

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Lina M. Khan, Chair
Rebecca Kelly Slaughter
Alvaro M. Bedoya

In the Matter of

SANOFI,
a corporation;

GENZYME CORPORATION,
a corporation;

and

MAZE THERAPEUTICS, INC.
a corporation;

Docket No. 9422

PUBLIC VERSION

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act (“FTC Act”), and by virtue of the authority vested in it by the FTC Act, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Genzyme Corporation, a wholly-owned subsidiary of Respondent Sanofi, (collectively, “Sanofi”) and Respondent Maze Therapeutics, Inc. (“Maze”) have executed an agreement pursuant to which Sanofi proposes to acquire an exclusive license to Maze’s glycogen synthase 1 (“GYS1”) products and related technology, including its lead clinical candidate MZE001 (the “Proposed Transaction”) in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint pursuant to Section 5(b) of the FTC Act, 15 U.S.C. § 45(b), and Section 11(b) of the Clayton Act, 15 U.S.C. § 21(b), stating its charges as follows:

NATURE OF THE CASE

1. For over a decade, Sanofi has been the monopolist supplier of drugs used to treat Pompe disease, a rare genetic disorder that causes progressive muscle damage and often leads to death. As a monopolist, Sanofi charges an average patient over \$750,000 for a course of annual treatment.

2. Maze has been developing a treatment for Pompe disease that would be easier and quicker for patients to consume. Recognizing that Maze’s innovative products risk dislodging its own dominance, Sanofi is now trying to buy out Maze rather than compete with it.

3. This is a case about a monopolist seeking to eliminate a nascent threat to its monopoly.

4. For over a decade, Sanofi has been the only supplier of Food and Drug Administration (“FDA”) approved treatments for Pompe disease. Sanofi’s first Pompe treatment, Lumizyme (alglucosidase alfa), won FDA approval in 2010 to treat patients eight years and older with late-onset Pompe disease (“LOPD”). Lumizyme remained the only available Pompe disease treatment until August 2021, when Sanofi launched a second treatment, Nexviazyme (avalglucosidase alfa). Lumizyme and Nexviazyme are both enzyme replacement therapies (“ERTs”), administered at clinics via biweekly intravenous (“IV”) infusions. Although the FDA approved a two-drug regimen developed by Amicus Therapeutics, Inc. (“Amicus”) on September 28, 2023 as a second-line therapy for certain Pompe disease patients who are not improving on their current (*i.e.*, Sanofi) ERT Pompe disease treatment, Sanofi possesses monopoly power in the sale of treatments for Pompe disease.

5. Maze is developing a GYS1 inhibitor drug to treat Pompe disease called “MZE001.” Unlike Sanofi’s Lumizyme and Nexviazyme ERTs, which are administered in biweekly IV infusions lasting several hours, MZE001 is an oral medication taken twice daily—which would significantly reduce the treatment burden for Pompe disease patients.

6. In April 2021, only one month after Maze first publicly revealed its clinical pipeline, Sanofi

[REDACTED] As Maze

continued to make progress in its development of MZE001,

[REDACTED] In doing so, Sanofi concluded that MZE001’s greatest commercial value is

[REDACTED] Indeed, if the Proposed Transaction is consummated, Sanofi plans on

[REDACTED]

7. Because MZE001 promises to offer similar therapeutic efficacy but significantly reduce patients’ treatment burden, Sanofi forecast that if MZE001 is approved

[REDACTED]

[REDACTED] Sanofi’s Senior Director of New Product Planning for Rare Diseases observed that

[REDACTED]

8. At first, Sanofi attempted to meet this competition by striving to innovate.

[REDACTED]

9. Maze's development of MZE001 spurred Sanofi to

[REDACTED]

In February 2022, Maze announced new preclinical data supporting MZE001's advancement and that it was initiating first-in-human trials. Sanofi then realized

[REDACTED]

A few months later, observing that MZE001 can be administered orally and cognizant of the drug's commercial promise, Sanofi concluded that it had to

[REDACTED]

10. Maze's series of positive announcements regarding MZE001 made it clear to Sanofi that [REDACTED] Sanofi therefore had two options. The first was to continue to compete on the merits by [REDACTED]

[REDACTED] The second was to eliminate competition by neutralizing the nascent competitive threat that MZE001 posed.

