THE NO KILL ZONE: THE OTHER SIDE OF PHARMA ACQUISITIONS

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For decades, the U.S. Federal Trade Commission (the "FTC") has used various weapons in its enforcement arsenal to challenge acquisitions by incumbents of pharmaceutical products under development – so-called "pipeline products." A competitive concern articulated in these cases is that in pharmaceutical markets with few current competing products, and few products under development, the combined firm's incentive to continue to develop the pipeline product may be diminished. This could result in the product candidate never making it to market, or being delayed in its development and introduction – thereby depriving the market of increased competition in the future.

Despite the FTC's strong enforcement record in this area, including approximately 50 consent decrees requiring divestitures of pre-marketed pharmaceutical products over the last 25 years and the largest civil disgorgement in a merger matter in FTC history,[2] in recent years the FTC has faced mounting pressure to ramp up efforts to challenge proposed acquisitions of pipeline products. In particular, in 2018, an economic paper entitled *Killer Acquisitions*[3] began making the rounds in the antitrust community. That paper argues that incumbent pharmaceutical companies may routinely acquire innovative pharmaceutical targets "solely to discontinue the target's innovation projects and preempt future competition," a phenomenon the paper deems "killer acquisitions."[4]

Based on their analysis of certain empirical data regarding pharmaceutical transactions over the last 25 years, the authors of *Killer Acquisitions* conclude that a drug development project is substantially less likely to be continued if it is acquired by a buyer with an "overlapping" product, as defined by the authors, especially if the buyer has market power. According to the methodology relied on by the authors, at least 5.3 to 7.4 percent of pharmaceutical acquisitions in the data set, or around 46 to 63 per year, were "killer acquisitions."[5]

2 See Press Release, Federal Trade Commission, "Mallinckrodt Will Pay $100 Million to Settle FTC, State Charges It Illegally Maintained its Monopoly of Specialty Drug Used to Treat Infants" (January 18, 2017), available at https://www.ftc.gov/news-events/press-releases/2017/01/mallinckrodt-will-pay-100-million-settle-ftc-state-charges-it.

The Killer Acquisitions paper discussed below cites this matter as a paradigmatic example of a "killer acquisition." There, according to the FTC's complaint, Mallinckrodt (through its Acthar product) was a monopolist in the U.S. market for adrenocorticotropic hormone (ACTH) drugs, used as a treatment for infantile spasms, a rare seizure disorder afflicting infants, as well as other medical conditions. In other parts of the world doctors treated patients suffering these conditions with Synacthen, a synthetic ACTH drug, but in the U.S. Synacthen remained a preclinical drug and had not been approved by the FDA. In 2013 Mallinckrodt acquired the U.S. rights to Synacthen from Novartis, outbidding other companies allegedly seeking to acquire and develop Synacthen and sell it at a discount to Acthar in the U.S. The FTC alleged that by acquiring Synacthen, Mallinckrodt "thwarted a nascent challenge to its Acthar monopoly." Complaint, *FTC v. Mallinckrodt ARD Inc. and Mallinckrodt plc*, No. 1:17-cv-00120 (D.D.C. January 18, 2017), available at https://www.ftc.gov/system/files/documents/cases/170118mallinckrodt_complaint_public.pdf.

3 Colleen Cunningham, Florian Elderder & Song Ma, *Killer Acquisitions* (April 2019), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3241707 ("Killer Acquisitions").

4 *Id.* at abstract.

5 *Id.* at 6.

While some advocates for stricter antitrust enforcement have seized onto the systemic "buy/kill" strategy suggested by *Killer Acquisitions*, it is critical to recognize that, by focusing on only the potential harms from such transactions, this analysis tells only one side of the story.

As we outline below, transactions involving pipeline pharmaceutical products frequently carry the potential for significant benefits to innovation and competition, and ultimately to the healthcare of patients, by making it *more* likely products successfully come to market. Indeed, putting such notoriously risky, complex and capital-intensive assets into the hands of experienced specialists well-positioned to navigate through late stage development and into commercialization, can vastly increase the odds that new products actually reach patients – and do so more quickly and more efficiently as compared to a world "but for" the transaction

It would be contrary to the purpose of antitrust laws to reflexively crack down on all pharmaceutical transactions without continuing to carefully weigh these very tangible competitive benefits. As the FTC recently observed, "[m]erger investigations are highly fact-specific" and assessing the potential for competitive harm must be "driven by evidence."[6] This article outlines examples of procompetitive benefits commonly generated by pharmaceutical transactions. Where the evidence shows that a proposed transaction carries the potential for such benefits, that information is crucial towards answering the ultimate question of whether or not the transaction is likely to result in a substantial lessening of competition.

