provision, pending review by this Court. Complaint Counsel did not oppose the request to stay certain portions of the Order, including the divestiture requirement, but argued that the remaining portions, including most of the hold-separate provisions, were necessary to preserve the status quo, protect competition during the pendency of this Court's review, and preserve potential post-appellate relief. The Commission has not yet ruled on the motion.

MCED test market. The Commission explained that the combined company would have an enormous financial incentive to use its leverage to ensure that its own subsidiary wins the MCED test innovation race because Illumina would earn more profit from the sale of Grail's tests than it would by supporting rival test developers. *Id.* at 44. And Illumina has several ways to act on that incentive. For example, it could raise costs for Grail's rivals or withhold or degrade rivals' access to supply, service, or new technologies. *Id.* at 43-44. *Id.* The Commission further found that real-world evidence of Illumina's past behavior reinforced the likelihood of competitive harm. *Id.* at 52. The threat to competition was not mitigated by Illumina's "Open Offer" to engage in supply agreements with its customers, which did not substitute for a competitive marketplace. *Id.* at 61-73.

The Commission rejected Illumina's arguments that the merger would generate efficiencies and procompetitive benefits that would outweigh its potential anticompetitive effects. Op. 74-87. Those claims were "unverified, not merger-specific and, to the extent that they might somehow come to pass, not likely to benefit the public." Op. 76. In particular, the Commission rejected the contention that the merger would save lives by enabling faster regulatory approval and greater acceptance by insurance companies. The claim rested "on the unsupported and vague assertions of management personnel," and other evidence "shows that standalone GRAIL had the incentive and ability to achieve acceleration through

means short of this anticompetitive Acquisition." Op. 78. Illumina thus "failed to show that the Acquisition, as opposed to the Galleri test, would save any lives." Op. 78. To the contrary, expert testimony showed that "innovation competition [in the MCED test market] could save substantially more lives" than those posited by Illumina's experts in their speculative acceleration calculation. Op. 83. The Commission concluded that "the course that Congress clearly enunciated in the antitrust laws is to let competition spur innovation among MCED test providers and thereby save lives," because "[w]hen competition is allowed to flourish, consumers benefit." *Id.*

ARGUMENT

Fifth Circuit Rule 27.5 provides that the Court may expedite an appeal "only for good cause." Illumina has not made any showing of good cause, and the schedule it proposes is manifestly unfair to the FTC. The request for expedition therefore should be denied.

I. THERE IS NO GOOD CAUSE FOR EXPEDITION BECAUSE ILLUMINA ADMITS IT CANNOT COMBINE OPERATIONS WITH GRAIL WHILE THE EC HOLD-SEPARATE ORDER REMAINS IN EFFECT.

Expedition is not warranted in this case because Illumina acknowledges that whatever happens here, it cannot combine operations with Grail while the EC's hold-separate order remains in effect. Although Illumina has a pending challenge to the EC's jurisdiction over the merger before the European Court of Justice, it

makes no showing that it is likely to prevail, and concedes that it does not expect a decision from the ECJ before "late this year or early next year." Mot. 5. The FTC's understanding is that ECJ is not hearing the case on an expedited basis, and a decision is more likely to come in early to mid-2024. Either timeline would allow the parties to brief this case on an ordinary schedule. There is no need to rush. Moreover, even if there were evidence supporting Illumina's claim that the merger will somehow save lives—which, as discussed below, there is not—that would not be a reason to expedite this case as long as the EC's order prevents Illumina and Grail from combining operations anyway.

Furthermore, given the complexity of this case, an expedited briefing schedule would be extremely prejudicial to the FTC. The voluminous trial record contains testimony from 56 fact witnesses and 10 expert witnesses and more than 4,500 exhibits. The Commission's decision is 98 single-spaced pages, and the ALJ's decision runs another 197 pages with more than 1,000 factual findings. Illumina has indicated the intent to raise a smorgasbord of legal challenges to the order, including four substantive antitrust arguments and another four constitutional arguments. Such a complex case should not be briefed on a truncated schedule, for the Court's sake as well as the parties'. Indeed, given the size of the record and the number of issues, the FTC may need extra time to adequately prepare its brief. The Court's rules acknowledge that extension is appropriate when

a matter is "so complex that an adequate brief cannot reasonably be prepared when due." 5th Cir. R. 31.4.2(b). Even with an extension, this case can be resolved before the ECJ issues a decision.[10]

Regardless, the specific schedule Illumina proposes is manifestly unfair on its face. Illumina proposes to file an opening brief on June 5, 2023, 61 days after the petition was filed and 66 days after the Commission decision. But Illumina's proposed schedule would accord the FTC only 21 days to file (until June 26) to file its response brief.[11] That imbalance is fundamentally unfair.

II. THERE IS NO BASIS FOR ILLUMINA'S CLAIM THAT EXPEDITION WILL SAVE LIVES.

Even if Illumina and Grail were not barred from combining operations by the EC order, their claim that expedition will "save lives" must be rejected because it is contrary to the Commission's factual findings. The Commission found that Illumina's claim that the merger would save lives by accelerating the regulatory approval and commercial acceptance of Galleri was based on unsupported speculation, and that in fact, blocking the merger was likely to save lives by promoting competition in the market for MCED tests, giving consumers access to

[10] Once briefing is completed, if the ECJ issues a decision in favor of Illumina, the FTC would not object to accelerating argument and decision. At present, however, Illumina has failed to justify any expedition.

[11] Illumina can begin preparing its brief immediately, but the FTC must wait until it sees Illumina's arguments.

more and better tests. Those findings are supported by substantial evidence and hence are "conclusive" in this Court. 15 U.S.C. § § 21(c), 45(c); *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 454 (1986).