11. Sanofi chose the second option. Internally, Sanofi executives made clear that acquiring MZE001 [REDACTED] would transform MZE001 from a threat into a shield to protect Sanofi's monopoly, [REDACTED]

[REDACTED]

12. In April 2022, Maze executives travelled to Boston to meet with Sanofi personnel to discuss [REDACTED]

[REDACTED] MZE001. The next month, high level Maze and Sanofi

executives met again in Cambridge, Massachusetts, to discuss potential business collaborations relating to MZE001. In an internal email, Maze’s then-Chief Business Officer described the deal structures discussed at the May 2022 meeting:

[REDACTED]

13. By June 2022, Maze

[REDACTED]

In July 2022, Sanofi presented financial terms for acquiring an exclusive license to MZE001. Maze and Sanofi executives continued to negotiate through the fall and winter, with

These negotiations culminated in a three-day in-person meeting between Maze and Sanofi executives in Cambridge in late March 2023 to finalize the language of the definitive license agreement, which the two companies ultimately executed on April 21, 2023 (the “License Agreement”).

14. For its part, Maze negotiated the License Agreement based on the understanding that

[REDACTED]

15. The anticompetitive impact of the License Agreement was immediate. Shortly after the agreement was signed,

[REDACTED]

Although the License Agreement has already lessened competition, if consummated, the Proposed Transaction would forever deprive Pompe disease patients of the benefits of competition between Sanofi and Maze

[REDACTED]

16. Although a small number of other firms have initiated Phase 1 clinical trials for other Pompe disease treatments, Sanofi forecasts that [REDACTED]

[REDACTED] In fact, Sanofi's internal models of the Proposed Transaction projected that MZE001 in a rival's hands could capture as much as [REDACTED]

17. The Proposed Transaction would eliminate the nascent threat MZE001 poses and, therefore, constitutes conduct that is reasonably capable of contributing significantly to Sanofi's continued monopoly power in treatments for Pompe disease, which violates Section 2 of the Sherman Act, and thus constitute an unfair method of competition in violation of Section 5(a) of the FTC Act.

18. The effect of the Proposed Transaction also may be substantially to lessen competition or tend to create a monopoly in the market for treatments for Pompe disease, which violates Section 7 of the Clayton Act.

JURISDICTION

19. Respondents are, and at all relevant times have been, engaged in commerce or in activities affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

20. The Proposed Transaction constitutes an acquisition subject to Section 7 of the Clayton Act, 15 U.S.C. § 18.

RESPONDENTS

21. Respondent Sanofi is a multinational pharmaceutical company headquartered in Paris, France. Sanofi shares are traded on the Paris and New York stock exchanges, and the company in 2022 reported total net sales of about \$47 billion. Sanofi is the product of a series of mergers, including its 2011 acquisition of Genzyme Corporation ("Genzyme"), which brought with it a specialty care business focused on drug development for rare diseases. Lysosomal Storage Disorders ("LSDs"), rare genetic conditions (such as Pompe disease) caused by enzyme deficiencies are a cornerstone of Sanofi's rare disease franchise. Currently, Sanofi has seven marketed therapies for LSDs, including its two medications for Pompe disease. Sanofi's Pompe treatments generated global revenues of approximately \$1.2 billion in 2022, approximately \$500 million of which was generated in the United States.

22. Respondent Genzyme is a Massachusetts corporation that is a wholly-owned subsidiary of Sanofi. Headquartered in Cambridge, Massachusetts, Genzyme researches, develops, and markets pharmaceutical products in the United States. Genzyme is a party to the License Agreement with Maze.

