UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

Statement of Chair Lina M. Khan
Joined by Commissioner Rebecca Kelly Slaughter
In the Matter of Sanofi/Maze Therapeutics
Commission File No. D09422

December 20, 2023

For Americans suffering from rare diseases, unlawful tactics that entrench pharmaceutical monopolies, quash innovative treatments, and maintain sky-high prices can have catastrophic effects. Often a rare disease will have only one FDA-approved treatment, creating a monopoly for the firm that owns the drug. The lack of competition allows the firm to name its own price and reap tremendous profits. To protect those monopoly profits, the firm may resort to unlawful tactics to kill off emerging competitive threats. This could include exclusionary conduct, such as leveraging must-have drugs in its portfolio to disadvantage rivals that are developing competing treatments.[1] Or the firm could just seek to buy out those competing treatments directly, eliminating the competitive pressure to innovate and offer more affordable drugs.

Sanofi attempted to do just that when it agreed to take an exclusive license to Maze Therapeutics, Inc.'s drug in development for a rare and debilitating genetic disorder called Pompe disease. Sanofi owns the only two FDA-approved treatments for the disease and on average charges $750,000 for an annual course of treatment. Maze has been developing a Pompe disease drug that successfully completed Phase I trials with results that show great promise. Unlike Sanofi's treatments, which require intravenous administration in a healthcare provider's office, Maze's drug is a pill that patients can take on their own. According to internal documents, Sanofi recognized Maze's drug as a threat to Sanofi's monopoly. Maze's drug would have the potential not only to take significant market share from Sanofi, but also to replace Sanofi's treatments as the standard of care for Pompe disease.

On December 11, 2023, the Federal Trade Commission issued an administrative complaint alleging that Sanofi's license agreement with Maze violated federal antitrust laws.[2] The FTC alleged that agreement constituted an acquisition whose effect may be substantially to reduce competition or tend to create a monopoly in violation of Section 7 of the Clayton Act. More than that, the FTC also alleged that the agreement constituted monopolization in violation of Section 2 of the Sherman Act, as well as an unfair method of competition in violation of Section 5 of the FTC Act. Within hours after the Commission issued the complaint, Sanofi

[1] Statement of Chair Lina M. Khan Joined by Commissioner Rebecca Kelly Slaughter and Commissioner Alvaro M. Bedoya, *In re Amgen Inc. & Horizon Therapeutics plc* (Sept. 1, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Statement-of-Chair-Lina-M-Khan-re-Amgen-Horizon.pdf.
[2] Compl. ¶ 1, *In re Sanofi & Maze Therapeutics, Inc.*, Docket No. 9422 (FTC Dec. 11, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/d9422_sanofi_maze_part_3_complaint_public_redacted.pdf.

announced that it would terminate the agreement. Today the Commission grants the parties' joint motion to dismiss the complaint.

The Commission's complaint against Sanofi and Maze reflected several advancements in our pharmaceutical merger enforcement program. The complaint recognized that early-stage drugs could pose a competitive threat to an existing monopoly drug, even if the ultimate success of the early-stage drugs is not guaranteed.[3] Specifically, the complaint charged that the merger would violate the antitrust laws by (1) eliminating existing competition in the research and development of Pompe disease drugs and (2) eliminating a nascent competitive threat from Maze, thereby entrenching Sanofi's dominance in Pompe disease drugs.[4] The complaint also broke new ground by charging that an acquisition of a product in the pipeline with no sales can still constitute illegal monopolization under Section 2.

The post-complaint abandonment of Sanofi's deal with Maze marks another successful effort by the Commission to protect competition in the pharmaceutical industry. Recently we settled another FTC complaint that, at the time, had been our first litigated pharmaceutical merger challenge in over a decade.[5] The FTC will continue to challenge illegal pharmaceutical mergers and other unlawful practices that would deny patients the benefits of fair competition and deprive them of access to affordable, innovative medicines.

This successful result would not have been possible without the creativity, tenacity, and talent of the FTC team that investigated and prepared to litigate this matter. I applaud the FTC staff—and the attorneys and managers of the Mergers I division in particular—for their excellent work and their unwavering dedication to protecting patients from unlawful practices by pharmaceutical companies.

***

[3] Press Release, Maze Therapeutics, Inc., Maze Therapeutics Announces FTC Action Seeking to Block Collaboration and License Agreement with Sanofi Regarding MZE001, a Potential Oral Substrate Reduction Therapy for Pompe Disease (Dec. 11, 2023), https://www.businesswire.com/news/home/20231211835372/en/Maze-Therapeutics-Announces-FTC-Action-Seeking-to-Block-Collaboration-and-License-Agreement-with-Sanofi-Regarding-MZE001-a-Potential-Oral-Substrate-Reduction-Therapy-for-Pompe-Disease (quoting Maze's CEO noting that "this is the first time ever the FTC has moved to block a license of a Phase 1 investigational medicine").

[4] These counts reflect, respectively, Guideline 2 and Guideline 6 of the 2023 Merger Guidelines. Fed. Trade Comm'n and U.S. Dep't of Justice, Federal Trade Commission and Justice Department Release 2023 Merger Guidelines (Dec. 18, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/2023_merger_guidelines_final_12.18.2023.pdf.

[5] Press Release, Fed. Trade Comm'n, FTC Approves Final Order Settling Horizon Therapeutics Acquisition Challenge (Dec. 14, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/12/ftc-approves-final-order-settling-horizon-therapeutics-acquisition-challenge.