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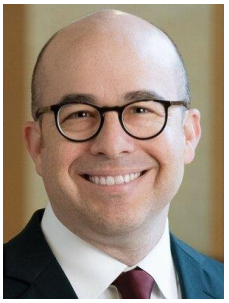
What FTC's 'Killer Acquisition' Theory Means For Pharma Cos.

By **Joshua Goodman, Luisa Di Lauro and Zachary Johns** (March 7, 2024, 6:46 PM EST)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The Federal Trade Commission recently filed a lawsuit seeking to block Sanofi's acquisition of a proposed exclusive license to a pharmaceutical treatment still under development by Maze Therapeutics Inc., which led the parties to abandon the transaction.[1]

In its complaint, the FTC alleged that the transaction would violate Section 2 of the Sherman Act by eliminating a nascent competitor, Maze, to an alleged monopolist, Sanofi.[2]

The FTC framed the case as one "about a monopolist seeking to eliminate a nascent threat to its monopoly,"[3] although the FTC also alleged that the deal would violate Section 7 of the Clayton Act — the antitrust law more typically used in government merger challenges.[4]

Sanofi/Maze is not the first time the FTC has alleged that a life sciences transaction violated Section 2 by eliminating nascent competition.

The FTC brought similar claims in 2017 against an exclusive license involving Questcor Pharmaceuticals Inc, later known as Mallinckrodt ARD, related to a drug that had yet to receive approval from the U.S. Food and Drug Administration, and in 2019 against Illumina Inc.'s proposed acquisition of Pacific Biosciences of California Inc.[5]

Sanofi/Maze builds on these enforcement actions and goes one step further by challenging a product that was in its early stages of development, having only completed Phase 1 clinical trials in the U.S., without any foreign availability.[6] The circumstances in which the agency may bring nascent competitor challenges appear to be expanding.

Below, we trace the evolution of this so-called killer acquisition theory through these recent cases as well as the 2023 merger guidelines, and we identify key takeaways to consider in future life sciences transactions.

Differing Standards Under Section 2 and Section 7

Typically, antitrust actions to block a transaction are brought under Section 7 of the Clayton Act. But, in the cases discussed below, the crux of the FTC's allegations was that one party to the transaction had an existing monopoly and that the transaction to acquire a nascent competitor maintained that monopoly

in violation of Section 2 of the Sherman Act.

Section 2 makes it unlawful for any person or entity to "monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize" any part of interstate commerce.[7]

Unlawful monopolization has two elements: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident."[8]

In contrast, Section 7 requires the FTC to show that "the effect of [an] acquisition may be substantially to lessen competition, or to tend to create a monopoly."[9]

There is no requirement to prove monopoly power under Section 7. However, in Section 7 cases where the alleged harm to competition comes from the loss of a potential competitor that has not yet entered the market, courts have typically applied the actual-potential-competition doctrine.[10]

Under this doctrine, courts have required, among other things, a showing that there is at least a reasonable probability that the potentially competitive product would actually have entered the market.[11]

In all three cases discussed below, the FTC brought Section 2 claims for monopolization, and, in the Illumina and Sanofi cases, the FTC also brought claims under Section 7.[12]

In all these cases, the FTC also alleged violations of Section 5 of the FTC Act,[13] which prohibits unfair methods of competition, and is generally found to be violated by conduct that violates other federal antitrust laws.

Mallinckrodt ARD/Novartis — 2017

In June 2013, Questcor Pharmaceuticals, which was the only supplier of an adrenocorticotropic hormone, or ACTH, product in the U.S., acquired the exclusive U.S. rights to develop, market and sell another ACTH product, known as Synacthen, from Novartis AG.[14]

At the time of the transaction, Novartis had not begun conducting clinical trials for Synacthen in the U.S., and there was therefore uncertainty surrounding whether the product would be approved by the FDA, despite it being approved outside of the U.S. to treat certain autoimmune and inflammatory conditions.[15]

