POTENTIAL AND NASCENT COMPETITION IN FTC MERGER ENFORCEMENT IN HEALTH CARE MARKETS

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I. INTRODUCTION

Popular interest in antitrust has been growing significantly in recent years, fueled in large part by a concern about what (if anything) can or should be done about "big tech." Critics argue that these companies owe their dominance, at least in part, to "hundreds of mergers," most of which involve what they term "nascent competitors."[2] While acquisitions of future competitors are gaining attention in the technology sector, the FTC has been scrutinizing these types of deals in the healthcare sector for years. Experience with the FTC's approach to these transactions may provide a roadmap to how the agency may evaluate transactions in other industries, including high tech, in the future.

The FTC considers the risk that a merger may lessen future competition under two related theories. One is the actual potential competition doctrine[3] of Section 7 of the Clayton Act, which condemns transactions between firms that do not currently compete, but may in the future, if certain criteria are met. Historically, the most difficult of those has been establishing the requisite likelihood that the entry will actually occur. The second involves looking at these transactions as a form of monopolization under Section 2 of the Sherman Act. Though that imposes a different set of requirements — particularly that one of the parties be a monopolist — it may accommodate less certainty that the non-incumbent will mature into a full-blown competitor. The difference between these two approaches can be seen by comparing the FTC's unsuccessful litigation to block the *Steris/Synergy* merger under Section 7, and its complaints that led to settlement and abandonment in the *Questcor/Novartis* and *Illumina/PacBio* deals under Section 2.

II. FUTURE COMPETITION THEORIES

A. Actual Potential Competition

Although the Supreme Court has not fully endorsed the actual potential competition doctrine, it set out the requirements for its successful invocation over forty years ago in the *Marine Bancorporation* case. According to the Court, a prerequisite for any potential competition case is that the market at issue be "substantially concentrated." Beyond that, it identified "two essential preconditions." The first is that the potential competitor must have "available feasible means for entering" the market other than through the merger in question. Second, "those means must offer a substantial likelihood of ultimately producing deconcentration of that market or other

2 See, e.g. Tim Wu & Stuart A. Thompson, "The Roots of Big Tech Run Disturbingly Deep," New York Times June 7, 2019, available at https://www.nytimes.com/interactive/2019/06/07/opinion/google-facebook-mergers-acquisitions-antitrust.html.

3 "Actual potential competition" differs from "perceived potential competition" in that the former focuses on the future effect of entry, while the latter is a form of current competition from a firm that is not (yet) actually in the market. The perceived potential competition theory requires evidence that the non-incumbent is already affecting competition in the market, which is often absent in future competition cases.

significant procompetitive effects."[4] In *Marine Bancorp*, the Court opted not to rule on the validity of the theory because it was satisfied that the entry could not occur due to the state banking regulatory regime, and formally reserved that question.

Subsequent cases accepted actual potential competition as a viable theory of harm, but most of the government's challenges failed. Courts, it turned out, were reluctant to find that the government had shown a sufficient likelihood the non-incumbent would actually enter, perhaps because many of these cases relied on "objective evidence" to show that the firm would enter. That is, the government asserted that the potential entrant had the incentive and ability to enter, so it likely would. Courts seemed suspicious of the government's hypothesizing, and established stiff probability requirements.[5] Some set the bar at "reasonable probability," "likely," or some close variant. Others required clear or unequivocal proof that the acquiring firm, in fact, would have entered the relevant market.[6] Some courts also added a temporal dimension by requiring proof that the hypothesized entry would occur in the near future.[7] By the time the FTC reconsidered the theory in 1984, it adopted a "clear proof" standard that was so strict that a concurring Commissioner declared that for "the Commission at least, actual potential competition theory is dead."[8]

About a decade later, the FTC began facing a string of mergers in the pharmaceutical sector, some of which raised important future competition questions. Unlike the earlier actual potential competition cases, in these there was ample "subjective evidence" — a commitment at the decisional levels of the companies, accompanied by substantial capital expenditures — that the parties were, in fact, *trying* to enter. But the development process often results in failure and FDA approval, is far from certain even for drugs that are in advanced clinical trials, so the language of the actual potential competition cases could have been an obstacle to challenging future overlaps in these cases. Nevertheless, the FTC has taken the view that because the pharmaceutical products at issue faced limited competition, new entry could produce significant pro-competitive benefits, even adjusting for the entry's probability of success.

