Theoretical Competition: FTC v. Steris, and the Viability of the Actual Potential Entrant Doctrine

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I. Introduction.

The healthcare industry is rapidly consolidating at every level. The majority of this consolidation has been within the hospital sector of the industry, and naturally Federal Trade Commission (“FTC”) scrutiny has followed along with it.1 While the discussion of whether the antitrust laws fit within the healthcare industry in general has more recently become a robust debate,2 the FTC has had substantial success in recent years challenging mergers that allegedly threaten competition in both the hospital and pharmaceutical industries.

When considering consolidation in the healthcare industry, one does not immediately think of the medical device sterilization market. Furthermore, the acquisition by a large domestic firm of a smaller international firm with no U.S. presence would not by itself raise any immediate threats to U.S. competition. However, the Steris-Synergy deal involved the duopolistic sterilization market and the purchase of an entity with a plan to enter and disrupt the U.S. market by the second largest entity in that market. This deal gave rise to one of the rare instances where the FTC challenged a merger based on the purchase of a potential competitor using the actual potential entrant theory.

The actual potential competitor theory under § 7 of the FTC Act provides a viable means for the FTC to challenge deals that may adversely affect competition by preventing it from ever

1 See, e.g., Bruce Japsen, FTC Signals Aggressive Stance on Healthcare Mergers, FORBES (Dec. 19, 2015, 10:51 AM), http://www.forbes.com/sites/brucejapsen/2015/12/19/ftc-signals-aggressive-stance-on-healthcare-mergers/#2715e4857a0b36f88bd76f41
occurring.\(^3\) Despite the fact the FTC’s injunction was denied and no appeal will be filed,\(^4\) the court’s decision is limited to the facts of the case, and does not negate the viability of the actual potential entrant theory. This article will examine the now-completed deal between Steris and Synergy, the FTC’s challenge, and where the Northern District of Ohio’s decision leaves the actual potential entrant theory for future challenges.

II. The Steris Acquisition of Synergy

a. Understanding the device sterilization industry

Steris’ Acquisition of Synergy implicated the medical device contract sterilization services market. There are three commonly employed means of sterilizing a medical device consistent with FDA requirements: gamma radiation, e-beam radiation, and EO gas sterilization.\(^5\) Gamma radiation is the most popular type of sterilization due to its thorough process that works best for implantable medical devices.\(^6\) EO gas and e-beam are less favored for medical devices due to their processes resulting in less cost efficient or less effective sterilization.\(^7\) A potential alternative to these three current methods is x-ray radiation sterilization. X-ray sterilization is proposed as equally effective to gamma radiation as a means of sterilization for medical devices, but there has never been a facility built in the U.S. with x-ray sterilization capabilities that meet FDA requirements and are cost efficient enough to justify a switch from gamma radiation.\(^8\)

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\(^3\) For a general overview of the economic theory underlying the actual potential entrant theory, see generally P. Dasgupta & J.E. Stiglitz, Potential Competition, Actual Competition, and Economic Welfare, 32 EUR. ECON. REV. 569 (1988) (explaining the developing of the economic theory behind the actual potential entrant legal theory later employed by the FTC).


\(^5\) Complaint at 2, Steris Corp., No. 9365 (FTC dismissed Oct. 30, 2015)[hereinafter Administrative Complaint].

\(^6\) Id.

\(^7\) Id.

\(^8\) See id. at 8.
Sterilization services are either provided by a contract provider or done in-house. In-house sterilization is extremely expensive to do properly, leaving only the largest device manufacturers with the capability to do it. Thus, the sterilization contract services market provides the majority of sterilization services to the healthcare industry. The sterilization market consists of several players, but North American firms generally have the largest global market share. The two largest contract sterilization firms in the world are Sterigenics and Steris, and prior to the merger, followed by Synergy as the third largest.

b. The Proposed Acquisition and Initial Challenge

Steris and Synergy came to an agreement for Steris to acquire Synergy for $1.9 billion, while maintaining its tax base in the U.K. in a tax-inversion deal. At the time of the acquisition, Synergy had no major U.S. operations, and Steris announced the motivation behind the deal was to make inroads into the European market. At a surface-level view the deal looked rather mundane from a U.S. antitrust perspective. However, in the years leading up to the deal Synergy had pursued an extensive strategy to bring x-ray sterilization to the United States. The FTC believed that the x-ray technology was imminently going to be brought to the United States as a new means of competition to the gamma-ray business of Steris and Sterigenics. The FTC, viewing the acquisition as a means of Steris eliminating future competition, challenged the deal

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9 Id. at 3.
10 Id. at 10-11.
13 Id.
in May 2015. Shortly thereafter, the FTC filed for a temporary restraining order and preliminary injunction in the Northern District of Ohio.