Under the deal, Questcor would need to seek FDA approval for Synacthen and then commercialize the product.[16] According to Questcor, because Novartis retained some manufacturing rights to Synacthen, the deal was not reportable under the Hart-Scott-Rodino Act rules in effect at the time.[17] Later in 2013, the FTC amended the Hart-Scott-Rodino rules to apply more broadly to exclusive licenses.[18]

The FTC began an investigation into whether the Synacthen acquisition violated antitrust laws, sending a subpoena and civil investigative demand to Questcor in 2014.[19] In January 2017, the FTC and certain states brought a Section 2 claim against Mallinckrodt ARD, Questcor's successor, alleging that Questcor eliminated a nascent competitive threat to its monopoly.[20]

According to the FTC, Questcor bid for the rights to Synacthen as a "defensive move designed to protect its monopoly over ACTH products in the United States" by eliminating the possibility that another company would develop Synacthen and compete against Questcor.[21]

The FTC pointed to documents Questcor produced that allegedly showed top company officials questioning whether Synacthen "would provide any affirmative value to Questcor."[22]

The FTC also alleged that Questcor "had only inchoate plans for Synacthen and conducted limited due diligence when it submitted its initial offer" despite offering substantially more guaranteed money than other bidders.[23]

Finally, the FTC alleged that, absent the Questcor transaction, another company would have acquired Synacthen and pursued plans to develop it to compete with Questcor's ACTH product at a lower price.[24]

In the 2017 settlement of the FTC's monopolization claim, Mallinckrodt ARD agreed to pay $100 million in equitable monetary relief and to license the Synacthen assets to another licensee approved by the FTC.[25]

Illumina/Pacific Biosciences — 2019

In 2019, after the settlement in Mallinckrodt ARD, the FTC challenged another life sciences transaction under Section 2 — Illumina's proposed acquisition of Pacific Biosciences.[26]

On Nov. 1, 2018, PacBio announced Illumina's proposed acquisition of the company and its next-generation DNA sequencing system.[27] At the time, Illumina only manufactured a short-read DNA sequencing system, which takes a piece of DNA and generates a short read at a lower cost.[28]

In comparison, PacBio only manufactured a long-read DNA sequencing system, which processes larger pieces of DNA, and so can better address complex genomic questions, but at a higher cost.[29]

At the time of the proposed acquisition, PacBio had introduced a commercialized product, but its market share was 2%-3% versus Illumina's share of more than 90%, according to the FTC.[30]

On Dec. 17, 2019, the FTC issued an administrative complaint and authorized a lawsuit in federal court alleging that the proposed acquisition violated Section 2 and Section 7.[31]

The FTC alleged that Illumina was a monopolist in the next-generation DNA sequencing market in the U.S., and that while Illumina had historically faced little competition, PacBio had emerged as a nascent competitor with a product that "offer[ed] substantial benefits over Illumina's systems."[32]

The FTC alleged that it was clear that PacBio and Illumina viewed each other as competitors. The FTC concluded that Illumina was seeking to "extinguish [PacBio] as a competitive threat" to maintain its monopoly.[33] Shortly after the FTC's complaint, Illumina and PacBio announced that they had mutually agreed to terminate their agreement.[34]

Sanofi/Maze Therapeutics — 2023

The FTC's latest nascent competition challenge involved treatments for Pompe disease, a rare genetic

disorder that causes progressive weakness to the heart and skeletal muscles.

For several years, two Sanofi products have been the only approved enzyme replacement therapies for Pompe disease.[35] These products require biweekly intravenous infusion in a doctor's office.

In February 2023, Maze successfully completed a Phase 1 clinical trial for its Pompe ERT product, MZE001, which is an oral therapy rather than an infusion.[36] Maze's CEO announced that Maze was finalizing plans to initiate its Phase 2 clinical program in patients in 2023, adding that "MZE001 has the potential to be the first oral therapy for Pompe disease to be used as a monotherapy option."[37]

A few months later, in May 2023, Maze announced that it had entered into a license agreement with Sanofi.[38] Under the agreement, Sanofi would acquire an exclusive global license to the product that Maze was developing, along with any related technology.[39] Since the exclusive license was treated as an asset acquisition, it was subject to Hart-Scott-Rodino Act reporting and FTC review.

