THE EVOLVING ROLE OF INNOVATION THEORIES OF HARM IN THE ANTITRUST ANALYSIS OF LIFE SCIENCE MERGERS

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CPI ANTITRUST CHRONICLE
November 2025

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THE EVOLVING ROLE OF INNOVATION THEORIES OF HARM IN THE ANTITRUST ANALYSIS OF LIFE SCIENCE MERGERS

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This article examines the Federal Trade Commission's evolving use of innovation competition theories of harm in merger review following the adoption of the new 2023 Merger Guidelines. Departing from the traditional antitrust theories of harm, innovation-based enforcement targets mergers that either suppress rivalrous research and development ("R&D") efforts or extinguish nascent technological competition. This article centers around the life sciences market, which is characterized by intensive and expensive R&D, long product development timelines, and significant regulatory barriers to reach commercialization. Through examining how the FTC has pursued innovation-based theories in practice in *Steris/Synergy Health*, *Sanofi/Maze Therapeutics*, and *Edwards Lifesciences/JenaValve*, this article presents both the evidentiary challenges in proving speculative future harm, while also illustrating situations where innovation challenges are necessary and effective. The preservation of innovation incentives is a legitimate and necessary antitrust objective, but overly aggressive enforcement at early stages also possesses the risk of chilling investment and impeding the very progress it aims to protect. Ultimately, the article concludes by calling for the development of principled thresholds and clearer evidentiary standards to delineate when R&D driven mergers warrant intervention.

I. INTRODUCTION

The Federal Trade Commission ("FTC") has increasingly prioritized innovation theories of harm in merger enforcement in life sciences markets. These theories may be raised as either standalone arguments or as complements to traditional theories.

Innovation competition in this context refers to rivalry in the research and development ("R&D") pipeline, anchoring on a firm's core intellectual property, well before a product has been introduced to the market for commercial use. There are two primary ways a merger can present innovation concerns. *First*, an incumbent firm with a product in the market acquires a firm with a product still in development that, if successful once commercialized, could challenge the incumbent. *Second*, if two firms merge, and both have products in development, the merger could reduce each firm's individual incentive to invest in future innovation, causing harm to customers. In either scenario, the merger reduces incentives to innovate.

Antitrust practitioners tend to agree that a merger can harm future innovation based on R&D overlaps between the parties. But practical questions arise. At what point in the product life cycle does the combination raise antitrust risk such that a merger (or exclusive license agreement) is impermissible under Section 7 of the Clayton Act? What facts are necessary predicates for the FTC to bring and prove a case based on potential harm to innovation?

To date, there are limited precedents that hold innovation competition alone is cognizable antitrust harm under Section 7 of the Clayton Act. In part, this is because an innovation theory of harm is inherently speculative, leaving a plaintiff with the difficult task of proving that R&D efforts will bear fruit and create commercially viable products that will impact competition. Additionally, defendants will often abandon their attempted merger in the face of litigation, leaving the innovation theories of harm untested. Merging parties often argue that mergers are a necessary aspect of bringing new products to market in life sciences R&D based industries through pooling capital, spreading risk, and diversifying expertise. Critiques of innovation-based merger enforcement question whether broader aggressive enforcement in the R&D space may unintentionally chill the innovation it aims to protect. As one life sciences trade group has argued, "[m]ergers and acquisitions allow life sciences companies of all sizes to bring together the resources, investment and expertise needed to develop and deliver new treatments and cures for patients."[2] The push to preserve earlier in time innovation through merger enforcement has profound implications in R&D-centered life sciences industries, such as pharmaceuticals, biotechnology, and medical devices. In these industries, innovation competition often means potential future competition and mergers often involve overlapping R&D pipelines.

This article explores the FTC's efforts to utilize innovation theories of harm and highlights the challenges these cases face. In this comment, we will discuss *Steris/Synergy Health, Sanofi/Maze*, and *Edwards Lifesciences/JenaValve* to illustrate both the promise and limitations of using innovation competition as the basis for blocking a merger.

