Killers Interrupted: Stopping Pharmaceutical Killer Acquisitions via IP Release Clause

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Pharmaceutical innovation relies on pharmaceutical firms' ability to acquire promising new molecules and the biotech firms that discovered them. Such nascent competitor acquisitions allow the pharmaceutical industry to efficiently finance the risky drug development process. But they also enable "killer acquisitions," where incumbents purchase startups and discontinue their promising drug projects to protect existing products. This practice threatens innovation, and therefore public health, by allowing incumbents to build and entrench market power. Current antitrust measures, such as blanket bans on nascent acquisitions and compulsory licensure of acquired technology, fail to distinguish between legitimate acquisitions and their killer doppelgangers. This paper proposes IP release clauses as a solution. These clauses would require incumbents to develop acquired intellectual property (IP) within set timelines or lose control through licensing or auction. By leveraging existing antitrust authorities and the repeat game nature of antitrust review, IP release clauses preserve the pharmaceutical industry's two-stage development model while targeting killer acquisitions. This tailored approach allows regulators to combat anti-competitive behavior with minimal impact on the pharmaceutical industry's research and development model.

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Introduction

Pharmaceutical innovation saves lives—both through the direct effects of novel drugs and the economic growth that they drive. Competition amongst nascent and incumbent firms is crucial for ensuring that the pharmaceutical industry remains innovative.[1] However, the industry has developed a bifurcated drug-development process that relies on nascent-competitor acquisitions (NCA) to fuel innovation.[2] Pharmaceutical and biotech startups focus their efforts on new-drug discovery, committing their resources to molecule hunting and early-stage trials.[3] Successful startups then sell their promising new projects, and often themselves, to incumbents who shepherd the project through later-stage trials, U.S. Food and Drug Administration (FDA) approval, and finally onto the market.[4]

This two-stage model is now the dominant method of drug development, accounting for 74% of newly approved drugs in the United States.[5] Bifurcation creates substantial economic benefits for the firms and the public. By defining clear roles for nascent and incumbent firms, the two-stage process helps allocate risk efficiently, facilitates specialization, and incentivizes investment. These benefits allow firms to successfully develop more drugs, leading to higher revenues and better selection for consumers.[6]

The model is not an unalloyed good, however. To function effectively, it requires incumbents to systematically purchase nascent projects and firms. Each purchase pairs the transfer of a potentially important new drug project with the elimination of a potentially important future competitor.[7] This inherent tension is worsened by incumbent firms' ability to intentionally abandon the promising drug projects they acquire. The frequency of NCAs provides ample opportunities for so-called "killer

1. *See* C. Scott Hemphill & Tim Wu, *Nascent Competitors*, 168 U. PA. L. REV. 1879, 1880 (2020) (describing the competitive pressure that nascent firms apply to incumbents).

2. *See* Joanna Shepherd, *Consolidation and Innovation in the Pharmaceutical Industry: The Role of Mergers and Acquisitions in the Current Innovation Ecosystem*, 21 J. HEALTH CARE L. & POL'Y 1, 17-21 (2018) (explaining that, due to a combination of technical and financial factors, venture-capital-backed startups now discover the majority of new drug candidates).

3. *See id.* at 21-23.

4. *See id.* at 23; Robert Yetter, *PDFUA Activities in Drug Development*, FDA 2-7, https://www.fda.gov/media/78711/download [https://perma.cc/ZAD9-UNL5] (describing the drug-development and FDA-approval process).

5. Murray Aitken & Michael Kleinrock, *Lifetime Trends in Biopharmaceutical Innovation*, IQVIA INST. FOR HUM. DATA SCI. 4 fig.2 (Jan. 2017), https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/lifetime-trends-in-biopharmaceutical-innovation.pdf [https://perma.cc/ZL3E-688T] ("Nearly three quarters of new medicines were patented by a different entity than the company that registered the drug with the FDA for marketing in the U.S.").

6. *See* Shepherd, *supra* note 2, at 25.

7. *See* Hemphill & Wu, *supra* note 1, at 1887 (describing the "future potency" of nascent competitors).

acquirers" to purchase innovative startups and immediately shutter their projects to protect the killer's existing market share.[8] Recent research estimates that between 5.3% and 7.4% of all pharmaceutical acquisitions—in the constructed sample—are killers.[9]

Antitrust regulation has not adapted to the threats posed by NCAs which present significant theoretical and practical challenges for traditional antitrust enforcement.[10] As a result, the overwhelming majority of nascent acquisitions escape antitrust scrutiny and close without modification.[11] In the pharmaceutical industry, this means that multiple potentially life-saving drug projects are killed each year for lack of sufficient antitrust enforcement.[12] Even if regulators were to focus their efforts on combatting killer acquisitions, current remedies risk making the cure worse than the illness. Killer intent is difficult to separate from the myriads of legitimate reasons for pharmaceutical incumbents to purchase innovative startups.[13] Current proposals for addressing killer acquisitions attempt to prevent them by chilling all NCAs. The most extreme proposal calls for an outright ban on NCAs for large companies.[14] Another would require incumbents to license all technologies acquired from a nascent

8. *See* Colleen Cunningham, Florian Ederer & Song Ma, *Killer Acquisitions*, 129 J. POL. ECON. 649, 650 (2021).

9. *Id.* at 654.

10. Ian Ayres, C. Scott Hemphill, & Abraham L. Wickelgren, *Shorting Your Rivals: Negative Ownership as an Antitrust Remedy*, 86 ANTITRUST L.J. 317, 319-20 (2024) (discussing the inadequacy of current antitrust regulation in addressing transactions with competitive benefits and harms).

11. The Federal Trade Commission challenged five NCAs from 2018 to 2021 across all industries. Noah Joshua Phillips, *Reasonably Capable? Applying Section 2 to Acquisitions of Nascent Competitors, Remarks at the Antitrust in the Technology Sector: Policy Perspectives & Insights from the Enforcers Summit* 2 (Apr. 29, 2021), https://www.ftc.gov/system/files/documents/public_statements/1589524/reasonably_capable_-_acquisitions_of_nascent_competitors_4-29-2021_final_for_posting.pdf [https://perma.cc/YQZ8-FYGY]. Over that period, 276 pharmaceutical mergers closed. Jeffrey Stoll, Kristin C. Pothier, Steve Sapletal, Alasdair Milton, Andrew M. Stephenson & Jeff Katz, *Biopharmaceuticals Deal Trends*, KPMG 2 fig.2 (2021), https://assets.kpmg.com/content/dam/kpmg/ie/pdf/2021/04/ie-2021-kpmg-biopharmaceuticals-deal-trends-stoll-040521.pdf [https://perma.cc/F94G-6KPK] (demonstrating that there were 76, 79, and 121 biopharmaceutical corporate acquisitions in 2018, 2019, and 2020, respectively).

12. Cunningham, Ederer & Ma, *supra* note 8, at 693 (estimating that "the number of total drug projects for which development continues would increase" by thirteen each year "if antitrust policy directly targeted killer acquisitions").

13. *See* Shepherd, *supra* note 2, at 23; Cunningham, Ederer & Ma, *supra* note 8, at 687-91; Amy C. Madl, *Killing Innovation?: Antitrust Implications of Killer Acquisitions*, 38 YALE J. ON REGUL. BULL. 28, 35-39 (2020).

14. *See* Mark A. Lemley & Andrew McCreary, *Exit Strategy*, 101 B.U. L. REV. 1, 95 (2021) (discussing an outright ban on NCAs by sufficiently powerful incumbents); *U.S. Senator Wants to Ban Big Tech from Buying Anything Ever Again*, REUTERS (Apr. 12, 2021, 04:55 PM EDT), https://www.reuters.com/technology/us-senator-wants-ban-big-tech-buying-anything-ever-again-2021-04-12 [https://perma.cc/9XCW-ALBJ] (discussing Senator Josh Hawley's proposal to ban any firm valued at over $100 billion from consummating mergers).

competitor under court supervision.[15] Neither approach is capable of distinguishing between pro-innovative, good-faith acquisitions and their killer doppelgangers. As such, both impose substantial costs on the pharmaceutical industry and consumers alike in the hopes of eliminating approximately 46 to 63 killer acquisitions per year.[16]

A more tailored approach is possible. Regulators can use the broad statutory language of existing antitrust laws and the highly structured nature of the pharmaceutical research-and-development (R&D) process to target killers through intellectual-property (IP) release clauses. IP release clauses would condition incumbent firms' control of acquired nascent IP on their continued development of that IP. Firms who fail to meet a set development timeline would then be required to release acquired projects back into the market through compulsory licensure or mandatory auction. These clauses can be implemented under the merger challenge and settlement powers granted to regulators under the Clayton[17] and Hart Scott Rodino (HSR)[18] Acts and offer regulators a targeted, market-based technique for minimizing the harms of killer acquisitions. Furthermore, IP release clauses would do so without requiring any additional statutory authority and through pre-judicial negotiation with pharmaceutical firms who are encouraged to cooperate in exchange for quicker, cheaper deal clearance and to protect their reputation with regulators.

This paper proceeds in four parts. Part I details the importance of NCAs in the pharmaceutical industry as well as the threats that they pose to innovation and competition. Regulators must carefully preserve the benefits of NCAs without allowing incumbents to systematically destroy innovative projects and firms. Part II identifies the challenges that NCAs pose to traditional antitrust enforcement and details two popular suggestions for managing the risks of NCAs: blanket bans and compulsory licensure. Both approaches are overly inclusive and needlessly decrease incentives for startup entry and drug development. Part III develops IP release clauses as a targeted, informationally efficient remedy that directly reduces the harms caused by killer acquisitions. Finally, Part IV discusses the benefits of IP release clauses compared to either blanket bans or compulsory licensure with respect to implementation, development incentive preservation, and specificity.

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15. *See, e.g.*, Richard Gilbert, *Compulsory Licensing: An Underrated Antitrust Remedy*, CPI ANTITRUST CHRON. 6-7 (Oct. 2019), https://www.competitionpolicyinternational.com/wp-content/uploads/2019/10/CPI-Gilbert.pdf [https://perma.cc/7JUK-9ZHU] (discussing compulsory licensure as a method for encouraging innovation in the production of biologics); Kevin A. Bryan & Erik Hovenkamp, *Startup Acquisitions, Error Costs, and Antitrust Policies*, 87 U. CHI. L. REV. 331, 353-54 (2020) (arguing that compulsory licensure is an effective remedy in startup acquisition cases).

16. Cunningham, Ederer & Ma, *supra* note 8, at 694.

17. 15 U.S.C. §§ 12-27 (2024).

18. *Id.* at § 18a.