On Dec. 11, 2023, the FTC issued an administrative complaint and authorized a lawsuit in federal court to block the Sanofi/Maze licensing deal, asserting claims under both Section 2 and Section 7.[40] The FTC characterized Sanofi as a "monopolist supplier of drugs used to treat Pompe disease."[41]

Relying on Sanofi's internal documents, the FTC alleged that after learning that Maze's treatment had reached Phase 2 clinical trials, and that the treatment offered similar therapeutic efficacy with reduced patient treatment burden, Sanofi sought to eliminate a nascent threat to its monopoly rather than try to compete with Maze.[42]

According to the FTC, the documents demonstrated that Sanofi's executives thought that acquiring Maze's treatment would transform Maze's treatment "from a threat into a shield to protect Sanofi's monopoly."[43]

The FTC also alleged that, by acquiring Maze, Sanofi was eliminating current competition between the companies to research and develop innovative treatments.[44]

The day the FTC announced its complaint, Sanofi terminated the deal.[45] Subsequently, FTC Chair Lina Khan stated "[t]he 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."[46]

What the 2023 Merger Guidelines Say About Nascent Competitors

The 2023 merger guidelines issued by the FTC and U.S. Department of Justice state that a nascent competitor is "a firm that could grow into a significant rival, facilitate other rivals' growth, or otherwise lead to a reduction in [a dominant firm's] power."[47]

Within Guideline 6, the agencies note that eliminating a nascent competitive threat can potentially lead to violations of both Section 2 and Section 7, and that that the agencies will undertake an analysis under Section 2 that is "separate from and in addition to" their Section 7 analysis.[48]

The guidelines go on to explain that, for their Section 2 analysis, the agencies will assess whether the acquired firm may be considered a nascent threat to the preservation of a monopoly "even if the impending threat is uncertain and may take several years to materialize."[49]

This part of the guidelines thus appears aligned with the Section 2 claims in the cases discussed above that involved products that had not yet received FDA approval.

When determining whether a merger or acquisition eliminates actual potential competition under Section 7, the guidelines incorporate a reasonable probability standard for evaluating the potential for entry, and assert that "the higher the market concentration, the lower the probability of entry that gives rise to concern."[50]

Future Considerations

The cases discussed above all show that the FTC is looking for, and giving weight to, both ordinary course documents and deal-centric documents that support its allegations. In its complaints, the FTC has particularly focused on documents illustrating the perception of a nascent product as a competitive threat.

When one party to a potential transaction is developing a product that could be viewed to potentially compete in the future with an existing product of another party, the parties evaluating the transaction should be mindful of what their documents will show and how those documents may be interpreted by enforcers.

Both the Sanofi/Maze and Mallinckrodt cases illustrate that products in early stages of development can trigger FTC concerns about protecting nascent competition where there is a dominant player in the market.

Following the termination of Sanofi/Maze, Chair Khan noted 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."[51]

However, in markets without a monopoly product, Section 2 does not apply, so the FTC will likely make its claims under Section 7. Under that statute, the FTC will likely need to address or distinguish the exacting requirements of the potential competition doctrine when it seeks to challenge acquisitions of early-stage drugs.

Lastly, the Sanofi/Maze and Mallinckrodt cases also serve as a good reminder that the FTC analyzes exclusive pharmaceutical licensing agreements in the same manner as it analyzes acquisitions, like Illumina/PacBio.

Exclusive licensing agreements may be Hart-Scott-Rodino reportable, as with Sanofi/Maze, but even if an agreement is not reportable for a particular reason, the FTC retains the ability to investigate and challenge consummated licensing agreements, as it did in Mallinckrodt. As asset acquisitions, exclusive licensing agreements should be carefully vetted for antitrust issues.

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[1] Press Release, Fed. Trade Comm'n, FTC Seeks to Block Sanofi's Acquisition of Rare Disease Drug that Threatens Sanofi's Monopoly (Dec. 11, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/12/ftc-seeks-block-sanofis-acquisition-rare-disease-drug-threatens-sanofis-monopoly; Press Release, Sanofi S.A. Inc., "Statement on FTC Challenge to Proposed License Agreement with Maze Therapeutics" (Dec. 11, 2023), https://www.sanofi.com/en/media-room/press-releases/2023/2023-12-11-21-08-20-2794272.

