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Antitrust Agencies Target Pharmaceutical Mergers in Enforcers Workshop and Lawsuit

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Last month the Federal Trade Commission ("FTC") sued to block the $27.8 billion acquisition of Horizon Therapeutics plc ("Horizon") by the biopharmaceutical corporation, Amgen Inc. ("Amgen"). The lawsuit was the latest move by the Biden Administration to tackle the high price of prescription drugs, which President Joe Biden described as "excessive" in his July 2021 Executive Order on Promoting Competition in the American Economy. Notably, this is the first FTC pharmaceutical merger challenge in over a decade. According to FTC Bureau of Competition Director Holly Vedova, the challenge is meant to send "a clear signal to the market: The FTC won't hesitate to challenge mergers that enable pharmaceutical conglomerates to entrench their monopolies at the expense of consumers and fair competition."

Although neither Amgen nor Horizon operates in the same prescription drug market, the FTC alleged that Amgen, a biopharmaceutical giant, could substantially lessen competition in select markets by offering discounts to insurers and pharmacy benefit managers ("PBMs") on certain drugs in exchange for giving their products preferential treatment. This type of discounting is called "cross-market bundling." The FTC was specifically concerned that if Amgen were to engage in cross-market bundling with Horizon's products, which include the only FDA-approved medications used to treat thyroid eye disease and chronic refractory gout, it would allow the combined firm to "entrench" the products' current monopolies and inhibit entry of potential competitors. In response, Amgen and Horizon agreed to pause the transaction until October 2023 but argued that it was novel for an antitrust agency to attempt to block a corporate merger using a theory of cross-market bundling.

Just two weeks after the Amgen-Horizon lawsuit, the FTC released a joint summary of a pharmaceutical merger analysis workshop with the Department of Justice ("DOJ"). In that summary, FTC Chair Lina Khan expressed concern about "illegal bundling and tying practices in the [pharmaceutical] industry." She stated that "killer acquisitions" made by pharmaceutical giants could shut down potential competitors and were a serious concern for the rising cost of prescription drugs. That said, only one case in the past fifteen years involved an anticompetitive bundling challenge in the pharmaceutical industry.

The pharmaceutical merger analysis workshop, held in June 2022, was the culmination of the

Multilateral Pharmaceutical Merger Task Force launched in March 2021 between the FTC, DOJ, several state Attorneys General, and the Canadian, European, and U.K. competition bureaus. Discussion at the workshop highlighted the antitrust agencies' skepticism of certain remedies and transactions between large pharmaceutical companies. DOJ Assistant Attorney General Jonathan Kanter stressed that competition in the pharmaceutical industry was important to "give patients access to medicine at affordable prices" and to innovate solutions for future problems, while FTC Chair Khan suggested that remedies, potential innovation, and prior bad acts should be incorporated into merger analysis in the future.

Proposed changes to future pharmaceutical merger review analyses included:

- Creating a presumption of harm for mergers and acquisitions involving two firms in the top decile of U.S. sales;
- Applying heightened scrutiny to mergers between larger corporations and mid-size corporations (in the second decile of U.S. sales), or two mid-size corporations, if any of the corporations had a must-have or blockbuster product;
- Abandoning the use of divestiture settlements in merger challenges;
- Seeking divestiture of existing drug products, instead of pipeline drug products;
- Requiring a commitment to maintain certain levels of R&D and patent output post-merger;
- Examining changes to incentives of non-merging firms, for example whether they will continue to invest in R&D or efforts to bring a drug to market;
- Examining the role of intermediaries, such as PBMs, to determine if a merger or acquisition could lead to anticompetitive outcomes; and
- Examining the relationship between prior bad conduct and intent and effects in merger reviews.

Although these proposals were for discussion purposes only, the proposals, along with the Amgen-Horizon acquisition challenge, indicate that antitrust agencies are likely to closely scrutinize pharmaceutical mergers moving forward. The FTC's suit against Amgen-Horizon demonstrates that the antitrust agencies are now willing to challenge such transactions. Pharmaceutical companies that are engaged in cross-bundling or that are contemplating a transaction involving an exclusive drug are advised to proceed with caution and take note of recent agency action.

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