I. NCAs in the Pharmaceutical Industry

NCAs play a critical role in the pharmaceutical industry. They are a necessary element of the two-stage R&D model that produces the majority of modern drugs.[19] By facilitating the transfer of promising projects from nascent startups to established incumbents, NCAs allow the pharmaceutical industry to spread risk, develop capabilities, and incentivize innovation and investment. These benefits, however, are paired with real competitive and innovative risks. The industry's systematic reliance on NCAs provides incumbents with ample opportunity to chill competition and destroy potentially disruptive drugs. Any antitrust intervention must acknowledge these competing effects of NCAs and carefully balance their welfare-enhancing benefits against their anti-competitive and innovation-chilling costs.[20]

A. The Importance of NCAs

NCAs allow the pharmaceutical industry to allocate risk, efficiently develop capabilities, and incentivize innovation and investment through a bifurcated R&D process. Nascent competitors are prototypically small, single-drug firms that rely on outside funding to cover their negative run-rates.[21] Their expertise centers around molecule and early-stage drug discovery with little focus on the later FDA approval and go-to-market stages of a drug's lifecycle. Conversely, the incumbent firms are typically large, profitable, multi-drug companies with expertise across the full spectrum of drug development, from early-phase trials to production and sales.[22]

This dichotomy allows the industry to effectively spread risk across the long and costly drug-development process. The average new drug in America takes eight years to progress from its first trials to the market, costing its developers $1.1 billion.[23] These significant costs and time horizons make drug development an extremely risky endeavor. The separation of the drug development process between high-risk, high-reward startups and less risky incumbents allows employees, firms, and investors to sort themselves according to their risk appetite.

Risk-tolerant startup founders assemble drug-discovery experts, raise funding, and begin to search for novel molecules and therapies. They

19. *See* Aitken & Kleinrock, *supra* note 5, at 4 fig.2.

20. *See* Ayres, Hemphill, & Wickelgren, *supra* note 10, at 320 (lamenting existing remedies' inability to effectively regulate mergers with pro- and anti-competitive effects).

21. *See* Shepherd, *supra* note 2, at 21-25.

22. *See id.*

23. *See, e.g.*, Jonathan J. Darrow, Jerry Avorn & Aaron S. Kesselheim, *FDA Approval and Regulation of Pharmaceuticals, 1983-2018*, 323 JAMA 164, 164 (2020); Olivier J. Wouters, Martin McKee & Jeroen Luyten, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323 JAMA 844, 845 (2020).

accept the massive uncertainty associated with molecule discovery in the hopes of earning high-multiple returns if they do identify a promising new project. These nascent firms attract investment from risk-tolerant venture capital and healthcare investors who are willing to take on a high-risk, high-reward asset. Many fail, but a select few identify a promising molecule that may, many years in the future, reach the market.

NCAs then facilitate the flow of promising nascent projects from the startups that discovered them to the incumbents who will develop, produce, and market them. Incumbent firms look nothing like their nascent counterparts. They are large, complex, and often derive their profits from the sale of several successful drugs. Their funding structures are multi-faceted with reinvested profits, debt, and equity financing combining to allow them to turn drug projects into drug profits.[24] Their investors seek stable returns without the existential risk associated with drug discovery. Instead, the existence of NCAs allows incumbents to focus their efforts on the comparatively lower-risk process of getting a new drug approved, produced, and onto the market.[25]

This bifurcated structure allows employees and investors to tailor their exposure based on their risk preferences. Further, it isolates the highest-risk activity, drug discovery, to small, single-drug startups whose failure poses no risk to economic markets or drug availability. These risk-management effects allow the pharmaceutical industry to continue to find and develop promising projects despite the massive costs and 90% failure rate that such efforts entail.[26]

The bifurcated structure also prevents wasteful duplication of capabilities. Firms specialize in different segments of the drug-development process, investing in only the capabilities required by their role. Established, multi-drug firms invest in large FDA-approval teams, production capacity, and go-to-market capabilities that are expensive to acquire and maintain. Incumbents finance these investments by leveraging their large capital stocks and recurring revenues, amortizing the costs by employing these capabilities across their portfolio of market and pre-market drugs.[27]

24. *See* Shepherd, *supra* note 2, at 23.

25 See Alexander Schuhmacher, Markus Hinder, Elazar Brief, Oliver Hassmann & Dominik Hartl, *Benchmarking R&D Success Rates of Leading Pharmaceutical Companies: An Empirical Analysis of FDA Approvals (2006-2022)*, 30 DRUG DISCOVERY TODAY 1, 2 (2025) (demonstrating the increased likelihood of FDA approval as a molecule moves through the drug development process).

26. *See* Helen Dowden & Jamie Munro, *Trends in Clinical Success Rates and Therapeutic Focus*, 18 NATURE REVS. 495, 495 (2019), https://media.nature.com/original/magazine-assets/d41573-019-00074-z/d41573-019-00074-z.pdf [https://perma.cc/88NX-GPTV].

27. *See* Shepherd, *supra* note 2, at 23; CONGRESSIONAL BUDGET OFFICE, *Research and Development in the Pharmaceutical Industry* 12 (April 2021), https://www.cbo.gov/publication/57126 [https://perma.cc/NY7V-BW9S].

Nascent firms, the majority of which are single-drug or -molecule operations, cannot similarly spread high overhead costs across multiple product lines. Instead, the bifurcated structure allows them to essentially "outsource" anything not directly related to molecule discovery or early-phase trials to incumbents.[28] By facilitating this specialization, NCAs help the pharmaceutical industry minimize the wasteful duplication of capabilities, minimize financial frictions, and ensure that sufficient capacity exists for each phase of the drug-development process.

Finally, the bifurcated structure attracts innovators and investors. Innovative chemists, doctors, and entrepreneurs face a choice: earn a high but capped salary at an incumbent firm or chase the riskier but potentially huge earnings associated with founding a successful biotech firm. Startup founders and investors typically look to realize those huge earnings in one of three ways: building a profitable, privately held company; accepting public funding via an initial public offering (IPO); or exiting via NCA.

Seeking profitability as a private company requires nascent firms to abandon their narrow, drug-discovery focus and build expensive development, approval, and go-to-market capabilities. Doing so is both extremely expensive and time consuming, requiring founders and investors to leave their capital and time at risk for at least eight years.[29] Getting a drug to market does not mean an immediate payday either, for the average drug takes years to recover its development costs and turn a profit.[30] These long timelines create high financial and opportunity costs for founders and investors, leading many to seek other exit opportunities.

IPOs allow founders and investors to achieve a return on their investment sooner. Exit via IPO allows nascent firms to attract capital from public financial markets. This influx of public capital permits founding teams and investors to simultaneously cash out a portion of their equity and raise the money required to build out expensive approval, production, and sales capacities without leaving their personal investments at risk for years on end. The average pharmaceutical IPO today requires no sales and allows nascent firms to scale their drug on positive trial results alone.[31] IPOs allow nascent firms to realize early investments in six years on

28. *See id.* at 23-24.

29. The average time from discovery to market for all novel drugs is eight years. *See* Darrow, Avorn & Kesselheim, *supra* note 23, at 164. However, this average includes drugs developed, at least in part, by incumbent firms with well-established capabilities, easy funding, and years of experience. Startups, even those founded by industry experts, will have to build in-house capabilities while simultaneously finding funding—delaying the time to market significantly.

30. The exact time to break even varies with initial investment and discount rate, but "the product life necessary to break even on average is 19 years" at a 10% cost of capital. *See* Henry Grabowski & John Vernon, *A Sensitivity Analysis of Expected Profitability of Pharmaceutical Research and Development*, 3 MANAGERIAL & DECISION ECON. 36, 38 (1982).

31. Jay R. Ritter, Initial Public Offerings: Median Age of IPOs Through 2023, at 8 tbl.4g (Feb. 2, 2024) (unpublished manuscript), https://site.warrington.ufl.edu/ritter/files/IPOs-Age.pdf [https://perma.cc/V83Y-ALH6].

average, reducing capital-recovery timelines significantly compared to bringing a drug to market as a private firm.[32]

NCAs provide founders and early investors an even quicker path to financial reward. The average timeline from founding to acquisition for pharmaceutical firms has been steadily declining over time with the median years to exit nearing a mere three by 2018.[33] NCAs provide would-be founders and investors a much quicker path from successful molecule discovery to financial reward than either marketing a drug themselves or scaling their company through an IPO. In so doing, they facilitate flows of human and financial capital into the industry by lowering capital lockup horizons and increasing the internal rates of return for nascent firms who do stumble upon a promising molecule. As a result, exit via NCA is a far more common exit strategy than exit via IPO, with the ratio between them—across all industries—approaching ten-to-one.[34]

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The high costs and long timelines of pharmaceutical R&D have led the industry to develop a bifurcated development model that relies on NCAs to facilitate the transfer of promising projects from lean, risk-hungry startups to stable, capable incumbents. By allowing such transfers, NCAs contribute to a system that improves risk allocation, reduces wasteful duplication of capabilities, and encourages innovation and investment.

B. The Dangers of NCAs

The many benefits of NCAs come with attendant drawbacks, however. Even acquisitions that are ultimately welfare enhancing reduce the potential for future competition. When an incumbent purchases a nascent firm, the acquired firm's competitive potential is permanently extinguished.[35] In any given acquisition, efficiency gains may nevertheless outweigh this anticompetitive effect—however, systematic acquisition of

32. *Id.*

33. Jonathan Norris, Andrew Olson, Ritish Patnaik & Thomas Joyce, *Trends in Healthcare Investments and Exits 2019*, SILICON VALLEY BANK 25 (2019), https://www.svb.com/globalassets/library/managedassets/pdfs/healthcare-report-2019-annual.pdf [https://perma.cc/4SE8-6M2Q]; *see also* Maxim Sheinin, Elektra Alivisatos, Elisabeth McKibben & Leslie Sandberg Orne, *Envisioning a Successful Exit: Lessons From Early-Stage US Biopharma M&As*, TRINITY LIFE SCIS. 5 (2016), https://trinitylifesciences.com/wp-content/uploads/2021/05/Trinity_Whitepaper_Envisioning_A_Successful_Exit.pdf [https://perma.cc/S4C7-QQWU] (indicating that the median time from company founding to exit via M&A in the biopharmaceutical industry had decreased to just 4.4 years in 2015).

34. *2020 Yearbook*, NAT'L VENTURE CAP. ASS'N 35-36 (2020), https://nvca.org/wp-content/uploads/2020/03/NVCA-2020-Yearbook.pdf [https://perma.cc/TY6F-QE5M] (documenting that the number of venture-capital-backed acquisitions was 836 in 2019, while the number of venture-capital-backed IPOs was 82 in the same year).

35. *See* Hemphill & Wu, *supra* note 1, at 1887 (describing the "future potency" of nascent competitors).

nascent competitors may allow an incumbent to solidify their market power and eliminate startup entry through low acquisition prices.[36]

This potential for calcification of market power is made more acute by the fact that NCAs destroy the very potential for new market entry that could discipline overly powerful incumbents.[37] Traditionally anti-competitive behavior, such as abusive horizontal mergers or refusals to deal, which allow an incumbent to raise its prices, leaves room for new entrants to win market share by providing substitutes at lower prices.[38] Those entrants can then grow into full-fledged competitors and drive the market back toward a competitive equilibrium.