23. Respondent Maze, founded in 2019, is a privately held biotechnology company headquartered in South San Francisco, California. In addition to MZE001, Maze's portfolio includes target therapies in the neurological, cardio/renal, and ophthalmology disease areas.

THE PROPOSED TRANSACTION

24. On April 21, 2023, Sanofi and Maze entered into the Proposed Transaction, pursuant to which Sanofi proposes to acquire an exclusive global license to Maze's GYS1 products and related technology, including its lead clinical candidate MZE001 in development for Pompe disease. In consideration of the licenses, Sanofi agreed to pay Maze \$130 million in cash, make a \$20 million equity investment in Maze when it completes its initial public offering, and pay Maze up to \$605 million in future contingent development and commercialization milestone payments, as well as royalties on future sales of the licensed product(s).

POMPE DISEASE

25. Pompe disease, also called glycogen storage disorder type II, is a genetic disorder caused by mutations in the gene that codes for the production of the enzyme acid alpha-glucosidase ("GAA"). The GAA enzyme functions in the lysosomes, an organelle in muscle cells responsible for breaking down the complex sugar glycogen into the simpler sugar glucose, which is the primary energy source for most cells. If the body cannot produce sufficient GAA enzyme, glycogen accumulates to toxic levels, resulting in damage and potentially cell death, particularly to smooth, cardiac, and skeletal muscle cells.

26. Pompe disease is a rare disease, with a worldwide incidence of approximately 1 in 40,000 individuals. Approximately one thousand patients are currently receiving treatment for Pompe disease in the United States. Because the symptoms of Pompe disease overlap with many other neuromuscular conditions, patients often experience a long diagnostic odyssey before receiving a correct diagnosis. Once a physician suspects their patient may have Pompe disease, the physician can diagnose the patient through GAA enzyme analysis and genetic testing. However, because newborn genetic screening testing is becoming more common, the number of diagnosed patients with Pompe disease is expected to increase in the future.

27. Pompe disease is a spectrum disease, with the severity of a patient's symptoms correlating to the degree of the impairment of the ability to produce the GAA enzyme. There are two classifications for Pompe disease: infantile-onset Pompe disease ("IOPD") and late-onset Pompe disease ("LOPD"). IOPD patients typically exhibit symptoms upon birth or shortly thereafter. These patients typically have a genetic variation that results in no GAA enzyme production, and they exhibit the most severe symptoms, including severe muscle weakness resulting in feeding problems and trouble breathing, an enlarged liver, and an enlarged heart due to cardiomyopathy. IOPD is rapidly progressive, and patients typically do not survive beyond the age of two without treatment. Any patient that begins to exhibit symptoms after one year of age is an LOPD patient. LOPD patients typically produce some, but insufficient, GAA enzyme and usually present with progressive muscle weakness and respiratory deterioration due to weakening of the diaphragm muscle. LOPD is a progressive disease, and patients' muscular abilities deteriorate over time, eventually resulting in death, typically through respiratory failure.

28. Today, enzyme replacement therapy ("ERT") is the only treatment for Pompe disease. ERT consists of bi-weekly IV infusions of a synthetic version of the human GAA enzyme that are administered in clinics under medical supervision to replace the GAA enzyme that a patient suffering from Pompe disease is unable to produce naturally.

29. Sanofi's treatments were the only drugs approved to treat Pompe disease in the United States prior to September 28, 2023, when the FDA approved Amicus's IV ERT Pombiliti (cipaglucosidase alfa-atga) in combination with Opfolda (miglustat) oral capsules, as a second-line therapy for Pompe disease. This two-component therapy is approved only for adults with LOPD who are not improving on their current Sanofi ERT. Amicus's product has little to no current market share. Sanofi's internal documents forecast that [REDACTED]

30. Maze's MZE001 GYS1 inhibitor aims to restore the balance of glycogen in a patient's cells by reducing the production of the glycogen substrate, rather than replacing or restoring the patient's GAA enzyme activity. GYS1 inhibitors are thus referred to as a substrate reduction therapy ("SRT").

