

# MERGER LAW FOR BIOTECH AND KILLER ACQUISITIONS

D. Daniel Sokol\*

## Abstract

This Essay suggests a framework for how to conceptualize “killer acquisitions” in the biotech sector. In a killer acquisition, a larger branded pharmaceutical company buys a start-up company with a pipeline product with the intention to shut the pipeline product down. The Essay offers a way to police against acquisitions that may hurt consumers and still encourage pro-competitive acquisitions that may improve innovation and consumer welfare.

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## INTRODUCTION

Since publication of an influential working paper in late 2018, “killer acquisitions,”<sup>1</sup> commentators in antitrust law and policy have focused on acquisitions of startup companies by larger companies in the same or complementary markets. While the initial focus of a concern for such deals was in pharmaceuticals,<sup>2</sup> the concern has moved more broadly in the legal and policy communities to medical devices<sup>3</sup> and online

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\* Professor, University of Florida Levin College of Law; Senior Advisor, White & Case LLP.

1. See Colleen Cunningham et al., *Killer Acquisitions* 1 (Apr. 19, 2020), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3241707](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3241707) [<https://perma.cc/EH2B-KVQL>].

2. See *id.*

3. Nicholas Kulish et al., *The U.S. Tried to Build a New Fleet of Ventilators. The Mission Failed.*, N.Y. TIMES (Apr. 20, 2020), <https://www.nytimes.com/2020/03/29/business/coronavirus-us-ventilator-shortage.html> [<https://perma.cc/EK49-MZHL>] (“Government officials and executives at rival ventilator companies said they suspected that Covidien had acquired Newport to prevent it from building a cheaper product that would undermine Covidien’s profits from its existing ventilator business.”).

platforms.<sup>4</sup> This concern has reached the highest levels of policy. For example, Senator Elizabeth Warren is drafting legislation to ban mergers in which the acquiring company has annual revenue of more than \$40 billion.<sup>5</sup> The U.S. Antitrust agencies have taken an increasingly serious look at the issue as well.<sup>6</sup>

The term “killer acquisitions” was coined by Professors Cunningham, Ederer, and Ma for particular pharma-related transactions, alluding to the risk that an originator (branded pharmaceutical company) acquires a start-up company with a pipeline product with the intention to shut the pipeline product down.<sup>7</sup> In their paper, the authors found that pharma companies undertake approximately fifty “killer acquisitions” on a yearly basis.<sup>8</sup> These “killer acquisitions” are ones where incumbent firms acquire innovative targets and shut down/discontinue the target’s product.<sup>9</sup> Professor Cunningham and co-authors inferred that the purpose of shutting down such innovation is to preempt future competition from a nascent competitor.<sup>10</sup> Their paper has caused a stir in the policy and academic communities for its broader implications on innovation policy. Ironically, this term got picked up regarding platform tech-related deals even though the context is quite different, and the term is not really appropriate in the tech setting.<sup>11</sup> Killer acquisitions in the tech setting raise related but different issues.

This Essay suggests a framework for how to conceptualize “killer acquisitions” in the biotech sector. In addition, this Essay offers a way to police against acquisitions that may hurt consumers and still encourage

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4. See C. Scott Hemphill & Tim Wu, *Nascent Competitors*, PENN. L. REV. (forthcoming 2020) (manuscript at 2); see also ORG. ECON. CO-OPERATION & DEV., START-UPS, KILLER ACQUISITIONS AND MERGER CONTROL – BACKGROUND NOTE 8, n.19 (May 12, 2020), [https://one.oecd.org/document/DAF/COMP\(2020\)5/en/pdf](https://one.oecd.org/document/DAF/COMP(2020)5/en/pdf) [<https://perma.cc/X5ZQ-RJX6>].

5. Eric Newcomer & Joshua Brustein, *Warren is Drafting U.S. Legislation to Reverse ‘Mega Mergers,’* BLOOMBERG L. (Dec. 4, 2019, 6:43 P.M.), <https://news.bloomberglaw.com/mergers-and-antitrust/warren-is-drafting-u-s-legislation-to-reverse-mega-mergers> [<https://perma.cc/L846-VUTZ>].

