Insight

FTC Action on Vertical Merger Could Stifle Game-Changing Cancer Technology

FRED ASHTON | SEPTEMBER 14, 2022

Executive Summary

- The Federal Trade Commission (FTC) recently sued to block an $8 billion vertical merger between two medical technology companies; for regulatory watchers, this action provides a window into the FTC's intentions for future oversight of vertical mergers and how the agency thinks about competition in this market.
- Grail, which is developing a multi-cancer early detection (MCED) test, and Illumina, a manufacturer and seller of sequencing instruments and consumables for next-generation sequencing systems, are seeking to merge to accelerate the development, approval, and adoption of Grail's MCED test.
- While there is disagreement between the courts about the legality of the merger, a closer analysis suggests that the procompetitive effects of the merger and steps taken by Illumina to ensure other MCED test developers continue to have access to its technology outweigh potential harms to competition.
- As the Biden Administration launches its moonshot to end cancer, it should be cautious of the potential harms of an overly aggressive antitrust enforcement regime, as it would delay the procompetitive effects of mergers generally, and in the case of Illumina and Grail, a game-changing advancement in cancer diagnostics.

Introduction

A recently proposed merger between two medical technology companies may provide a window into the Federal Trade Commission's (FTC) intentions for future oversight of vertical mergers. In March 2021, the FTC sued to block the $8 billion vertical merger between Illumina and Grail. Grail is currently developing a multi-cancer early detection (MCED) test, which uses a liquid biopsy process to examine DNA in the bloodstream to determine if cancer cells have shed any DNA. Because these tests can screen for multiple types of cancers in asymptomatic patients, early-stage treatments could considerably improve patient outcomes. Grail's flagship MCED test, called Galleri, relies on Illumina's next-generation sequencing (NGS) platform.

NGS platforms are used for DNA sequencing. MCED testing requires a cost-effective NGS platform with a high degree of accuracy and throughput to make it commercially feasible. Illumina's platform is currently the only viable option for MCED tests. That is why Grail, and its competitors, use it in their development. The market structure of only one upstream firm led the FTC to assert that the proposed acquisition would "diminish innovation in the U.S. market for MCED tests" and that "Illumina can raise prices charged to Grail competitors for NGS instruments and consumables; impede Grail's competitors' research and development efforts; or refuse or delay executing license agreements that all MCED test developers need to distribute their tests to third-party laboratories."

On September 1, 2022, an FTC administrative law judge (ALJ) ruled against the FTC. Less than a week later, however, the European Union's antitrust enforcer, the European Commission (EC), complicated matters by blocking the merger. The FTC appealed the ALJ's ruling while Illumina and Grail are appealing the EC judgment.

The conflicting rulings made it apparent that one of the judgments is flawed. At a time when the Biden Administration is launching its cancer moonshot, the administration's whole-of-government approach in pursuit of a more aggressive antitrust enforcement regime would delay the procompetitive effects of mergers, generally, and in the case of Illumina and Grail, a game-changing advancement in cancer diagnostics.

Background of Vertical Mergers and Guidelines

In 2020, the Antitrust Division of the Department of Justice (DOJ) and the FTC jointly published Vertical Merger Guidelines (VMG), which describes how the two agencies analyze the competitive effects of a merger between an upstream and a downstream firm.

In September 2021, the FTC withdrew its approval of the VMG on the basis that it included "unsound economic theories that are unsupported by the law or market realities."

FTC Commissioners Noah Joshua Phillips and Christine S. Wilson disagreed. The commissioners issued a dissenting statement and asserted that the majority "prefer[ed] unchecked regulatory power over guidance" and that "[t]he uncertainty the Majority create[d] … is particularly troubling in light of the administration's promises to increase merger enforcement."

Without understanding the analytical framework used by the FTC, companies considering a vertical merger face great uncertainty. This "unchecked regulatory power" could lead to procompetitive deals being abandoned and result in harm to consumers.

The History of Illumina and Grail

Illumina formed Grail in 2015 with the purpose of "[enabling] the early detection of cancer in asymptomatic individuals through a blood screen, – the 'holy grail' of early cancer detection." This newly formed company was powered by Illumina's NGS technology.

In 2016, Illumina spun off Grail but remained the majority owner by providing more than $100 million of Grail's initial financing. The spinoff enabled Grail to assume greater risks in its pursuit of MCED technology and attract outside investors including Arch Venture Partners, Bezos Expeditions, and Bill Gates.

A year later, Grail raised $1 billion in outside investment, diluting Illumina's stake to under 20 percent. With this capital raise, Illumina lost representation on Grail's board of directors. Today, Illumina has a 12 percent equity stake in Grail and is entitled to a percentage of Grail's net revenues in perpetuity.

In September 2020, the two firms entered a merger agreement. In the press release, the firms stated that the goal was to accelerate the adoption of NGS-based early multi-cancer detection tests to reach more patients faster.