THE RELEVANT PRODUCT MARKET

31. A relevant product market in which to analyze the Proposed Transaction is no broader than pharmaceutical treatments for Pompe disease ("Pompe Drugs").

32. The only currently available treatments for Pompe disease are ERT drugs. These drugs attack the root cause of Pompe disease by supplying synthetic versions of the human GAA enzyme that Pompe patients are unable to produce.

33. There is no reasonably interchangeable substitute for Pompe Drugs. The only other option available to Pompe disease patients is palliative care, such as respiratory support, occupational therapy, speech therapy, and physical therapy. These non-pharmaceutical therapies are not reasonable functional substitutes for Pompe Drugs because they do not arrest or slow the progression of Pompe disease.

34. Because there is no substitute for Pompe Drugs, there is no cross-elasticity of demand between them and any other therapy for Pompe disease. Sanofi has repeatedly and profitably raised Lumizyme's and Nexviazyme's prices without patients switching to any other treatment and without considering the price for any other treatment. The annual cost of treatment for either Lumizyme or Nexviazyme for a patient of average weight is over \$750,000.

35. Industry participants, including, but not limited to Respondents, recognize the existence of a separate and distinct market for Pompe Drugs in their regular course of business. Physicians and payors consider Sanofi's ERTs to be the only standard of care for Pompe disease. Moreover, when Respondents and other industry participants identify present and future participants in this market, they focus exclusively on drugs that are or will be FDA-approved specifically for Pompe disease.

THE RELEVANT GEOGRAPHIC MARKET

36. The relevant geographic area in which to analyze the effects of the Proposed Transaction on competition is the United States.

37. The FDA regulates the production, research, development, testing, manufacture, marketing, and promotion of drug products in the United States. A company must perform the

necessary clinical trials and obtain FDA approval before marketing a drug in the United States. Accordingly, drugs sold outside the United States, but not approved for sale in the United States, do not provide viable alternatives for customers, even if the prices for Pompe Drugs currently available in the United States increase significantly.

38. Respondents consider the United States to be a distinct market for Pompe Drugs in their regular course of business due to, among other reasons, its separate regulatory and approval process.

MARKET STRUCTURE

39. Sanofi's current market share in the United States market for Pompe Drugs, or any other relevant product market in which it sells Lumizyme or Nexviazyme, is approximately 100 percent. Amicus's Pompe Drug has little to no current market share.

MONOPOLIZATION & UNFAIR METHODS OF COMPETITION

A. Sanofi is a Monopolist in Pompe Drugs

40. Sanofi possesses monopoly power in the United States market for Pompe Drugs, as evidenced by supracompetitive prices and restricted output.

41. Sanofi's share of the market for Pompe Drugs in the United States is currently approximately 100 percent, and Sanofi's ordinary course market forecasts predict [REDACTED]

42. This market has high entry barriers, including, among other things, the substantial cost and time required to discover, develop, and gain FDA approval for new Pompe Drugs. Marketed products are also protected by patents and other proprietary intellectual property.

i. Direct Evidence of Sanofi's Monopoly Power

43. Sanofi has repeatedly and profitably raised Lumizyme's and Nexviazyme's prices [REDACTED] and without inducing patients to switch to any other treatment or payers to curtail coverage for the medications. Following fifteen years of price increases, the annual cost of treatment for either Lumizyme or Nexviazyme for a patient of average weight is over \$750,000. The fact that Sanofi does not [REDACTED]

[REDACTED] is additional direct evidence that Sanofi is able to charge supracompetitive prices without fear of competition from alternative treatments.

44. The extraordinarily high profit margins Sanofi realizes on its Pompe Drugs are additional direct evidence of Sanofi's monopoly power. In 2022, Sanofi enjoyed gross margins of over [REDACTED] percent, and net operating margins of over [REDACTED] percent, on sales of Lumizyme and Nexviazyme in the United States.

