Federal Trade Commission v. Steris Corporation: High Barriers to Proving Likely Anticompetitive Effects from Loss of Future Competition

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It has been more than fifty years since the Supreme Court first deliberated over the potential competition doctrine in *United States v. Penn-Olin Chemical Co.*,[1] where the Court recognized that Section 7 of the Clayton Act may be violated based on that theory of competitive harm. While the Court generally recognized the potential competition doctrine in *Penn-Olin*, it did not distinguish between the present and future effects on competition. This key distinction underlies two distinct theories of harm that comprise the potential competition doctrine – "perceived potential competition" and "actual potential competition."

In the decades since *Penn-Olin*, only a few unicorns make up the body of case law of litigated merger cases alleging harm based on the potential competition doctrine. In the dearth of case precedent there is a glaring lack of judicial instruction in how courts and parties should approach the actual potential competition theory. Unlike the perceived potential competition theory, which has been validated by the Supreme Court, the Court has refused to endorse the actual potential competition theory on several occasions, leaving its viability open to question and criticism.[2]

The potential competition doctrine as it stands today was largely penned by Justice Powell ten years after *Penn-Olin.* In *United States v. Marine Bancorporation*, the Court reaffirmed its acceptance of the perceived potential competition theory, but cast a dark and lingering shadow over the actual potential

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[1] 378 U.S. 158 (1964).

[2] *See, e.g., United States v. Falstaff Brewing Corp.*, 410 U.S. 526 (1973); *United States v. Marine Bancorporation, Inc.*, 418 U.S. 602 (1974).

competition theory.[3] *Marine Bancorp* did not do away with the actual potential competition theory, but it did erect high barriers to proving that an acquisition is illegal on that basis.

In the fall of 2015, the Federal Trade Commission ("FTC") crashed head-on into those barriers, ending its courtroom winning streak, and leaving many antitrust practitioners speculating whether the FTC could overcome the evidentiary burden of proof in any actual potential competition merger matter. In *Federal Trade Commission v. Steris Corporation,* the U.S. District Court for the Northern District of Ohio initially delivered promising news to the FTC by assuming the validity of the actual potential competition doctrine for purposes of deciding likelihood of success on the merits. But the District Court went on to find that "the evidence unequivocally" supported the defense and that the "FTC has failed to carry its burden," ultimately denying the FTC's motion for preliminary injunction.[4]

Despite the Supreme Court never having recognized the validity of the actual potential competition theory, the antitrust agencies often secure consent settlements from merging parties aimed at curing competitive harm resulting from the loss of future competition, especially in high tech and life sciences transactions. Most often parties in those cases settle such allegations in order to close the rest of the transaction, and realize the efficiencies and benefits resulting from the deal.

With the FTC's *Steris* loss on the scoreboard, should we expect to see major changes to the approach taken by the FTC and DOJ in demanding settlements in merger matters where the reviewing agency is concerned about future loss of competition? Will merging parties more often push the agency to

[3] "[A]lthough the concept of perceived potential entry has been accepted in the Court's prior Section 7 cases, the [actual] potential competition theory upon which the government places principal reliance in the instant case has not." *Marine Bancorp*, 418 U.S. at 625.

[4] *FTC v. Steris Corp.*, No. 1:15-cv-1080, 2015 WL 5657294 (N.D. Ohio Sept. 24, 2015).

prove the theory in court rather than settling? The answer to both questions is "probably not" because other forces that are unaffected by the *Steris* decision drive that answer. But in the aftermath of *Steris* we could potentially, or actually, see more nuanced changes in the way that merging parties defend such transactions and how the agencies style their theories of competitive harm.

Actually, Not All Potential Competition Cases are the Same: Actual v. Perceived Potential Competition

The potential competition doctrine is comprised of two distinct theories of competitive harm: the perceived potential competition theory and the actual potential competition theory. The theories share several common elements and characteristics with the other, but there are substantial differences in their application and the potential competitive harm that flows from each. At the core of the doctrine is the premise that a firm with market power competing in a concentrated industry may employ a profit-maximizing strategy of acquiring a firm that is not a current competitor in order to eliminate its threat as a potential entrant.

Under the perceived potential competition theory, a merger between a major incumbent player and a potential entrant that is not actually in the process of entering the relevant market may substantially reduce competition by eliminating the threat of entry by the acquired firm. The harm to competition by eliminating a perceived competitor is the loss of current procompetitive dynamics in the marketplace that are generated by the incentives for incumbent players to keep prices down in order to avoid drawing entry by the target firm. Removing the threat of entry "that is waiting in the wings" from the marketplace effectively removes a current competitive constraint on prevailing prices that negatively impacts the present performance of the market.

In contrast, the actual potential competition doctrine is concerned not about loss of current procompetitive market influences, but rather with the state of

competition in the future. As the theory goes, a merger between a significant incumbent competing in a concentrated market and a potential entrant that is actually in the process of entering the market eliminates the possibility that the market would have become more competitive if the to-be-acquired firm had actually entered instead of merging with the significant incumbent.