6. See Kelly Fayne & Kate Foreman, *To Catch a Killer: Could Enhanced Premerger Screening for “Killer Acquisitions” Hurt Competition?*, 34 ANTITRUST MAG. 8, 8 (2020) (“The [killer acquisition] topic has also made it into U.S. Senate hearings, the antitrust conference circuit, and speeches by the Antitrust Division Assistant Attorney General and FTC leadership.”).

7. Cunningham et al., *supra* note 1, at 1.

8. *Id.* at 35 (estimating that 7.1% of all acquisitions or about fifty-four acquisitions every year are killer acquisitions).

9. *Id.* at 1.

10. *See id.*

11. See Ariel Katz, *Pharmaceutical Lemons: Innovation and Regulation in the Drug Industry*, 14 MICH. TELECOMM. & TECH. L. REV. 1, 1 (2007); D. Daniel Sokol, *Vertical Mergers and Entrepreneurial Exit*, 70 FLA. L. REV. 1357, 1357 (2018) (stating that vertical merger policy that would unduly restrict large tech firms for innovation in the economy would hurt incentives for innovation in the economy by chilling business formation in start-ups).

pro-competitive acquisitions that may improve innovation and consumer welfare.

### I. CREATING AN ANTITRUST FRAMEWORK FOR PHARMA MERGERS

In the pharma setting, antitrust law needs to be careful to properly identify issues that killer acquisitions raise. That is, where the technologies are different or mechanisms of action are different, it makes little sense to kill a pipeline product absent specific facts that suggest otherwise. To do otherwise would chill innovation.

There needs to be an evidentiary basis on specific deals with theories of harm that match up with facts to block a given merger. The two key evidentiary issues are: (i) where the acquirer pays a lot of money and the target has invested into the pipeline product (given it is already so advanced that it is an actual threat to the acquirer), why assume it will be killed, especially if there is at least some room for product differentiation (e.g., in anti-depressants); and (ii) how can we be sure the pipeline product would have become a significant constraint, i.e., the deal (assuming it will be killed) will lead to a substantial lessening of competition (given that internal sales forecasts are often overly optimistic)? Without theories backed up by actual facts, antitrust law will chill innovation as investors are scared off from backing the next generation of biotech ventures for fear of lack of exit options for founders and investors to reap the rewards of a successful exit.

The nature of innovation, due to the regulatory process and the particular issues involved in bringing pharmaceuticals to market, is different in pharma than in digital tech. If the pipeline product is close enough to the market to be a threat, creating concerns for antitrust authorities that it will be killed, the antitrust authorities have a good idea of what the acquiring firm will do and can check competitors' pipelines to see what the competitors have.<sup>12</sup> By contrast, this approach tends to be much more elusive in digital transactions. For example, when Microsoft acquired Skype, many observers wondered how Skype would evolve and relate to Microsoft's products.<sup>13</sup>

Of course, a large pharma company may buy a pharma start-up not only because of a single pipeline product, and certainly not always with the intention of killing parts of the pipeline to shut the product down, hence the call for clear evidence (such as unequivocal internal documents) on the intent to kill the start-up. Pharma is different from platform tech and complementors for a different reason. In pharma, the

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12. The authorities may not have reliable information about sales prospects but will have some idea nevertheless.

13. Tomio Geron, *Microsoft's Acquisition of Skype: Is it Worth it?*, FORBES (May 10, 2011, 1:00 A.M.), <https://www.forbes.com/sites/tomiogeron/2011/05/10/microsofts-acquisition-of-skype-internet-and-mobile-plays/-256923934dea> [<https://perma.cc/W3UW-29W8>].

regulations mean each drug—even very similar drugs—are distinct. In this sense, acquisitions are fueled by the acquiring firm’s need to promote something new.

In short, very close substitutes in pharma can be sold side by side without cannibalizing due to the eccentric and, typically American, overdone regulatory structure. The FDA is too big a barrier to new drugs coming to market.<sup>14</sup> Businesses without that regulatory structure, such as platform-related tech, work differently.