II. HISTORICAL BACKGROUND

This section briefly surveys the historical context for innovation theories of harm in merger reviews. The 2010 Horizontal Merger Guidelines were the first to prominently feature innovation competition, noting that "[c]ompetition often spurs firms to innovate" and explaining "whether a merger is likely to diminish innovation competition by encouraging the merged firm to curtail its innovative efforts below the level that would prevail in the absence of the merger."[3] At the same time, the 2010 Guidelines acknowledge the potential for procompetitive benefits: "whether the merger is likely to enable innovation that would not otherwise take place, by bringing together complementary capabilities that cannot be otherwise combined or for some other merger-specific reason."[4]

The 2023 Merger Guidelines frequently emphasize innovation competition, and generally track the 2010 Guidelines' analytical approach, "[f]irms can compete for customers by offering varied and innovative products and features."[5] Mergers may harm competition by reducing the merged firm's incentive "to continue or initiate development of new products that would have competed with the other merging party, but post-merger would 'cannibalize' what would be its own sales."[6] Elsewhere, the 2023 Guidelines suggest that product markets can be defined

2 *Life Sciences Mergers and Acquisitions (M&A): Myths vs. Facts*, Partnership for the U.S. Life Science Ecosystem ("PULSE") (Oct. 3, 2023), https://pulseforinnovation.org/life-sciences-mergers-and-acquisitions-ma-myths-vs-facts/#:~:text=Mergers%20and%20acquisitions%20(M&A)%20allow,class%20American%20life%20science%20ecosystem.

3 See U.S. Dep't of Justice & Fed. Trade Comm'n, Horizontal Merger Guidelines, § 6.4 (2010), https:// www.justice.gov/atr/horizontal-merger-guidelines-08192010.

4 *Ibid.*

5 See U.S. Dep't of Justice & Fed. Trade Comm'n, Merger Guidelines § 4.2.E. (2023), https://www.justice.gov/atr/ 2023-merger-guidelines. 2023 HMG.

6 *Ibid.*

around new products that might result from future innovation, even if they do not yet exist.[7] Unlike the 2010 Guidelines, the 2023 Guidelines do not explicitly recognize the potential for mergers to increase innovation by bringing together complementary capabilities.

The agencies have brought several enforcement actions adopting innovation theories of harm in recent years, with mixed results. The FTC's 2015 challenge to the proposed acquisition of Synergy Health plc ("Synergy") by Steris Corporation ("Steris") illustrates the fact-intensive nature of these cases. At issue was the market for contract sterilization services for healthcare products in the United States. The FTC alleged this market was dominated by Steris and another company, Sterigenics, both of which used existing gamma sterilization technologies. The FTC further alleged that Synergy would have entered the U.S. market with a novel x-ray sterilization technology that would disrupt the Steris/Sterigenics duopoly but abandoned its plans because of the announced merger with Steris and the FTC's subsequent investigation. The merging parties countered that Synergy abandoned its U.S. x-ray project due to a lack of customer commitment and prohibitively high capital costs.

In the *Steris* court's view, the key question was whether the FTC could show that, absent the merger, Synergy would have entered the U.S. contract sterilization market by building one or more x-ray facilities in the U.S. within a reasonable period of time.[8] The court concluded the FTC had not met this burden. The court closely examined the facts regarding Synergy's decision-making process and efforts to enter the U.S. It found that Synergy terminated its U.S. entry project because it was unable to secure any U.S. customer commitments for the business, due to the high costs and regulatory uncertainty of switching from gamma to x-ray sterilization.[9] Further, Synergy faced prohibitively high capital costs to build x-ray sterilization facilities in the U.S. and had limited success with its ex-U.S. x-ray sterilization plant.[10] The court did not accept the FTC's contention that the merger announcement (and the FTC's subsequent investigation) caused Synergy to cancel its entry plans, because Synergy employees continued to work towards Board approval of the U.S. x-ray project for several months after the merger was announced (and while the FTC investigation was ongoing).[11]

The FTC's subsequent attempts at using innovation theories in merger enforcement (either as standalone theories or as part of a broader case) included the challenges to Otto Bock's consummated acquisition of Freedom Innovations in 2017 (alleging harm to innovation in the microprocessor prosthetic knees products and technology market); Illumina's proposed acquisition of Pacific BioSciences in 2019 (alleging the merger would eliminate a nascent competitor whose offerings were becoming more competitive to Illumina's offerings); Illumina's proposed acquisition of Grail in 2021 (alleging the merger would diminish innovation in multi-cancer early detection tests); and Meta's proposed acquisition of Within in 2022 (alleging that Meta, a potential entrant, chose instead to buy a rival and eliminate future competition).