The key distinction is when the harm to competition occurs. Perceived potential competition is based on a *current* assessment of market conditions that are influenced by the perception that a firm on the edge of the market may enter. Actual potential competition requires more speculation in predicting what a *future* market would look like post-entry of the new competitor, and then assessing likely effects on competition, assuming that the competitor *actually* enters. The posited end result under both theories is the same: consumers are denied the benefits that the potential entrant brings to the marketplace, either currently or in the future, and prices are higher as a result.

Judicial Underpinnings of the Potential Competition Doctrine

The Supreme Court first endorsed the potential competition doctrine in connection with the government's challenge to dissolve a joint venture between Pennsalt and Olin Mathieson, at the time called Penn-Olin Corporation, which sold sodium chlorate in the southeastern region of the United States.[5] The Supreme Court reversed the district court, which had dismissed the government's complaint because there was no showing that "*both* companies would have entered the market as individual competitors if Penn-Olin had not been formed."[6] The Supreme Court observed that the district court "made no decision concerning the probability that one would have built [a plant] 'while the other continued to ponder.'"[7] In that regard, the *Penn-Olin* Court ultimately found that "There still remained for consideration the fact that [the formation of] Penn-Olin eliminated

[5] *United States v. Penn-Olin Chem. Co.*, 378 U.S. 158 (1964).

[6] *Id*. at 173.

[7] *Id.*

the potential competition of the corporation that might have remained at the edge of the market, continually threatening to enter."

While the Supreme Court recognized that "(p)otential competition . . . as a substitute for . . . (actual competition) may restrain producers from overcharging those to whom they sell or underpaying those from whom they buy,"[8] under the factual record at the time of the decision the Court found there was no violation of § 1 of the Sherman Act, and thus vacated and remanded for further consideration. The *Penn-Olin* Court did not distinguish between the present and future effects on competition that underlie the two distinct theories of harm, leaving it to future courts to elaborate on the boundaries of the doctrine.

Nearly a decade passed following *Penn-Olin* until the next "potential competition" Supreme Court decision in *United States v. Falstaff Brewing Corp*. The Court, however, expressly declined to provide any view on the validity of the "actual potential competition" theory in its opinion.[9]

The "modern" state of the potential competition doctrine is founded in a decision authored by Justice Powell in 1974, in *United States v. Marine Bancorporation*. [10] In that case, the government challenged the acquisition of a bank located in Spokane, Washington by another bank that was based in Seattle, but neither bank operated in the other's respective geographic area.

The United States asserted that the transaction would violate Section 7 of the Clayton Act because it would eliminate the possibility that the acquiring bank based in Seattle would otherwise enter the Spokane market, and also because the

[8] *Id.* at 174, quoting Wilcox, Competition and Monopoly in American Industry, TNEC Monograph No. 21, 7-8 (1940).

[9] *Falstaff Brewing*, 410 U.S. at 537-38 ("We leave for another day the question of the applicability of Section 7 to a merger that will leave competition in the marketplace exactly as it was, neither hurt nor helped, and that is challengeable under Section 7 only on the grounds that the company could, but did not, enter…and there is less competition than there would have been had entry been in such manner.").

[10] *See Marine Bancorp,* 418 U.S. at 633.

merger would eliminate a perceived competitor. The Court reaffirmed its acceptance of the perceived potential competition theory, but again cast a shadow over the actual potential competition theory.[11] While *Marine Bancorp* did not do away with the actual potential competition theory, it did erect "formidable barriers" to proving that an acquisition is illegal on that basis.[12]

The *Marine Bancorp* Court established two "essential preconditions" that must be found to exist before a court could even consider application of the actual potential competition theory to invalidate an acquisition: (1) that the potential entrant has "feasible means" for entering the market (other than through the contemplated acquisition); and (2) that those means offer a substantial likelihood of ultimately producing a lasting deconcentration of the market.

In determining whether "feasible means of entering exist," courts were directed to examine numerous factors, including the firm's interest in entering, its economic incentives, the capabilities and expansion history of the potential entrant, and the performance as well as the structural characteristics of the market.[13] The point of this evidentiary examination is to determine whether, absent the transaction, the potential entrant would likely enter the market. As discussed below, this is exactly the question that Judge Polster directed the parties to address, and the FTC failed to affirmatively answer, during the hearing in the *Steris* matter.

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[11] "[A]lthough the concept of perceived potential entry has been accepted in the Court's prior Section 7 cases, the [actual] potential competition theory upon which the government places principal reliance in the instant case has not." *Id.* at 625.

[12] In his dissenting opinion, Justice White expressed the view that the majority opinion "erects formidable barriers to the application of the potential-competition doctrine…To show that the potential entrant, waiting in the wings, is exercising a present influence on the market, or that its loss as a de novo or toehold entrant may be a substantial injury to competition, it will not be enough to prove ability and willingness to enter, along with the probability, or even certainty, of entry. Nor will it suffice to prove that the potential or actual entrant would be a profitable concern and successfully prevent the major figures in the market from increasing their market shares. The courts must also examine conditions in the market and conclude for themselves that there is a realistic expectation that the new entrant will appropriate part of the business of the major competitors in the market." *Id*. at 654 (White, J., dissenting).