## II. KILLER ACQUISITIONS AND THE START-UP ECOSYSTEM

Entrepreneurship is unique, relative to other types of business law, because it involves high risk.<sup>15</sup> Venture capitalists (VCs) have a portfolio of investments to reduce risk because any one investment is not likely to yield big returns. This is important given the limited time frame (typically ten years) in which the capital needs to be returned at the end of the fund. As such, VCs do not make money on over half of their average portfolio of investments.<sup>16</sup> Corporate venture capitalists (CVC) invests in a portfolio of companies for similar reasons.<sup>17</sup> Pharma tends to have less CVC than other fields and some VCs do not invest in pharma because of the longer time horizon and regulatory risk.

It would be a mistake to assume that antitrust enforcers could easily figure out which nascent firms might be competitors rather complementary firms, let alone which firms might develop new markets.<sup>18</sup> Pharma is very unpredictable. To give one example, Lipitor

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14. See Jonathan J. Darrow et al., *FDA Approval and Regulation of Pharmaceuticals, 1983-2018*, 323 J. AMER. MED. ASSOC. 164, 169 (2020) (stating that the 1962 Drug Amendments imposed increased costs on pharmaceutical manufacturers).

15. See D. Gordon Smith & Darian M. Ibrahim, *Law and Entrepreneurial Opportunities*, 98 CORNELL L. REV. 1533, 1562 (2013) (“[T]he reality is that many, or even most, entrepreneurs fail.”).

16. See John H. Cochrane, *The Risk and Return of Venture Capital*, 75 J. FIN. ECON. 3, 30 (2005) (identifying a high average return that reflects a “small possibility of earning a truly astounding return, combined with the much larger probability of a more modest return”).

17. See Will Drover et al., *A Review and Road Map of Entrepreneurial Equity Financing Research: Venture Capital, Corporate Venture Capital, Angel Investment, Crowdfunding, and Accelerators*, 43 J. MGMT. 1820, 1835 (2017).

18. See CHRISTINE S. WILSON, U.S. FED. TRADE COMM’N, VERTICAL MERGER POLICY: WHAT DO WE KNOW AND WHERE DO WE GO? 3–5 (2019), [https://www.ftc.gov/system/files/documents/public\\_statements/1455670/wilson\\_-\\_vertical\\_merger\\_speech\\_at\\_gcr\\_2-1-19.pdf](https://www.ftc.gov/system/files/documents/public_statements/1455670/wilson_-_vertical_merger_speech_at_gcr_2-1-19.pdf) [<https://perma.cc/RR92-7T64>]; see also Richard J. Gilbert & Steven C. Sunshine, *Incorporating Dynamic Efficiency Concerns in Merger Analysis: The Use of Innovation Markets*, 63 ANTITRUST L.J. 569, 570 (1995); D. Bruce Hoffman, Acting Director, Fed. Trade Comm’n: Bureau of Competition, Remarks at Credit Suisse 2018 Washington Perspectives Conference: Vertical Merger Enforcement at the FTC 2–3 (Jan. 10, 2018),

was considered to be an also-ran drug as it was the fifth statin on the market.<sup>19</sup> Parke-Davis could not predict how well it would do. Instead, it gave away half the rights because it thought Lipitor would be a me-too, nothing-to-see-here statin.<sup>20</sup> Lipitor quadrupled its pre-launch sales estimates in year one.<sup>21</sup> It was the largest selling drug in the world with sales topping out near \$13 billion.<sup>22</sup> Lipitor is also a story that says future sales of any pharma product are inherently impossible to judge. Lipitor extends lives in asymptomatic persons.<sup>23</sup> This result was not known when Lipitor was in the pipeline.