III. The FTC Actual Potential Competitor Argument

a. Legal Background

The FTC’s suit alleged both a violation of §5 of the FTC Act claim for employing an unfair method of competition resulting in an illegal agreement, and of §7 of the Clayton Act as an illegal acquisition. §5 of the FTC Act provides the FTC jurisdiction to intervene in instances where an individual or an entity is engaged in an unfair method of competition affecting commerce. § 7 of the Clayton Act grants the FTC the ability to prevent acquisitions that would tend to substantially lessen competition or create a monopoly. Under § 13(b) of the FTC Act, the FTC may seek an injunction to prevent a violation or potential violation of a law it enforces.

The 2010 joint FTC-DOJ guidance for horizontal agreements notes that the FTC and DOJ consider “mergers and acquisitions involving actual or potential competitors”, but does not provide a definition for a potential competitor. Instead, the Supreme Court has indicated that a potential competitor is a firm that 1) has an “available feasible means” for entering the market and 2) those means create a substantial likelihood of increasing competition and decreasing concentration of that market. The FTC utilized the “actual potential entrant” theory in litigating

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15 See id.
19 See U.S. DEP’T OF JUS. & FED. TRADE COMM’N, HORIZONTAL MERGER GUIDELINES 1 (2010).
20 See U.S. v. Marine Bancorporation, Inc., 418 U.S. 602, 633 (1974). The Court specifically cites U.S. v. Falstaff Brewing Corp., 410 U.S. 526 (1973) to examine the perceived potential entrant theory. Id. at 624. “In other words, the Court has interpreted § 7 as encompassing what is known as the wings effect--the probability that the acquiring
the case. Under this theory, the FTC claimed that the acquisition of a potential entrant into a market violates §7 of the Clayton Act when 1) the relevant market is highly concentrated; 2) the competitor “probably” would have entered the market; 3) its entry would have had pro-competitive effects; and 4) there are few other firms that can provide the same level of competition.\footnote{FTC v. Steris Corp., 2015 WL 5657294 at *3 (N.D. Ohio Sept. 24, 2015).}

In analyzing a merger, the standard process is to examine the relevant product markets, looking particularly at the effect of a small but significant increase in price (SSNIP) on consumer choice of competing products. Next, a court examines the relevant geographic markets for concentration, giving particular weight to Herfindahl-Hirschman Index (HHI) as an indicator of concentration within a given market. Finally, a court will look to whether there are high barriers of entry to get into the market, and the total anti-competitive effects resulting from the proposed combination, along with any merger-specific pro-competitive benefits.

b. FTC Arguments

Although the trial documents filed are heavily redacted, a great deal of information on the FTC’s perspective of using harm to future competition can be gleaned. The FTC found the relevant product market to be contract radiation sterilization services, and sought to narrow the market only to gamma and x-ray sterilization services for healthcare device manufacturers that could not switch to e-beam sterilization.\footnote{Memorandum in Support of FTC Motion for Temporary Restraining Order and Preliminary Injunction at 8, FTC v. Steris Corp., 2015 WL 5657294 (N.D. Ohio, Sept 24, 2015), No. 15-cv-01080.} The FTC’s product market definition placed Steris in a position where it could allegedly target and price discriminate against customers who could not afford to do sterilization in house or economically switch to another form of sterilization.
The FTC next included the 500-mile radius around any particular sterilization plant as the geographic market. The logic behind this geographic market argument was that Synergy’s plans indicated that it would imminently open up sterilization plants in markets directly competing with Steris and Sterigenics. Thus, the merger’s effect would be to remove a competitor that although not currently in its geographic market at all, would be entering and competing in that market but for the merger.