B. Monopolization

Section 2 of the Sherman Act is directed at conduct by a monopolist. To be actionable, the conduct must be engaged in by a monopolist, be willful, and must be something other than competition on the merits. The latter requirement excludes a whole category of activity — for example, innovation or non-predatory aggressive pricing — that may harm competitors, but not competition, and therefore is not the type of conduct Section 2 prohibits. For the remainder, the question is whether the conduct is anticompetitive, whether there are genuine and legitimate business justifications for it, and, if so, whether its anticompetitive effect outweighs any procompetitive effect.[9]

Mergers can be a form of prohibited conduct under Section 2,[10] since, as some commenters have observed, nothing can be more certain to exclude a competitor than eliminating it altogether.[11] At the same time, the common belief is that Section 7 "requires much less" to prove a violation.[12] That may not be true, however, when the target is a future competitor because of the difference in way courts have treated potential competitors under Section 7 and nascent competitors under Section 2, respectively. While Section 7 decisions have permitted acquisitions when the non-incumbent's entry is less than "probable," Section 2 has taken a harsher view of conduct aimed at nascent competitors. As the *Microsoft* court stated, "it would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors, at will."[13] Applying that reasoning to mergers, acquisitions by monopolists of nascent competitors could be a form of anticompetitive conduct under Section 2.

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4 418 U.S. 602, 633 (1974).

5 Cf. *Id.* at 623 (stating that the government's case asked the Court "[t]o assume, *on the basis of essentially no evidence*, that the challenged merger will tend to produce a state-wide linkage of oligopolies[.]") (emphasis added))

6 See ABA Antitrust Section Antitrust Law Developments (8th ed.) (Cataloging the standards for the likelihood of entry potential courts have applied in actual competition cases).

7 BOC Int'l v. FTC, 557 F.2d 24, 28-29 (2d Cir. 1977).

8 See, e.g. B.A.T. Indus., 104 F.T.C. 852, 947 (1984).

9 *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966); *United States v. Microsoft*, 253 F.3d 34, 58-59 (D.C. Cir. 2001).

10 See, e.g. *Grinell*, 384 U.S. 563.

11 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 912b, at 92 (stating that an acquisition "tends to maintain a monopoly by cutting off an avenue of future competition before it has a chance to develop. As a result, condemnation under § 2 is appropriate").

12 *Fraser v. Major League Soccer, LLC*, 284 F.3d 47, 61 (1st Cir. 2002).

13 *Microsoft*, 253 F.3d at 59, 79.

The question of what qualifies as a nascent competitor thus becomes pivotal in a Section 2 merger case. In *Microsoft*, the court considered whether Microsoft's exclusionary practices toward middleware providers — Netscape and Java — could constitute anticompetitive conduct. In reaching the conclusion that it could, the court favorably referenced the district court's "ample findings" that these middleware providers "showed potential."[14] The district court's findings focused mostly on the *threat* they posed to Microsoft, including that (1) Microsoft viewed middleware as a threat to Windows; (2) the middleware providers strove to reduce reliance on Microsoft's OS; and (3) these views were shared by other industry participants.[15] Thus, the evidence that middleware posed a threat to Windows was sufficient to make them "nascent competitors."

It is important to stress that none of the district court's findings went to whether middleware had a substantial likelihood of displacing Windows or otherwise deconcentrating the market in the near future. Indeed, the *Microsoft* court emphasized that was not even germane to its inquiry. "[T]he question in this case is not whether Java or Navigator *would actually have developed* into viable platform substitutes."[16] The court also had no concern that "[i]t would take several years for middleware ... to evolve ... into a product that can constrain operating system pricing."[17] Areeda & Hovenkamp agree with this formulation as it applies to mergers. They would condemn an acquisition by a monopolist of "any firm that has the economic capabilities for entry and is a *more-than-fanciful possible entrant* ... unless the acquired firm is no different ... from many other firms."[18] Therein lies a fundamental difference between Section 2 and Section 7: Section 7 has been interpreted to require a counterfactual showing that, but for the merger, the market likely would become more competitive, while Section 2 focuses on whether the firm is a threat at the time of the acquisition.[19]

