CLIENT ALERT

Illumina/Grail – FTC's First Vertical Merger Challenge in Decades

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On March 30, 2021, the Federal Trade Commission announced that it voted in unanimous, bipartisan fashion (4-0) to file a complaint to block Illumina's proposed acquisition of Grail. Illumina sells next-generation gene sequencing (NGS) equipment and consumables, while Grail is developing a multi-cancer early detection test that uses Illumina's NGS platform. The FTC alleges a vertical theory of harm whereby the merger would give Illumina both the incentive and ability to disadvantage Grail's multi-cancer testing competitors by raising their costs for, or by foreclosing them from, accessing Illumina's must-have NGS technology. This is the first time in recent memory that the FTC is challenging a vertical merger in court; it represents the FTC's first challenge under newly issued Vertical Merger Guidelines; and it is the first suit filed under Acting FTC Chair Rebecca Slaughter—all of which demonstrates that the FTC is likely to take a more aggressive approach to vertical merger enforcement for at least the next four years.

Theory of Harm

The FTC alleges that Illumina's proposed acquisition of Grail would substantially lessen competition in the U.S. multi-cancer early detection (MCED) test market by diminishing innovation and potentially increasing prices and reducing the choice and quality of MCED tests.

According to the complaint, Illumina is a near monopolist in next-generation DNA sequencing (NGS), which is a critical input in MCED tests. The complaint identifies Thermo Fisher and Beijing Genomics Institute (BGI) as the only other providers of NGS products. The complaint is heavily redacted, but appears to discount Thermo Fisher as a significant competitive option, and the FTC highlights that BGI is enjoined from selling in the U.S. during the duration of a patent infringement lawsuit filed by Illumina.

Grail makes non-invasive, early detection liquid biopsy tests that can screen for multiple types of cancer in asymptomatic patients at very early stages using DNA sequencing. While other firms are also developing MCED tests, the complaint's description of Grail's MCED test suggests that the parties anticipate Grail will likely be first to market. The FTC alleges that Illumina's NGS platform is an essential input for the development and commercialization of these MCED tests.

The crux of the FTC's complaint is that Illumina, as the dominant provider of a critical input into MCED tests, has the *ability* to foreclose or disadvantage Grail's rivals and that it would also have an *incentive* to disadvantage or foreclose close competitors to Grail because the value of foregone NGS-product sales to rivals "will be offset by the gain in MCED testing revenue captured by Grail."

Ability—Foreclosure or Raising Rivals' Cost

According to the FTC's complaint, MCED test developers—like Grail and its rivals—must rely on Illumina's platform, service, and support to research, develop, launch, and sell their MCED tests successfully. The FTC alleges that Grail and its rivals have no viable substitutes for Illumina's NGS platforms.

The FTC highlights "several tools" that Illumina could allegedly use to harm Grail's rivals: (1) raising prices for NGS instruments and consumables; (2) impeding a rival's research and development efforts by delaying or foreclosing access to new technology and reducing the levels of technical assistance; or (3) refusing or delaying the execution of agreements required to sell distributed in vitro diagnostic versions of the test to commercial labs and which first required for FDA premarket approval.

The complaint lists several of Grail's competitors which would be harmed by such a strategy. More generally, the FTC alleges that such a strategy would greatly harm competition between MCED test competitors, and innovation in this market.

Incentive—Profits Maximization by Harming Grail's Rivals

Several firms are apparently racing against Grail to bring MCED tests to market. According to the complaint, the financial benefits to Illumina of capturing a larger share of the U.S. MCED test market sales via Grail—by Illumina harming Grail's MCED rivals either through raising the cost of NGS products to those MCED rivals or not selling its NGS products to those rivals at all—will outweigh any Illumina loss in sales of NGS products. The complaint notes that the addressable U.S. MCED test market is worth tens of billions of dollars annually.

No Likely Entry or Elimination of Double Marginalization to Offset Harm

The FTC alleges that Illumina and Grail cannot prove 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 acquisition. Moreover, post-transaction the parties' strategy to disadvantage rivals could make it make it more difficult for rivals to obtain or generate data creating additional barriers to entry.

Finally, the FTC alleges that the parties cannot demonstrate that the transaction will eliminate double-marginalization (i.e., the costs savings from eliminating a merging supplier's margin in the price of goods sold to its downstream merger partner) sufficiently to offset the transaction's likely anticompetitive harm.

Second Litigated Vertical Merger Challenge in last 40 years

The only other litigated vertical merger challenge in the last 40 years—DOJ's failed attempt to block AT&T's acquisition of Time Warner—indicates that the agencies may face an uphill battle in court bringing vertical challenges. After losing its challenge in the district court, DOJ appealed to the D.C. Circuit, where the court found no error in the trial court's decision and specifically refused to articulate a legal standard for vertical mergers: "there is no need to opine on the proper legal standards for evaluating vertical mergers because, on appeal, neither party challenges the legal standards the district court applied, and no error is apparent in the district court's choices."