The anticompetitive harms of NCAs cannot be corrected by market entry, however. In fact, the harm is precisely the systematic elimination of the would-be entrants.[39] Worse still, an incumbent who does achieve market dominance through systematic NCAs is then able to reduce the price it is willing to pay to acquire nascent firms, greatly reducing the incentive for new firm entry and further cementing the incumbent's position.[40]

The competitive risks posed by systematic NCAs are heightened by the potential for incumbents to undertake killer acquisitions wherein the established firm purchases a nascent competitor with the intention of terminating its innovative project(s).[41] Doing so allows killer acquirers to protect their own product lines from the potential disruption of the nascent project by ensuring that neither the nascent firm nor another incumbent is able to bring it to market. In the pharmaceutical industry, 5.3% to 7.4% of all acquisitions appear to be killers with incumbents shuttering nascent projects that would compete with existing product lines.[42] Killer acquisitions occur when a nascent project threatens to reduce sales by more than the acquisition price of the nascent firm. By eliminating this potential threat, killer incumbents protect future sales and maximize their long-run profitability.[43] This private profitability, however, comes at the cost of lost innovation and reduced competition resulting in public-welfare losses.

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36. Kevin A. Bryan & Erik Hovenkamp, *Antitrust Limits on Startup Acquisitions*, 56 REV. INDUS. ORG. 615, 615-16, 631 (2020).

37. *Id.* at 631.

38. *See* Bryan & Hovenkamp, *supra* note 15, at 334-36.

39. *Id.*

40. *See* Bryan & Hovenkamp, *supra* note 36, at 631.

41. *See* Cunningham et al., *supra* note 8, at 650.

42. *Id.* at 649, 651 (recognizing that "some degree of acquirer-target overlap is necessary" to motivate a killer acquisition).

43. *See id.* at 662-67 (discussing the acquisition incentives and profit calculations of killer acquirers); Bryan & Hovenkamp, *supra* note 15, at 334 (arguing that incumbents can profit maximize by acquiring promising nascent firms before they blossom into competitors).

NCAs facilitate pharmaceutical innovation and create economic and scientific value for shareholders and consumers alike. They also create opportunities for powerful incumbents to solidify their market power by systematically eliminating potential entrants. Antitrust regulators must recognize both aspects of pharmaceutical NCAs and carefully tailor any interventions to ensure that the industry's bifurcated R&D model remains feasible while limiting incumbents' abuses.

II. Unique Antitrust Challenges of NCAs

NCAs allow the pharmaceutical industry to spread risk, develop capabilities, and attract innovators and investors. These benefits allow the industry to remain financially viable while also ensuring that consumers have access to an ever-widening array of treatments. NCAs also empower incumbents to eliminate nascent competitors systematically and cut down innovative projects prematurely. This tension makes policing pharmaceutical NCAs a delicate task for antitrust and competition-policy regulators.[44] Further complicating the regulators' role is the uneasy fit between dominant consumer-harm theories of antitrust and the diffuse, pernicious effects of systematic NCAs and killer acquisitions. While regulators are beginning to respond, the number of enforcement actions remains low, with incumbents across a wide variety of industries acquiring nascent competitors with little oversight.[45]

A. Theoretical Challenges

NCAs do not fit neatly into the dominant consumer-harm model of antitrust.[46] By definition, nascent firms do not meaningfully compete with the firms seeking to acquire them.[47] Nascent firms control very little, if any, market share when they are acquired, which makes the immediate price effect of the transaction insignificant. The long-term impact of removing the nascent firm from a market depends on the ultimate success of the firm's innovative projects. Such success is necessarily unknowable at the time of a merger, which prevents regulators from meeting their burden of persuasion in nascent-merger-challenge cases.[48] This means that

44. *See* Ayres et al., *supra* note 10, at 318-20.

45. *See supra* note 11.

46. *See generally* Phillip Areeda & Donald F. Turner, *Predatory Pricing and Related Practices Under Section 2 of the Sherman Act*, 88 HARV. L. REV. 697 (1975) (introducing consumer-harm tests as a foundational tool of antitrust practice); U.S. DEP'T OF JUST. & FED. TRADE COMM'N, MERGER GUIDELINES (Dec. 18, 2023), https://www.justice.gov/d9/2023-12/2023%20Merger%20Guidelines.pdf [https://perma.cc/YTL9-4QEB] (encouraging antitrust regulators to review the legality of mergers on the basis of consumer price effects).

47. *See* Hemphill & Wu, *supra* note 1, at 1880.

48. The success of a pharmaceutical startup is not reducible to traditional risk analysis; a mechanical accounting of past successes and their rates does little to help a regulator or court

traditional, price-based, empirical antitrust models are inadequate for capturing and conveying the competitive harms posed by NCAs.[49]

Further, many nascent competitors do not fit neatly into the vertical-versus-horizontal dichotomy that defines modern merger-enforcement policy.[50] The pharmaceutical industry's bifurcated model, discussed in Part I, exemplifies this problem. If pharmaceutical startups are primarily involved in molecule creation and early-stage trials with the intent to sell their molecules to incumbents, then the nascent and incumbent firms are in a vertical relationship. Such acquisitions do not eliminate would-be competitors because the nascent firms never intended to mature into full-fledged horizontal competitors. However, some percentage of those startups would, absent acquisition by an incumbent, develop their novel projects into marketable drugs and mature into horizontal competitors. The relationship between nascent and incumbent pharmaceutical firms is therefore endogenous to antitrust enforcement decisions, making it difficult to understand NCAs as either horizontal or vertical.[51] This endogeneity complicates enforcement efforts, confuses regulators and judges, and has prevented antitrust enforcers from developing a coherent NCA policy.

Finally, the specific competitive harms imposed by NCAs undermine the logic of traditional error-cost thinking. In more traditional areas of antitrust policy, the common idea that false positives (overenforcement) are more costly than false negatives (underenforcement) is motivated by the notion that would-be monopolists or oligopolists are and will be constrained from abusing their power by future market entrants.[52] However, NCAs directly interrupt this feedback loop by allowing powerful incumbents to acquire would-be competitors before their entry drives down prices. Lax regulation of these acquisitions allows powerful incumbents to eliminate the very market entrants that would police them and thereby encourages market concentration.

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understand the chances that a given pharmaceutical incumbent will develop into a bona fide competitor. Instead, startup success involves the much deeper form of uncertainty championed by Frank Knight, a form that makes it nearly impossible for regulators to meet their burden of persuasion to win under current antitrust case law. *See* FRANK H. KNIGHT, RISK, UNCERTAINTY, AND PROFIT 19-20 (1921); Ayres et al., *supra* note 10, at 322.

49. *See* Hemphill & Wu, *supra* note 1, at 1886-89 (describing the important competitive and innovative roles played by independent, nascent competitors); Lemley & McCreary, *supra* note 14, at 91-94 (discussing the failure of current antitrust analysis, litigation, and remedies to effectively address anticompetitive behavior in high-tech markets).

50. *Compare* U.S. DEP'T OF JUST. & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES (2010), *with* U.S. DEP'T OF JUST. & FED. TRADE COMM'N, VERTICAL MERGER GUIDELINES (2020) (demonstrating the importance of horizontal/vertical distinctions for antitrust regulation and enforcement).

51. *See* Lemley & McCreary, *supra* note 14, at 93 (discussing the complications that modern high-tech mergers present for traditional vertical/horizontal determinations in antitrust enforcement).

52. *See* Bryan & Hovenkamp, *supra* note 15, at 334-36.

The potential for killer acquisitions provides further theoretical complications. Recent literature has developed a preliminary model of killer acquisitions and demonstrated that they are occurring in the pharmaceutical market.[53] However, the subjective nature of killer intent complicates efforts to develop *ex ante* identification techniques that do not rely on tangible manifestations of intent.[54] As a result, the literature is able to sound the alarm on killer acquisitions but has been unable to help regulators combat them.

B. Current Approaches

These theoretical challenges have led to a sluggish regulatory response with the pharmaceutical industry consummating the overwhelming majority of NCAs without challenge.[55] This laissez-faire approach allows the industry's bifurcated R&D model to flourish at the cost of ignoring the competitive harms that NCAs, and particularly killer acquisitions, impose. The inaction of antitrust regulators is not for lack of statutory authority. Section 7 of the Clayton Act[56] provides ample language for regulating NCAs while section 201 of the HSR Act[57] helps regulators identify potentially problematic mergers.

The Clayton Act, passed in 1914, established the Department of Justice (DOJ) and Federal Trade Commission's (FTC) authority to police competitive behavior that falls short of the Sherman Act's monopolistic threshold.[58] In particular, section 7 outlaws any merger or acquisition that will have the effect of substantially lessening competition.[59] The Hart-Scott-Rodino Antitrust Improvements Act of 1976 augments the federal government's antitrust powers.[60] It requires parties seeking a merger over a value threshold to report the merger to DOJ and the FTC and observe a thirty-day waiting period.[61] This waiting period allows the agencies to investigate potentially problematic mergers and decide whether to subpoena additional information from the parties to determine whether to challenge the merger.

Either DOJ's Antitrust Division or the FTC can then challenge a proposed merger in federal court and seek a temporary restraining order

53. *See* Cunningham et al., *supra* note 8, at 671-72 (describing a modeling framework for *ex post* identification of likely killers).

54. *See* Hemphill & Wu, *supra* note 1, at 1903-04.

55. *See supra* note 11.

56. Clayton Antitrust Act of 1914, ch. 323, § 7, 38 Stat. 730, 731-32 (codified as amended at 15 U.S.C. § 18).

57. Hart-Scott-Rodino Antitrust Improvements Act of 1976, Pub. L. No. 94-435, § 201, 90 Stat. 1383, 1390 (codified as amended at 15 U.S.C. §§ 18a).

58. *See* 15 U.S.C. § 2.

59. *See* Clayton Antitrust Act of 1914, § 7, 38 Stat. at 731-32.

60. *See* Hart-Scott-Rodino Antitrust Improvements Act of 1976, § 201, 90 Stat. at 1390.

61. 18 U.S.C. § 18a(b) (2024).

during the pendency of the case.[62] It is at this point that the prosecuting agencies and the merging parties can begin consent-decree negotiations.[63] Consent decrees are settlement agreements that allow a merger to proceed under specific conditions, such as asset divestiture or compulsory licensure.[64] They allow regulators and merging entities to proactively remedy any anti-competitive effects, thereby avoiding the need for a trial. Any proposed consent decree must be published in the Federal Register at least sixty days before its effective date and published in two general-circulation newspapers.[65] During this time, interested parties may submit written comments to the prosecuting agency; the government must consider each comment and publish responses to certain of them.[66] Finally, the court overseeing the case must approve the proposed decree as being in the public interest.[67] In doing so, the court must consider the "competitive impact" of the decree as well as its impact on relevant markets, injured individuals, and the public at large.[68] After court approval, the consent decree will then become effective, with the prosecuting agency retaining authority to ensure that the post-merger entity continues to comply with the decree's provisions.