The final step in a Section 2 case is to assess any "procompetitive justification — a non-pretextual claim that [the monopolist's] conduct is indeed a form of competition on the merits because it involves, for example, greater efficiency or enhanced consumer appeal," and balance it against the anticompetitive effect of the acquisition.[20] Efficiency claims are common in merger cases, and there is an extensive body of Section 7 law and guidelines that could govern how the FTC and courts might asses them. Under the *Merger Guidelines* and case law, only verifiable, merger specific efficiencies qualify.[21] That filter may also apply in a Section 2 case. It is an open question, however, as to how the balancing of any remaining pro-competitive efficiencies against a merger's anticompetitive effect would play out, since courts rarely reach that stage in Section 2 cases. Regardless, merging parties could face an uphill battle in front of the antitrust agencies since the *Merger Guidelines* state, "Efficiencies almost never justify a merger to monopoly or near-monopoly,"[22] a view consistent with the "overwhelming, substantial" efficiencies Areeda & Hovenkamp would require in Section 2 merger cases.[23]

14 *Id.* at 79.

15 *United States v. Microsoft*, 84 F. Supp. 2d 9, 28-30 (D.D.C. 1999).

16 *Microsoft*, 253 F.3d at 79 (emphasis added).

17 *Id.* at 54.

18 Areeda & Hovenkamp, *supra* note 11, ¶ 701d.

19 *Accord*, *Microsoft*, 253 F.3d at 79 (quoting Areeda & Hovenkamp, Antitrust Law ¶ 650c (1996)) (stating that "courts [may] infer 'causation' from the fact that a defendant has engaged in anticompetitive conduct that 'reasonably appears capable of making a significant contribution to . . . maintaining monopoly power'").

20 *Microsoft*, 253 F.3d at 59.

21 See, e.g. U.S. Dep't of Justice & Fed. Trade Comm'n, 2010 Horizontal Merger Guidelines §10 (hereinafter "Merger Guidelines").

22 Merger Guidelines §10. The Guidelines state that they apply to "mergers and acquisitions involving actual or potential competitors ("horizontal mergers") under the federal antitrust laws," including Section 2. *Id.* §1.

23 Areeda & Hovenkamp, *supra* note 11, ¶ 701h (stating that they would require an "overwhelming demonstration that substantial efficiencies are involved and . . . cannot be achieved in other ways" when a monopolist seeks to acquire a nascent competitor)). This standard is similar to the "*extraordinarily great* cognizable efficiencies" requirement set out in the Merger Guidelines in instances "[w]hen the potential adverse competitive effect of a merger is likely to be particularly substantial." Merger Guidelines § 10 (emphasis added).

III. FUTURE COMPETITION IN FTC HEALTH CARE MERGER CASES

A. Section 7 Actual Potential Competition Cases

The Commission has challenged — and obtained divestitures in — numerous pharmaceutical merger cases under an actual potential competition theory where one (or both) of the merging parties had a product in development that could provide important competition to the other at some future date. The FTC's recent settlement in the *Bristol-Myers Squibb/Celgene* matter is a good example of the type of pharmaceutical case where it routinely seeks relief.[24] At the time of the deal, Celgene had a popular oral psoriasis drug on the market, Otezla, and BMS had an oral psoriasis drug in development that would compete closely and directly with Otezla, if approved. Although the drug development process is inherently uncertain and protracted, there was a strong, bi-partisan consensus that the relief was warranted, as there has been for years in similar cases.[25]

The FTC's challenge to the *Steris/Synergy* merger shows how difficult it can be to prove that entry is "probable" in litigation.[26] Steris Corporation was one of only two companies providing gamma-ray sterilization services to medical device firms in the United States, and Synergy Health plc was a British company that offered sterilization services around the world, but did not have gamma-ray sterilization capabilities in the United States. Synergy recognized this gap limited its attractiveness to some global players, so it was keen to bring this service the United States market. Its problem was that there were no available sources of the required radioactive material, so it had been developing a new, potentially superior, technology for several years. By the time of the merger, according to the complaint, Synergy was in the advanced stages of planning its entry into the United States, including negotiating for physical locations for its facilities, contracting for the required equipment, and assembling a U.S. sales and marketing team. Then, in the middle of the merger review process, the company terminated this effort — just after FTC staff advised Synergy of its concerns. At trial, Synergy officials testified that they had scuttled their plans for legitimate reasons, asserting that the uncertainty of the financial payback would have doomed the project before it would have made the investment. That post-acquisition rationale was enough for the court to be convinced that Synergy's entry into the United States was not "probable."