As the Commission correctly determined, the claim of saving lives depends on a chain of speculation. Briefly, Grail currently sells the Galleri MCED test on a limited basis as a "laboratory-developed test," which does not require FDA approval, at a cost of approximately $949. Op. 12. Illumina admits that the test is not covered by insurance and is "cost prohibitive for most Americans." Mot. 1. To sell the test more broadly (a necessary event for the life-saving hypothesis), Grail would first need to obtain FDA approval, but it has not even filed an application yet. Even if Grail were to obtain FDA approval for Galleri (itself not a given), it will then need to persuade third-party payors (*e.g.*, Medicare and private health insurers) to cover the test, and then need to convince doctors and patients of the test's benefits.

Illumina tells the Court that a "conservative[e]" estimate is that allowing the companies to combine operations will accelerate Galleri's adoption by one year. Mot. 12. But as the Commission found, Illumina's trial expert "did not opine on whether Illumina *could* accelerate FDA or payer approval" by one year, but instead "simply relied upon Illumina's own claims that it could achieve such acceleration." Op. 78. The company's claim was based in turn on a "vague assertion" by an

executive and not supported by any analysis. Op. 79. Illumina did not "project how specific regulatory milestones for Galleri will actually change as a result of the Acquisition, [or] explain how and when Illumina's intervention will change them." Op. 79. Furthermore, the Commission found that Grail had already demonstrated significant experience and expertise in dealing with the FDA, and that Illumina "ha[d] not demonstrated exceptional [FDA premarket approval] expertise that GRAIL could not replicate." Op. 80. And "[e]ven if GRAIL's regulatory capabilities were somehow shown to be inadequate," Illumina "failed to demonstrate that Grail could not or would not expand its capabilities without the Acquisition." Op. 81. If Galleri represents the lifesaving breakthrough now posited, then "[s]tandalone GRAIL would have a massive incentive to accelerate market acceptance," *e.g.*, by expanding its own capabilities or contracting with other capable firms. *Id.* For similar reasons, the Commission found that claims that the merger could accelerate payer acceptance were also unverified and not merger-specific. Op. 81-83.

On the other side of the coin, the Commission credited expert testimony that competition in the market to develop and commercialize MCED tests "could save substantially more lives than those posited by" Illumina's expert based upon the company's unsupported acceleration claim. The best way to save lives, the Commission found, would be to allow competition to flourish. Op. 83.

Illumina does not even attempt to argue that the Commission's factual findings on these points are not supported by substantial evidence. Since there is no basis for concluding that the merger will save lives, that argument does not demonstrate any good cause for expediting this case.

III. ILLUMINA'S REMAINING ARGUMENTS LACK MERIT.

Illumina makes a hodgepodge of other arguments for expedited treatment, none of which withstand scrutiny. First, it argues that allowing the two companies to combine operations will save money by eliminating double marginalization and implementation of supply chain and operating efficiencies, and that some of these savings will be passed along to consumers. Mot. 13-14. But any putative benefits flowing from the merger are irrelevant to whether expedited treatment should be granted here, since the EC's order bars Illumina and Grail from combining operations until at least the end of the year (and likely beyond). In any event, the Commission's decision found the claimed efficiencies and benefits were vague, unverified, and could be achieved without the merger. Op. 84-85. Furthermore, even if efficiencies could produce cost savings that would be passed along to consumers, that hypothetical benefit must be weighed against the harm to consumers from potential foreclosure of competition in the MCED test market.

Illumina's allegations of constitutional violations likewise do not amount to good cause for expediting this appeal. Illumina cites *Elrod v. Burns*, 427 U.S. 347

(1976), and *Deerfield Medical Center v. City of Deerfield Beach*, 661 F.2d 328 (5th Cir. 1981), for the broad proposition that "violations of constitutional rights constitute irreparable harm." Mot. 15. But *Elrod* holds that "[t]he loss of *First Amendment freedoms* … unquestionably constitutes irreparable injury," 427 U.S. at 373 (emphasis added), while *Deerfield Medical* applied that principle to a deprivation of the constitutional right to privacy, 661 F.2d at 338. Illumina does not allege any ongoing denial of First Amendment rights, privacy rights, or comparable individual liberties. At most, it alleges infirmities in the structure and procedures of the Commission as established by Congress more than 100 years ago. To the extent Illumina alleges that it was harmed by the Commission's structure or its processes, that harm has already occurred; Illumina has not attempted to show any ongoing deprivation of rights that might justify expedition. Illumina seems to be arguing that merely alleging some form of constitutional violation (*e.g.*, a denial of due process) should enable an appellant to jump the line and have its case heard before other litigants. We know of no authority to support this far-reaching proposition.

Finally, Illumina is flatly wrong that expediting the appeal "will harm no one" and will "serve the public interest." Mot. 16, 17. As discussed above, expediting the appeal would be highly prejudicial to the FTC, given the size of the record and the number of issues that Illumina plans to raise on appeal. Conversely,

as we have shown, denying expedition will not harm Illumina because it cannot combine operations with Grail while the EC hold-separate order remains in effect. And the interests of justice as well as the Court's own interests will be best served by a full adversary process in which all parties have an adequate opportunity to brief the many issues in this case and the Court has sufficient time to consider and rule upon them.

CONCLUSION

The Court should deny the motion to expedite.

Respectfully submitted,

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April 17, 2023

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CERTIFICATE OF COMPLIANCE

I certify that the foregoing response complies the type-volume limit of Fed. R. App. P. 27(d)(2)(A) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), it contains 3640 words. It complies with the typeface and type-style requirements of Fed. R. App. P. 32(a)(5) and (a)(6) and 5th Cir. R. 32.1 because the text is in 14-point Times New Roman type and the footnotes are in 12-point Times New Roman type.

April 17, 2023

/s/ *Matthew M. Hoffman*
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