Relying on this consent-decree process, lawmakers and academics have proposed a number of approaches for regulating NCAs. Two of the most popular approaches are blanket bans and compulsory licensure.[69] Blanket bans represent the polar opposite of today's lax regulatory environment and would flatly prohibit incumbents from purchasing nascent competitors. While this would stop incumbents from abusing NCAs, the bans would destroy the bifurcated R&D structure that is so important to pharmaceutical innovation. Alternatively, compulsory-licensure schemes would require incumbents to license any technologies acquired via NCA to interested competitors. While this approach better acknowledges the innovative importance of nascent acquisitions, it still distorts incentives for post-acquisition development needlessly.

62. 15 U.S.C. § 25 (2024).

63. For a comprehensive, if dated, overview of consent decrees, see Michael E. Debow, *Judicial Regulation of Industry: An Analysis of Antitrust Consent Decrees*, 1987 U. CHI. L.F. 353, 354-357. For a more modern overview of DOJ policy, see U.S. DEP'T OF JUST., ANTITRUST DIV., MERGER REMEDIES MANUAL 1-3 (Sept. 2020), https://www.justice.gov/atr/page/file/1312691/dl [https://perma.cc/33SW-WVK3].

64. *See id.* at 1.

65. 15 U.S.C. § 16(b)-(c) (2024).

66. *Id.* § 16(d).

67. *Id.* § 16(e)-(f).

68. *Id.* § 16(e)(1).

69. Other suggested approaches include the use of "change of control of research" as a reporting factor, altering standard payment terms, and a ban on upfront cash payments in nascent mergers. *See, e.g.*, Björn Lundqvist, *Killer Acquisitions and Other Forms of Anticompetitive Collaborations (Part I): A Case Study on the Pharmaceutical Industry*, 5 EUR. COMPETITION & REG. L. REV. 186, 188 (2021); Madl, *supra* note 13, at 48.

1. Blanket Bans

Blanket bans are a common suggestion in both the nascent-competitor literature and amongst change-minded politicians.[70] Senator Hawley recently proposed an amendment to the Clayton Act which would ban companies valued at more than $100 billion from consummating *any* merger.[71] This amendment would fundamentally disrupt the pharmaceutical R&D system, for many pharmaceutical incumbents engaged in the bifurcated R&D system would be categorically banned from acquiring biotech startups under Hawley's plan.[72]

Proponents of banning incumbents from acquiring nascent competitors cite the pro-competitive impact of allowing nascent firms to grow into bona fide competitors.[73] This proposition may be true as a static matter. Holding incentives for startup entry constant, requiring nascent firms to develop into full-fledged market participants would increase the total number of competitors in a given market, which would in turn increase competition, decrease concentration, and briefly improve consumer welfare. However, a blanket ban would have a substantial impact on startup entry. As discussed above, NCAs provide an important exit opportunity for founders and investors alike.[74] A blanket NCA ban delays exit for founders and investors by requiring them to scale their companies considerably more than would be necessary to sell to an incumbent firm. This dynamic would chill the formation of innovative startups as the increased costs and exit timeline would encourage talent and capital to deploy elsewhere.[75] The effects of a blanket ban would quickly overwhelm any short-run uptick in competition as the rate of startup entry would be lower than the rate at which existing startups either exit or fail.[76]

70. *See, e.g.*, Lemley & McCreary, *supra* note 14, at 95; Competition and Antitrust Law Enforcement Reform Act of 2021, S. 225, 117th Cong. § 4(b) (2021) (amending the Clayton Act's definition of unlawful acquisition to, in effect, include the majority of NCAs involving established incumbents); REUTERS, *supra* note 14. *See generally* Trust-Busting for the Twenty-First Century Act, S. 1074, 117th Cong. (2021) (encapsulating Senator Hawley's proposal to ban firms valued over $100 billion from consummating *any* mergers).

71. Trust-Busting for the Twenty-First Century Act, S. 1074, 117th Cong. (2021).

72. For instance, Eli Lilly and Co.; Johnson & Johnson; AbbVie, Inc.; Merck & Co., Inc.; Pfizer Inc.; Amgen, Inc.; Bristol-Myers Squibb Co.; and Gilead Sciences, Inc. all maintain market capitalizations well in excess of $100 billion. *See Drug Manufacturers - General*, YAHOO FIN., https://finance.yahoo.com/sectors/healthcare/drug-manufacturers-general [https://perma.cc/J47J-EZ7P].

73. *See, e.g.*, Competition and Antitrust Law Enforcement Reform Act § 2(a)(12), (20).

74. *See supra* Section I.A.

75. *See* D. Daniel Sokol, *Vertical Mergers and Entrepreneurial Exit*, 70 FLA. L. REV. 1357, 1357 (2018) (arguing that any merger policy which inappropriately restricts firms from consummating acquisitions "would hurt incentives for innovation in the economy by chilling business formation in start-ups").

76. Estimates of startup failure in the pharmaceutical industry exceed 75% and can reach as high as 90%. This high failure rate means that any chilling of startup entry will quickly result in

Further, blanket bans are very difficult to implement under current law. Modern antitrust practice reads the operative provisions of the Clayton Act narrowly and places a high burden of proof on antitrust regulators seeking to block a merger.[77] This legal environment makes it unlikely that a court would endorse a blanket NCA ban under existing antitrust law. To be sure, senators on both ends of the ideological spectrum have called for new legislation banning NCAs.[78] However, given current congressional incapacity and the resurgence of anti-regulatory rhetoric, it is unlikely that such a ban will be passed any time soon.[79]

Without statutory change, antitrust regulators cannot implement a blanket ban via settlement or consent decree either. The overwhelming majority of modern antitrust regulation is accomplished at the consent-decree stage with regulators and merging firms agreeing to cure perceived antitrust defects.[80] However, because a blanket ban would need to categorically reject all nascent-competitor mergers, there would be no proposed mergers to consent to. Antitrust regulators would therefore need to implement a ban either through regulation or a litigation strategy—two methods that would face withering judicial scrutiny.[81]

2. Compulsory Licensure

Compulsory licensure represents a more moderate and practical regulatory approach. Under a compulsory-licensure regime, NCAs would be permitted on the condition that the incumbent-acquirer license all

a decrease in total nascent competitors in the industry. *See* Elizabeth Pollman, *Startup Failure*, 73 DUKE L. REV. 327, 329-30 (2023) (describing the high failure rate of even venture-capital-backed startups and highlighting estimation difficulties).

77. *See generally* Andrew I. Gavil, *Burden of Proof in U.S. Antitrust Law*, *in* ISSUES IN COMPETITION LAW AND POLICY 125 (2008) (outlining the burdens of proof, production, and persuasion that regulators must meet when challenging a merger under the Clayton Act).

78. *See* Competition and Antitrust Law Enforcement Reform Act of 2021, S. 225, 117th Cong. § 4(b) (2021) (introduced by Sen. Amy Klobuchar but never advanced out of committee); Trust-Busting for the Twenty-First Century Act, S. 1074, 117th Cong. (2021) (introduced by Sen. Josh Hawley but never advanced out of committee).

79. The last substantial amendment of the antitrust laws was the passage of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, Pub. L. No. 94-435, 90 Stat. 1383. Nearly fifty years have passed since, with no substantive additions to the nation's antitrust laws despite consistent focus by various congressional members and caucuses over that time. *See generally* Filippo Lancieri, *The Political Economy of the Decline of Antitrust Enforcement in the US*, PROMARKET (Feb. 2, 2024), https://www.promarket.org/2024/02/02/the-political-economy-of-the-decline-of-antitrust-enforcement-in-the-us (describing the political economy of antitrust reform and why it has prevented substantial changes to antitrust law or policy).

80. DOJ's Antitrust Division discharged over 90% of merger challenges via consent decree from 2016-2021. *See* U.S. DEP'T OF JUST., ANTITRUST DIV., CONG. SUBMISSION FY 2022 PERFORMANCE BUDGET 27 (2022).

81. *See supra* Section II.A (discussing the evidentiary and theoretical challenges that NCAs pose for regulators attempting to win injunctions in court).

acquired technologies to interested firms under regulatory supervision.[82] Compulsory licensure, unlike a blanket ban, is a well-established antitrust remedy with decades of history. Federal courts have consistently approved compulsory-licensure regimes to remedy the anticompetitive effects of mergers, and DOJ and the FTC regularly include licensure remedies in their internal manuals.[83] Relative to a blanket ban, compulsory licensure is a widely accepted remedy that regulators can employ without legislative action or doctrinal change.

However, that does not mean it is the right one for regulating NCAs in the pharmaceutical industry. Compulsory licensure stops incumbents from hoarding nascent projects by preventing them from exercising exclusive control over acquired drugs. This lack of exclusivity would interrupt the important role that NCAs play in facilitating the pharmaceutical industry's bifurcated development. Incumbents who know that they must share acquired projects with their competitors are less likely to purchase nascent firms in the first place, will do so at lower valuations and are less likely to invest in ongoing development for fear of losing out to competitors racing them to market.[84] Further, broad compulsory licensure requirements would create significant free-rider effects with incumbents forgoing the considerable expenditures associated with NCAs and instead waiting to access the projects through the comparatively cheaper licensure process.[85] While compulsory licensure's impact on the model would be less catastrophic than an outright NCA ban, simple compulsory licensure casts too broad a regulatory net and affects both welfare-enhancing NCAs and their killer twins.

* * *

NCAs test dominant models of competitive harm and confound consumer-harm focused regulators and courts who fail to see the diffuse, time-shifted harms that a poorly regulated NCA regime creates. Popular current reforms lack the nuance required to balance these harms against

82. *See* Makan Delrahim, Deputy Assistant Att'y Gen., U.S. Dep't of Just., Antitrust Div., Forcing Firms to Share the Sandbox: Compulsory Licensing of Intellectual Property Rights and Antitrust 2-6 (May 10, 2004) (detailing the history of compulsory licensure as an antitrust remedy), https://www.justice.gov/atr/file/518076/dl [https://perma.cc/5RL6-FV8J].

83. *See, e.g.*, Besser Mfg. Co. v. United States, 343 U.S. 444, 447,448 (1952) (imposing compulsory licensing on a "fair" and "reasonable" basis); United States v. Gen. Elec. Co., 115 F. Supp. 835, 843-46 (D.N.J. 1953) (ordering General Electric to license its lightbulb technology on a cost-free basis); *Merger Remedies Manual*, *supra* note 64 (prescribing compulsory licensure as an appropriate remedy in a wide array of horizontal- and vertical-merger scenarios).

84. *See* Richard J. Gilbert & Carl Shapiro, *An Economic Analysis of Unilateral Refusals to License Intellectual Property*, 93 PROC. NAT'L ACAD. SCI. 12749, 12753 (1996) (detailing the innovative costs of compulsory licensure).