In a world filled with uncertainty as to technological breakthrough and regulatory approval, with significantly more information than an outsider (such as an antitrust agency reviewing a deal), even the best VCs and CVCs have trouble picking winners and losers. Just because a larger firm acquires a start-up, the best technologies, people, and ideas cannot easily be implemented in terms of capturing value from acquisitions by larger firms. Though it is possible that a particular transaction might create competition problems, the solution is to address specific deals with a sufficient factual record. To wholesale attack an entire business model<sup>24</sup> that has been the primary form of exit for entrepreneurs not merely in platform-based tech but also in biotech would create economy-wide problems by depressing firm innovation and improved consumer welfare.

When certain avenues for firm exit are closed off via limits to acquisition because of an overly stringent antitrust regime, such as

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[https://www.ftc.gov/system/files/documents/public\\_statements/1304213/hoffman\\_vertical\\_merger\\_speech\\_final.pdf](https://www.ftc.gov/system/files/documents/public_statements/1304213/hoffman_vertical_merger_speech_final.pdf) [<https://perma.cc/68Z2-GC3H>].

19. *Lipitor Becomes World's Top-Selling Drug*, CRAIN'S N.Y. BUS. (Dec. 27, 2011, 11:00 P.M.), [https://www.crainsnewyork.com/article/20111228/HEALTH\\_CARE/111229902/lipitor-becomes-world-s-top-selling-drug#:~:text=A%20striking%20graph%20of%20those%20years%20after%20it%20was%20launched.\[https://perma.cc/E7TF-TXDB](https://www.crainsnewyork.com/article/20111228/HEALTH_CARE/111229902/lipitor-becomes-world-s-top-selling-drug#:~:text=A%20striking%20graph%20of%20those%20years%20after%20it%20was%20launched.[https://perma.cc/E7TF-TXDB)].

20. *See id.* (“Pfizer bought out Warner-Lambert in 2000 to block two other companies trying to acquire it and get control of Lipitor.”).

21. *See id.*

22. PFIZER INC., 2006 FINANCIAL REPORT 16 (2006), [https://s21.q4cdn.com/317678438/files/doc\\_financials/Annual/2006/financial2006.pdf](https://s21.q4cdn.com/317678438/files/doc_financials/Annual/2006/financial2006.pdf) [<https://perma.cc/39SW-2ALK>].

23. *See* MALENE LOPEZ KRISTENSEN ET AL., BMJ OPEN, THE EFFECT OF STATINS ON AVERAGE SURVIVAL IN RANDOMISED TRIALS, AN ANALYSIS OF END POINT POSTPONEMENT 1, 4 (2015), <https://bmjopen.bmj.com/content/bmjopen/5/9/e007118.full.pdf> [<https://perma.cc/RU6K-MMDP>] (“[T]he benefit [of statins] in terms of mortality or non-fatal cardiovascular outcomes cannot reasonably be challenged.”); *Lipitor Becomes World's Top-Selling Drug*, *supra* note 19 (“Back in the early 1980s, the public was just starting to learn what cholesterol was. There was little evidence that controlling it with medication could be so crucial in preventing disability and early death . . .”).

24. *See* Robert H. Lande & Sandeep Vaheesan, *Preventing the Curse of Bigness Through Conglomerate Merger Legislation*, 52 ARIZ. ST. L.J. 75, 105 (2020) (supporting the notion that major horizontal mergers are likely to result in increased inefficiency).

vertical acquisition by larger firms, the entrepreneurial system suffers. Specifically, entrepreneurs would be chilled from creating start-ups if they could not easily create a liquidity event to extract financial rewards from their investment. In other words, the prospect of being bought by a larger firm often incentivizes start-ups to innovate in the first place; VCs are similarly incentivized when thinking of funding the start-ups. If antitrust law starts reversing the burden of proof or generally making the acquisition of start-ups more difficult for strategic buyers, this could stifle innovation rather than incentivize it.<sup>25</sup>

#### A. *Entrepreneurial Exit and Competition in Pharmaceutical Acquisitions*

One reason for the need for acquisitions of smaller companies in biotech is that research and development (R&D) in large pharma firms often dries up over time.<sup>26</sup> Acquisitions of smaller firms may allow for a replenishing of basic R&D, where the risk of basic R&D has been shifted to the smaller firm.<sup>27</sup> Further, the smaller firm has certain capabilities that the large firm lacks.<sup>28</sup> For example, a smaller firm may be better at producing product innovations due to specialized technological knowledge,<sup>29</sup> whereas the larger firm may be better at process innovations.<sup>30</sup>