III. *SANOFI/MAZE*—INCUMBENT ACQUISITION OF A POTENTIALLY COMPETING R&D PROJECT

In December 2023, the FTC sued to block Sanofi's proposed acquisition of an exclusive license to Maze Therapeutics Inc.'s experimental therapy to treat Pompe disease. Pompe is a rare, debilitating, and potentially fatal genetic disorder that causes progressive muscle damage and has a small total addressable market of 5,000-10,000 cases globally. Rare diseases tend to draw less overall development from potential market participants. The potential return on investment is typically lower than for more common diseases, and there are fewer opportunities for therapies to recoup the high R&D costs. That said, having the sole or dominant therapy for a rare disease is valuable, as it provides a more certain path to recovering investment costs given other market participants are unlikely to enter—unlike in common diseases where large patient populations draw multiple competitors with a larger addressable market that can support more robust R&D.

At the time of the transaction, Sanofi was the sole supplier of U.S. Food and Drug Administration ("FDA") approved drugs to treat Pompe. Sanofi's Pompe treatments include Lumizyme and Nexviazyme, both of which are intravenous infusions administered at clinics biweekly. For its part, Maze was progressing a pre-Phase 2- developmental drug, MZE001, that used a different method of action than Sanofi's drugs. It was poised to become the first oral medication available for Pompe, with the potential to simplify the treatment protocol for patients.

Although MZE001 completed Phase I testing at the time of the proposed acquisition, it still had a long and expensive road ahead in the regulatory process. There are four main phases of clinical trials for new drugs. Phase II is early in the drug-development process and can vary

7 *Ibid.* § 4.3.D.7.

8 *Fed. Trade Comm'n v. Steris Corp.*, 133 F. Supp. 3d 962, 978 (N.D. Ohio 2015).

9 *Ibid.* at 978—81.

10 *Ibid.* at 978—82.

11 *Ibid.* at 983—84.

widely but typically costs around $60 million.[12] During Phase II the effectiveness is measured in a few hundred volunteers. Only 33 percent of drugs successfully pass Phase II into Phase III.[13] In Phase III, researchers give the experimental drug to 300-3,000 volunteers with the disease or condition and compare the results to a control group receiving the standard treatment or a placebo.[14] This comparison formally assesses the new drug's efficacy and adverse reactions. As the longest and most expensive phase, lasting one to five years and costing an average of $350 million (with the potential to surpass $1 billion), Phase III is a critical hurdle. To gain regulatory approval and market the drug, a company typically needs to complete at least two successful Phase III trials demonstrating its safety and efficacy. A pharmaceutical company cannot request FDA approval to market the drug **until** the drug clears Phase III. MZE001 therefore only represented a potential competitor if one assumed the years and substantial investment required to reach commercialization, as well as a successful Phase III trial. In the eyes of the FTC, the mere *possibility* and prospect of a future competitor being purchased warranted scrutiny and *Sanofi/Maze* marks the first time the FTC took action against the acquisition of a pre-Phase II drug.

In the complaint, the FTC alleged that Sanofi's motivation to buy Maze's innovative oral therapy was to "eliminate a nascent competitor poised to challenge Sanofi's monopoly in the Pompe disease therapy market." The FTC presented two complementary theories of harm. One, that the deal extinguished a nascent, competitive threat, and two, that the market already benefited from the existing innovation competition. Specifically, the FTC alleged:

> 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.[15]

The FTC's enforcement action relied on Sanofi's internal documents which although redacted in the complaint, allegedly explain that Sanofi viewed Maze's oral therapy as an existential threat to Sanofi's Pompe drugs. A company's internal documents are especially important in innovation-based merger cases because when an incumbent anticipates head-to-head competition the FTC may use those documents as direct evidence in support of its theory of harm. A few examples from the complaint include: "Although a small number of other firms have initiated Phase I clinical trials for other Pompe disease treatments, Sanofi forecasts that [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]."[16] Additionally, "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."[17] Finally, "observing that MZE001 can be administered orally and cognizant of the drug's commercial promise, Sanofi concluded that it had to [REDACTED]."[18]

Sanofi defended the transaction, as merging parties often do, by stating that the merger was necessary to fund the development phases and commercialize the Maze product.[19] This is a common business justification in life sciences industries where startups do not always have the knowledge, expertise, capacity, or financial wherewithal to bring a product to market.

The parties abandoned the transaction after the FTC's challenge, leaving the question of whether an exclusive license of a pre-Phase II clinical product was likely to substantially lessen innovation competition in the future unanswered by the court. Nevertheless, the FTC likely claims a victory over the fate of Maze. Five months after Sanofi abandoned the merger, Maze's MZE001 product was purchased by Shionogi, a Japanese

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12 Brian Roden, *The Staggering Cost of Drug Development: A look at the Numbers*, GreenField (Aug. 10, 2023), https://greenfieldchemical.com/2023/08/10/the-staggering-cost-of-drug-development-a-look-at-the-numbers/.

