## FTC Shows Aggressive Enforcement Agenda in Decision to Unwind Vertical Merger in Healthcare Technology

The federal agencies have been flexing their muscles in antitrust enforcement in recent years to reinvigorate competition. This month, the Federal Trade Commission (FTC) <u>ordered</u> the unwinding of a completed merger that combined gene sequencing company Illumina and cancer test developer Grail. This move is highly unusual not only because of the vertical nature of the consolidation, which typically receives less antitrust scrutiny, but also how the Commission unanimously voted to undo a consummated merger while overturning an administrative court ruling in the process. For these reasons, this latest development may have implications in antitrust enforcement far beyond the biotech industry.

The Illumina and Grail saga dates back to September 2020, when Illumina first announced the deal to acquire Grail for \$8 billion. The transaction to combine the entities is known as a "vertical merger" as the two companies do not directly compete for customers. Rather, the two businesses operate at different levels in the supply chain for DNA sequencing. Illumina is a leading DNA gene sequencing company based in San Diego, while Grail is a small startup business in the biotech industry that relies on DNA sequencing to develop the technology to detect cancer. Grail was founded by Illumina as a research project, and the cancer testing company spun off as a stand-alone company in 2016.

Although the companies don't share customers, the FTC was

concerned that reuniting the companies would hinder competition of Grail's competitors in the cancer early detection business, because they similarly rely on Illumina's DNA sequencing services. In March 2021, the Commission voted to file a complaint to block the transaction through its internal administrative process called an adjudicative proceeding, which the FTC often uses without having to file in federal court. As part of the FTC in-house proceedings, an administrative law judge (ALJ) would issue an initial decision in the case. Either party may appeal the ruling to the full Commission, upon which the Commission would hold oral arguments and issue a final decision and order. That decision could be appealed to the federal court of appeals, and finally to the Supreme Court if necessary.

Despite a pending FTC investigation and challenge, Illumina completed its acquisition of Grail in August 2021. After the parties consummated the transaction, the FTC case proceeded and was heard before an ALJ in September 2022, who issued an <u>initial</u> <u>decision</u> in favor of the transacting parties. In dismissing the FTC case, the <u>opinion cited</u> a lack of evidence that Grail has any actual rivals competing at its level in the cancer detection business and that Illumina has long-term supply agreements with its sequencing customers that guarantee prices for its products.

Not deterred, the FTC appealed the ruling to the full Commission for review. After oral arguments in December, the Commission issued its decision on April 3, overturning the ALJ decision in a 4-0 ruling and <u>ordered</u> Illumina to unwind the consummated merger and divest Grail. Writing for the Commission, FTC Chair Lina Khan stated in <u>the opinion</u> that the deal would stifle competition by diminishing innovation, increasing prices, and decreasing the choice and quality of cancer detection tests. Moreover, the merger would give Illumina financial incentives to benefit Grail by raising prices or impede access to Illumina's services, to the detriment of Grail's competitors. Notably, Christine Wilson, the sole Republican in the Commission who has strongly criticized Khan for her aggressive agenda, also issued a <u>concurring opinion</u> in this case before resigning from the FTC.

This development is highly atypical and significant for two reasons. First, this case is one of a few in which the FTC challenged a vertical merger. Federal agencies, including the Department of Justice (DOJ), have been quick to raise challenges in horizontal deals between direct competitors, because of more obvious antitrust concerns and the more straightforward legal and economic theories in proving anticompetitive effects. Vertical consolidation, on the other hand, has traditionally received less antitrust scrutiny and is more convoluted to challenge. Neither the FTC nor the DOJ have seen much success in that realm. Second, antitrust enforcers typically try to block a transaction before it occurs, and rarely do they seek remedies post-transaction. Once a merger is consummated, it is difficult to "unscramble the egg" and undo the combination. Perhaps counting on these two factors in their favor, Illumina and Grail boldly proceeded with the merger amidst regulatory challenge and potential court battles. Little did they expect that in 2023, the FTC would order a divesture to undo the vertical merger which has been closed since 2021.

Nonetheless, the FTC is increasingly showing its resolve to strengthen its antitrust enforcement efforts, given the rising number of healthcare technology mergers in recent years, and Illumina and Grail may be just the beginning. Along with the DOJ, which recently withdrew long-standing antitrust enforcement guidance governing certain healthcare agreements, the federal agencies may be going to new lengths and exploring new antitrust theories in their enforcement agenda, including unwinding consummated mergers and challenging vertical and cross-market mergers that are sweeping through the nation.

This new wave of enforcement action will no doubt extend beyond the biotech market to impact the broader healthcare industry. Whether this decision will hold up in federal court, however, is the biggest burning question for many stakeholders closely watching the healthcare markets. Illumina and Grail have already filed an appeal to the 5th Circuit Court of Appeals along with a motion to expedite. The outcome of the litigation will certainly have significant implications for antitrust enforcement on a much larger scale. Be sure to stay tuned to The Source Litigation and Enforcement Highlights for the latest developments.