85. *Id.*

the substantial benefits that NCAs provide to the pharmaceutical industry and American society more broadly.[86] A better way must be found.

III. Intellectual Property Release Clauses

I propose the IP release clause as just such a way. IP release clauses would condition exclusive control over acquired nascent IP on incumbent-acquirers' continued development of that IP. Incumbents who achieve verifiable development progress in accordance with established timelines would retain exclusive control over acquired projects. Alternatively, incumbents who are unable to meet their timelines and fail to convince regulators that they deserve a good-faith extension would be forced to either license the acquired project under regulatory supervision or auction it off to interested competitors. Such an approach uses the wealth of drug development information available to merging parties and antitrust regulators to build merger-approval contracts which bind only after an incumber-acquirer fails to develop a promising drug on schedule.[87]

Conditioning exclusive control over nascent IP on continued, verifiable development directly mitigates the innovative losses imposed by killer acquisitions. Firms that are unable to meet their timelines, either because they have killed a promising project or because the project becomes legitimately untenable, will be forced to release the IP back into the market. Competitors will then have an opportunity to review the project and determine if the original incumbent-acquirer will lose control over it. Projects that still appear promising, and therefore have a higher likelihood of having been killed, will receive auction bids or licensure requests, and the original acquirer will lose exclusivity. Conversely, projects that appear unviable are less likely to receive interest from competitors and are more likely to remain with the original incumbent-acquirer.

The combination of development-based exclusivity with a market-based release mechanism creates opportunities for promising but undeveloped projects to get a second life with a new firm. The combination also obviates the need for regulators to develop an ex-ante identification strategy for killers. Instead, IP release clauses are self-triggering, coming into effect only after a merger has resulted in stalled development. Compared to blanket bans or unconditional licensure requirements, IP release clauses offer a targeted method for minimizing the effects of killer acquisitions that does not unduly affect the majority of NCAs.

Further, IP release clauses can be implemented under existing antitrust law. Regulators' merger review and consent decree powers allow

86. *See* Ayres et al., *supra* note 9, at 319.

87. *See id.* at 322 (lamenting the failure of antitrust authorities to "leverage the existence of contractible information in constructing preconditions for merger approval").

them to investigate potential killers and encourage would-be acquirers to help develop and eventually accept an IP release clause. In this way, IP release clauses are no different than the myriad of consent decree remedies that regulators and courts have developed in the roughly 130 years since the Sherman Act inaugurated American antitrust law.[88]

A. Legal Authorities

Regulators can implement IP release clauses under existing antitrust and competition law. Section Seven of the Clayton Act prohibits mergers that "may substantially [] lessen competition."[89] Section Seven further grants regulators the authority to investigate proposed NCAs and negotiate consent decree settlements.[90] Going one step further, the HSR Act requires parties to report mergers over a deal value threshold to antitrust authorities for pre-clearance.[91] Regulators are then empowered to investigate the proposed merger and work with the parties to remedy any potential antitrust concerns via informal consultation or consent decree. Whether as a reactive Clayton suit or as part of a HSR pre-clearance investigation, current law provides regulators with the settlement/consent decree powers needed to implement IP release clauses.

The HSR pre-clearance process provides the simplest implementation opportunity for sufficiently sized mergers.[92] During initial HSR investigations, regulators will have the opportunity to examine proposed mergers to identify any antitrust defects. Problematic mergers are then referred for a second stage of review and consent decree negotiations can begin.[93] The time, cost, and risk of these second-stage

88. *See generally* U.S. DEP'T OF JUST. ANTITRUST DIV., *supra* note 63 (detailing the many consent-decree-based remedies that regulators use to ameliorate merger defects).

89. *See* 15 U.S.C. § 18.

90. *Id.*

91. *Id.* § 18(a) (requiring firms proposing a merger over a value threshold to notify DOJ or the FTC and mandating a waiting period during which antitrust regulators can investigate the proposed merger).

92. The HSR adopts a complicated set of reporting thresholds that are updated on a yearly basis. For 2024, all deals in excess of $478 million must be reported and a statutory waiting period applies. For deals valued between $119.5 and $478 million, reporting is required, and a waiting period applies if one party has at least $239 million in net sales/total assets and the other has at least $23.9 million in net sales/total assets. Deals with a value below $119.5 million generally do not require notification. *See New HSR Thresholds and Filing Fees for 2024*, FED. TRADE COMM'N (Feb 5., 2024), https://www.ftc.gov/enforcement/competition-matters/2024/02/new-hsr-thresholds-filing-fees-2024 [https://perma.cc/DFG7-7GBB] [hereinafter *HSR Reporting Thresholds*]; FTC PREMERGER NOTIFICATION OFFICE, TO FILE OR NOT TO FILE: WHEN YOU MUST FILE A PREMERGER NOTIFICATION REPORT FORM 4-15 (2008), https://www.ftc.gov/sites/default/files/attachments/premerger-introductory-guides/guide2.pdf [https://perma.cc/T37Q-B5D9].

93. *See Premerger Notification and the Merger Review Proces*s, FED. TRADE COMM'N, https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws/mergers/premerger-notification-merger-review-process [https://perma.cc/4L7K-KFJ9].

investigations provide strong incentives for both the incumbent-acquirer and nascent-acquiree to agree to an IP release clause.[94]

Regulators can still investigate NCAs that do not meet the HSR's size threshold under their Clayton Section Seven powers. Identifying and challenging potential killer acquisitions below the HSR threshold will require regulators to proactively monitor the pharmaceutical industry to identify likely killers and initiate antitrust reviews. Given the necessarily small size of nascent pharmaceutical firms, many potential killer acquisitions will fall below the HSR threshold.[95] With only approximately 100 total pharmaceutical mergers every year, it is feasible for regulators to actively monitor the industry and initiate challenges to potential killers.[96]

Existing legal authorities provide regulators the investigative and settlement powers they need to implement IP release clauses. Although killers are difficult to definitively identify absent smoking-gun emails or other documents, recent research has identified factors that increase the chances an NCA becomes a killer. By focusing on deals which include these killer risk factors, antitrust regulators can more efficiently identify potentially problematic mergers for further review and judiciously seek to apply IP release clauses.

All killer acquisitions involve some degree of overlap between the nascent project and the acquirer's existing products.[97] This overlap create incentives for incumbent-acquirers to shutter the potentially disruptive project in order to protect the market share of their existing drug.[98] These incentives are strongest when the patent for the overlapping drug will remain in force for a longer period of time allowing the incumbent to reap high returns without competition from generic manufacturers.[99] Therefore, regulators should search for and target NCAs that involve a high degree of overlap between the nascent project and an existing project with many years of market exclusivity and/or patent protections remaining.[100]

Acquisitions of projects targeted at low-competition markets further increase the chances that an NCA develops into a killer. Lower competition, and the higher prices it allows, means that incumbents stand

94. *See* Kelly Fayne & Kate Foreman, *To Catch a Killer: Could Enhanced Premerger Screening for Killer Acquisitions Hurt Competition*, 34 ANTITRUST 8, 11-12 (2020).

95. *See HSR Reporting Thresholds*, *supra* note 92; Cunningham, Ederer & Ma, *supra* note 8, at 685-87 (presenting evidence of strategic deal sizing to avoid reporting requirements); Thomas G. Wollman, *How to Get Away with Merger: Stealth Consolidation and its Effects on U.S. Healthcare* 4 (Nat'l Bureau of Econ. Rsch. Working Paper No. 27274, 2024) (detailing that sub-HSR-threshold mergers currently escape antitrust scrutiny).

96. *See* KPMG, *supra* note 11, at 3 fig.2.

97. *See* Cunningham, Ederer & Ma, *supra* note 8, at 651 (identifying that "some degree of acquirer-target overlap is necessary" to motivate a killer acquisition).

98. *See id.*

99. *See id.* at 681-82.

100. U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-40, DRUG INDUSTRY: PROFITS, RESEARCH AND DEVELOPMENT, AND MERGER AND ACQUISITIONS DEALS 7 (2017) (describing the market exclusivity and patent protection timelines associated with different classes of drugs).

to lose more from an innovative drug making it to the market regardless of who owns it.[101] In a highly competitive market, an additional entrant will take a small percentage of every competitors' market share, resulting in a low absolute value of lost profits for each incumbent.[102] However, in a weakly contested market, a new entrant can take a large percentage of each incumbents existing market share, resulting in significant lost profits for the incumbents. As a result of this dynamic, nascent projects aimed at weakly contested markets are more likely to be acquired and killed by incumbents looking to safeguard their profits.[103]

Finally, projects that consume rare or unique trial resources may be more likely to be killed.[104] The trial-intensive development and approval process for pharmaceuticals creates competition for trial resources such as patients, facilities, and practitioners.[105] In drug markets where the competition for trial resources is particularly fierce, an incumbent may seek to remove competition by killing an innovative project that would soon compete for later-stage trial resources.

These risk factors can help regulators identify potential killers and focus their IP release clauses efforts. Crucially, however, regulators do not need to develop a more elaborate killer identification strategy nor prove to a preponderance of the evidence that a merger will be a killer. Instead, they can use their consent decree powers, and the significant leverage those powers afford them, to secure IP release clauses that will bind only after an incumbent fails to develop a still promising drug.

IP release clauses would join a growing list of consent decree provisions which seek to constrain post-merger behavior through pre-merger contracting with regulators. A recent proposal along this line calls for antitrust regulators to impose "negative ownership" provisions to mitigate the chance of post-merger collusion with remaining competitors.[106] Much like IP release clauses, these negative-ownership provisions seek to use information that is available only after the merger is consummated to encourage competitive behavior.[107] Proponents of negative-ownership provisions identify modifying executive compensation, encouraging merged entities to sell options contracts on

101. Cunningham, Ederer & Ma, *supra* note 8, at 680.

102. *See id.* at 661.

103. *See id.*

104. *See* Madl, *supra* note 3, at 37. Luke Gelinas, Holly Fernandez Lynch, Barbara E. Bierer & I. Glenn Cohen, *When Clinical Trials Compete: Prioritising Study Recruitment*, 43 J. MED. ETHICS 803, 804-05 (2017) (detailing the competitive market for trial resources such as patients).

105. *See* Gelinas, Lynch, Bierer & Cohen, *supra* note 104; *see generally* Anup Malani & Tomas Philipson, *Can Medical Progress be Sustained? Implications of the Link Between Development and Output Markets* 1 (Nat'l Bureau of Econ. Rsch., Working Paper No. 17011, 2011) (describing the important role that the supply of trial participants has on pharmaceutical innovation).

106. *See* Ayres, Hemphill & Wickelgren, *supra* note 10, at 320.

107. *See id.* at 322.

their rivals' stock prices, or contractually obligating merged firms to pay their consumers if the firm's rivals overperform post-merger as legally available methods for reducing collusion. Compared to these interventions, IP release clauses seek only to leverage extant development data and familiar IP distribution techniques to encourage good-faith development of promising drug projects.