45. Although Sanofi was aware that Amicus Therapeutics' two-component ERT for Pompe disease was likely to receive FDA approval and launch in 2023, Sanofi has not reduced its pricing for Lumizyme and Nexviazyme in anticipation of the launch of Amicus's Pompe Drug. Because Amicus Therapeutics' two-component ERT was only approved as a second-line therapy (for patients not improving on Sanofi's therapies), Sanofi has little to no incentive to decrease its list prices or offer significant discounts or rebates on Lumizyme and Nexviazyme, which remain the only FDA-approved treatments for newly diagnosed patients starting treatment for Pompe disease.

ii. Indirect Evidence of Sanofi's Monopoly Power

46. Sanofi's current market share in this relevant market, or any other relevant market in which it sells Lumizyme or Nexviazyme in the United States, is approximately 100 percent.

47. Sanofi's high market share is protected by significant barriers to entry and the lack of competitive Pompe Drug launches on the horizon. Other than Amicus' second-line treatment,

[REDACTED]

B. MZE001 Constitutes a Nascent Threat to Sanofi's Monopoly

48. Sanofi's proposed acquisition of an exclusive license to MZE001 would eliminate a nascent threat to Sanofi's monopoly for FDA-approved treatments for Pompe Drugs in the United States.

i. MZE001 Targets the Same Indication as Sanofi's Nexviazyme

49. The target product profile for MZE001 largely overlaps with the product profile for Sanofi's Lumizyme and Nexviazyme. If Maze or another pharmaceutical partner gained FDA approval for MZE001,

[REDACTED] Nexviazyme is currently approved as a first-line therapy for LOPD patients one year of age and older.

50. There is significant expected demand for an oral Pompe disease monotherapy with similar safety and efficacy to ERTs, because it would significantly reduce patients' treatment burden. ERTs typically require patients to visit an infusion center or physician's office every two weeks for IV infusions lasting up to five hours. In contrast, a patient can take an oral medication like MZE001 at home without the need for supervision by a medical professional.

51. Sanofi's commercial team responsible for Pompe disease recognizes

[REDACTED]

[REDACTED]

52. After conducting market research on how physicians would view MZE001, Sanofi's Director of New Product Planning for Rare Diseases concluded [REDACTED]

[REDACTED]

53. Likewise, internal Maze documents discussed that MZE001 could [REDACTED]

[REDACTED]

ii. Maze's Preclinical and Clinical Studies Demonstrate MZE001's Threat to Impact Sanofi's Monopoly

54. MZE001 is the lead program in Maze's research and development pipeline. Prior to negotiations with Sanofi, Maze took several concrete steps toward gaining FDA approval for the drug. Maze [REDACTED] successfully completing Phase 1 clinical trials with positive results. Maze [REDACTED]

[REDACTED]

In a February 2023 press release announcing positive data from its Phase 1 clinical trials for MZE001, Maze also announced it was poised to begin Phase 2 clinical trials for MZE001 later in 2023. [REDACTED]

[REDACTED]

55. The results of preclinical and clinical studies for MZE001 showcase the drug's promise. In February 2022, Maze published results from preclinical studies which demonstrated, among other conclusions, that MZE001 potently and selectively inhibited glycogen synthesis in human and animal *in vitro* assays, including in cells from healthy volunteers and patients with Pompe disease, as well as *in vivo* mouse and canine studies, and that MZE001's GYS1 inhibition was generally well tolerated.