[2] See generally Compl., In re Sanofi v. Maze Therapeutics Inc., Docket No. 9422 (FTC Dec. 11, 2023) [hereinafter Sanofi Compl.]; see also Compl., FTC v. Sanofi, No. 23-cv-13046 (D. Mass. Dec. 11, 2023).

[3] See Sanofi Compl., supra note 3, ¶ 3.

[4] See id. ¶¶ 18, 80.

[5] See generally Compl., In re Illumina Inc. & Pacific BioSciences of California, Inc., Docket No. 9387 (FTC Dec. 17, 2019) [hereinafter Illumina Compl.]; Compl., FTC v. Mallinckrodt ARD Inc., No. 17-cv-00120 (D.D.C. Jan. 25, 2017) [hereinafter Mallinckrodt Compl.].

[6] See Sanofi Compl. ¶ 54.

[7] 15 U.S.C. § 2.

[8] See U.S. v. Microsoft Corp., 253 F.3d 34, 50 (D.C. Cir. 2001).

[9] 15 U.S.C. § 18.

[10] See FTC v. Meta Platforms Inc., 654 F. Supp. 3d 892, 925-26 (N.D. Cal. 2023).

[11] See id. at 926-27.

[12] Sanofi Compl., supra note 3, ¶¶ 77, 80; Illumina Compl., supra note 6, ¶¶ 83, 86; Mallinckrodt Compl., supra note 6, ¶ 60.

[13] 15 U.S.C. § 45.

[14] Andrew Pollack, Questcor Pays $135 Million to Acquire Rights to a Competitor's Drug, N.Y. Times, June 14, 2013, https://www.nytimes.com/2013/06/15/business/questcor-pays-135-million-for-rights-to-competitors-drug.html#:~:text=The%20company%2C%20Questcor%20Pharmaceuticals%2C%20has,treat%20various%20immune%2Drelated%20ailments.

[15] Mallinckrodt Compl., supra note 6, ¶ 34; see also Press Release, Questcor Pharmaceuticals, Inc., Questcor Pharmaceuticals, Questcor Pharmaceuticals Acquires Rights to Synacthen (June 11, 2013), https://mallinckrodt.gcs-web.com/news-releases/news-release-details/questcor-pharmaceuticals-acquires-rights-synacthenr.

[16] See Press Release, supra note 16.

[17] Pollack, supra note 15.

[18] See "Premerger Notification; Reporting and Waiting Period Requirements," 78 Fed. Reg. 68,705, 68,706–07 (Nov. 15, 2013).

[19] Mallinckrodt Pub. Ltd. Co., Annual Report (Form 10-K) (Feb. 27, 2018).

[20] See generally Mallinckrodt Compl., supra note 6, ¶¶ 1, 8.

[21] See id. ¶¶ 8, 33.

[22] See id. ¶ 40.

[23] See id. ¶¶ 33, 48.

[24] See id. ¶ 33, 42, 50.

[25] Press Release, Fed. Trade Comm'n, Mallinckrodt Will Pay $100 Million to Settle FTC, State Charges it Illegally Maintained its Monopoly of Specialty Drug Used to treat Infants (Jan. 18, 2017), https://www.ftc.gov/news-events/news/press-releases/2017/01/mallinckrodt-will-pay-100-million-settle-ftc-state-charges-it-illegally-maintained-its-monopoly; see "[Proposed] Stipulated Order for Permanent Injunction and Equitable Monetary Relief," Dkt. 17-cv-00120 (D.D.C. Jan. 18, 2017).

[26] See generally Illumina Compl., supra note 6.

[27] Press Release, Illumina Inc., Illumina to Acquire Pacific Biosciences for Approximately $1.2 Billion, Broadening Access to Long-Read Sequencing and Accelerating Scientific Discovery (Nov. 1, 2018), https://www.pacb.com/press_releases/illumina-to-acquire-pacific-biosciences-for-approximately-1-2-billion-broadening-access-to-long-read-sequencing-and-accelerating-scientific-discovery/.