[13] *Id.* at 642.

Ultimately the *Marine Bancorp* Court found that the government could not establish the existence of the two "essential preconditions," noting that "unequivocal proof that an acquiring firm actually would have entered de novo but for a merger is rarely available."[14] Because the government had failed to carry its evidentiary burden, the Court never addressed the validity of the actual potential competition theory of harm.

Federal Trade Commission v. Steris Corporation: **Background and Proceedings**

On May 29, 2015, the FTC filed a complaint for a temporary restraining order and preliminary injunction against Steris Corporation ("Steris") and Synergy Health plc ("Synergy"), requesting the court prevent Steris from acquiring its potential competitor, Synergy, in violation of Section 7 of the Clayton Act.[15]

At the time the complaint was filed, Steris and Synergy were the number two and number three providers of contract sterilization services in the world, behind market leader, Sterigenics International LLC ("Sterigenics"). Sterilization services are essential to many healthcare products and are required by the Food and Drug Administration to eliminate bacteria from implantable medical devices.

There are three primary methods of contract sterilization services currently used in the United States: gamma radiation, electron beam radiation ("e-beam"), and ethylene oxide ("EO") gas. Each method has its own benefits, and customers choose sterilization methods based on their products' physical characteristics and packaging. Outside of the United States, x-ray sterilization has also entered the contract sterilization market, but that method has yet to enter the United States.

[14] *Id.* at 624.

[15] Plaintiff Federal Trade Commission's Complaint for Temporary Restraining Order and Preliminary Injunction, *FTC v. Steris Corp.*, No. 15-cv-1080 (ECF No. 19) ("Compl.").

The FTC's complaint maintained that x-ray radiation is a close substitute for gamma radiation because it "offers comparable, and possibly superior, depth of penetration."[16]

According to the FTC, Sterigenics and Steris accounted for approximately 85% of all U.S. contract sterilization services. Both Sterigenics and Steris offered gamma radiation services, and Sterigenics also offered e-beam radiation. While Synergy offered gamma and x-ray radiation services *outside* of the United States, it only offered e-beam radiation in the United States, and was not a meaningful competitor in the U.S. market.

The FTC acknowledged that Synergy was a "small U.S. contract radiation player today," but alleged that Synergy was "an actual potential entrant with its x-ray sterilization business, which would substantially augment its competitive significance."[17] The FTC contended that the acquisition of an actual potential competitor violates Section 7 if four conditions are met: (1) the relevant market is highly concentrated; (2) the competitor "probably" would have entered; (3) its entry would have had pro-competitive benefits; and (4) there are few other firms that can enter effectively.[18]

While the defendants challenged the validity of the actual potential competition doctrine, the District Court reasoned that the FTC had clearly endorsed the theory by filing the complaint and the administrative law judge would be employing it during the administrative proceeding. For purposes of deciding the likelihood of success on the merits, the District Court therefore assumed the validity of the doctrine and instead focused on whether the FTC was likely to win based on the evidence. In doing so, Judge Polster essentially left the doctrine exactly as it was, neither hurt nor helped, which preserves the agency's

[16] Compl. ¶ 4.

[17] *Id.* ¶ 11.

[18] *Steris Corp.*, 2015 WL 5657294, *3.

ability to continue to pursue it as a theory of harm in negotiated settlements of merger matters.

The District Court held a three-day hearing, considering testimony from seven witnesses. Prior to the hearing the court directed counsel to focus on the second prong of the FTC's actual potential competition doctrine, i.e. whether, absent the acquisition, the evidence shows that Synergy "probably" would have entered the U.S. contract sterilization market by building one or more x-ray facilities within a reasonable period of time. While Judge Polster described that question as "prong two" of the FTC's four-pronged set of elements, it is also the same question presented as "essential precondition" number one in *Marine Bancorp*.

In attempting to meet its burden, the FTC pointed to the fact that Synergy had publicly committed to introducing its x-ray technology into the United States. While these plans were apparently scrapped about four months after the merger announcement, the FTC contended that the project's termination was the result of the proposed merger: "the Merger would allow Steris to insulate itself against this competitive threat, which would have targeted Steris and Sterigenics' customers, especially its core gamma sterilization customers, and resulted in lower prices, improved quality, and increased choice for contract sterilization."[19] Further, the FTC argued that any documents or statements made after the merger announcement stating otherwise should be treated with skepticism because they are subject to manipulation "as appears to have occurred here."[20]

FTC Crashes into High Evidentiary Barriers in Steris/Synergy Case

The District Court's extensive evidentiary examination focused on many of the factors that *Marine Bancorp* directed courts to consider, including

[19] Compl. ¶ 2.

[20] Memorandum in Support of Plaintiff Federal Trade Commission's Motion for Temporary Restraining Order and Preliminary Injunction at 12 n.75, *FTC v. Steris Corp*., No. 15-cv-1080 (ECF No. 21).

evaluating Synergy's interest in entering the U.S. market, its economic incentives, the capabilities and expansion history of Synergy, and the performance of the sterilization market in terms of supply and demand conditions. In doing so, the judge determined that the evidence "unequivocally shows that the problems that plagued the development of x-ray sterilization as a viable alternative to gamma sterilization in 2012…were the same problems that justified termination of the [U.S.] project in 2015: the failure to obtain customer commitments and the inability to lower capital costs."[21]

The District Court viewed Synergy's decision to terminate its U.S. x-ray plans as completely independent from the decision to merge with Steris, and that it was unlikely that Synergy would enter the U.S. in the absence of the transaction. The District Court assessed Synergy's normal-course project approval process in great detail, including how it had been implemented in past projects, and determined that Synergy was unlikely to receive approval from its Board because the project proposal failed to meet any of the objective profitability hurdles required in order to make such an investment.

The lynchpin in the District Court's decision was the substantial evidence showing how much effort Synergy put in to trying to secure customer commitments. Synergy's normal corporate practice was to secure take-or-pay contracts before making a significant capital investment. Not one customer would enter into a take-or-pay contract for x-ray sterilization in the U.S. and only six out of 185 customers would even agree to enter into a non-binding letter of intent. Further, testimony from the FTC's own witnesses, which included two customers, demonstrated that their "interest in x-ray sterilization was primarily academic." The District Court further found that there were significant barriers to customers switching to x-ray sterilization, including substantial costs and FDA approval requirements.

[21] *Steris Corp.*, 2015 WL 5457294, *22.

Additionally, the costs of the project would consume Synergy's entire annual discretionary capital budget. Synergy had only $25 - $40 million per year budgeted for capital projects, and the cost to build two x-ray facilities was projected to exceed that amount. The Court referred to the potential investment as a "bet the farm" proposition, where very little risk could be tolerated. In the end, the costs of entry combined with a complete lack of customer support led the court to conclude that the FTC had not proven that it was likely to succeed on the merits.

Will The Trend Towards Pre-Litigation Settlement in Mergers Based on Theories of Actual Potential Competition Continue Post-*Steris*?

Given the FTC's loss in *Steris* why would parties continue to settle based on a speculative theory of harm? We take our cue here from the settlement record between the FTC and parties in the pharmaceutical industry, even after the FTC suffered a major loss in *Lundbeck*.

Historically, nearly all FTC challenges to pharmaceutical mergers have been resolved, most often with the merging parties agreeing to divest or license a few drugs to address FTC concerns. In 2011, the FTC suffered a significant loss in the first-ever appellate antitrust decision dealing with a pharmaceutical industry merger. In *Federal Trade Commission v. Lundbeck, Inc.*, the Eighth Circuit affirmed the District Court's ruling that the FTC failed to prove that the two drugs at issue, Indocin and NeoProfen, were in the same relevant market, even though both drugs were used to treat the same clinical indication, a serious and potentially deadly congenital heart defect affecting premature babies.[22] The District Court was persuaded by testimony from doctors, who were determined to be the products' "consumers" for purposes of the antitrust analysis. The Court found that doctors prescribed the drugs based on their effectiveness and side-

[22] *FTC v. Lundbeck, Inc.*, 650 F.3d 1236 (8th Cir. 2011).

effect profile without paying attention to price, indicating a low cross-elasticity of demand between the two drugs.

Lundbeck remains the only litigated merger case in the pharmaceutical industry, with parties continuing to settle by agreeing to divestitures or other remedies.[23] While *Lundbeck* specifically highlights the litigation risk the FTC faces relating to market definition in the pharmaceutical industry, the case has not dramatically moved the needle when it comes to leverage at the negotiating table. Similarly *Steris* highlights the litigation risk the agencies face in actual potential competition matters, but that Achilles heel is equally unlikely to change the government's leverage in reaching settlement.

Potential competition concerns often arise in large deals combining firms that sell a broad portfolio of products, the vast majority of which do not raise competitive concerns. Rather than holding up the entire deal pending lengthy litigation proceedings, parties often agree to divestitures in order to close quickly. The same incentives for merging parties to settle quickly in order to realize the efficiencies and benefits of the broader transaction apply with equal force with respect to the precedent that *Steris* provides in actual potential competition cases.

Predicting the Future of Matters Involving Future Competition Concerns

The actual potential competition theory—while speculative, unendorsed by the Supreme Court, and recommended for abandonment by the leading antitrust treatise[24]—plays a powerhouse role in the agencies' enforcement arsenal.

[23] Very often these settlements are based on a theory of actual potential competition involving "pipeline" products under development. The theory is that competition would be increased if the pipeline product succeeds in coming to the market, and that the acquiring firm that already offers a competing product would no longer have the incentive to continue to invest in innovation and development of the potentially competing future products.

[24] *See* Philip E. Areeda & Herbert Hovenkamp, Antitrust Law: an Analysis of Antitrust Principles and Their Application ¶ 1134 (2015) ("Analyzing potential competition mergers required heroic speculation about likely or probable events, and the competitive consequences of the potential rivals' entry by alternative means. In order for the theories to work, markets had to have sufficiently high entry barriers so that nearly all firms were unlikely entrants, but yet there had to be a small number of firms with an identifiable entry advantage that made them sufficiently likely

Both the FTC and the DOJ increasingly express concern regarding reduction in future competition with respect to price, quality and innovation. Signaling what would come, references to potential competition concerns were woven throughout the agencies' 2010 Horizontal Merger Guidelines (the "2010 Guidelines"). In a shift from the guidelines issued in 1992 and 1997, the 2010 Guidelines expressly contemplate harm from a merger of a large incumbent and its potential competitor,[25] indicate that "committed entrants"[26] will be included as market participants, introduce the concept of "rapid entrants"[27] as market participants, and insert an entirely new section on innovation competition.

Unlike the previous guidelines, the 2010 Guidelines set out an analytical framework to assess whether a transaction may "diminish innovation competition by encouraging the merged firm to curtail its innovative efforts."[28] The 2010 Guidelines theorize that where a firm is engaged in efforts to introduce new products that would capture substantial revenues from the other merging firm, incentives to continue existing product development efforts may diminish. They also posit that innovation may decline where a merger would combine two of a small number of firms with the capabilities to successfully innovate in a specific direction.

In the years since release of the 2010 Guidelines, dozens of enforcement actions resulting in settlement based on potential competition issues illustrate the

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entrants…In sum, applying the potential competition doctrines generally required tribunals to pile one highly speculative conclusion upon another, resulting in an unacceptable propensity for error.").

[25] "In analyzing mergers between an incumbent and a recent or potential entrant, to the extent the Agencies use the change in concentration to evaluate competitive effects, they will do so using projected market shares. A merger between an incumbent and a potential entrant can raise significant competitive concerns. The lessening of competition resulting from such a merger is more likely to be substantial, the larger is the market share of the incumbent, the greater is the competitive significance of the potential entrant, and the greater is the competitive threat posed by this potential entrant relative to others." U.S. Dep't of Justice & Fed. Trade Comm'n, Horizontal Merger Guidelines (2010) at § 5.2.

[26] 2010 Guidelines § 5.1

[27] *Id*.

[28] 2010 Guidelines § 6.4.

agencies' increased reliance on this theory—in industries ranging from generic pharmaceuticals, to medical devices, to cross platform audience measurement. With no sign of abatement in the enforcement trend relating to future competition, here we ask and answer the question: what is "just around the corner" for these theories of harm?[29]

The cliché "you can't know where you are going until you know where you've been" is an appropriate starting point to respond to the question.[30] Below we review some of the most recent enforcement actions based on an alleged loss of actual potential competition.

Innovation Competition Continues as a Central Issue in High Tech Mergers

It is now crystal clear that innovation competition is an important issue for enforcers. As one senior Antitrust Division official emphasized, "protecting innovation is often a decisive factor in our enforcement decisions," and evidence of "pre-merger 'one-upmanship' is a significant red-flag."[31] Emblematic of these types of concerns, the FTC's challenge to media research company Nielsen Holdings NV's acquisition of Arbitron Inc. is especially striking. In that matter, both firms were developing national syndicated cross-platform audience measurement services, which allow audiences to be measured accurately across multiple platforms, such as TV and online.

[29] FTC Chairwoman Edith Ramirez has indicated that "Effective merger enforcement requires that we look carefully at likely competitive effects that may be just around the corner…" *See* Press Release, "FTC Puts Conditions on Nielsen's Proposed $1.26 billion Acquisition of Arbitron" (Sept. 20, 2013) (quoting FTC Chairwoman Edith Ramirez), https://www.ftc.gov/news-events/press-releases/2013/09/ftc-puts-conditions-nielsens-proposed-126-billion-acquisition.

[30] In sage commentary on this old adage, James Burke observed "Why should we look to the past in order to prepare for the future? Because there is nowhere else to look."

[31] Renata B. Hesse, Deputy Assistant Attorney General for Criminal and Civil Operations, Antitrust Division, U.S. Dept. of Justice, "At the Intersection of Antitrust & High-Tech: Opportunities for Constructive Engagement," Remarks as Prepared for the Conference on Competition and IP Policy in High-Technology Industries (Jan. 22, 2014), https://www.justice.gov/atr/file/517776/download.