B. Components of an IP Release Clause

IP release clauses consist of two provisions: a development timeline and a release method. Development timelines condition an acquirer's exclusive control over a nascent project on the incumbent-acquirer continuing to achieve development milestones for the project. The wealth of pharmaceutical development data that the industry has collected since the FDA's creation allow regulators and firms alike to tailor development timelines to the specific needs of the acquired project. This ensures that acquiring firms have sufficient time to navigate the highly variable drug development process. To ensure that acquirers are not punished for unforeseen development setbacks, IP release clauses will also include extension provisions that allow regulators to stretch development timelines for incumbents who can prove they are making sufficient efforts to develop in good faith.

Release plans specify how undeveloped nascent projects will be released if an incumbent fails to meet their development timeline or secure an extension. This can be done either by compulsory licensure or mandatory auction and ensures that undeveloped projects are offered back up for development by competing firms.

1. Development Timelines

Pharmaceutical R&D is a highly formal and meticulously regulated process. Federal law requires all marketed pharmaceuticals to pass a series of tests and trials before receiving FDA approval.[108] Each step of this process, from the earliest stage drug discovery efforts to final FDA approval, requires companies to run trials, collect data, and validate the feasibility of the project before advancing. These verifiable outputs of the R&D process make IP release clauses possible.

Step One of the pharmaceutical R&D process is discovery and development wherein biotech startups and pharmaceutical research teams

108. The FDA's authority over new drug approval stems from the Food, Drug, and Cosmetics Act which prohibits any person from "introduc[ing] . . . into interstate commerce any new drug, unless an approval filed pursuant [to relevant subsections] is effective with respect to such drug." 21 U.S.C. § 355. The FDA has since developed a multistage process for approving new drug applications involving multiple rounds of trials and data review. *See* Yetter, *supra* note 4 for an overview of the FDA approval process' various stages.

work to identify specific molecules that may have therapeutic potential. During this step, researchers test thousands of compounds, collecting data on how the most promising ones are metabolized, what side effects they may engender, and how they compare to other drugs already on the market.[109]

The most promising compounds progress to Step Two, during which scientists collect preclinical research data.[110] The primary focuses of Step Two are appropriate dosing and potential toxicity. Step Two data must be collected and reported in accordance with FDA regulations which specify how studies must be conducted, by whom, and what information must be collected.[111]

Before a drug candidate can advance to Step Three, the company developing it must submit an Investigational New Drug (IND) application to the FDA which includes data collected in Steps One and Two and a proposed human trial protocol.[112] The FDA then assigns the IND application to a team including medical doctors, pharmacologists, pharmakineticists, statisticians, chemists, and microbiologists for review and approval. Only after a drug candidate passes this thorough pre-clinical review can it advance to Step Three wherein scientists collect clinical data in human trials.[113] Step Three is by far the most time-consuming and expensive part of the drug development process. A successful drug candidate will move through four phases of clinical trials. Phase One trials seek to establish the safety and proper dosage of a drug by administering it to between twenty and one hundred patients.[114] Phase Two trials seek to understand the efficacy and potential side effects of the drug by administering it to hundreds of patients over the course of several months to two years.[115] Phase Three trials monitor the long-term efficacy and incidence of adverse reactions in thousands of patients over the course of years.[116] Finally, Phase Four trials confirm the safety and efficacy of the drug by administering it to a final set of several thousand patients.[117] The FDA mandates specific laboratory procedures, data collection, and reporting requirements for each phase of trial and no drug candidate can

109. *See Step 1: Discovery and Development*, FED. DRUG ADMIN. (Jan. 4, 2018), https://www.fda.gov/patients/drug-development-process/step-1-discovery-and-development [https://perma.cc/JN39-ETBA].

110. *See Step 2: Preclinical Research*, FED. DRUG ADMIN. (Jan. 4, 2018), https://www.fda.gov/patients/drug-development-process/step-2-preclinical-research [https://perma.cc/D9J6-46FR].

111. *See* 21 C.F.R. § 58 (2024).

112. *See Step 3: Clinical Research*, FED. DRUG ADMIN. (Jan. 4, 2018), https://www.fda.gov/patients/drug-development-process/step-3-clinical-research [https://perma.cc/YYE2-BC9V]; 21 C.F.R. § 312 (2024).

113. *See* FED. DRUG ADMIN., *supra* note 112.

114. *See id.*

115. *See id.*

116. *See id.*

117. *See id.*

advance to the market without data from two large, controlled clinical trials.[118]

Upon successful completion of Step Three, the company developing a drug candidate will submit an "application for marketing" to the FDA who will review all of the data collected through the entire development pipeline and make a final safety and effectiveness determination. Once the FDA approves a drug candidate's marketing application, its developer can finally put their drug onto the market.[119] Even after marketing, the company responsible for the drug must continue to report to the FDA on an annual basis about the safety, current uses, and continued efficacy of the drug.[120]

This rigorous and statutorily mandated process creates a mass of tangible outputs at each stage of the development process. The FDA has approved over 20,000 pharmaceutical drugs since its inception.[121] These successes and the order of magnitude more projects which eventually failed have created a mass of data about the average time-to-completion for each phase of the development process.[122] Private parties already use this data to condition payments under R&D licensing contracts through milestone payment provisions.[123] IP release clauses would merely use this contractable information to formulate merger approval preconditions that afford incumbents sufficient time to achieve development success without

118. *See* Content and Format of a New Drug Application, 21 C.F.R. § 314.50 (detailing the data requirements for each phase of clinical trials and how that data must be reported).

119. *See* Step 4: FDA Drug Review, FED. DRUG ADMIN. (Jan. 4, 2018) (providing an overview of the final FDA review and approval process before a drug can enter the market), https://www.fda.gov/patients/drug-development-process/step-4-fda-drug-review [https://perma.cc/4W9C-Y3R7].

120. *See* Postmarketing Reporting of Adverse Drug Experiences, 21 C.F.R. § 314.80(c)(2) (2024).

121. FOOD & DRUG ADMIN., FDA AT A GLANCE (Apr. 2023), https://www.fda.gov/media/176816/download [https://perma.cc/6HA7-5RNA].

122. *See* Gail A. Van Norman, *Drugs, Devices, and the FDA: Part 1*, 1 JACC: BASIC TO TRANSLATIONAL SCIENCE 170, 175 tbl.7, 177 fig.1 (2016) (describing the various stages of the drug approval process, their tangible outputs, and success rates).

123. *See* Adam Golden & Jeff Jay, *Milestone Payments in Life Sciences M&A and Licensing Transactions*, FRESHFIELDS (July 1, 2022), https://blog.freshfields.us/post/102hs5t/milestone-payments-in-life-sciences-ma-and-licensing-transactions [https://perma.cc/9VY7-HFF8] (noting the ubiquity of milestones in life sciences licensing contracts and the advantages and disadvantages of conditioning payment on a development timeline); *Successful Partnering in Drug Development*, MAYER BROWN 21 https://law.shu.edu/documents/successful-partnering-drug-development.pdf [https://perma.cc/6CG9-YKD9] (establishing principles for the successful implementation of milestone payment provisions in drug development contracts); Jorge Conde & Becky Pferdehirt, *Anatomy of a Biotech Business Development Deal*, ANDREESSEN HOROWITZ (Jan. 25, 2022), https://a16z.com/anatomy-of-a-biotech-business-development-deal [https://perma.cc/5XAC-TGGP] (same); *see generally* Pascale Crama, Bert De Reyck, & Zeger Degrave, *Milestone Payments or Royalties? Contract Design for R&D Licensing*, 56 OPERATIONS RSCH. 1539, 1539-40 (describing the common use of milestone payments in R&D contracts); Nalini Dayanand & Rema Padman, *Project Contracts and Payment Schedules: The Client's Problem*, 47 MGMT. SCI. 1654, 1663-1665 (2001) (modeling optimal milestone and timeline development when the steps of a project are known).

allowing them to circumvent the release provision by securing an overly lax timeline.[124]

Timelines can either be provided by merging parties or imposed by regulators. Party-supplied timelines are preferable because they allow incumbent-acquirers to consider firm-specific factors that will be missed by FDA averages. Some acquisitions will be easier for a given firm to develop due to expertise, trial resources, or other firm-specific details. Other acquired projects will be in areas that the firm has less experience in or that will require new trial infrastructure. Encouraging incumbents to offer their own timelines will allow them to incorporate these idiosyncrasies into a more accurate development plan, the honing of which pharmaceutical incumbents already have expertise in.[125] However, party-supplied plans must be carefully scrutinized by regulators to ensure that the parties have not submitted unreasonably lax timelines that serve to insulate the acquirer from the consequences of killing development. Regulators can leverage publicly available data to ensure that firm-submitted plans do not unreasonably deviate from the average development timeline for the acquired drug's therapeutic class and method of action.[126]

The wealth of development data allows regulators and firms to craft timelines that encourage firms to work rapidly without punishing them for unforeseen development setbacks. To further this flexibility, IP release clauses must also include an extension process that allows regulators to stretch timelines for firms who encounter abnormally time-consuming hurdles. Here again, the formal nature of the development process allows extensions to be granted based on verifiable development efforts. Extensions will be granted for firms that are able to produce evidence of industry-standard trial efforts, identify a specific development hurdle that has caused the delay, and create a plan for remedying the delay that will allow them to meet their development timeline going forward.[127] Much as the development timeline itself leverages FDA data and regulations, the extension process can rely on FDA expertise to evaluate the development

124. *See* Ayres, Hemphill & Wickelgren, *supra* note 10, at 322.

125. *See supra* note 123.

126. *See Pharmaprojects,* CLINICAL INTELLIGENCE (Dec. 31, 2024), https://clinicalintelligence.citeline.com/drugs/results [https://perma.cc/L73G-F38Q] (providing a database of all candidate drugs as they progress through the R&D process which is sortable by therapeutic class and mechanism of action). For an example of data coverage, see Cunningham, Ederer & Ma, *supra* note 8, at 668-70, which describes the specific data set that Cunningham and her coauthors used to build their ex-post killer identification strategy. For an overview of the average timelines from discovery to FDA approval, see Dean G. Brown, Heike J. Wobst, Abhijeet Kapoor, Leslie A. Kenna & Noel Southall, *Clinical Development Times for Innovative Drugs*, 21 NATURE REV.: DRUG DISCOVERY 793, 794 fig.2 (2022).

127 See generally Final Judgment, at 38, United States v. Bayer AG, No. 1:18-cv-01241 (D.D.C. 29 May 2018) (appointing a monitoring trustee, who is empowered to investigate potential breaches and recommend corrective actions, to ensure compliance with the terms of the consent decree).

efforts of firms seeking an extension.[128] By allowing extensions only after verifiable efforts have been made and a revised development plan has been submitted, this approach prevents IP release clauses from punishing good-faith incumbents who encounter an unexpected delay without allowing killer incumbents from securing erroneous extensions.

The combination of a tailored development timeline and a bright-line extension standard allow regulators to build IP release clauses which condition IP exclusivity on verifiable development efforts. This conditionality allows IP release clauses to trigger only when an acquirer actually fails to develop acquired IP, increasing the specificity of the remedy and substantially reducing its impact on the majority of nascent acquisitions that are proposed without killer intent.

2. Release Method

Development timelines and extension standards allows incumbent-acquirers to retain control over acquired IP so long as they continue to make verifiable, good-faith development efforts. The second component of an IP release clause, the release method, specifies what happens to acquired IP when incumbents fail to make such efforts. Releasing undeveloped IP back onto the market allows still-promising projects a second chance at development instead of languishing on the original acquirer's shelves. This second chance can come via compulsory licensure or mandatory auction.

Regardless of the specific form of release, regulators must ensure that would be licensees or re-acquirers have sufficient access to development data to evaluate the project's potential. IP release clauses will require incumbents who fail to meet their development timelines to allow interested competitors to review all project data prior to submitting a

128. The FDA and antitrust regulators regularly collaborate to protect competition and innovation in the pharmaceutical industry. For drug candidates that have already proceeded to Step Three of the drug development process, the same NDA review team that approved the drug's original trial protocol can be consulted to review the legitimacy of an extension request. More generally, the FDA and antitrust regulators have a long history of cooperating closely to police anti-competitive or innovation reducing behavior in the pharmaceutical industry. *See, e.g.*, Press Release, Fed. Drug Admin. & Fed. Trade Comm'n, Joint Statement of the Food & Drug Administration and the Federal Trade Commission Regarding a Collaboration to Advance Competition in the Biologic Marketplace 5 (Feb. 3, 2020), https://www.fda.gov/media/134864/download [https://perma.cc/DU4U-7V3J] (establishing collaboration on the identification of anti-innovative behavior in the production of novel biologics); Press Release, Fed. Trade Comm'n, FTC Issues Policy Statement on Brand Pharmaceutical Manufactures' Improper Listing of Patents in the Food and Drug Administration's 'Orange Book,' (Sept. 14, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-issues-policy-statement-brand-pharmaceutical-manufacturers-improper-listing-patents-food-drug [https://perma.cc/Q4XA-9MZG] (quoting FDA Commissioner Robert M. Califf as stating "the FDA stands ready to assist the FTC as part of our long history of collaboration to protect American consumers, including our continued engagement under the Executive Order on Competition in the American Economy to help identify and address efforts to block or delay generic drug and biosimilar competition").

licensure offer or participating in an auction. The highly formal nature of drug development allows regulators to specify required disclosures in accordance with FDA regulations.[129] Further, the sophisticated nature of pharmaceutical incumbents will allow would-be re-acquirers to evaluate the potential of released projects and bid on only those that retain a viable chance of reaching the market.[130]

This market-based release mechanism further reduces the need for regulators to identify killer intent. Released projects that retain a high degree of promise will receive bids from competitors while projects that fail trials or are otherwise unattractive will not. This creates a self-targeting mechanism that punishes the most likely killer incumbents while allowing good faith, but unsuccessful, incumbents to retain their failed projects.

Compulsory licensure would require the original acquirer to license the nascent project to competitors under regulatory supervision. Requiring licensure only after a verified failure to develop improves the specificity of this approach over its legally familiar, but unconditional cousin.[131] Instead of requiring all incumbents to license nascent IP, this form of IP release clause allows incumbents who meet their development timelines to retain exclusive control over their acquisitions as if the IP release clause did not exist. Only after an incumbent-acquiree fails to meet their timeline requirements will they be forced to license the technology to competitors and lose their ability to exercise dominion over the project.

Release via compulsory licensure has the advantage of being familiar to regulators and courts who have recognized compulsory licensure agreements as an antitrust remedy since at least the 1950s.[132] For instance, in *Besser Manufacturing Co. v. United States*, the Supreme Court approved the imposition of a mandatory licensure scheme to remedy the competitive harms imposed by Besser's overaggressive acquisition of intellectual property.[133] More recently, the FTC successfully mandated compulsory licensure in a pharmaceutical antitrust case where the acquired firm marketed the lone competitor to the acquirer's approved drug.[134] Further, licensure allows multiple firms to simultaneously develop released projects, potentially increasing the odds that the project reaches the

129. For a discussion of the kinds of R&D data that the FDA mandates, see *supra* Section III.B(1); *see also* Content and Format of a New Drug Application, 21 C.F.R. § 314.50 (detailing the data requirements for each phase of clinical trials and how that data must be reported).

130. *See* JEFFREY GORDON & JAMISON LYNCH, DRUG DEVELOPMENT: VALUING THE PIPELINE – A UK STUDY 16, 20 (2009) (reporting that pharmaceutical executives already use auctions to value their drug development projects).

131. *See supra* Section II.B.2.

132. Besser Mfg. Co. v. United States, 343 U.S. 444, 447 (1952).

133. *Id.* at 447.

134. Stipulated Order for Permanent Injunction and Equitable Monetary Relief, *Fed. Trade Comm'n v Mallinckrodt ARD, Inc*, No 1:17-cv-00120, *10-14, *16-18 (D.D.C. Jan. 30, 2017).

market.[135] However, the non-exclusive access that licensure creates limits each firm's expected pay-out from successful development which may soften their development efforts. Additionally, compulsory licensure requires intensive efforts from regulators who must carefully consider the terms of the ensuing licensure agreements and ensure subsequent compliance.[136]

Mandatory auctions offer a simpler option for getting acquired projects into new hands after the original acquirer fails to meet its development timeline. Pharmaceutical firms already organize auctions amongst themselves for promising drug candidates to help with project valuation and prioritization.[137] Further, the use of auctions to value and liberate intellectual property has been judicially sanctioned since at least 2004.[138] IP release clause auction provisions can build on this industry practice and legal precedent by mandating an auction whenever the original incumbent-acquirer fails to meet the development timeline set out in the consent decree. Just as with compulsory licensure, competing firms will be allowed to review the project's trial and related data prior to the auction date.

Previous work on the use of auctions to liberate intellectual property advocates the use of a Vickrey auction format with the original acquirer unable to bid on retaining control.[139] This format incentives would-be re-acquirers to bid their true valuations for the project and eliminates any negative signaling effect that may arise from the original acquirer's choice to participate or not.[140]

Mandatory auctions require less ongoing oversight by regulators relative to conditional compulsory licensure, reducing regulatory costs and allowing both the original and re-acquirer to continue their business efforts with minimal regulatory intrusion. Auctions further provide the re-acquirer with IP-exclusivity, eliminating the potential development disincentive associated with multi-party licensing.

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135. *See* Bryan & Hovenkamp, *supra* note 36, at 617 (discussing how compulsory licensure can improve welfare and efficiency by diffusing technologies throughout an industry).

136. *See* Delrahim, *supra* note 82, at 13-16.

137. *See* GORDON & LYNCH, *supra* note 130, at 16.

138. *See* Massachusetts v. Microsoft Corp., 373 F.3d 1199, 1206 (D.C. Cir. 2004) (affirming the use of mandatory auction to distribute IP licenses).

139. *See* Michael Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 Q. J. ECON. 1137, 1147-48 (1998); William Vickrey, *Counterspeculation, Auctions, and Competitive Sealed Tenders*, 16 J. FIN. 8, 20 (1961) (establishing the "Vickrey" auction format of sealed bids with the winning bidder paying a price equal to the second highest bid).

140. Vickrey, *supra* note 139, at 20-23 (demonstrating the benefits of a Vickrey auction for eliciting true valuations from participants and avoiding profit loss from evaluative or strategic errors).

IV. Benefits of IP Release Clauses

IP release clauses offer a better alternative for regulating NCAs than either the under-enforcement status quo or the two reform proposals detailed in Section II.B above. They target their dispossessive effects on only those acquired projects where the acquirer has demonstrably failed to meet their development timeline on a drug with still-promising chances of reaching the consumer market. As such, IP release clauses have only a minimal impact on the non-killer acquisitions which comprise the majority of pharmaceutical NCAs. These non-killer acquisitions, the results of which account for 74% of newly approved drugs in America, represent the most traveled channel for new drug development and put roughly thirty-five new drugs a year onto pharmacy shelves.[141] IP release clauses offer regulators a tool for policing the real competitive and innovative harms posed by killer acquisitions without unduly interfering with the bifurcated R&D structure that fuels modern pharmaceutical innovation.[142]

This balance between mitigating the real innovative and medical harms of killer acquisitions and facilitating the flow of promising drug candidates from biotech startups to established pharmaceutical firms is the greatest strength of IP release clauses.[143] While blanket bans and compulsory licensure approaches seek to minimize killer acquisitions by chilling all acquisitions, IP release clauses combine ex-ante contracting and ex-post enforcement to target acquirers who halt development despite the acquired projects continued promise. Further, they are implementable under current law and require only limited review by typically laissez-faire federal courts to become enforceable.[144] They also operate in a manner that reduces incentive distortions relative to either blanket bans or compulsory licensure while directly addressing the innovative harm posed by killer acquisitions.

A. Implementation Advantages

As discussed above, IP release clauses can be implemented without any additional statutory language. The plain text of the Clayton Act supports regulatory action against NCAs. The particular competitive and innovative harms posed by killer acquisitions, and lack of countervailing

141. *See Novel Drug Approvals at FDA*, FOOD & DRUG ADMIN. (Feb. 6, 2025), https://www.fda.gov/drugs/development-approval-process-drugs/novel-drug-approvals-fda [https://perma.cc/8ALL-QX4W] (providing annual new drug approval reports).

142. For details on this structure, see *supra* Section I.A.

143. *See* Ayres, Hemphill & Wickelgren, *supra* note 10, at 320 (extolling the benefits of remedies that can effectively balance competitive harms against efficiency gains).

144. *See* Bryan & Hovenkamp, *supra* note 36, at 347-48 (discussing the evidentiary challenges facing regulators trying to win NCA cases in federal court); Hebert Hovenkamp & Fiona Scott Morton, *Framing the Chicago School of Antitrust Analysis*, 168 U. PA. L. REV. 1843, 1844-53 (2020) (providing a broad history of how "Chicago School" antitrust analysis won over the federal bench resulting in unmeetable evidentiary burdens and chronic underenforcement).

efficiency or other benefits, further strengthen the case for intervention.[145] Nevertheless, current consumer-harm-based antitrust analysis struggles to account for the subtler and slower competitive harms that nascent competitor and killer acquisitions inflict.[146] IP release clauses offer antitrust regulators a consent-decree based mechanism for addressing these harms.