13 *Clinical Trials Phases Defined*, Dep't of Psychiatry & Behav. Neurosci., Univ. of Cincinnati Coll. Of Med., https://med.uc.edu/depart/psychiatry/research/clinical-research/crm/trial-phases-1-2-3-defined (last visited Oct. 20, 2025).

14 *Step 3: Clinical Research*, Food and Drug Administration (FDA), https://www.fda.gov/patients/drug-development-process/step-3-clinical-research (last visited Oct. 20, 2025).

15 See Complaint, *In re Sanofi*, FTC Docket No. 9422 at 65 (Dec. 11, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/d9422_sanofi_maze_part_3_complaint_public_redacted.pdf.

16 *Ibid.* at 16.

17 *Ibid.* at 57.

18 *Ibid.* at 9.

19 "We respectfully disagree with the action by the FTC which also delays potential advancements that could impact the lives of patients. The Maze partnership was designed to apply Sanofi's resources, knowledge, and expertise to accelerate the development of MZE001, with the hope of addressing unmet medical needs for this devastating condition." Press Release, Sanofi, *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.

pharmaceutical company that did not have a drug in the Pompe market before acquiring MZE001. Shionogi's CEO Isao Teshirogi stated that the merger "will help meaningfully advance our commitment to developing innovative medicines that address unmet medical needs and complement Shionogi's rapidly expanding pipeline in the focus areas designated in our medium-term business plan STS2030 revision."[20] Shionogi is about to begin a Phase II study of MZE001.[21]

Some industry participants argue that the FTC's approach in *Sanofi/Maze* is likely to discourage investment and dealmaking in early-stage biotech. For example, Vijay Pande, a General Partner at Andreessen Horowitz, an investor in Maze, at the time of the challenge warned regulators that their actions "could have a chilling effect" on acquisitions that are critical for biotech firms' path to market. The acquisition of an exclusive license toMZE001 by Shionogi demonstrates that if a product is promising, a buyer may emerge that does not present anticompetitive issues: competition and innovation can be simultaneously preserved.

Sanofi/Maze shows the FTC's willingness to challenge mergers even where the potential competitor is far from commercialization. It also underscores that with innovation-based mergers, direct evidence is indicative of innovation competition and future head-to-head competition. In *Sanofi/Maze*, several key facts contributed to the strength of the FTC's case. *First*, it was a rare disease in a market with one therapeutic provider. *Second*, the target was likely to disrupt a monopoly and although Maze was pre-Phase II, very early in its development, it was unlikely that there was a robust pipeline of development as an alternative to Maze. *Third*, Sanofi's internal views and "admissions" in contemporaneous documents were suggestive of the potential for competition in the future that would be extinguished by the merger.

IV. *EDWARDS LIFESCEINCES/ JENAVALVE*—MERGERS OF POTENTIALLY COMPETING R&D PROJECTS

In the most recent example of an innovation competition case, the FTC sued to enjoin Edwards Lifesciences's acquisition of JenaValve on August 6, 2025. Unlike *Sanofi*, Edwards does not focus on a nascent competitor challenging an incumbent. Here, the FTC alleges *both* parties are actively developing medical devices that will treat the same disease, and each party is racing to bring their product to market on similar development timelines.

The products at issue in the FTC's challenge are transcatheter aortic valve replacement devices used for patients with aortic regurgitation (TAVR-AR devices). Aortic regurgitation is a potentially fatal heart condition that affects more than eight million Americans. Currently, the only FDA treatment for aortic regurgitation is open-heart surgery and the products at issue represent innovation to the standard of care.

While it does not have a TAVR-AR device, Edwards participates more broadly in the space for medical devices that address cardiac issues. Prior to attempting to acquire JenaValve in August 2024, it purchased JC Medical in July 2024. JC Medical's J-Valve and JenaValve's Trilogy were allegedly the only two products with ongoing clinical trials for a TAVR-AR devices in the U.S. The FTC alleges that "Edwards' attempt to buy the U.S. market for TAVR-AR devices would eliminate the head-to-head competition that has spurred innovation for lifesaving artificial heart valves."[22] The FTC believes that post-merger, Edwards would have less reason to aggressively invest in both pipelines, meaning that at least one project would lose priority, be delayed, or even abandoned.[23] By controlling the only two viable pipeline competitors, the FTC alleges Edwards would gain full control over the market for TAVR-AR devices.