The FTC Complaint

The crux of the FTC complaint is that a merger between Illumina and Grail would "diminish innovation in the U.S. market for MCED tests." It makes this allegation on the basis that Illumina is the only supplier of the NGS system required for MCED tests. This market dynamic, the FTC asserted, gives Illumina the "ability to foreclose or disadvantage Grail's MCED rivals." They could do this by "rais[ing] the test developer's price for NGS instruments and consumables … impede the rival's research and development efforts by denying important technical assistance and other proprietary information needed to obtain FDA approval or design a commercially successful MCED test, or … refuse or delay the execution of a license agreement required to sell distributed in vitro diagnostic versions of the test."

The FTC also claimed that "new entry of an MCED test that does not rely on Illumina's NGS platform would be timely, likely, or sufficient to offset the anticompetitive effects of the proposed Acquisition."

Flaws in the FTC Complaint

Defining the relevant market and estimating the effects a merger could have on consumer welfare (i.e., price and choice) are key elements to an antitrust case.

In the complaint, the FTC stated that the relevant market was "research, development, and commercialization of MCED tests in the United States." But in nearly the same breath, the FTC admitted that "no MCED test is currently commercialized." A commercially viable MCED test would add to the broader cancer-detection market, thus increasing competition, not detracting from it.

Furthermore, absent sales, quantity, and price data, not knowing how MCED tests will be adopted and used in the field of oncology, and with no information regarding payor reimbursement, it is impossible for the FTC to sufficiently quantify the competitive effects of the merger. The assertion that competition in the MCED market and consumers will be harmed by the merger is nothing more than conjecture.

The FTC also claimed that the merger between the two firms would create the incentive for Illumina to foreclose on the progress of other firms using its NGS technology to develop their own MCED tests in favor of Grail. Yet, without a market to measure, it is difficult to prove this would be a sound business strategy for the combined firm.

Illumina and Grail's Response to the FTC

In response to the FTC's pretrial briefing, Illumina and Grail showed that the combined firm "lack[s] the ability and incentive to foreclose" on rival MCED test developers. Illumina and Grail's pretrial briefing outlined commitments made to Illumina customers in what they call the "Open Offer." The Open Offer included:

- A 12-year supply agreement in which Illumina will "not increase the price of any of the supplied sequencing instruments or consumables";
- A commitment to, by 2025, "decrease the cost of sequencing on Illumina's highest throughput sequencing instrument, using the highest throughput consumable, by at least 43%, for all customers, regardless of application or use case"; and
- "All customers shall receive 'universal' pricing for any new sequencing product, and customers shall receive access to the same sequencing products at the same pricing as GRAIL under a 'most-favored nations' clause."

The two firms also noted that Open Offer provides additional protections including "audit and arbitration provisions."

In the ruling, the judge noted that "Illumina's standardized, long-term supply agreement … constrains Illumina from harming Grail's alleged rivals, and the FTC staff's argument to the contrary is unconvincing."

The Merger Could *Create* a Market, Not Hinder it

Illumina and Grail claimed that the merger would enable Grail to leverage Illumina's existing regulatory infrastructure to accelerate the approval and adoption of MCED tests. This acceleration would create a commercialized market for the test while adding a new product to the broader cancer-detection market.

Nevertheless, navigating the convoluted Food and Drug Administration regulatory process is expensive and time consuming. Without Illumina's in-depth knowledge, the commercialization of Grail's MCED test could be delayed. Additionally, the firms acknowledge that "receiving coverage from private and public payors, such as Medicare, will be critical to ensuring broad access to Galleri." This, too, is a benefit Grail would receive from a merger with Illumina to quicken the rollout of the MCED test.

Moreover, vertical synergies eliminate something called "double marginalization." This happens when a "merged firm is no longer paying a markup on the product it is now supplying to itself." In this case, Grail no longer needs to pay the markup for Illumina's NGS technology and consumables. The elimination of this double marginalization allows the combined firm to sell its product at a more competitive price, benefiting consumers.

The European Commission Wrinkle

Shortly after the ALJ decision, the EC blocked the merger between the two firms using the same argument that failed the FTC. This decision was promptly appealed by Illumina and Grail.

While the judgement itself was surprising, the method used to gain jurisdiction in July 2021 was equally unexpected. The merger did not originally qualify for review per European rules since Grail does not do any business in Europe. Member states can, however, "refer transactions to the commission when their governments lack jurisdiction." Six countries requested that the EC investigate, giving them jurisdiction.

The EC order adds a layer of uncertainty that could inhibit Grail's ability to deliver an MCED test resulting in a loss for consumers and, more important, potential patients.

Conclusion

Broadly, this case is an example of how the whole-of-government approach to antitrust championed by the Biden Administration and a lack of a concrete analytical framework for vertical mergers can result in "unchecked regulatory power." It has led the FTC to ignore market realities in pursuit of a more aggressive antitrust enforcement regime.

In the case of Illumina and Grail, claims made by the FTC were not grounded in fact, but in hypothetical inference. The hostility toward mergers, especially between large firms, risks the loss of procompetitive benefits, and at a time when the Biden Administration has launched its cancer moonshot, the delay of a potentially game-changing diagnostic tool for cancer detection.