[28] See Illumina Compl., supra note 6, ¶¶ 18, 20-22; see also Press Release, supra note 28.

[29] See Illumina Compl., supra note 6, ¶¶ 18, 20-22; see also Press Release, supra note 28.

[30] Illumina Compl., supra note 6, ¶¶ 41, 46.

[31] Id. ¶¶ 79-86; see also Press Release, Fed. Trade Comm'n, FTC Challenges Illumina's Proposed Acquisition of PacBio (Dec. 17, 2019), https://www.ftc.gov/news-events/news/press-releases/2019/12/ftc-challenges-illuminas-proposed-acquisition-pacbio.

[32] See Illumina Compl., supra note 6, ¶¶ 1-2, 4-7.

[33] See id. ¶¶ 4, 6, 8, 39-40, 57-66, 70.

[34] See Press Release, Illumina Inc., Illumina and Pacific Biosciences Announce Termination of Merger Agreement (Jan. 2, 2020), https://www.illumina.com/company/news-center/press-releases/2020/eb4a5eba-6b79-41fd-b932-b89e7cd1cceb.html.

[35] Sanofi's predecessor, Genzyme, obtained FDA approval for the first ERT for Pompe disease in 2006, two years after a split FTC voted to close an investigation into Genzyme's acquisition of Novazyme, which was also developing a Pompe ERT at that time. See Carla Bolano-Diaz & Jordi Diaz-Manera, Therapeutic Options for the Management of Pompe Disease; Current Challenges and Clinical Evidence in Therapeutics and Clinical Risk Management, 18 Ther. Clin. Risk Manag. 1099, 1101; see also Press Release, Fed. Trade Comm'n, FTC Closes its Investigation of Genzyme corporation's 2001 Acquisition of Novazyme Pharmaceuticals, Inc. (Jan. 13, 2004), https://www.ftc.gov/news-events/news/press-releases/2004/01/ftc-closes-its-investigation-genzyme-corporations-2001-acquisition-novazyme-pharmaceuticals-inc.

[36] Press Release, Maze Therapeutics, Inc., Maze Therapeutics Announces Positive Phase 1 Results from First-in-Human Trial Evaluating MZE001 as a Potential Oral Treatment for Pompe Disease (Feb. 27, 2023), https://mazetx.com/maze-therapeutics-announces-completion-of-phase-1-first-in-human-trial-evaluating-mze001-as-a-potential-oral-treatment-for-pompe-disease/.

[37] See id.

[38] Press Release, Maze Therapeutics, Inc., Maze Therapeutics Announces Exclusive Worldwide License Agreement with Sanofi for MZE001, an Oral Substrate Reduction Therapy for the Treatment of Pompe Disease (May 1, 2023), https://mazetx.com/maze-therapeutics-announces-new-clinical-data-supporting-mze001-as-a-potential-treatment-for-pompe-disease-2/.

[39] See id.

[40] See generally Sanofi Compl., supra note 3; see also Compl., supra note 3.

[41] See Sanofi Compl., supra note 3, ¶ 1.

[42] See id. ¶¶ 3, 7, 9-11. 57-58.

[43] See id. ¶ 11.

[44] See id. ¶¶ 61-63, 65, 68.

[45] See Press Release, supra note 2.

[46] Statement of Chair Lina M. Khan Joined by Commissioner Rebecca Kelly Slaughter In the Matter of Sanofi/Maze Therapeutics Commission File No. D09422 (Dec. 20, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/statement_of_chair_khan_joined_by_commr_slaughter_re_sanofi-maze_abandonment.pdf.

[47] Dep't of Justice & Fed. Trade Comm'n, Merger Guidelines (Dec. 18,

2023), https://www.justice.gov/d9/2023-12/2023%20Merger%20Guidelines.pdf.

[48] See id. at 20-21.

[49] See id. at 21 (emphasis added).

[50] See id. at 10-11.

[51] Press Release, supra note 47, at 2.