I. FRAMEWORK FOR ASSESSING ACQUISITIONS OF PHARMACEUTICAL PIPELINE CANDIDATES

The FTC's starting point for assessing acquisitions by incumbents of potentially overlapping pipeline products is outlined in the Horizontal Merger Guidelines. Section 6.4 of the Guidelines provides that the FTC will consider whether a "merger is likely to diminish innovation competition by encouraging the merged firm to curtail its innovative efforts," either in the "form of reduced incentive to continue with an existing product-development effort or reduced incentive to initiate development of new products."[7]

Key factors in this analysis include "the extent to which successful innovation by one merging firm is likely to take sales from the other, and the extent to which post-merger incentives for future innovation will be lower than those that would prevail in the absence of the merger."[8] At the same time, the Guidelines instruct that the FTC also consider "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."[9]

The FTC's close investigation of Roche's proposed acquisition of Spark Therapeutics, over the course of 2019, illustrates one application of this framework. There, the key question the FTC faced was the first type of innovation harm outlined in the Guidelines: whether Roche would have the incentive to delay or discontinue Spark's developmental gene therapy for hemophilia A, given Roche's existing hemophilia A monoclonal antibody treatment. In short, was Roche acquiring a potential competitive entrant to "kill" it or otherwise minimize its competitive significance?

The FTC ultimately answered the question in the negative, voting 5-0 to allow the acquisition. In its closing statement the FTC explained that it "closely scrutinize[s] incumbents' acquisitions of current, potential, and nascent competitors, particularly where the incumbent has market power."[10] The all-important question is whether such acquisitions may "diminish competition and harm consumers," for example by leaving the "incumbent with the incentive to degrade or eliminate the acquired firm's products or services, or to delay development of a next-generation product."[11] The FTC concluded, however, that because Spark was "only one of several companies currently developing a gene therapy treatment for hemophilia A," Roche "would have the incentive to accelerate, rather than decelerate the development of Spark's gene therapy."[12]

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6 Statement of the FTC, *In the Matter of Roche Holding/Spark Therapeutics*, Comm'n File No. 1910086 (December 16, 2019), available at https://www.ftc.gov/system/files/documents/public_statements/1558049/1910086_roche-spark_commission_statement_12-16-19.pdf.

7 U.S. DOJ & FTC, Horizontal Merger Guidelines § 6.4 (August 19, 2010), available at http://www.justice.gov/atr/public/guidelines/hmg.pdf (the "Horizontal Merger Guidelines").

8 *Id.*

9 *Id.*

10 Statement of the FTC, *supra* note 6, at 1.

11 *Id.*

12 *Id.*

II. M&A EXIT STRATEGY IS A CLASSIC PART OF THE BIOPHARMA LIFECYCLE THAT MOTIVATES *EX ANTE* INVESTMENT IN INNOVATION

As an initial matter, the potential to innovate a new product and ultimately sell it off is a key driver of innovation and a classic lifecycle for biopharma development founders and investors who expend substantial time, money and effort developing new products. Without the potential for a successful exit through a sale or a license, investors may not have the same incentives to infuse money into development, and companies and founders may not have the same incentives in innovate in the first place.

As *Killer Acquisitions* itself notes, it is possible that the "presence of an acquisition channel may also have a positive effect on welfare if the prospect of entrepreneurial exit through acquisition (by an incumbent) spurs *ex ante* innovation," which would "have to be weighed against the ex-post efficiency loss due to reduced competition."[13]

In fact, studies show that an "active acquisition market encourages innovation, particularly by small firms in an industry," for which "exit through strategic sales becomes an important motivation to continue to spend on R&D."[14] Smaller, innovative pharmaceutical firms routinely pursue business models of developing promising candidates and then selling or licensing the assets prior to later stage development and commercialization. And larger pharmaceutical companies may be better suited for this work, allowing for specialization that optimizes limited resources. The welfare benefits of entrepreneurial exit are a very important counterweight to mechanically ramping up enforcement over pharmaceutical transactions.