56. In February 2023, Maze announced positive results from the MZE001 Phase 1 clinical trial in 112 healthy volunteers. Maze's Chief Medical Officer ("CMO") stated that the clinical data "showcases [MZE001's] ability to potently and selectively inhibit GYS1, the enzyme that controls glycogen production, a key driver of Pompe disease[.]" He further stated

that the Phase 1 data “mirror [Maze’s] preclinical findings and provide proof of mechanism for MZE001.” Maze’s CMO also contrasted the results against the current standard of care – Sanofi’s ERTs. “While enzyme replacement therapy has brought significant benefit to patients, glycogen accumulation in muscle continues to allow the disease to progress, specifically impacting ambulation and respiratory function. By leveraging large sources of matched genetic and clinical data with our Compass platform, we were able to design MZE001 to address longstanding questions around safety and efficacy that previously precluded development of a substrate reduction therapy.”

iii. Sanofi Internally Assessed MZE001 as a Threat to Its Monopoly

57. Because of MZE001’s promise as a first-to-launch oral SRT for Pompe disease, Sanofi employees repeatedly recognized the threat MZE001 posed to Sanofi’s monopoly.

[REDACTED]

58. Consistent with these conclusions, Sanofi’s internal forecasts evaluating the Proposed Transaction projected [REDACTED]

[REDACTED]

59. [REDACTED]

C. Absence of Procompetitive Justifications

60. Respondent Sanofi cannot demonstrate procompetitive justifications for the Proposed Transaction that increase competition on the merits and produce benefits to competition. Any proffered justifications are pretextual and do not outweigh the anticompetitive effect of Sanofi removing a threat to its monopoly. Any purported benefits could be accomplished through other means without eliminating competition between Sanofi’s Pompe drugs and MZE001.

SUBSTANTIAL LESSENING OF COMPETITION

61. The Proposed Transaction would eliminate all ongoing competition between Maze and Sanofi for Pompe Drugs, depriving patients, doctors, and payers of the benefits of competition, including greater innovation.

62. If Sanofi did not acquire MZE001, MZE001 would continue development as part of Maze, an independent player already engaged in the business of developing a Pompe Drug and working diligently to commercialize it.

63. The Proposed Transaction could delay MZE001's FDA approval timeline. Maze, either independently or partnered with another firm, has strong financial incentives to progress MZE001 through the clinical trial process quickly, because only upon receiving FDA approval will MZE001 begin to generate revenue in the relevant market. [REDACTED]

64. The Proposed Transaction may substantially lessen competition, further harming patients, physicians, and payors by eliminating close competition between Maze and Sanofi.

65. Pharmaceutical companies compete not only on price, but also to develop better treatments to meet unmet needs. In a competitive market, pharmaceutical companies are driven by the incentive to research and develop innovative treatments. When multiple companies strive to develop new drugs, that innovation race produces tangible benefits for consumers. An awareness of the innovation efforts of other firms—information that is often publicly available for drugs in the clinical development pipeline—pushes the pace car of research and development for competing firms.

66. At present, Maze and Sanofi are [REDACTED] Maze's preclinical data and successful Phase 1 clinical trial has pressured Sanofi [REDACTED]

67. In February 2022, Maze announced that it would be initiating first-in-human trials for MZE001. Sanofi then realized [REDACTED]

[REDACTED]

68. If consummated, the Proposed Transaction would eliminate this close ongoing competition. The elimination of competition would dramatically reduce Sanofi's financial incentives to continue [REDACTED]

69. Respondents cannot demonstrate that entry or expansion of products in the market for Pompe Drugs in the United States would be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Transaction.

70. Successful entry into the United States Pompe Drug market would be difficult, time consuming, and costly, requiring specialized know-how, advanced technology, and specialized equipment and facilities. Before a prescription pharmaceutical product may be sold in the United States, it must be approved by the FDA as safe and effective for its intended indication. The approval process is lengthy and costly. Development of a drug indicated for Pompe disease can take several years and can cost hundreds of millions of dollars.

71. Respondents cannot demonstrate merger-specific, verifiable, and procompetitive efficiencies likely to pass through to consumers of sufficient magnitude and likelihood to rebut the evidence of the Proposed Transaction's anticompetitive effects.

VIOLATIONS

COUNT I – MONOPOLIZATION & UNFAIR METHODS OF COMPETITION

72. The allegations of Paragraphs 1 through 71 are incorporated by reference.

73. Respondent Sanofi has, and at all relevant times had, monopoly power in the relevant market for Pompe Drugs, as well as in any other relevant market in which it sells Lumizyme or Nexviazyme.