The FTC contended that as a result of the acquisition, advertisers, ad agencies and programmers would likely pay more for such services because Nielsen and Arbitron were best positioned to introduce such products, as were the only firms with the technology, assets and brand recognition necessary to enter. While acknowledging that competitive effects can be difficult to predict when a product is not yet on the market, a majority of FTC commissioners reasoned that merger enforcement should interdict competitive problems in their incipiency and that "certainty about anti-competitive effect is seldom possible and not required for a merger to be illegal."[32]

FTC Chairwoman Ramirez asserted that "[e]ffective merger enforcement requires that we look carefully at likely competitive effects that may be just around the corner."[33] According to the FTC, "Under the order, the acquirer will get everything it needs to replicate Arbitron's participation in a national syndicated cross-platform audience measurement service. The order also contains terms designed to ensure the success of the acquirer as a viable competitor, such as requiring that Nielsen provide technical assistance and remove barriers that might otherwise keep the acquirer from hiring key Arbitron employees."[34]

While a majority of the FTC commissioners signed off on this enforcement action, it was not without controversy. One Republican commissioner acknowledged the FTC's "institutional limitations" and the "present inability of economic theory and evidence to support confident and reliable prediction" in a passionate dissent in *Nielsen Holdings*, stating:

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[32] *In re Nielsen Holdings N.V. and Arbitron Inc.*, File No. 131-0058, Statement of the Federal Trade Commission (Sept. 20, 2013) (*citing* 2010 Horizontal Guidelines § 1), https://www.ftc.gov/system/files/documents/cases/140228nielsenholdingstatement.pdf.

[33] Press Release, "FTC Puts Conditions on Nielsen's Proposed $1.26 billion Acquisition of Arbitron" (Sept. 20, 2013) (quoting FTC Chairwoman Edith Ramirez), https://www.ftc.gov/news-events/press-releases/2013/09/ftc-puts-conditions-nielsens-proposed-126-billion-acquisition.

[34] *Id*.

> [I]t is inherently more difficult in future market cases to define properly the relevant product market, to identify likely buyers and sellers, to estimate cross-elasticities of demand or understand on a more qualitative level potential product substitutability, and to ascertain the set of potential entrants and their likely incentives.[35]

As in *Nielsen Holdings*, which involved two parties that allegedly constantly vied against one another, "one-upmanship" was also at issue in the FTC's challenge to Integrated Device Technology's proposed acquisition of PLX Technology. The FTC's complaint emphasized that the two semiconductor manufacturers frequently competed to add features and functionality to their products, and that the acquisition would eliminate such competition.[36] Similarly, in *United States v. Bazaarvoice* the DOJ's complaint focused on and highlighted company documents suggesting that competition between the merged firms had been an important driver of each company's innovation.[37]

The proposed transaction between Applied Materials and Tokyo Electron hit a dead-end due to, at least in part, concerns relating to future competition in innovation. According to press reports, DOJ staff had informed the companies that their proposed US$29 billion merger—which would have combined the #1 and #3 firms in the semiconductor manufacturing equipment industry—raised significant competitive concerns. Staff further indicated that the divestiture scenario they offered was not sufficient to remedy the agency's concerns. Ultimately the parties abandoned the transaction.

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[35] Dissenting Statement of Commissioner Joshua D. Wright (Sept. 20, 2013), https://www.ftc.gov/sites/default/files/documents/cases/2013/09/130920nielsenarbitron-jdwstmt.pdf.

[36] *In re Integrated Device Technologies, Inc. and PLX Technology, Inc*., File No. 121-0140, Administrative Complaint (Dec. 18, 2012), https://www.ftc.gov/enforcement/cases-proceedings/121-0140/integrated-device-technology-inc-plx-technology-inc-matter.

[37] Complaint, *United States v. Bazaarvoice, Inc*., Docket No. 13-cv-00133-WHO (N.D. Cal. Jan. 10, 2013).

A senior Antitrust Division official commented that, "The semiconductor industry is critically important to the American economy, and the proposed remedy would not have replaced the competition eliminated by the merger, particularly with respect to the development of equipment for next-generation semiconductors."[38] Emphasis on 'equipment for next-generation semiconductors' reflects the DOJ's ongoing interest in preserving technology competition not only in terms of price, but also in innovation.

Future Competitive Effects are a Focus in Generic Pharma Markets

In assessing the potential competitive effects of generic drug mergers, the FTC often expresses concern that a proposed transaction may substantially reduce competition by eliminating a future competitor whose impending entry may further increase competition. In discussing application of the actual potential theory of competitive harm, one FTC official explained:

For many years, the Commission has been concerned about the elimination of a future competitor in markets for generic pharmaceuticals, either where one firm has an FDA-approved generic product and the other firm is working to introduce another generic version, or where the merging firms are two of only a limited number of likely entrants. In either scenario, the competitive concern is that the acquisition would likely delay the introduction of a generic version and thereby deprive consumers of the increased competition and likely price reductions that would have occurred.[39]

There are many examples of the FTC taking enforcement action against a generic pharmaceutical merger based on the actual potential competition theory,

[38] Press Release, "Applied Materials Inc. and Tokyo Electron Ltd. Abandon Merger Plans After Justice Department Rejected Their Proposed Remedy" (Apr. 27, 2015) (quoting Deputy AAG Renata B. Hesse), https://www.justice.gov/opa/pr/applied-materials-inc-and-tokyo-electron-ltd-abandon-merger-plans-after-justice-department.

[39] Deborah L. Feinstein, Director, Bureau of Competition, Federal Trade Commission, Director's Report Spring 2015 at 9 (2015), https://www.ftc.gov/system/files/documents/public_statements/637441/bc_directors_report_-_spring_2015.pdf.

alleging the acquisition will delay the introduction of a generic version of a brand pharmaceutical. The *Actavis/Warner Chilcott* enforcement action is illustrative of the agency's concern and reliance on the actual competition theory. Among other demands, the FTC required divestitures of the rights to three generic drugs under development to resolve charges that Actavis' proposed $8.5 billion acquisition of Warner Chilcott would be anti-competitive.[40] In each of the three alleged markets, Warner Chilcott offered a branded drug in a market in which no generic equivalent had yet been introduced. The FTC required divestitures in all three markets, asserting that Actavis' products were likely to be the first generic competitors to Warner Chilcott's branded versions, and that the transaction would harm future competition because the combined firm would have the incentive to delay generic entry in each market.

The actual potential entry theory was also a factor in the FTC's proceedings against Impax's proposed $700 million acquisition of CorePharma LLC. In that matter, the FTC required the divestiture of CorePharma's rights and assets to generic pilocarpine tablets, used to treat dry mouth, and generic ursodiol tablets, used to treat biliary cirrhosis and gall bladder diseases.[41] With regard to generic pilocarpine tablets, the FTC complaint alleged that only two suppliers marketed the product, and that, while neither Impax nor CorePharma had yet entered this product, they were the only likely new entrants in the near future.

With regard to the generic ursodial tablets, there were four existing suppliers competing in the market, including Impax. At the time of the merger, CorePharma was alleged to be one of a limited number of firms likely to enter the market in the near future. While the merger would not have reduced the number of current generic suppliers below four, the FTC insisted on a divestiture of

[40] *In re Actavis, Inc. and Warner Chilcott PLC*, FTC No. 131-0152, Final Decision and Order (Dec. 11, 2013), https://www.ftc.gov/sites/default/files/documents/cases/131_0152_c4414_actavis_warner_decision_and_order_public_version.pdf.

[41] *In re Impax Laboratories, Inc., et al.,* FTC No. 151-0011, Complaint (Mar. 6, 2015), https://www.ftc.gov/system/files/documents/cases/150305impaxcmpt.pdf.

CorePharma's pre-market generic ursodiol assets, due in part to recent industry supply shortages.

In another matter, to complete its $4 billion acquisition of Ranbaxy Laboratories Ltd., Sun Pharmaceuticals was required to divest Ranbaxy's interests in generic minocycline tablets and capsules, which are used to treat a wide array of bacterial infections. According to the FTC's complaint, the proposed merger would likely have harmed future competition by reducing the number of suppliers of generic minocycline tablets because Ranbaxy was one of three firms currently supplying tablets and Sun was one of only a limited number of firms with minocycline tablets in development and an ANDA under review by the FDA.[42]

In its enforcement action against Mylan's proposed $1.85 billion acquisition of Agila Specialties, the FTC alleged that the deal would have reduced competition, either by eliminating current competition in concentrated existing markets, or by eliminating potential competition among a small number of actual future competitors. The agency required divestures of 11 generic injectable drugs before allowing the merger to proceed.

The FTC's challenge regarding meropenem, an ultra-broad spectrum antibiotic used as a last resort to treat serious bacterial infections in an intensive care setting, was particularly remarkable.[43] The FTC's complaint acknowledged that there were four existing market participants and others in addition to Mylan and Agila with a generic in development. Even though neither Mylan nor Agila had a meropenem product on the market, the FTC contended that divestiture was necessary because the four existing competitors used two sources of supply, and

[42] *In the Matter of Sun Pharmaceutical Industries Ltd, Ranbaxy Laboratories Ltd, and Daiichi Sankyo Co, Ltd*, File No. 141-0134, Complaint (Jan. 30, 2015), https://www.ftc.gov/system/files/documents/cases/150130sunranbaxycmpt.pdf.

[43] *In re Mylan Inc., Agila Specialties Global Pte. Limited, Agila Specialties Private Limited*, *and Strides Arcolab Limited*, FTC No. 131- 0112, Complaint (Sept. 26, 2013), https://www.ftc.gov/sites/default/files/documents/cases/130926mylancmpt.pdf.

Mylan and Agila were the only likely entrants that would use alternative suppliers.

Continuing the line of FTC enforcement actions where neither party had a product on the market yet and were each therefore an "actual potential competitor" in the market, the FTC required divestitures to resolve charges that Endo Health Solutions' proposed acquisition of Boca Life Science Holds and Boca Pharmaceutical would have reduced competition among generic drugs. The FTC there required divestitures in two generic markets "that [did] not yet exist," alleging that the merging parties were two of only a few likely entrants into those future markets, which the FTC alleged would be highly concentrated at the time the firms entered. [44] The FTC also required a divestiture in one market with two incumbent generic competitors where Endo had previously commercialized a product but withdrew it from the market and Boca was alleged to be the next likely entrant. The FTC indicated that Endo "could relaunch its product at any time" and the merger therefore could reduce the number of competitors from four to three.[45]

Innovation Concerns Remain a Central Issue in Life Sciences Mergers, Including Pioneer Drugs and Medical Devices