B. Section 2 Monopolization Cases Involving Acquisitions of Nascent Competitors

The FTC has brought two merger challenges under a Section 2 "nascent competition" theory in the past three years, one involving Questcor's acquisition of a drug from Novartis, and the other involving Illumina's proposed acquisition of Pacific Biosciences of California.[27] These cases had in common that they involved an acquisition by a monopolist of a firm that threatened the monopoly position, but faced considerable hurdles to entering and successfully competing. In both, the FTC appeared to be relying on Section 2 to sidestep the requirement in Section 7 case law that it prove that the entry was likely to be successful.

Mallinckrodt (which had acquired Questcor after the acquisition) involved an acquisition by the only U.S. supplier of adrenocorticotropic hormone ("ACTH"), a drug used to treat a rare form of epilepsy in infants, among other applications. In other parts of the world, a synthetic analog, Novartis's Synacthen, was used instead of Acthar. Questcor had been very aggressive in raising the price of Acthar over the preceding decade, but recognized that doing so could create an incentive for Novartis (or some other firm) to try to bring Synacthen to the United States, even though Synacthen was not FDA-approved and there was considerable uncertainty about whether it could be. Despite these barriers, according

24 Bristol-Myers Squibb Co. and Celgene Corp., Docket No. 4690 (November 15, 2019), available at https://www.ftc.gov/system/files/documents/cases/191_0061_c4690_bms_celgene_complaint_0.pdf.

25 Though some Commissioners have dissented in cases where pharmaceutical divestitures were ordered, none have cited the probability of approval as being too remote or distant to fall within the proscriptions of Section 7 in the last thirty years. See, e.g. *Bristol-Myers Squibb*, F.T.C. Docket No. 4690 (Comm'r Slaughter, *dissenting*) (stating that the divestiture "remedies a serious concern about a drug-level overlap between BMS's development-stage [product] and Celgene's on-market Otezla," but dissenting because she believed that it "does not fully capture all of the competitive consequences of [large pharmaceutical] transactions."). The last time a Commissioner dissented in a pharmaceutical case on the grounds that entry was not sufficiently probable was in 1990. See, Roche Holding, 113 F.T.C. 1086, 1107-08 (1990) (Comm'r Owen, *dissenting*).

26 *FTC v. Steris Corp.*, 133 F. Supp. 3d 962 (N. D. Ohio 2015); Steris Corp. and Synergy Health PLC, Docket No. 9365 (May 29, 2015), available at https://www.ftc.gov/system/files/documents/cases/150529sterissynergypart3cmpt.pdf.

27 Mallinckrodt Ard Inc., Civil Action No. 1:17-cv-00120 (January 18, 2017), available at https://www.ftc.gov/system/files/documents/cases/170118mallinckrodt_complaint_public.pdf; Illumina, Inc. & Pacific Biosciences of California, Inc., F.T.C Docket No. 9387 (December 17, 2019) (hereinafter "Mallinckrodt Complaint") available at https://www.ftc.gov/system/files/documents/cases/d9387_illumina_pacbio_administrative_part_3_complaint_public.pdf. The FTC has used Section 2 in one other merger matter. See, Thoratec & HeartWare Int'l, F.T.C. Docket No. 9339 (July 29, 2009), available at https://www.ftc.gov/sites/default/files/documents/cases/2009/07/090730thorateadmincmpt.pdf. *Thoratec* involved an acquisition by a monopolist incumbent of a product that was in development, and the uncertainties of the clinical trial and regulatory approval process made it difficult to predict that the entry was likely.