Edwards strongly disagrees with the FTC's allegations. The company argues that the acquisition of JenaValve will actually "accelerate the availability, adoption and continued innovation of a life-saving treatment for patients suffering from AR."[24] Instead of delaying or abandoning one of the TAVR-AR device projects, Edwards would combine complementary R&D efforts. This would expedite the launch of a TAVR-AR device,

20 *Shionogi secures license for Maze's Pompe disease treatment*, Pharm. Tech., (May 10, 2024), https://www.pharmaceutical-technology.com/news/shionogi-pompe-disease-treatment/?cf-view.

21 *Study of S-606001 as an Add-on to Enzyme Replacement Therapy (ERT) in Participants with Late-onset Pompe Disease (LOPD)*, Nat'l Lib. Of Med., NIH, ClinicalTrials.gov Identifier NCT07123155 (sponsor Shionogi Inc.; last update posted Oct. 16, 2025), https://clinicaltrials.gov/study/NCT07123155.

22 *FTC Challenges Anticompetitive Medical Device Deal,* Federal Trade Commission, Aug. 6, 2025, https://www.ftc.gov/news-events/news/press-releases/2025/08/ftc-challenges-anticompetitive-medical-device-deal.

23 Complaint, *In re Edwards Lifesciences Corp.*, Docket No. 9442, at ¶¶ 7, 11, 29–33, 38–46 (FTC Aug. 6, 2025) (public version), https://www.ftc.gov/system/files/ftc_gov/pdf/d9442_p3_complaint_public_redacted_0.pdf.

24 See Press Release, Edwards Lifesciences, *Edwards Lifesciences Comments on FTC's Action to Block Proposed Acquisition of JenaValve* (Aug. 6, 2025), https://www.edwards.com/newsroom/news/2025-08-06-edwards-lifesciences-comments-on-ftc-s-action-to-b.

as JenaValve's fate was uncertain given its financial insecurity at the time of the merger. Edwards believes they are not eliminating a future rival, but instead salvaging an innovation effort that otherwise will not survive.

Like Sanofi, it remains to be seen whether the sole competitor, here, Edwards J-Valve, will ultimately purchase JenaValve, and unlike *Sanofi*, it looks like a court will have the opportunity to decide.

Edwards also differs from *Sanofi* in the nature of the alleged threat to innovation. Specifically, in *Sanofi*, the potential competitor, Maze, was pre-Phase II for a novel more efficient treatment for Pompe disease, meaning the threat was still speculative. By contrast, in *Edwards*, both firms are actively engaged in clinical trials for the same type of device, with parallel product development timelines, which is the alleged innovation competition.

The *Edwards* case is an innovation competition case to watch.

V. CONCLUSION

Innovation-focused merger enforcement is a relatively undefined frontier in antitrust, with a broad scope of competition. In the absence of price competition and defined market shares, innovation-focused merger enforcement instead considers how firms are pushing one another to improve and disrupt the market (or spark the creation of new markets). Predicting future competition is inherently uncertain, and acting too aggressively can result in unanticipated harm, especially in R&D focused markets like the life sciences industries.

To avoid inadvertently stifling innovation, the agencies should issue guidance outlining key factual considerations for pursuing innovation theories of harm in merger enforcement. For example, the actual maturity of the R&D asset could serve as a key threshold; challenges may be more appropriate when there is a combination of two later stage products that are more likely to get to market. Likewise, if the products are competing for a small patient population, heightened scrutiny may be warranted. Agencies may also look as to whether the products are likely to be viewed as substitutes by either prescribers, payers, or regulators.

Such parameters will provide smaller firms and their investors sound guidance that balances the need to protect innovation competition but that doesn't flag that every acquisition in the R&D market will face regulatory opposition. Without clear parameters, the consequence may be reduced investment in life sciences startups. Large firms may avoid acquiring promising R&D projects altogether, which could lead to less investment and ultimately fewer therapies getting to patients.

The selection of cases pursued by the FTC should illustrate the principles laid out in the 2023 Merger Guidelines, and the FTC should continue to bring cases involving products that will realistically make it to commercialization and are likely to compete with one another. Meanwhile, the FTC should distinguish deals where the acquisition facilitates innovation by providing resources to enable a product that would otherwise never make it to market.

By pursuing cases grounded in evidence, the innovation-based theory can be applied judiciously to identify real prospective competitive overlap. Moving forward, the success of innovation-based enforcement will rely on such discipline to ensure that both competition and the dynamic process of discovery are protected.

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