III. PHARMACEUTICAL TRANSACTIONS OFTEN GENERATE OTHER SIGNIFICANT PROCOMPETITIVE BENEFITS

Killer Acquisitions theorizes one motive for acquisitions of innovating pharmaceutical firms: to "terminate the development of the target's innovations to preempt future competition."[15] But the paper itself acknowledges there may be other reasons underlying these transactions, such as that "firms that are better at exploiting technologies acquire innovative targets to realize synergies, effectively enabling specialization and subsequently increasing innovation and overall welfare."[16]

There are in fact myriad reasons innovating firms may be acquired by incumbents, and in many cases these acquisitions produce significant competitive benefits that may not have been achieved if the transaction did not occur. Below we explore several common reasons for pharmaceutical M&A and licensing transactions that carry the potential for generating significant procompetitive benefits, particularly in cases of acquisitions by larger incumbents of innovative early-stage pharmaceutical companies.

A. Combining Complementary R&D Capabilities and Technologies

Acquisitions by incumbents of potentially competitive pipeline products may combine complementary R&D capabilities and technologies in ways that make it more likely the program will produce a successful therapy, or will do so more quickly, more efficiently, or more effectively.

These types of transactions, for example, may provide early-stage developers with access to specialized knowledge about a therapeutic area, or even just allow the leading experts to work together in ways that would not be possible absent a transaction. These transactions may provide access to a complementary technology that enhances the potential efficacy or safety of a pipeline product. They may also enable development of combination products that would not otherwise be possible, for example due to IP rights, proprietary data belonging to the other party, or costs of or access to sufficient quantities of the other side's product for clinical trials.

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13 *Killer Acquisitions*, supra note 3, at 50-51.

14 Gordon M. Phillips & Alexei Zhdanov, *R&D and The Incentives From Merger and Acquisition Activity*, National Bureau Of Economic Research: Working Paper 18346 (August 2012), available at https://www.nber.org/papers/w18346.pdf.

15 *Killer Acquisitions*, *supra* note 3, at 1.

16 *Id.*

In its merger reviews, the FTC has in the past credited these types of benefits. For example, while the FTC has indicated it will "examine whether the merged firm [is] likely to have a reduced incentive to invest in R&D," it will also assess "whether it [is] likely to have the ability to conduct R&D more successfully."[17] Where it is, it may be that "the merger is likely to be procompetitive, and thus patients' lives are more likely to be saved by [the] merger than to be put at risk."[18]

This was a key factor in the FTC's investigation of *Genzyme/Novazyme*. That matter involved a merger to monopoly: Genzyme and Novazyme were the only two companies engaged in the development of a treatment for Pompe disease, a rare inherited neuromuscular disorder that typically was fatal and which had no known treatment at the time of the merger. The FTC nevertheless allowed the merger because "on balance, rather than put patients at risk through diminished competition, the merger more likely created benefits that will save patients' lives."[19]

Chairman Muris, writing for the majority, concluded the "merger made possible synergies that will help avoid a delay in the Novazyme program."[20] In particular, the merger allowed for "comparative experiments and provided information that enabled the Novazyme program to avoid drilling dry holes," and that "[b]y accelerating the Novazyme program, the merger may have increased its odds of success."[21] The Commission noted that "for a fatal disease without any effective therapy, acceleration of the first effective treatment remains of paramount importance."[22]

B. Leveraging Late-Stage Clinical Development and Regulatory Expertise

Developing pharmaceutical product candidates is notoriously risky, time-consuming, and expensive, requiring lengthy clinical trials, sophisticated data collection and analysis, strategic development capabilities and access to significant resources over many years. Recent reports indicate, for example, that the overall likelihood of approval from Phase 1 for developmental candidates is 9.6 percent,[23] and that such development takes on average 12 years from pre-clinical testing to approval and costs over $1 billion.[24]

Smaller pharmaceutical companies focused on early stage clinical development may lack the specialized expertise both for developing and running complex later-stage clinical trials, as well as interfacing with regulatory agencies across the world in shepherding a drug candidate through its final stages to approval. Larger pharmaceutical companies with existing approved products, on the other hand, often have invaluable expertise with this process in the relevant therapeutic area.

Marrying promising clinical-stage candidates with this expertise can substantially increase the chances the candidate comes to market quickly and efficiently. Incumbents in the relevant therapeutic area are often uniquely well-positioned to aid in the design of later-stage clinical trials, as well as to set up and recruit patients for large trials and quickly and efficiently address feedback and guidance from the FDA and other regulatory agencies.