An entrepreneurial firm may want to exit via acquisition as part of its business plan (this business model in biotech in both pharma and medical devices is common as an alternative to IPO). This situation can be win-win. A smaller firm may want to be acquired by a larger biotech firm not merely to cash out founders and VCs, but also to help with successful development and commercialization of the technology: marketing, distribution, improved production facilities (and possible R&D synergies), regulatory support with regard to FDA, and filings regarding

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25. See D. Daniel Sokol, *Antitrust's "Curse of Bigness" Problem*, 118 MICH. L. REV. 1259, 1262 (2020) (stating "if the claim is that antitrust must change because of new realities in concentration and tech, it is incumbent on those proposing changes to offer a workable system. The strength of the current approach is how it marries economic analysis with legal administrability").

26. Matthew J. Higgins & Daniel Rodriguez, *The Outsourcing of R&D Through Acquisitions in the Pharmaceutical Industry*, 80 J. FIN. ECON. 351, 381 (2006).

27. See *id.*

28. See *id.* at 370.

29. See Gary Dushnitsky & Michael J. Lenox, *When do Firms Undertake R&D by Investing in New Ventures?*, 26 STRATEGIC MGMT. J. 947, 948–49 (2005) ("[E]ntrepreneurial ventures are likely to be the source of highly valuable and innovative ideas.").

30. See Nandini Lahiri & Sriram Narayanan, *Vertical Integration, Innovation, and Alliance Portfolio Size: Implications for Firm Performance*, 34 STRATEGIC MGMT. J. 1042, 1045–47 (2013).

intellectual property.<sup>31</sup> As such, the larger firm can transform the basic technology of an entrepreneurial firm into a drug that can be commercialized. The acquirer benefits from both economies of scope and from possible spillovers that can be leveraged within a firm across product lines.<sup>32</sup>

### B. *More Empirical Studies are Needed*

There has been a limited number of empirical studies to assess the effect of acquisitions on innovation in the pharmaceutical industry. One of the key difficulties with conducting these kinds of studies is how innovation's effect can be measured.<sup>33</sup>

It is not that some sort of situation of a killer acquisition could not happen in pharma. Rather, it is that there is some endogeneity in the results as to what was a “kill” because many drugs that do not make it to market (other than those for whom the drug just does not ultimately work) is due to eccentric U.S. drug regulation, which is demonstrably too strict and keeps many medicines sold in Europe off the American market.<sup>34</sup> Strategic alliances are common in biotech,<sup>35</sup> but their implication seems to have been ignored as part of the policy debate on killer acquisitions.

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31. See Marco Ceccagnoli et al., *Corporate Venture Capital as a Real Option in the Markets for Technology*, 39 STRATEGIC MGMT. J. 3355, 3356 (2018); see also Ashish Arora et al., *A Breath of Fresh Air? Firm Type, Scale, Scope, and Selection Effects in Drug Development*, 55 MGMT. SCI. 1638, 1649 (2009); Umit Ozmel et al., *Strategic Alliances, Venture Capital, and Exit Decisions in Early Stage High-Tech Firms*, 107 J. FIN. ECON. 655, 665 (2013).

32. See Yu Yu et al., *Choosing the Right Target: Relative Preferences for Resource Similarity and Complementarity in Acquisition Choice*, 37 STRATEGIC MGMT. J. 1808, 1809 (2016).

33. Patricia M. Danzon et al., *Mergers and Acquisitions in the Pharmaceutical and Biotech Industries*, 28 MANAGERIAL & DECISION ECON. 307, 326 (2007); K.D.S. Fernald et al., *The Moderating Role of Absorptive Capacity and the Differential Effects of Acquisitions and Alliances on Big Pharma Firms' Innovation Performance*, 12 PLoS ONE 17 (2017); see, e.g., Lars Schweizer, *Organizational Integration of Acquired Biotechnology Companies into Pharmaceutical Companies: The Need for a Hybrid Approach*, 48 ACAD. MGMT. J. 1051, 1066 (2005) (stating that, so far, there is no consensus on measuring M&A success).

34. Daniel B. Kramer et al., *Regulation of Medical Devices in the United States and European Union*, 366 NEW ENG. J. MED. 848, 848 (2012) (“Reports suggest that European patients have access to some high-risk medical devices, such as coronary stents and replacement joints, earlier than American patients.”).

35. See David T. Robinson & Toby E. Stuart, *Financial Contracting in Biotech Strategic Alliances*, 50 J.L. & ECON. 559, 559 (2007) (“[S]urvey evidence from the Pharmaceutical Research and Manufacturers of America (PhRMA) suggests that roughly 25 percent of the \$26 billion in United States-based, industrially financed, pharmaceutical R&D that occurred in 2000 took place in over 700 collaborative agreements with outside organizations.”); Frank T. Rothaermel & David L. Deeds, *Exploration and Exploitation Alliances in Biotechnology: A System of New Product Development*, 25 STRATEGIC MGMT. J. 201, 201 (2004).

### C. *How to Measure the Effect of Acquisitions on Innovation*

How then does one properly measure innovation? Largely, it depends on the particular transaction, the particular market dynamics, and the evidence. It is not an exact science but rather depends on the facts. Nevertheless, agency guidance is helpful to establish the types of questions to ask. In *Dow/DuPont*, for example, the European Commission looked at patent shares based on patent citations (but only for so-called high quality patents, and making further exclusions from the patent universe); sales derived from “new [active ingredients]”; and they came up with “innovation spaces” (which were in essence equivalent to downstream markets) and took worldwide downstream market shares to measure innovation space shares.<sup>36</sup>

In its review of pharmaceutical acquisitions in the past, the FTC has used two types of analytical frameworks: (a) actual or potential future competition affecting prices in a current or future product market, and (b) effect on an innovation or R&D market, where innovation itself is the “product” at issue.<sup>37</sup> Both approaches are valuable and offer a roadmap of how such an analysis should be undertaken generally in pharma acquisition cases. As these acquisitions are non-horizontal, the proper legal test requires weighing both the pro and anti-competitive effects of such transactions more holistically, which is developed in-depth in a related paper.<sup>38</sup>

Studying an issue, such as pharma acquisitions, is helpful, and perhaps some sort of workshop convened by the FTC with professors in economics and strategy would be useful to understanding the extant literature, current gaps, and ways to operationalize findings that may be unique to the pharmaceutical sector.

### CONCLUSION

Pharma provides significant value to U.S. consumers. It is a source of innovation and improved health-quality outcomes. Antitrust agencies must guard against anti-competitive mergers within pharma. However, antitrust law must balance intervention with incentives to allow firms to innovate and make strategic acquisitions when such acquisitions improve

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36. Commission Decision (EC) No. 139/2004 of 27 March 2017, art. 8, 2017 O.J. (C 7932) at 43–45.

37. See Mark D. Whitener, *Competition and Antitrust Enforcement in the Changing Pharmaceutical Marketplace*, 50 FOOD & DRUG L.J. 301, 301 (1995); see also Deborah L. Feinstein, Director, Fed. Trade Comm’n: Bureau of Competition, Remarks at Advanced Antitrust U.S.: The Forward-Looking Nature of Merger Analysis 4 (2014).

38. See generally Roger D. Blair et al., *Analyzing Vertical Mergers: Accounting for the Unilateral Effects Tradeoff and Thinking Holistically About Efficiencies*, 27 GEO. MASON L. REV. 761 (forthcoming 2020) (stating “antitrust needs to embrace a ‘holistic efficiency analysis,’ which incorporates [a] broader set of efficiencies that is well recognized in the academic literature”).

consumer welfare. This Essay proposes a framework, based on economic effects, that identifies where regulators should look for evidence and what sort of evidence leads to better decision-making as to which deals present competitive threats in pharma.