Although the enforcement agencies may face an unpredictable and challenging landscape in court, acting FTC Chairwoman Slaughter is a proponent of stronger vertical merger enforcement and has expressed skepticism about the purported benefits of vertical mergers. Acting Chairwoman Slaughter was quoted in the FTC's press release announcing its challenge to the Illumina/Grail merger, stating "[i]f this acquisition is consummated, it would likely reduce innovation in this critical area of healthcare, diminish the quality of MCED tests, and make them more expensive." Based on the facts alleged in the complaint, the FTC may view this merger challenge as a good vehicle to develop vertical merger precedent.

Illumina Response/Remedy

In response to the FTC's challenge, Illumina has offered behavioral-type remedies, including a commitment to enter into a 12-year supply contract for its sequencing products and support services; a guarantee that it will not discontinue any of the sequencing products supplied under the offer as long as the customer continues to buy the product; and a guarantee of no price increases for the sequencing products covered. This offer appears aimed at convincing the judge that the proposed fix alleviates any competitive concerns, but risks conceding that there are competitive issues that requiring fixing.

Referrals from National Competition Authorities to the European Commission

This transaction is also under review in Europe. Although the transaction does not meet the EU or the national merger thresholds, the French Competition authority, encouraged by the European Commission (EC), and supported by the Dutch and Belgian competition authorities, requested a referral of the transaction to the EC. This is seen as a test case for the EC's recent policy shift that it will, in certain circumstances, accept merger-referrals even from national authorities that didn't have jurisdiction to examine the deal. The EC considers that this change of approach is needed to capture transactions involving firms with little actual revenue (which may be below the jurisdictional thresholds) which could nonetheless play a significant competitive role.

Illumina challenged the referral requests by the French and Dutch authorities before the respective national courts. Illumina lost before both the French and Dutch courts on March 31, 2021 and April 1, 2021. The UK's CMA has also indicated that it has jurisdiction to review the transaction.

Takeaways

This case is notable for several reasons:

- ***Vertical Merger Challenge.*** Vertical merger litigation is rare and the Antitrust Division lost the last litigated case (AT&T/Time Warner). If this case fully litigates, it will be the first FTC vertical merger litigated in decades. This will also be the agencies' first litigated vertical merger under the new Vertical Merger Guidelines issued in June 2020. Notably, Acting FTC Chair Slaughter and Commissioner Chopra, who voted to issue the complaint here, voted against issuing the Vertical Merger Guidelines because, in their view, the new guidelines took a too-favorable view of vertical mergers and did not address all the potential harms from such mergers.
- ***Focus on Innovation.*** Historically, merger challenges have focused primarily on how a merger will harm price competition and result in higher prices. The complaint here focuses on how the transaction will harm innovation competition and only, arguably secondarily, "*potentially* higher costs and reduced choice and quality." (emphasis added) As shown here, the antitrust agencies are now giving ever greater attention to non-price harms in merger analysis, including potential harm to quality, service, and innovation.
- ***Nascent Market Focus.*** The FTC alleges harm in the MCED test market. Neither Grail nor any other firm has launched a product or has any sales. Indeed, the FTC's complaint does not—and cannot—cite any market shares in the MCED test market. And there is no guarantee that Grail, or any other test developer, will actually obtain FDA approval and be able to launch a test commercially. But the FTC is basing this challenge on its concern that the transaction could harm

competition in a still-developing nascent market that has significant potential for critical advancements in detecting cancers.

- ***Can't Go Back Home Again?*** Interestingly, Illumina founded Grail in 2015, but in 2017 it reduced its ownership below a 20% voting interest. Illumina currently owns 14.5% of Grail voting shares. Having sold its controlling interest, that FTC is treating this proposed acquisition without regard to that history.
- ***Litigating the Fix.*** With its 12-year contract offer to MCED test developers, Illumina and Grail are effectively trying to "litigate the fix." While this approach has not always been successful, it has apparently helped parties in some cases that the transaction would not harm customers. The merging parties' here are squarely aiming to address potential price and non-price harms by make price, supply, and service commitments for over a decade.
- ***EU and National Competition Authorities Referrals:*** The EC's new approach to merger referrals will increase unpredictability of merger control in the EU, in particular for transactions involving nascent competitors or innovators that have little or no turnover at the time of the transaction. Until recently, any review by the EC of such transactions, like the Illumina/Grail merger, could be excluded as they did not meet the revenue-based jurisdictional threshold for notification. Building on a trend initiated by the German and Austrian authorities that introduced transaction value-based merger control thresholds in 2017, the EC is now availing itself of the means to review such transactions, even post-closing and regardless of the value of the transaction and the turnover generated by the firms involved.

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