Indeed, in our experience, a common outcome from acquisitions of earlier stage pharmaceutical companies by an experienced incumbent is that the development timeline is immediately materially advanced – sometimes by a year or more – often reflecting the clinical development and regulatory expertise the acquirer brings to the table.

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17 Statement of FTC Chairman Timothy Muris, *In the Matter of Genzyme Corporation / Novazyme Pharmaceuticals, Inc.* at 6, Comm'n File No. 0210026 (January 13, 2004), available at https://www.ftc.gov/system/files/attachments/press-releases/ftc-closes-its-investigation-genzyme-corporations-2001-acquisition-novazyme-pharmaceuticals-inc./murisgenzymestmt.pdf.

18 *Id.* at 20.

19 *Id.* at 1.

20 *Id.* at 17.

21 *Id.*

22 *Id.* at 19.

23 David W. Thomas et al., *Clinical Development Success Rates 2006-2015*, Biotechnology Innovation Organization, Biomed Tracker at 2, available at https://www.bio.org/sites/default/files/legacy/bioorg/docs/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf.

24 G.A. Norman, *Drugs, Devices, and the FDA: Part 1: An Overview of Approval Processes for Drugs*, 1(3) JACC: Basic to Translational Science 170-179 (2016), available at https://www.sciencedirect.com/science/article/pii/S2452302X1600036X.

C. Generating Efficiencies in Increased Utilization of Existing Commercialization Capabilities

Smaller pharmaceutical companies often are primarily focused on R&D rather than marketing. These companies may have no existing commercialization expertise or assets, or if they do, they are limited to small sales teams marketing in specialized or orphan indications with limited reach. Often, these companies are capital-constrained and have little or no interest in or capacity to scale up a large commercialization infrastructure to market a newly approved drug.

This again contrasts with large pharmaceutical incumbents, that typically have well-established sales organizations targeting patients and health care professionals in the relevant therapeutic area, and sophisticated expertise in securing reimbursement, negotiating for favorable formulary positioning, and navigating the various other hurdles in successful drug marketing and distribution. Further, larger pharmaceutical companies with an established sales infrastructure typically benefit from significant economies of scale when introducing and commercializing a new drug, efficiencies that are not available to startups or early stage pharmaceutical companies that lack a sales and marketing organization.

Acquisitions by such incumbents can vastly increase the likelihood the new drug will successfully get to market, gain market acceptance, and be made available to patients that need it most. We have been involved in transactions, for example, where the target's budget "but for" the transaction anticipates the need to spend tens of millions of dollars building out a brand new, untested sales organization. The ability for the acquiring firm to get the new product to patients more quickly, at less cost, and with less risk, are all important considerations in assessing competitive effects from a proposed transaction.

D. Removing a Blocking Patent Position

Acquisitions by incumbents may also generate significant procompetitive benefits by resolving a potential blocking patent position, that could at minimum substantially delay entry during the patent suit (barring an at-risk launch), or in a successful patent enforcement action preclude entry altogether for the life of the relevant patent(s).

Even where a target may be able to overcome a patent, doing so typically entails a costly and protracted process, as it can take three to four years or more to invalidate an Orange Book-listed pharmaceutical patent in federal court (including appeals) or through Inter Partes Review before the Patent Trial and Appeal Board.

To be sure, the existence of any theoretical patent dispute is not a panacea to a proposed merger. For example, in response to the FTC's suit to block Boston Scientific's acquisition of Cardiovascular Imaging Systems ("CVIS"), the parties argued the merger should be allowed because it resolved ongoing patent litigation and absent the acquisition Boston Scientific would not be able to compete because its product infringed. The FTC pointed out, however, that in the underlying patent litigation Boston Scientific had taken the position that the CVIS patents were invalid, a position inconsistent with its antitrust arguments. The FTC also contended the parties may have instead negotiated a cross-license, which would achieve the same benefits of the merger without eliminating competition between the competitors.[25]

However, a transaction that effectively resolves a valid blocking position, allowing for earlier entry than would otherwise be possible, offers the potential for significant procompetitive benefits without an offsetting reduction of competition.[26]

The Horizontal Merger Guidelines recognize, for instance, that merger analysis must account for "future competitive significance," and that "if the relevant assets would otherwise exit the market, customers are not worse off after the merger than they would have been had the merger been enjoined."[27] Indeed, FTC officials have in the past recognized that an acquisition may be "efficient if it defuses a legitimate blocking patent suit and thereby avoids the delays inherent in such litigation," and that such "speed-to-market type efficiencies are potentially heightened

25 Memorandum of Points and Authorities in Support of the Federal Trade Commission's Motion for Preliminary Injunction at 40, *FTC v. Boston Scientific Corp.*, No. 95-00198 (D.D.C. January 27, 1995).

26 See, e.g. Herbert Hovenkamp et al., IP & Antitrust § 7.4, (3d. ed. 2019) ("If the IP right is valid and infringed, so that the defendant could not lawfully participate in the market, the merger does not eliminate a legitimate competitor in that market, though it might foreclose the possibility that the purchased company would have developed a non-infringing technology.").

27 See Horizontal Merger Guidelines, *supra* note 7, §§ 5, 11.

in the pharmaceutical context where new drugs sometimes assume life-and-death importance."[28]

IV. SELLERS HAVE STRONG INCENTIVES AND ABILITY TO PROTECT AGAINST "KILLER ACQUISITIONS"

In addition to the fact that pharmaceutical transactions often have the potential for generating significant procompetitive benefits, which should be taken into account in any analysis of competitive effects, there are also a large number of transactions that carry less risk of being killer acquisitions. Caution is warranted before broadly heightening antitrust scrutiny over such transactions, which may well generate the types of benefits to competition described above without the competitive concerns of the type articulated in *Killer Acquisitions*.

Much more so than transactions in many other industries, pharmaceutical deals are characterized by very large potential earnout payments. One recent study of private-target life sciences transactions, for example, finds that over 80 percent of biotech/pharmaceutical deals over the last decade included at least some form of an earnout, compared to around 15 percent in non-life sciences deals.[29] This study also finds that in such biotech/pharmaceutical deals the value of the potential earnout typically substantially outweighed the up-front payments, comprising on average around 70 percent or more of the aggregate deal value.[30]

In transactions involving this type of compensation structure, sellers have very strong incentives to protect against the potential for a killer acquisition: if the project is killed, the earnout will generally not be paid and the seller will forego a significant portion of its compensation. Sophisticated sellers are also well positioned to contractually protect against the risk that a development project will be artificially killed (e.g. for non-scientific or health reasons). For example, sellers can negotiate strong best efforts clauses dictating the buyer's project development obligations and requiring the buyer to advance the project in good faith, and reversionary rights and compensation in the event the project does not move forward.

Absent a sham to cover an otherwise anticompetitive deal, a transaction that involves a large potential earnout, coupled with strong efforts clauses and reversionary rights, should ordinarily raise less concern that the deal may be a killer acquisition warranting closer FTC scrutiny.

The FTC has in the past recognized that earnout payments can have competitive implications. For example, in *Genzyme/Novazyme*, the merger agreement provided for significant potential milestone payments to Novazyme if products employing Novazyme's technologies were FDA-approved, and Genzyme had placed Novazyme shareholders in key positions at the merged company. The FTC noted that if Genzyme's intent was to delay or kill the development of the Novazyme product, it would have been irrational to create such a compensation structure and then place Novazyme shareholders in positions where they would quickly become aware of steps to eliminate or delay the Novazyme program.[31]

V. CONCLUSION

Advocates for stronger antitrust enforcement have argued that the risk of killer acquisitions warrants stricter scrutiny of pharmaceutical transactions overall. But even taking analyses such as *Killer Acquisitions* at face value, the asserted increased potential for harm to competition from acquisitions by incumbents should be balanced against the substantial benefits to innovation and competition often made possible by such transactions. These very tangible competitive benefits are crucial when assessing whether a transaction is likely to lessen competition substantially.

28 Statement of Former FTC Commissioner Sheila F. Anthony, *Riddles and Lessons from the Prescription Drug Wars: Antitrust Implications of Certain Types of Agreements Involving Intellectual Property*, Presented Before the Attendee of The ABA Antitrust and Intellectual Property: The Crossroads Program (June 1, 2000), available at https://www.ftc.gov/es/public-statements/2000/06/riddles-lessons-prescription-drug-wars-antitrust-implications-certain.

29 Don Morrissey & Leo Jiang, SRS Acquiom, 2019 SRS Acquiom Life Sciences M&A Study at 17 (September 16, 2019).

30 *Id.* at 18-19.

31 Statement of FTC Chairman Timothy Muris, *supra* note 17, at 15-16.

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