The FTC continues to challenge mergers between competing pioneer drug firms and medical device manufactures based on a theorized reduction in actual potential competition, often requiring multiple divestitures to resolve competitive concerns. Novartis/GlaxoSmithKline is illustrative of the trend. In order for Novartis to move forward with its $16 billion acquisition of GlaxoSmithKline's portfolio of cancer-treatment drugs, it was required to divest assets related to BRAF and MEK inhibitor drugs to Array BioPharma. At the time that the

[44] *In re Endo Health Solutions Inc*., FTC No. 131-0225, Analysis of Agreement Containing Consent Orders to Aid Public Comment (Jan. 31, 2014), https://www.ftc.gov/system/files/documents/cases/140131endobocaanalysis.pdf.

[45] *Id.*

transaction was announced, the FTC alleged that Novartis and GSK were two of a small number of companies with either a BRAF or MEK inhibitor currently on the market or in development, and two of only three companies marketing or developing a BRAF/MEK combination product to treat melanoma.[46]

Without a remedy, the FTC alleged that the transaction would eliminate likely future competition between GSK and Novartis in the markets for BRAF and MEK inhibitors because Novartis likely would have obtained FDA approval for and launched its LGX818 and MEK162 products in the near future in direct competition with GSK's combination offering for treating metastatic melanoma patients.[47] The FTC also asserted that the transaction would likely reduce the development of BRAF and MEK inhibitors to treat other types of cancer because GSK and Novartis were each currently developing their respective BRAF and MEK inhibitors for several of the same indications in addition to treating melanoma.

Similarly, the FTC raised concerns about the elimination of future competition in connection with Medtronic, Inc.'s proposed $42.9 billion acquisition of Covidien. Medtronic said the acquisition would expand its product portfolio and allow it to better compete with Johnson & Johnson, the largest medical device company. But the FTC contended that the U.S. market for drug-coated balloon catheters was highly concentrated with only one current supplier, CR Bard, Inc., and that Medtronic and Covidien were the only likely near-term new entrants to this market. [48] To resolve the FTC's concerns, Medtronic agreed to divest Covidien's drug-coated balloon catheter assets.

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[46] *In re Novartis AG and GlaxoSmithKline,* FTC No. 141-0141, Complaint (Feb. 23, 2015), https://www.ftc.gov/system/files/documents/cases/complaint_0.pdf.

[47] *In re Novartis AG and GlaxoSmithKline,* FTC No. 141-0141, Analysis of Agreement Containing Consent Orders to Aid Public Comment (Feb. 23, 2015), https://www.ftc.gov/system/files/documents/cases/analysis_0.pdf.

[48] *In re Medtronic, Inc. and Covidien plc*, FTC No. 141-0187, Analysis of Agreement Containing Consent Orders to Aid Public Comment (Nov. 26, 2015), https://www.ftc.gov/system/files/documents/cases/141126medtronicanalysis.pdf.

Conclusion: When Will the Next Unicorn Come and What to Expect Until Then

The above-described enforcement actions demonstrate the agencies' heightened focus on potential harm from elimination of actual potential competition, illustrating the range of theories that have been alleged to date. Due to the forces that drive settlement negotiations *Steris* is unlikely to significantly change the frequency or dynamics in negotiating settlements in potential competition matters, although that could change on the margins. Cases most likely to head towards litigation include those that can't be effectively remedied, like in *Steris*.

While it did not advance the resolution of whether the actual potential competition theory is viable, the *Steris* decision is valuable in providing an analytical framework that will assist merging parties in assessing potential risk and defending matters involving actual potential competition. Equally, it provides guideposts to the agencies in how they may potentially succeed in litigating a potential competition case by overcoming the *Marine Bancorp* barriers.

The FTC's decision not to appeal the District Court's *Steris* decision reflects that the agency is content to move forward without clarity on the viability of the doctrine because that result is better than testing the limits and risking a "bad answer" to that question, which would shake the credibility of the agency alleging the theory in negotiated settlements. If other District Courts adopt the analytical approach employed by Judge Polster in *Steris*, it may be unlikely that any District Court will take a position on the validity of the theory. In those circumstances, if the FTC loses again at the District Court level based on that theory of harm, it is unlikely the agency will ever appeal, just as it did not appeal *Steris*.

On the flip side, if the FTC does succeed at the District Court level based on the actual potential competition doctrine, whether the merging parties will

appeal and proceed to bear the time and cost burdens of administrative litigation also may be unlikely. With this potential stalemate, it may be decades before the next unicorn comes, where a court takes a position on the issue, and even more unlikely that the case would rise to the level of the Supreme Court. And even then, there is no guarantee the Court would expound on the viability of the theory under Section 7.

In the meantime, the FTC and DOJ are likely to continue developing theories of potential harm to future competition employing novel concepts like "rapid entrants," which have not be widely utilized since the 2010 Merger Guidelines were released. Theories relating to potential harm to innovation are also likely to continue unaffected by *Steris*, especially in high tech and life sciences merger matters.