United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
December 15, 2023
Lyle W. Cayce
Clerk

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.

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[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

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