to the FTC complaint, Questcor had viewed Synacthen as a threat for years and had monitored that threat. When Questcor learned that another company was interested in acquiring the drug and bringing it to the United States, immediately submitted a take-out bid. On these facts, the FTC charged that the acquisition was a "defensive move" by Questcor to "extinguish[] a nascent competitive threat to its [Acthar] monopoly." Notably, in its complaint, the FTC conceded that there was "significant uncertainty that Synacthen, a preclinical drug, would be approved by the FDA."[28]

Like *Mallinckrodt, Illumina* involved a proposed acquisition by a company the FTC claimed was monopolist. At the time of the merger, Illumina was the leading supplier, by far, of "next generation sequencing" ("NGS") systems. Its products are based on a "short read" technology that produces very high throughput at low cost, and have been so successful that Illumina had, according the FTC, more than a 90 percent share of the NGS market. PacBio had a very small share of the market but was one of only three other suppliers of NGS systems at the time of the merger. Its products use a different technology, "long read," to provide more detailed sequencing information, but at a significantly higher cost and lower throughput. In recent years, however, PacBio had been making advancements that improved accuracy and lowered cost. According to the FTC, Illumina had been monitoring PacBio's product improvements and viewed PacBio's product and technology as a significant competitive threat. The FTC charged that the merger violated both Section 7 and Section 2, but it is clear that it was relying heavily on its Section 2 theory, perhaps to overcome uncertainty about how the market would develop. As a senior FTC official said at the time of the challenge, "[w]hen a monopolist buys a potential rival, it can harm competition. These deals help monopolists maintain power. That's why we're challenging this acquisition."[29]

IV. CONCLUSION

While it may appear the FTC is taking two distinct approaches to future competition cases, that may not be what is really happening. *Steris* demonstrated that courts can be reticent to find a firm a likely future competitor, but subsequent cases show that the Commission remains concerned about future competition cases even where there is considerable uncertainty the entry effort will be successful. The FTC's continuing investigation and challenges of these deals under both Section 7 and Section 2 may suggest that it considers the threshold requirement of a high probability of entry in future competition cases to be too stringent to capture the potential anticompetitive effects of these transactions.

This explanation would align with the agency's guidance. The *Merger Guidelines* formulation for analyzing the competitive effect of a merger involving an actual potential competitor is a function of the "market share of the incumbent," the "competitive significance of the potential entrant," and it "competitive threat ... relative to others."[30] The "competitive significance" of the entrant is the product of both its probability of successful entry *and* its impact if, and when, it occurs. The FTC's cases under Section 2 thus far appear to fit the category of "lower probability/high market share," as do its Section 7 pharma cases (like *BMS*), which considered probability of entry against the closeness of the competition, if it emerges. In that way, both categories hew to a "sliding scale" between the probability and competitive impact of entry implied by the guidelines.

The FTC's evaluation of future competitive effects has application beyond health care. The agency has been public about the attention it is paying to acquisitions of nascent competitors by major technology platforms.[31] A number of commenters have suggested that Section 2 may be an appropriate vehicle for challenging those types of transactions, given the limitations actual potential competition doctrine under the case law.[32] The FTC's recent work suggests that it is more likely to use Section 2 as one of its tools in tackling potential competition mergers — particularly where there is strong evidence of monopoly power, a feature that it may believe is present in some technology markets. That may provide the FTC with a possible way to circumvent the requirements of the Section 7 actual potential competition case law in litigation, but it would not be a departure from the its thinking in future competition cases as reflected in its health care actions and the Guidelines.

28 Mallinckrodt Complaint ¶¶ 1, 8, 34.

29 FTC, "FTC Challenges Illumina's Proposed Acquisition of PacBio" (December 17, 2019), available at https://www.ftc.gov/news-events/press-releases/2019/12/ftc-challenges-illuminas-proposed-acquisition-pacbio.

30 Merger Guidelines § 5.3.

31 FTC, "FTC to Examine Past Acquisitions by Large Technology Companies: Agency Issues 6(b) Orders to Alphabet Inc., Amazon.com, Inc., Apple Inc., Facebook, Inc., Google Inc., and Microsoft Corp." (February 11, 2020).

32 See, e.g. C. Scott Hemphill, *Disruptive Incumbents: Platform Competition in an Age of Machine Learning*, 119 COLUM. L. REV. 1973, 1984–89 (2019).

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