74. Maze's MZE001 is a nascent threat to Sanofi's monopoly power.

75. The Proposed Transaction, if consummated, would eliminate the nascent competitive threat that MZE001 poses to Sanofi's monopoly power and, therefore, constitutes anticompetitive conduct reasonably capable of contributing significantly to Sanofi's continued monopoly power.

76. Sanofi lacks any legitimate business justification for its anticompetitive conduct, and any claimed justification is pretextual and does not outweigh the anticompetitive effect of the Proposed Transaction.

77. The Proposed Transaction constitutes monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, and Respondents' acts and practices are anticompetitive in nature and tendency and thus constitute unfair methods of competition in violation of Section 5(a) of the FTC Act, as amended, 15 U.S.C. § 45(a).

COUNT II – ILLEGAL ACQUISITION

78. The allegations of Paragraphs 1 through 71 above are incorporated by reference.

79. The Proposed Transaction would eliminate ongoing competition between Respondents Sanofi and Maze in the relevant market for Pompe Drugs. Although other firms also are engaged in research and development for Pompe Drugs, Maze and Sanofi are particularly close competitors [REDACTED]

[REDACTED] As a result, patients and physicians will lose the benefit of the competitive process by which Sanofi and Maze are [REDACTED]

[REDACTED] Respondents cannot show that any cognizable efficiencies are of a character and magnitude such that the Proposed Transaction is not likely to be anticompetitive.

80. The Proposed Transaction, if consummated, may substantially lessen competition or tend to create a monopoly in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18, and constitutes an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

NOTICE

Notice is hereby given to the Respondents that the fifteenth day of May, 2024, at 10 a.m. EST, is hereby fixed as the time, and the Federal Trade Commission offices at 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580, as the place, when and where an evidentiary hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act and the Clayton Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

You are notified that this administrative proceeding shall be conducted as though the Commission, in an ancillary proceeding, has also filed a complaint in a United States District Court, seeking relief pursuant to Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. 53(b), as provided by Commission Rule 3.11(b)(4), 16 CFR 3.11(b)(4). You are also notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the fourteenth (14th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted. If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings and conclusions under Rule 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to file an answer within the time above provided shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions, and a final order disposing of the proceeding.

The Administrative Law Judge shall hold a prehearing scheduling conference not later than ten (10) days after the Respondents file their answers. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the pre-hearing scheduling conference (but in any event no later than five (5) days after the Respondents file their answers). Rule 3.31(b) obligates counsel for each party, within five (5) days of receiving the Respondents' answers, to make certain initial disclosures without awaiting a discovery request.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that the Proposed Transaction challenged in this proceeding violates Section 5 of the Federal Trade Commission Act, as amended, and/or Section 7 of the Clayton Act, as amended, the Commission may order such relief against Respondents as is supported by the record and is necessary and appropriate, including, but not limited to:

1. If the Proposed Transaction is consummated, full divestiture or reconstitution of all associated and necessary assets, in a manner that fully restores competition, eliminates the effects of the Proposed Transaction, and replaces the lost competitive intensity.
2. A prohibition against any transaction between Respondents that combines their businesses in the relevant market, except as may be approved by the Commission.
3. A requirement that, for a period of time, Respondents provide prior notice to and obtain prior approval of the Commission before all Proposed Transactions, mergers, consolidations, or any other combinations of their businesses in the relevant market with any other company operating in the relevant market.
4. A requirement to file periodic compliance reports with the Commission.
5. A requirement that Respondents' compliance with the order be monitored at Respondents expense and by an independent monitor for a term to be determined by the Commission.
6. Any other relief appropriate to correct or remedy the anticompetitive effects of the Proposed Transaction or to restore MZE001 as a viable, independent competitor in the relevant market.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C., this eleventh day of December, 2023.

By the Commission.

April J. Tabor
Secretary



SEAL: