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ABSTRACT

Mergers and acquisitions in the pharmaceutical industry face increasing regulatory scrutiny due to their unclear impact on drug innovation. This article reviews academic literature, highlighting theoretical mechanisms by which mergers can affect innovation and the empirical challenges in measuring this impact. Theoretical literature suggests both positive (e.g., improved funding access, enhanced asset complementarity) and negative impacts (e.g., reduced competition). However, empirical studies are limited and yield mixed results due to differences in innovation measurement and models. The article underscores the limitations of existing empirical literature and calls for further research to better understand these impacts on consumer welfare.

Les fusions et acquisitions dans l'industrie pharmaceutique sont de plus en plus surveillées par les régulateurs en raison de leur impact potentiel sur l'innovation, qui reste mal comprise. Cet article examine la doctrine académique, en mettant en lumière les mécanismes théoriques par lesquels les fusions peuvent affecter l'innovation et les défis empiriques pour mesurer cet impact. La doctrine théorique suggère des impacts positifs (meilleur accès au financement, meilleure complémentarité des actifs) et négatifs (réduction de la concurrence). Cependant, les études empiriques sont limitées et donnent des résultats mitigés. L'article souligne les limites de la doctrine empirique et appelle à des recherches supplémentaires pour mieux comprendre ces impacts sur le bien-être des consommateurs.

* The views expressed herein are those of the authors and do not necessarily represent the views of Cornerstone Research.

I. Introduction

1. The pharmaceutical industry heavily relies on continued investments in research and development (R&D) to drive innovation. Pharmaceutical companies use mergers and acquisitions[1] strategically to strengthen market positions, expand product portfolios, access new technologies, and enhance innovation capabilities.

2. Regulators are increasingly focusing on the impact of pharmaceutical mergers on innovation. The new merger guidelines issued by the U.S. Department of Justice (DOJ) and the Federal Trade Commission (FTC) in December 2023 signaled a more expansive scrutiny of mergers that includes merger impacts on both "*actual potential entrants*" and "*perceived potential entrant*[s]."[2] Even before the new guidelines, U.S. and European regulators evaluated the potential impacts of high-profile pharmaceutical mergers on research incentives and competition in drug development, particularly in instances where the parties had overlapping drug development pipelines.[3] For example, the European Commission (EC)'s assessment of pharmaceutical mergers takes into account actual competition, overlaps between parties' existing products and pipeline products, overlaps

1 For simplicity, in the rest of the article we use "mergers" as a shorthand for any merger and/or acquisition activity. The types of mergers we focus on in the paper can generally be described as horizontal mergers, i.e., mergers of two pharmaceutical firms both devoted to drug development.

2 DOJ and FTC, Merger Guidelines, 18 December 2023, Guideline 4, https://www.justice.gov/d9/2023-12/2023 Merger Guidelines.pdf.

3 For example, U.S. and European regulators pursued such theories in their review of the *BMS-Celgene*, *Illumina-Pacific Biosciences*, and *Roche-Spark* transactions. *See* Eur. Comm., decision C(2019) 5799 final of 29 July 2019, *BMS/Celgene*, case M.9294; FTC, Bristol-Myers Squibb Company and Celgene Corporation; Analysis of Agreement Containing Consent Orders To Aid Public Comment, 84 FR 66191, 3 December 2019; FTC press release, FTC Challenges Illumina's Proposed Acquisition of PacBio, 17 December 2019, https://www.ftc.gov/news-events/news/press-releases/2019/12/ftc-challenges-illuminas-proposed-acquisition-pacbio; FTC, Statement of the Federal Trade Commission In Re Roche Holding/Spark Therapeutics, 16 December 2019, https://www.ftc.gov/system/files/documents/public_statements/1558049/1910086_roche-spark_commission_statement_12-16-19.pdf; CMA, Pharmaceutical Merger Cleared by CMA, 16 December 2019, https://www.gov.uk/government/news/pharmaceutical-merger-cleared-by-cma.

between parties' ongoing pipeline products, and overlaps between parties' capabilities of innovating in certain product spaces.[4]

3. This article examines the current state of the academic literature, highlighting the insights that can be gained from the research, and identifying the remaining gaps. The literature identifies various mechanisms through which mergers in the pharmaceutical industry can impact innovation. On the one hand, pharmaceutical mergers can create economies of scale and scope, enhance asset complementarity, increase entrants' incentives to innovate, improve funding access, and optimize resource allocation across research projects, all bolstering innovation. On the other hand, stronger market positions resulting from mergers may reduce innovation incentives and future competition if merging parties stop investing in the development of drugs they acquire.[5] Relative to the large body of literature studying the various mechanisms at play, empirical studies measuring the impact of pharmaceutical mergers on innovation are scarce. Existing studies vary in important aspects, such as how they measure innovation and the time horizon of analysis. More importantly, these studies are often unable to disentangle the various mechanisms through which pharmaceutical mergers can impact innovation. As a result, the aggregate effect of pharmaceutical mergers on innovation and consumer welfare remains an open question for future empirical research.

II. There are various mechanisms through which pharmaceutical mergers can impact innovation

4. We now describe some of the mechanisms through which mergers in the pharmaceutical industry can impact innovation, as shown by the academic literature.

5. Economies of scale and scope. R&D costs are fixed costs that all pharmaceutical firms must incur to innovate. Research has shown that larger firms can exploit economies of scale in research activities to achieve lower per-unit development costs, which in turn can lead to improved innovation output.[6] This has been shown to hold in the pharmaceutical industry by Cockburn and Henderson (1996), among others.[7] Additionally, mergers can generate economies of scope, which arise when the cost of jointly conducting multiple but related activities is lower than when conducting them separately.[8] Indeed, knowledge synergies, which are a special case of economies of scope, can enhance research performance regardless of changes in R&D inputs.[9] By generating economies of scope and knowledge spillovers, mergers can have a positive impact on innovation, as shown by Jullien and Lefouili (2018).[10] Similarly, Cockburn and Henderson (2001) find that economies of scope lead to superior research and development performance in the pharmaceutical industry.[11]

4 See V. Dolka, S. Karkela, Aiste Slezeviciute, Zsolt Vertessy, *Competition Policy Brief*, Assessing Innovation Competition in Pharma Mergers, April 2024, at p.18.

5 The complex relationship between mergers and innovation goes back to the classic Schumpeterian view of innovation. Joseph Schumpeter argued that large, established firms might stifle innovation due to their focus on protecting existing market share. J. A. Schumpeter, *Socialism, Capitalism and Democracy*, Harper, New York, 1942. Mergers, in this view, could exacerbate this trend. Conversely, Kenneth Arrow proposed that larger firms possess the resources and capabilities to undertake high-risk, high-reward research projects, potentially accelerating innovation. K. Arrow, Economic Welfare and the Allocation of Resources for Invention, in *The Rate and Direction of Inventive Activity: Economic and Social Factors*, Princeton University Press, 1962, pp. 609–626.

6 *See*, e.g., J. A. Schumpeter, *Capitalism, Socialism & Democracy*, 3rd ed., Routledge, London and New York, 1950; W. M. Cohen and R. C. Levin, Empirical Studies of Innovation and Market Structure, in *Handbook of Industrial Organization*, Vol. 2, R. Schmalensee and R. Willig (eds.), Elsevier, Amsterdam 1989, pp. 1059–1107; V. Maksimovic and G. Phillips, The Market for Corporate Assets: Who Engages in Mergers and Asset Sales and Are There Efficiency Gains?, *The Journal of Finance*, Vol. 56, No. 6, 2001, pp. 2019–2065 ("Maksimovic and Phillips (2001)"); M. Igami and K. Uetake, Mergers, Innovation, and Entry-Exit Dynamics: Consolidation of the Hard Disk Drive Industry, 1996–2016, *The Review of Economic Studies*, Vol. 87, No. 6, 2020, pp. 2672–2702 ("Igami and Uetake (2020)"); J. Bena and K. Li, Corporate Innovations and Mergers and Acquisitions, *The Journal of Finance*, Vol. 69, No. 5, 2014, pp. 1923–1960 ("Bena and Li (2014)"). Bena and Li illustrate how mergers can improve innovation through economies of scale by using the example of the merger between Pharmacia and Upjohn Monsanto. The companies were operating in different, but complementary, therapeutic areas. Monsanto's most successful product (Celebrex) used a novel technological platform known as Cox-2-specific inhibitors; the merger allowed Pharmacia & Upjohn access to this technology. Similarly, Pharmacia & Upjohn had strong expertise in biotechnology (genomics) based on large biotech proteins, which had not been adopted by Monsanto in its small chemicals prior to the merger. The merger allowed the creation of a critical mass for expanding in-house clinical research; the typical scale of R&D projects increased, while the lead time of research decreased. *See also* S. Nicholson, Financing Research and Development, in *The Oxford Handbook of the Economics of the Biopharmaceutical Industry*, P. M. Danzon and S. Nicholson (eds.), Oxford University Press, 2012, pp. 47–74 ("Nicholson (2012)"); D. N. Lakdawalla, Economics of the Pharmaceutical Industry, *Journal of Economic Literature*, Vol. 56, No. 2, 2018, pp. 397–449 ("Lakdawalla (2018)").

7 R. M. Henderson and I. M. Cockburn, Scale, Scope, and Spillovers: The Determinants of Research Productivity in Drug Discovery, *RAND Journal of Economics*, Vol. 27, No. 1, 1996, pp. 32–59. For a review of the relationship between M&As, innovation, and economies of scale in the pharmaceutical industry, *see*, e.g., Nicholson (2012), *supra* note 5, and Lakdawalla (2018), *supra* note 5.

8 For a discussion of economies of scope, *see* J. C. Panzar and R. D. Willing, Economies of Scope, *The American Economic Review*, Vol. 71, No. 2, 1981, pp. 268–272.

9 Bena and Li (2014), *supra* note 5; Lakdawalla (2018), *supra* note 5; C. Ornaghi, Mergers and Innovation in Big Pharma, *International Journal of Industrial Organization*, Vol. 27, No. 1, 2009, pp. 70–79 ("Ornaghi (2009)").

10 B. Jullien and Y. Lefouili, Horizontal Mergers and Innovation, *CEPR Discussion Paper* No. 12773, 2018 ("Jullien and Lefouili (2018)"). Specifically, Jullien and Lefouili show that mergers can have a positive impact on innovation when there are significant knowledge spillovers and when merging firms can benefit from asset complementarities and coordination of research activities. Furthermore, to the extent a merger leads to economies of scope and scale that allow the merged firm to conduct R&D more efficiently and less costly, this may enable the merged firm to charge lower drug prices. *See*, e.g., B. Mermelstein, V. Nocke, M. A. Satterthwaite and M. D. Whinston, Internal versus External Growth in Industries with Scale Economies: A Computational Model of Optimal Merger Policy, *Journal of Political Economy*, Vol. 128, No. 1, 2020, pp. 301–341. Indeed, the majority of new drugs never manage to generate enough sales to cover the average R&D costs. J. DiMasi and H. Grabowski, R&D Costs and Returns to New Drug Development: A Review of the Evidence, in *The Oxford Handbook of the Economics of the Biopharmaceutical Industry*, P. M. Danzon and S. Nicholson (eds.), Oxford University Press, 2012, pp. 22–46.

11 I. M. Cockburn and R. M. Henderson, Scale and Scope in Drug Development: Unpacking the Advantages of Size in Pharmaceutical Research, *Journal of Health Economics*, Vol. 20, No. 6, 2001, pp. 1033–1057.

6. Technology transfer and asset complementarity. In innovative industries like the pharmaceutical industry, mergers often involve large firms acquiring technologies from smaller, more innovative companies.[12] Studies argue that such technology transfers can spur innovation when firms have complementary assets. The property rights theory, developed by Grossman and Hart (1986), Hart and Moore (1990), Hart (1995), Hart (2009), and Hart and Holmstrom (2010),[13] illustrates how a single firm controlling complementary assets can lead to optimal investment levels compared to rival firms separately controlling those assets and failing to internalize the benefits of their investments.[14] More recently, Cabral (2018) has shown that the technology transfer that occurs with an acquisition increases incremental innovation because the acquired firm internalizes the acquiring firm's higher value from innovation.[15]

7. Entry for buyout. Pharmaceutical mergers, particularly acquisitions of small biotech firms by large pharmaceutical firms, can also increase the aggregate level of innovation through a mechanism called "innovation for buyout."[16] While large firms find it optimal to buy other firms to gain access to successful innovation, small firms have greater incentives to invest in R&D when facing an active takeover market, as they benefit from the acquisition. Phillips and Zhdanov (2012) capture this mechanism in a model where a firm's incentives to conduct R&D increase with the probability of being acquired but diminish with the firm's size.[17] Similarly, Hollenbeck (2019) shows that the prospect of a buyout incentivizes firms to enter the market and invest in innovation in order to become an attractive merger target.[18] This mechanism is also present in Cabral (2018), who cautions that as a result, restrictive merger policies may hinder entry by small innovative firms and thereby reduce innovation.[19] Furthermore, Dijk et al. (2024) identify a new way in which the "innovation for buyout" can increase consumers' surplus, which is by affecting the direction of innovation.[20] The study shows that when anticipating an acquisition, start-up firms change their investment portfolios to increase acquisition rents.[21] The change in allocation of resources generated by the prospect of an acquisition can align private and social incentives to invest in projects with the highest social return, increasing aggregate investments and consumer welfare.

8. Financial constraints. When firms have financial constraints, mergers can provide access to the acquirer's internal funds and boost innovation by reducing a target's cost of investing.[22] Financial frictions are particularly relevant in the pharmaceutical industry, where it can take 10 to 15 years and over USD 2.5 billion to develop a drug and obtain regulatory approval to market it.[23] This mechanism is illustrated by Fumagalli et al. (2020), who model the trade-off between increased innovation from the mitigation of financial frictions and the reduced innovation from the incumbent's incentives to terminate the acquired projects—the latter is the "killer acquisition" motive that we discuss further below.[24] The article models the optimal merger policy for innovation by balancing these two incentives; the optimal policy will depend on the severity of the industry's financial frictions. Financial frictions are also considered

12 J. Asker and V. Nocke, Collusion, Mergers, and Related Antitrust Issues, in *Handbook of Industrial Organization*, Vol. 5, K. Ho, A. Hortaçsu and A. Lizzeri (eds.), Elsevier, Amsterdam, 2021, pp. 177–279.

13 S. J. Grossman and O. D. Hart, The Costs and Benefits of Ownership: A Theory of Vertical and Lateral Integration, *Journal of Political Economy*, Vol. 94, No. 4, 1986, pp. 691–719; O. Hart and J. Moore, Property Rights and the Nature of the Firm, *Journal of Political Economy*, Vol. 98, No. 6, 1990, pp. 1119–1158; O. Hart, *Firms, Contracts, and Financial Structure*, Clarendon Press, New York, 1995; O. Hart, Hold-Up, Asset Ownership, and Reference Points, *The Quarterly Journal of Economics*, Vol. 124, No. 1, 2009, pp. 267–300; O. Hart and B. Holmstrom, A Theory of Firm Scope, *The Quarterly Journal of Economics*, Vol. 125, No. 2, 2010, pp. 483–513.

14 This is also the main idea articulated by Rhodes-Kropf and Robinson (2008), i.e., that complementarities of assets can only be realized if the assets are joined together in a single firm. *See* M. Rhodes-Kropf and D. T. Robinson, The Market for Mergers and the Boundaries of the Firm, *The Journal of Finance*, Vol. 63, No. 3, pp. 1169–1211.

15 Cabral (2018) argues that the prospect of selling to the acquirer increases the payoffs from innovation to the acquired firm. *See* L. Cabral, Standing on the Shoulders of Dwarfs: Dominant Firms and Innovation Incentives, *CEPR Discussion Paper* No. 13115, 2018 ("Cabral (2018)"). The Cabral (2018) model features two firms—a dominant and a fringe firm—which choose at every point in time how much to invest in innovation. An acquisition is modeled as a technology transfer from the technological leader to the laggard by which the latter becomes the new technological leader. The technology is transferred to the dominant firm because the fringe firm internalizes the dominant firm's value from innovation, and the prospect of selling to a "giant" further increases the payoffs from innovation by a fringe firm.

16 E. Rasmusen, Entry for Buyout, *The Journal of Industrial Economics*, Vol. 36, No. 3, 1988, pp. 281–299. This study shows that new companies enter the market simply because the possibility of a buyout makes their entry profitable, which otherwise it would not be. *See also* E. Dijk, J. L. Moraga-González and E. Motchenkova, How Do Start-up Acquisitions Affect the Direction of Innovation?, *The Journal of Industrial Economics*, Vol. 72, No. 1, 2024, pp. 118–156 ("Dijk et al. (2024)").

17 G. M. Phillips and A. Zhdanov, R&D and the Incentives from Merger and Acquisition Activity, *NBER Working Paper* No. 18346, 2012.

18 In the model offered by Hollenbeck (2019), firms compete by innovating on product quality. *See* B. Hollenbeck, Horizontal Mergers and Innovation in Concentrated Industries, *Quantitative Marketing and Economics*, Vol. 18, 2019, pp. 1–37.

19 Cabral (2018), *supra* note 14, also considers the trade-off between "radical innovation"—defined as innovation that creates a new dominant firm—and incremental innovation. The study notes that mergers can decrease radical innovation because the possibility of a technology transfer increases the opportunity cost of the acquired firm to invest in radical innovation.

20 Dijk et al. (2024), *supra* note 15. Distortions in the direction of innovation is a topic that has gained substantial attention in the recent literature. *See*, e.g., H. Hopenhayn and F. Squintani, On the Direction of Innovation, *Journal of Political Economy*, Vol. 129, No. 7, 2021, pp. 1991–2022.

21 Dijk et al. (2024), *supra* note 15.

22 I. Erel, Y. Jang and M. S. Weisbach, Do Acquisitions Relieve Target Firms' Financial Constraints?, *The Journal of Finance*, Vol. 70, No. 1, 2015, pp. 289–328; Lakdawalla (2018), *supra* note 5.

23 The 2024 Competition Policy Brief recognizes that "A "big pharma" company buying a start-up may grant the target the financial and operational capability to effectively bring a product to the market with pro-competitive effects." See V. Dolka, S. Karkela, Aiste Slezeviciute, Zsolt Vertessy, *Competition Policy Brief*, Assessing Innovation Competition in Pharma Mergers, April 2024, at p.17. PhRMA, Biopharmaceuticals in Perspective, 2020 ("PhRMA Chart Pack"), at 27; Lakdawalla (2018), *supra* note 5, at 411.

24 C. Fumagalli, M. Motta and E. Tarantino, Shelving or Developing? The Acquisition of Potential Competitors under Financial Constraints, *Economic Working Paper Series Working Paper* No. 1735, July 2020, n. 637. On the one hand, the incumbent firm has sufficient funds to invest in the project, whereas the smaller firm is credit-constrained and lacks the funds to develop the project further. Thus, the acquisition of a smaller firm by a larger incumbent may allow the merged entities to develop a project that would otherwise never reach the market. On the other hand, the incumbent firm can decide to shelve the project and not move forward with development.

by other studies in the context of risk-averse firms.[25] In the presence of costly external finance, as is the case in the pharmaceutical industry,[26] smaller firms with variable and uncertain cash flows tend to reduce investments in innovation. Mergers provide cash flows and cheaper internal funds to target firms, driving innovation by small risk-averse firms, as empirically documented in the pharmaceutical industry by Krieger et al. (2022). This study finds that positive shocks to cash flows increase innovation, especially for riskier, novel, and more clinically beneficial drugs.[27]

9. Optimal project selection. Pharmaceutical mergers can also affect innovation by changing the resource allocation among projects. For example, mergers can incentivize firms to pursue the optimal R&D mix, as shown by Maksimovic and Phillips (2001), among others.[28] Moraga-González et al. (2022) develop a model that examines how mergers affect the investment portfolios chosen by merging and non-merging firms.[29] Pre-merger, firms tend to over-invest in projects with the highest profitability and under-invest in projects that are more socially desirable.[30] Mergers enable parties to internalize the impact of their investments on each other's probability of success, boosting investments in socially desirable projects.[31]

10. Reduced competition. At the same time, mergers can also hinder innovation by increasing the merged firms' market power, potentially reducing output levels and innovation incentives if these incentives are tied to short-term output levels. For example, the value of cost-reducing innovation decreases with a firm's output level. This is shown by Motta and Tarantino (2021), who developed a model where enhanced market power through a merger reduces output and, hence, the incentives of the merged firm to innovate.[32] A similar mechanism arises with demand-enhancing innovation. Federico et al. (2017) and Federico et al. (2018) show that in the presence of product substitutability, if one firm invests more in demand-enhancing innovation, then it reduces the market shares and profits of rival firms. Following a merger, the parties will internalize this effect, reducing the merged firm's incentives to innovate to avoid profit cannibalization.[33,34]

11. Foreclosing future competition. Cunningham et al. (2021)[35] argue that an established pharmaceutical company may have economic incentives not only to engage in less innovation to avoid cannibalization of its existing product sales but also to stifle the innovation of other companies.[36] One mechanism through which such companies can stifle innovation is through acquiring rival companies and discontinuing the development of their pipeline products (i.e., through "killer acquisitions").[37] The authors note that these economic incentives exist when there is an overlap between the target's pipeline products and the acquirer's existing products, i.e., when the two sets of products will be expected to compete against each other in the future.[38,39]

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25 Lakdawalla (2018), *supra* note 5, observes that if firms are risk-averse and there are capital market imperfections, pharmaceutical companies will seek to smooth cash flows over time.

26 Nicholson (2012), *supra* note 5.

27 Krieger et al. (2022) employ a model that captures the high cost of external financing in the pharmaceutical industry, where negative shocks to firms' net worth lead firms to develop fewer novel drugs. *See* J. Krieger, D. Li and D. Papanikolaou, Missing Novelty in Drug Development, *The Review of Financial Studies*, Vol. 35, No. 2, 2022, pp. 636–679.

28 Maksimovic and Phillips (2001), *supra* note 5.

29 J. L. Moraga-González, E. Motchenkova and S. Nevrekar, Mergers and Innovation Portfolios, *The RAND Journal of Economics*, Vol. 53, No. 4, 2022, pp. 641–677.

30 The authors consider a model where two rival firms invest in two independent types of projects that correspond to two independent innovation areas. The model incorporates two innovation externalities: (i) business stealing externality—if a firm invests more in a given project, it reduces the rival firm's probability to win the contest for that innovation area; (ii) business giving externality—if a firm allocates more resources to one project, this decreases the aggregate resources allocated to the other innovation area, and thus increases the probability that the rival firm wins the context for innovation. Before a merger, firms do not internalize the innovation externalities, and this distorts their investment decisions away from the socially optimal allocation of resources.

31 The authors find that this result is robust to multiple extensions of the model, one of which allows for market power.

32 M. Motta and E. Tarantino, The Effect of Horizontal Mergers, When Firms Compete in Prices and Investments, *International Journal of Industrial Organization*, Vol. 78, 2021.

33 At the same time, the authors show that a merger that leads to less product market competition can increase the merged firm's profits and thus its incentives to innovate. This mechanism could offset the negative effect of the previous channel, making the outcome of mergers on demand-enhancing innovation ambiguous. Denicolò and Polo (2018) argue that mergers can actually spur innovation by preventing duplication of efforts. The authors argue that Federico et al. (2017) results flip when the restrictive assumption that firms spread their R&D expenditures evenly across research units is relaxed. *See* V. Denicolò and M. Polo, Duplicative Research, Mergers and Innovation, *Economics Letters*, Vol. 166, No. C, 2018, pp. 56–59; G. Federico, G. Langus and T. Valletti, A Simple Model of Mergers and Innovation, *Economics Letters*, Vol. 157, No. C. 2017, pp. 136–140; G. Federico, G. Langus and T. Valletti, Horizontal Mergers and Product Innovation, *International Journal of Industrial Organization*, Vol. 59, 2018, pp. 1–23.

34 Haucap et al. (2019) show that in very research-intensive areas, a merger can reduce innovation due to the merged firm's internalization of the business-stealing effects of innovation. *See* J. Haucap, A. Rasch and Joel Stiebale, How Mergers Affect Innovation: Theory and Evidence, *International Journal of Industrial Organization*, Vol. 63, 2019, pp. 283–325 ("Haucap et al. (2019)").

35 C. Cunningham et al., Killer Acquisitions, *Journal of Political Economy*, Vol. 129, No. 3, 2021, pp. 649–702 ("Cunningham et al. (2021)").

36 Ibid. at 651, 655.

37 See V. Dolka, S. Karkela, Aiste Slezeviciute, Zsolt Vertessy, *Competition Policy Brief*, Assessing Innovation Competition in Pharma Mergers, April 2024, at p.17, "the result of an acquisition could be that the purchaser discontinues its own or target's R&D efforts, which can lead to price increases and reduced choices."

38 Ibid. at 651. The Cunningham et al. (2021) model also has two other predictions: (i) that economic incentives to engage in "killer acquisitions" are stronger the less competitive the market is for the acquirer's existing products; (ii) that economic incentives are stronger when the acquirer's existing products are far from patent expiration. In both situations, the model implies that the acquirer has more economic profits to lose in case of future competition from the target and, therefore, the acquirer has stronger economic incentives to foreclose such competition by engaging in a "killer acquisition."

39 Other studies, such as Igami and Uetake (2020), *supra* note 5, show that the incentives to foreclose future competitors through acquisitions need to be evaluated and balanced against the synergies that can arise from the merged firms' combining their R&D capabilities. Similarly, Gilbert and Katz (2018) show that the prospect of a merger can induce potential target firms to differentiate their products from the acquirer's products to better satisfy consumers' preferences for broader product choice. If the parties merge, the acquirer would not have economic incentives to "kill" the acquired products because having multiple products allows the merged firm to increase profits, opposite to the mechanism of "killer acquisitions." *See* R. J. Gilbert and M. L. Katz, Dynamic Merger Policy and Pre-Merger Product Choice by an Entrant, *International Journal of Industrial Organization*, Vol. 81, 2022, pp. 1–18.

III. Empirical studies on the impact of pharmaceutical mergers on innovation are scarce and find mixed results

12. Compared to the extensive literature on the mechanisms through which mergers can affect innovation, empirical studies on the size of that impact in the pharmaceutical industry are limited and have found mixed results. Several studies find that pharmaceutical mergers can bolster innovation. Higgins and Rodriguez (2006),[40] Grabowski and Kyle (2008),[41] and Ringel and Choy (2017)[42] all find evidence that pharmaceutical mergers can improve a company's R&D pipeline and the likelihood that drug candidates successfully progress through development stages to commercialization. Grabowski and Kyle (2008) also show that small pharmaceutical firms can particularly benefit from merging with established firms to successfully bring a new drug to the market. Conversely, Danzon et al. (2007) find no effects on R&D expenses three years following the merger.[43]

13. Karim and Meder (2019)[44] focus on the impact of pharmaceutical mergers on firms' R&D strategies. This study finds that post-merger merging firms shift development focus and become less likely to initiate new projects in the same therapeutic areas, possibly to prevent redundancy and streamline research efforts. At the same time, post-merger, the merging firms are much more likely to enter related therapeutic areas but ones in which they have not been active before the merger.

14. Other studies describe a more complex relationship between pharmaceutical mergers and innovation. For example, Haucap et al. (2019) find that, on average, mergers among large pharmaceutical firms reduce patenting and R&D activity, both within the merged entities and non-merging competitors; however, the results are highly heterogeneous and depend on the market considered.[45] The decline in innovation measured in the study is concentrated in technological fields with high levels of pre-merger innovation activity; the study also shows that a pharmaceutical merger can increase innovation—by both the merged firm and its non-merging competitors—in technological fields with low levels of pre-merger innovation activity. Recently, studies such as Schutz (2023)[46] and Bonaimé and Wang (2024)[47] find that while pharmaceutical mergers may increase R&D spending, they may lead to only incremental improvements rather than the development of entirely new drug therapies.