The remainder of the FTC’s argument was largely based on Synergy’s extended plan to bring x-ray technology to sterilization facilities in the U.S. The FTC argued that the merger’s purpose was to prevent Synergy from entering the U.S. market, preventing any possible challenger to the current market structure. Effectively, the FTC believed that Synergy’s stated financial difficulties in bringing x-ray sterilization to the U.S. were not sufficient to deter their plan to bring the technology to the U.S. Rather, the argument was that the merger constituted a favorable deal for Synergy that was designed to eliminate an imminent competitor. The FTC concluded that Synergy’s imminent entrance would have benefited consumers, and decreased market concentration.

IV. The Decision on the Injunction

The court’s rejection of the FTC’s position is significant for two reasons. First, the court did not examine the FTC’s actual potential entrant theory on the basis that it was the theory that would be used in the administrative suit. Second, the court was critical of the FTC’s position...

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23 Administrative Complaint, supra note 5, at 12; see also Memorandum in Support of FTC Motion for Temporary Restraining Order and Preliminary Injunction at 13, FTC v. Steris Corp., 2015 WL 5657294 (N.D. Ohio, Sept 24, 2015), No. 15-cv-01080. (stating that without the merger, Synergy would enter and decrease total HHI by more than 200 points).

based on the facts presented, rather than the law, highlighting that the actual potential entrant theory may be viable under a better set of facts.

The judge’s findings on the FTC’s actual potential entrant theory provide substantial insight on the viability of the doctrine. The court stated the purpose of § 7 of the Clayton Act was to enable the FTC the ability to prevent a merger prior to its occurrence to prevent the substantial lessening of competition, noting Congressional intent to permit the FTC to challenge with a probability of lessening of competition, not the certainty of its occurrence.25 The court accepted the aforementioned four elements the FTC claimed constituted a violation of § 7 of the Clayton Act under the actual potential entrant theory, noting the defendants’ objection to it as disfavored by the Supreme Court.26 Instead, the court looked specifically to the second prong of the proposed test: whether Synergy probably would have entered the market.

The court found the evidence regarding Synergy’s likelihood of entering the U.S. market underwhelming. The testimony of various executives at Synergy indicated that although the project had moved into early phases of implementation, it had quickly exceeded the available budget, and the likelihood of being able to enter into the U.S. market without spending the company into debt was unlikely.27 Furthermore, Synergy had been unable to get customer commitments to industry-standard contracts, making it difficult to justify the risk of entering into the U.S. market. Even the x-ray machines that Synergy had entered into exclusive contracts to get had become increasingly expensive and unproven in their ability to effectively compete with gamma sterilization.28

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25 Id. at *3.
26 Id. at *22.
27 See id. at *15-*16
28 Id. at *20-*21.
The court further noted that the entry into the U.S. market did not have final board approval, was not financially feasible, and did not appear to have any likelihood of business success. The court additionally disagreed with the FTC’s timing argument. Instead, the court found that the business issues surrounding the move to the U.S. did not fully deter Synergy from entering the U.S. market after the merger was announced. Instead, the attempt to bring the x-ray facilities to the U.S. continued on for several months after the merger announcement, before recognizing it had become futile as a business strategy. As a result, the court rejected the FTC’s timing argument.

After denying the motion for temporary restraining order and preliminary injunction, the administrative law judge dismissed the complaint. The FTC announced shortly thereafter that it would not appeal either decision.29 The merger between the second largest and third largest sterilization firms for medical devices is now consummated, but the actual potential entrant theory survives for now.

V. Conclusion

The challenge of the Synergy acquisition was a case of unfavorable facts leading to a correct decision of law. The decision is unlikely to be influential in the development of the actual potential entrant theory in the ongoing waves of consolidation, but does indicate the FTC’s willingness to use such a theory. Outside of discussions of economic theory, the actual potential entrant theory has only been employed in a handful of cases, most of which were litigated in the late 70s or early 80s—the FTC’s most recent success with the theory occurred in 1981.30

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30 See Yamaha Motor Co. v. FTC, 657 F.2d 971, 980 (8th Cir. 1981).
The FTC’s willingness to utilize the theory again now, in an era where the agency has enjoyed unprecedented success, indicates the FTC may invoke it again with better facts with a higher likelihood of success. As a result, acquisitions where a potential entrant is acquired by a firm with a substantial market presence should be handled with caution. While the actual potential entrant theory is of some controversy in terms of economic realities, it remains for the moment a viable theory under law and will continue to be available to the FTC and other plaintiffs for the foreseeable future.