15. Ornaghi (2009)[48] also investigates the innovation outcomes of large pharmaceutical mergers. This study shows merging companies reduce R&D spending and

40 Higgins and Rodriguez (2006) analyze a sample of 160 pharmaceutical and biotechnology acquisitions between 1994 and 2001. They find that acquisitions can improve "pipeline scores," defined by the count of drugs at each stage of development weighted by the average probability of success for a project at that stage. *See* M. J. Higgins and D. Rodriguez, The Outsourcing of R&D Through Acquisitions in the Pharmaceutical Industry, *Journal of Financial Economics*, Vol. 80, 2006, pp. 351–383.

41 Grabowski and Kyle (2008) study the effects of mergers on the progress of individual projects rather than overall R&D spending. Using data on over 4,500 firms between 1990 and 2007, the study estimates the likelihood of a project advancing to the next stage of development within five years while also controlling for merger activity. The authors find that a company's experience in drug development stages, especially the crucial phase III trials, is linked to a higher chance of success. *See* H. Grabowski and M. Kyle, Mergers and Alliances in Pharmaceuticals: Effects on Innovation and R&D Productivity, in *The Economics of Corporate Governance and Mergers*, K. Gugler and B. Yurtoglu (eds.), Edward Elgar Publishing, Cheltenham, 2008, pp. 262–287.

42 Ringel and Choy (2017) find that mergers among the largest pharmaceutical companies between 2001 and 2011 increased R&D productivity by 1.83 times in the three-year period after a merger. *See* M. S. Ringel and M. K. Choy, Do Large Mergers Increase or Decrease the Productivity of Pharmaceutical R&D?, *Drug Discovery Today*, Vol. 22, No. 12, 2017, pp. 1749–1753.

43 P. M. Danzon, A. Epstein and S. Nicholson, Mergers and Acquisitions in the Pharmaceutical and Biotech Industries, *Managerial and Decision Economics*, Vol. 28, No. 4/5, 2007, pp. 307–328.

44 Karim and Meder (2019) explore the impact of mergers on innovation by looking at how resources are used after the merger. The study analyzes how different types of overlaps between merging firms (i.e., overlaps in the area of drug development, overlaps in the therapeutical field and indirect overlaps through joint activities or collaboration) affect resources' allocation post-merger. The analysis does not look to answer whether there is an increase in drug development post-merger. Instead, the study assesses the extent to which a company's development trajectory changes post-merger. *See* S. Karim and H. Meder, New Product Developments Post-M&As—Changes in Development Trajectory of Pharmaceutical Firms, Working Paper, 2019.

45 Haucap et al. (2019), *supra* note 33. Additionally, the paper studies only horizontal mergers among big pharmaceutical firms. Therefore, the analysis excludes acquisitions of small biotech firms.

46 Schutz (2023) shows that pharmaceutical mergers between 2007 and 2016 were associated with a decrease in the number of primary filed patents, an increase in R&D expenses, and an unchanged number of drugs passing through clinical trials and new drugs in development. The study also finds an insignificant impact on the number of discontinued drugs. The author suggests that companies might be acquiring existing technologies/products patented by smaller firms and thus replenishing their drug portfolios through acquisition. *See* S. Schutz, Mergers, Prices, and Innovation: Lessons from the Pharmaceutical Industry, Working Paper, 2023 ("Schutz (2023)").

47 Bonaimé and Wang (2024) use data on new drug approvals to isolate the impact of pharmaceutical mergers on new drug applications. They show that mergers increase new drug applications. However, the study shows that this increase seems to be driven mostly by "secondary" applications, which are filed in relation to changes in the product label or the manufacturing process. The study finds that mergers do not have a statistically significant impact on "primary" applications, which are filed for first-time new drugs. *See* A. Bonaimé and Y. Wang, Mergers, Product Prices, and Innovation: Evidence from the Pharmaceutical Industry, *The Journal of Finance*, Vol. 79, No. 3, 2024, pp. 2195–2236 ("Bonaimé and Wang (2024)").

48 Ornaghi (2009), *supra* note 8, investigates the innovation outcomes of large pharmaceutical mergers between 1988 and 2004. The study combines financial data of large pharmaceutical companies, data on U.S. patents, and information on new drugs recorded in the Food and Drug Administration (FDA) *Orange Book*. By leveraging a propensity score matching approach, this study finds that merging companies decrease R&D expenditures and the number of filed patents compared to non-merging firms.

patents filed compared to non-merging firms. Yet, the study also finds that higher product relatedness pre-merger can improve R&D outcomes post-merger. As Ornaghi (2009) explains, firms with a larger share of drugs in the same therapeutic areas before the merger may be better at leveraging economies of scale achieved through the merger.

16. By contrast, Cunningham et al. (2021) demonstrate that greater product relatedness pre-merger can result in increased project abandonment post-merger. The authors compare "overlapping" mergers, i.e., mergers where the acquirer and the target have drug projects and/or existing drug products in the same therapeutic area, with "non-overlapping" mergers, i.e., where the acquirer and the target have products and projects in different therapeutic areas. Cunningham et al. (2021) show that drug projects in "overlapping" mergers are 23.4% less likely to have continued development post-merger relative to drug projects in "non-overlapping" mergers.[49] The authors conclude that between 5.3% and 7.4% of all mergers in their study sample are what they call "killer acquisitions."[50]

17. These mixed findings from the empirical studies make it hard to conclude whether pharmaceutical mergers have a positive or negative effect on innovation and why. The first issue lies in how innovation itself is measured. Different studies use different measures of innovation, including patent counts, R&D investments, new drug applications, and development likelihood.[51] These measures capture innovation at different stages (discovery versus development) and can be impacted differently by mergers. For example, patent counts reflect early discoveries but do not guarantee a project's success. Similarly, R&D spending measures short-term development activity but does not reliably measure the impact on the discovery of new drugs, which involves a lengthy and risky development process.[52]

18. Even when studies use comparable innovation metrics, they differ in the geographic market, the product market, the type of transaction, and the time period analyzed. For example, some articles analyze mergers within specific regions (e.g., Europe vs. U.S.) or therapeutic areas, and it is unclear whether the results can be extrapolated to other regions or therapeutic areas.[53] Additionally, the studies analyze mergers involving companies of different sizes, research focus, marketing, manufacturing capabilities, targeted patient populations, and cash flows. These differences generate various strategic motives to engage in mergers, with resulting effects on innovation tied to these differences. Data inconsistencies make conclusions even more challenging, with studies using data from different decades and covering varying timeframes after the merger (ranging from 3 to 10 years).[54] Any of these factors can significantly influence the size and direction of the estimated impact of mergers on innovation.

19. Results of the studies also depend on the specific assumptions or models used by the researchers. For example, the findings of Cunningham et al. (2021) critically depend on the authors' ability to accurately detect if there is an overlap between a target firm's development projects and the acquirer's existing drugs or its own development projects.[55] As the authors explain, without an overlap, i.e., without the expectation that a target firm's drug project will be a future competitor to the acquirer's drugs/projects, there will be no motive for the acquirer to "kill" such a project. Yet, determining if such an overlap exists is inherently difficult, given that pharmaceutical development is long and uncertain.[56] A drug project that is initially being investigated as a treatment in a therapeutic class may receive marketing approval for a different therapeutic class following subsequent clinical testing. Even if a drug receives marketing approval for the same therapeutic class for which it was initially being investigated, it may receive subsequent marketing approval for uses in different therapeutic classes, and those uses may end up accounting for the majority of a drug's sales.[57] [58]

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49 Cunningham et al. (2021), *supra* note 34, at 652.

50 Ibid. at 654, 692–693.

51 Cunningham et al. (2021), *supra* note 34; Bonaimé and Wang (2024), *supra* note 45; Schutz (2023), *supra* note 44.

52 It costs an estimated USD 2.6 billion in pre-tax development expenditures, often over a decade or more, to navigate the development of a drug from initial clinical studies through FDA approval. The overall probability of clinical success (i.e., the likelihood that a drug that enters clinical testing will eventually be approved) is estimated to be 11.83%. *See* J. A. DiMasi, H. G. Grabowski and R. W. Hansen, Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, *Journal of Health Economics*, Vol. 47, 2016, pp. 20–33 ("DiMasi et al. (2016)"), at 26.

53 Haucap et al. (2019), *supra* note 33, study European transactions and European product markets. Other studies focus on U.S. transactions and U.S. product markets.

54 For example, the study dataset in Ornaghi (2009), *supra* note 8, includes 27 large public pharmaceutical mergers between 1988 and 2004; the study dataset in Schutz (2023), *supra* note 44, includes 68 pharmaceutical mergers between 2007 and 2016; and the main study dataset in Bonaimé and Wang (2024), *supra* note 45, includes 162 pharmaceutical mergers between 2013 and 2019.

55 As the authors acknowledge, "some degree of acquirer-target overlap is necessary for the killer-acquisition motive to exist." See Cunningham et al. (2021), supra note 34, at 651.

56 PhRMA Chart Pack, *supra* note 22, at 27; Lakdawalla (2018), *supra* note 5, Figure 1, at 400; M. E. Blume-Kohout, Does Targeted Disease-Specific Public Research Funding Influence Pharmaceutical Innovation, *Journal of Policy Analysis and Management*, Vol. 31, No. 3, 2013, pp. 641–660.

57 For example, the drug thalidomide was first developed in Germany and used as a sedative in the 1950s; a decade into its use in a number of countries worldwide, it was discovered that use during pregnancy can cause birth malformations, and the drug was withdrawn from the marketplace. In the U.S., the drug was not approved for marketing until 1998, when it received FDA approval and was marketed under the brand name Thalomid as a leprosy treatment. This 1998 FDA approval capped nearly four decades of research into the drug's properties for treating a number of different dermatologic and inflammatory conditions. It was not until the mid-1990s when the drug was first shown to have anti-angiogenic properties, and it was not until 2000 when the first reports emerged of its effectiveness as a cancer treatment for multiple myeloma, followed by FDA approval for this indication in 2006 (*see* W. Rehman, L. M. Arfons and H. M. Lazarus, The Rise, Fall and Subsequent Triumph of Thalidomide: Lessons Learned in Drug Development, *Therapeutic Advances in Hematology*, Vol. 2, No. 5, 2011, pp. 291–308; Drugs@FDA, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm).

58 The difficulty in assessing overlaps between pipeline products explains why the Competition Authorities rarely assess competitive constraints exerted by drugs in early stages of development. See V. Dolka, S. Karkela, Aiste Slezeviciute, Zsolt Vertessy, Competition Policy Brief, Assessing Innovation Competition in Pharma Mergers, April 2024, at p.19. « […] in most cases potential competitive constraints exerted by drugs in preclinical stages are only exceptionally assessed. This is because at a very early stage the indication and therapeutic use of the pipeline may still be undetermined, and it may be difficult to predict the competitive interaction between the various drugs. »

20. Similarly, Bonaimé and Wang (2024) find a positive impact of mergers on innovation through an increase in "secondary" new drug applications related to product label or manufacturing process innovation, but no increase in "primary" applications for entirely new compounds. Schutz (2023) also finds no significant impact of mergers on the discovery of new drugs, though the study does find an increase in R&D spending. Some of these findings, however, may be driven by the short post-merger time period analyzed—generally three to five years post-merger.[59] By contrast, it takes a new drug compound on average nearly three years (over 31 months) from synthesis to initial human testing and then another nearly eight years (over 95 months) for clinical development.[60]

21. Additionally, while a few studies acknowledge that there can be alternative explanations or alternative mechanisms that could drive the results they find, none of them are able to fully disentangle the various mechanisms identified by the theoretical literature. For example, Ornaghi (2009) acknowledges the difficulty in empirically measuring most factors that affect how pharmaceutical companies make R&D and M&A decisions. Similarly, Cunningham et al. (2021) acknowledge that there can be information asymmetries about the quality of a project between an acquirer and a target firm.[61]

22. Most importantly, all the empirical studies that quantify the impact of pharmaceutical mergers on innovation do not analyze how the impact on innovation affects consumer welfare. Indeed, as noted above, many of these studies only measure innovation in terms of number of filed patents or drug applications[62] without any analysis of whether those patented inventions or new drug applications led to successful new drug launches and, even if launched, offered substantive therapeutic benefits over already existing drugs. For example, Cunningham et al. (2021) do not offer any evidence that the "killer" acquisitions they claim to identify are ones that resulted in the "killing" of new, viable therapeutics.[63]

IV. Conclusion

23. The academic literature has identified various mechanisms through which pharmaceutical mergers can impact innovation. However, there are few empirical studies assessing the overall impact of pharmaceutical mergers on innovation, and the studies available find mixed results. The studies differ in how they measure innovation and other key inputs, and each focuses on a limited set of mechanisms, making it challenging to compare results across different studies and evaluate the overall impact of pharmaceutical mergers on innovation. More empirical research is needed to compare the magnitudes of the various mechanisms identified by the theoretical literature. Without such research, we continue to have limited insight into which mechanisms are more important than others and, thus, into the overall impact of pharmaceutical mergers on drug innovation and consumer welfare. ■

59 Bonaimé and Wang (2024), *supra* note 45, also conduct a sensitivity test where they expand both the pre- and the post-merger period of analysis to ten years.

60 DiMasi et al. (2016), *supra* note 50, at 26; D. L. Jardim, M. Schwaederle, D. S. Hong and R. Kurzrock, An Appraisal of Drug Development Timelines in the Era of Precision Oncology, *Oncotarget*, Vol. 7, No. 33, 2016, pp. 53037–53046.

61 Cunningham et al. (2021), *supra* note 34, acknowledge that the acquirer may have lesser knowledge than the target about the quality of the latter's drug projects, and this could potentially explain why some acquisitions result in project termination; however, according to the authors, this cannot explain why such project terminations are more likely to occur in acquisitions with overlapping projects than in acquisitions without such projects given that in the former type of acquisition the acquirer is likely to have relatively more knowledge than in the latter type of acquisition. But there is another type of information asymmetry that could also explain the Cunningham et al. (2021) study results. By definition, relative to acquirers in non-overlapping acquisitions, acquirers in overlapping acquisitions have experience in the same therapeutic classes where the target firm is pursuing drug projects. This experience may enable acquirers in overlapping acquisitions to discern issues with the target's drug projects more quickly and thereby terminate such projects more efficiently relative to acquirers in non-overlapping acquisitions. In other words, it is their superior ability to detect "lemons" that may lead acquirers in overlapping acquisitions to be more likely to stop project development in those acquisitions rather than a desire to "kill" potential future competitors.

62 For example, Haucap et al. (2019), *supra* note 33; Schutz (2023), *supra* note 44.

63 For instance, one of the anecdotal examples that the authors offer for a "killer acquisition" is Questcor's supposed failure to develop Synacthen. A closer look into the development history of Synacthen, however, suggests that the drug would not have been successfully developed even if Questcor never acquired it. Specifically, after the acquisition, Questcor sublicensed Synacthen to another company. That company, West Therapeutic Development, in partnership with Assertio Therapeutics, also failed to obtain regulatory approval for the drug in the U.S., and subsequently abandoned development efforts. The failure of the new licensee and its development partner to develop Synacthen for commercialization in the U.S. market cannot be explained with the same "killer acquisition" motive that Cunningham et al. (2021), *supra* note 34, attribute to Questcor. *See* FTC press release, FTC Approves Sublicense for Synacthen Depot Submitted by Mallinckrodt ARD Inc, 14 July 2017, https://www.ftc.gov/news-events/news/press-releases/2017/07/ftc-approves-sublicense-synacthen-depot-submitted-mallinckrodt-ard-inc; Assertio Therapeutics, Inc. press release, Assertio Therapeutics Announces Submission of NDA for FDA Approval of Cosyntropin Depot, 20 December 2018, https://www.globenewswire.com/news-release/2018/12/20/1670383/0/en/Assertio-Therapeutics-Announces-Submission-of-NDA-for-FDA-Approval-of-Cosyntropin-Depot.html; Assertio Therapeutics, Inc. press release, Assertio Therapeutics Provides Regulatory Update on Long-Acting Cosyntropin, 21 October 2019, https://www.globenewswire.com/news-release/2019/10/21/1932625/0/en/Assertio-Therapeutics-Provides-Regulatory-Update-on-Long-Acting-Cosyntropin.html; Assertio Therapeutics, Inc. press Release, Assertio Therapeutics Announces Sale of NUCYNTA® Franchise to Collegium Pharmaceutical for $375.0 Million, 6 February 2020, https://www.globenewswire.com/news-release/2020/02/06/1981407/0/en/Assertio-Therapeutics-Announces-Sale-of-NUCYNTA-Franchise-to-Collegium-Pharmaceutical-for-375-0-Million.html.

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