Antitrust regulators possess immense powers to investigate and shape pharmaceutical mergers. Either through the HSR pre-clearance process or as the result of proactive Clayton challenges, regulators can place a hold on the vast majority of potential mergers. These holds are immensely costly for the merging firms and pose existential risks for would-be nascent acquirees.[147] These costs, and merging firms' desire to minimize them, create substantial leverage for antitrust regulators whose approval can fast track merger closure and therefore the magnitude of costs imposed. These dynamics create powerful incentives for good-faith acquirers, killer acquirers, and nascent firms alike to engage with and ultimately accept IP release provisions.

For good-faith acquirers, IP release provisions are a vehicle for shorter pre-merger review timelines and slightly lower acquisitions prices. Good-faith acquirers intend to develop acquired projects with the hope of winning FDA approval and marketing them to consumers. An IP release clause with a reasonable development timeline and appropriate extension mechanisms will have no effect on these plans. IP release provisions do slightly reduce option value for good-faith acquirers; however, this loss is at least partially compensated by lower merger review costs and a cheaper topline acquisition price.[148]

These benefits accrue to cooperative killer acquirers as well, albeit in a more complicated manner. Securing a consent decree that limits future

145. *See generally* Tim Wu, *Taking Innovation Seriously*, 78 ANTITRUST L.J. 313, 315-16 (2012) (arguing that antitrust law must play an active role in fostering innovation); Ronald W. Davis, *Innovation Markets and Merger Enforcement: Current Practice in Perspective*, 71 ANTITRUST L.J. 677, 687-95 (2003) (cataloging enforcement actions brought under innovation-protection theories).

146. Traditionally anti-competitive mergers between well-established horizontal competitors create immediate and quantifiable price and quality effects. By contrast, systematic NCAs and the killer acquisitions that they facilitate exact their competitive burden slowly, allowing incumbents to gradually build market power until they can exact rents in the form of higher prices and lower quality. *See supra* Section II.A; *cf.* ROB NIXON, SLOW VIOLENCE AND THE ENVIRONMENTALISM OF THE POOR 2 (2011) (describing the concept of slow violence as that which is attritional and dispersed across time and space).

147. *See* Fayne & Foreman, *supra* note 94, at 8-9; Peter Boberg & Andrew Dick, *Findings from the Second Request Compliance Burden Survey*, *in* THE THRESHOLD: NEWSLETTER OF THE MERGERS & ACQUISITIONS COMM. 26, 30, 33-34 (2014) (estimating that the average second request required merging parties to produce nearly 30 gigabytes of documents at a cost of $4.3 million).

148. By conditionalizing the exclusive right to acquired IP, a release provision is likely to decrease the private valuations of both good-faith and killer acquirers alike. *See* Bryan & Hovenkamp, *supra* note 36, at 626-27 (demonstrating that a compulsory licensure reduces acquisition prices); Gilbert & Shapiro, *supra* note 84 (same).

litigation risks is particularly beneficial to killer acquirers as the chances of post-merger antitrust litigation are higher for them given the ultimately anti-competitive purpose of the acquisition.[149] The decreased pre-merger review costs and lower legal risks do come at the cost of shorter IP exclusivity, however. However, the agreed upon development timeline will reflect the years-long R&D process that all drug projects must complete, meaning that killer acquirers will still be able to ward off competition from the novel IP for a substantial period of time. Given that most brand name drugs generate the majority of their lifecycle profits in the few years after FDA approval, being able to keep a promising competitor off the market for even a few months is a valuable result.[150]

For a killer acquirer who expects to interact with antitrust regulators only once, IP release clauses pose both benefits and costs with the killer acquirer's ultimate decision to accept or reject such a provision depending on a variety of factors. Their private estimation of post-acquisition litigation risks, the number of years that their existing drug remains protected by patent and exclusive marketing rights, and their estimation of the ultimate success of the acquired project in the hands of a good-faith competitor would all affect this calculus. As a result, some one-shot acquirers may accept an IP release clause while others would wage a vigorous fight against one.

However, many would-be killers will frequently engage with antitrust regulators as they engage in the bifurcated R&D scheme detailed in Section I.A. In this repeat-game scenario, antitrust regulators have additional leverage over would-be killers. The substantial costs of antitrust review and regulators' ability to delay mergers incentivizes repeat-acquirers to develop and maintain a reputation for antitrust compliance and good-faith behavior with their regulators in order to minimize the chances of their proposed mergers receiving heightened scrutiny.[151] Often, these incentives lead merging parties to "proactively offer commitments to

149. *See* Hemphill & Wu, *supra* note 1, at 1905-08 (detailing the myriad post-acquisition legal risks that await killer acquirers).

150. The front-loaded nature of drug profitability derives in large part from the exclusive marketing rights afforded to a pharmaceutical company upon FDA approval. During the period of exclusivity, the FDA may not approve a competitor drug for marketing. *See* U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 100; 21 U.S.C. § 355(c)(3)(E)(ii) (providing five years of exclusive marketing for chemical entities never before approved by the FDA); 42 U.S.C. § 262(k)(7)(A) (providing twelve years of exclusive marketing for new biologics); 21 U.S.C. § 355(c)(3)(E)(iv) (providing three years of exclusive marketing for newly approved uses of a drug); 21 U.S.C. § 360cc (providing seven years of exclusive marketing for orphan drugs).

151. *See generally* Boberg & Dick, *supra* note 147, at 33 (estimating that the average second request required merging parties to produce nearly 30 gigabytes of documents at a cost of $4.3 million); 18 U.S.C. § 18a(b) (mandating a thirty-day waiting period before sufficiently-sized transactions can close); *DAMITT 2023 Annual Report: Minding the Gap in Merger Enforcement*, DECHERT LLP 8 (Jan. 30, 2024), https://www.dechert.com/bin/BriefcasePdfBackgroundJobServlet [https://perma.cc/XY8V-WLVQ] (demonstrating that the average antitrust merger investigation took 10.6 months to conclude in 2023).

[regulators] that . . . . [will] reduce or eliminate the anticompetitive consequence of the deal."[152] Whether the IP release clauses is proactively designed by the merging parties or requested by regulators, would-be killer acquirers who expect to have a mix of killer and good-faith acquisitions before regulators are incentivized to accept an IP release clause on one transaction to avoid harming their reputation with the same regulators who will review their subsequent deals. For these repeat killer acquirers, the loss of total control over acquired IP arising from an IP release clause is compensated by both the ability to meaningfully, if temporarily delay development and the reputational benefits of complying with antitrust regulators. Together, these benefits argue in favor of cooperating with regulators to craft an IP release clause that is acceptable to both the merging parties and the government.

Finally, nascent competitors are highly incentivized to cooperate with regulators and agree to IP release provisions. Nascent firms are extremely vulnerable to prolonged pre-merger review periods as associated costs often represent substantial portions of their financial resources.[153] Further, the risk that a proposed merger may dissolve during the pre-merger review process represents an existential threat to startups who often overextend their financial resources to source and finalize deals.[154] The negative signaling value of a failed merger attempt is substantial and can prevent otherwise valuable startups from securing the ongoing funding needed to continue developing projects and identifying additional potential acquirers. These forces combine to incentivize nascent firms to take any available steps for shortening pre-merger review timelines and increasing the odds of successfully reaching a consent decree. However, IP release clauses are not without some costs for nascent firms. The lack of permanent IP exclusivity will drive down valuations for both good-faith and killer acquirers resulting in lower acquisition offers and smaller returns for founders, investors, and employees.[155] Despite this effect and given the growing chorus of political and academic voices calling for interventions ranging from blanket bans to the outlawing of lump sum acquisition

152. Ayres, Hemphill & Wickelgren, *supra* note 10, at 340.

153. *See* Fayne & Foreman, *supra* note 94, at 11-12; ASHWIN SINGHANI, RICH RAMKO, & ARDA URAL, A COMPLEX PATH FORWARD – BEYOND BORDERS: EY BIOTECHNOLOGY REPORT 2023, at 9 (finding that most small biotech companies cannot afford more than two years of operational costs, let alone the large lump sum costs associated with premerger review compliance).

154. *See* Fayne & Foreman, *supra* note 94, at 11 ("[A] $2 million to $9 million premerger review bill could eat up a significant amount of cash for a firm that is in a race to make it to the next round of financing.").

155. *See* Bryan & Hovenkamp, *supra* note 36, at 626-27; Gilbert & Shapiro, *supra* note 84, at 12753 (detailing the innovative losses resulting from a loss of IP exclusivity under mandatory licensure).

pricing, IP release provisions that allow exit by acquisition to remain viable while minimizing valuation distortions are preferable.[156]

Regulators wield substantial power over merging firms through their pre-clearance and merger challenge authorities. This power, combined with the unique economic risks of the merger process itself, provides powerful incentives for acquiring incumbents and nascent firms alike to cooperate with regulators seeking to impose an IP release clause. The combination of statutory power and private economic incentives reduces the need for regulators to rely on courts while still reducing the innovative and future competitive harms inflicted by killer acquisitions.

B. Innovation Incentive Advantages

Beyond their implementation advantages, IP release clauses also incentivize more innovation than either blanket bans or compulsory licensure. A blanket ban on NCAs would force nascent firms with promising projects to develop them to market-readiness on their own. As discussed above, this would massively increase the fundraising, human capital, and risk-tolerance requirements of nascent firms.[157] Only the most promising, well-capitalized, and risk-tolerant startups would be able to shoulder these burdens. Many otherwise promising firms would likely shutter, their investors and founders moving on to less time-intensive and risky opportunities. Blanket bans would also cause new startup entry to substantially decline as visionary founders and venture investors seek less time-intensive and heavily regulated markets to engage with.[158]

IP release clauses also drive more innovation than under a non-conditional licensure regime. Mergers consummated under an IP release provision afford the acquirer exclusive control over acquired IP so long as they meet the agreed-upon timelines or secure good-faith extensions. This exclusivity will increase the expected value of the project if it reaches the market relative to an unconditional compulsory licensure scheme by preventing competitors the opportunity to race the original acquirer to market.[159] By allowing acquirers to maintain exclusive control over projects that they develop, IP release clauses improve the expected payout of a drug project and therefore increase incumbent-acquirers' incentive to develop the drug to market.[160]

156. *See supra* Section II.A (reporting the broad range of voices calling for sweeping nascent acquisition reform).

157. *See supra* Section I.A.

158. *See* Sokol, *supra* note 75, at 1362-63.

159. *See generally* Thomas H. Lee, *"Me Too" Products – Friend or Foe?,* 350 NEW ENG. J. MED. 211, 211-12 (2004) (explaining why being the first to bring a new class of drug to the market is most profitable).

160. *See* Gilbert & Shapiro, *supra* note 84.

C. Specificity and Information Utilization

Finally, IP release clauses are an improvement over other proposed approaches because they more specifically address the costs imposed by killer acquisitions. Further, they do so in a manner that does not require regulators to develop an ex-ante identification strategy.

Killer acquisitions impose social costs by removing potentially welfare-enhancing drugs from the development process. Killer acquirers increase their private profits at the cost of potential future consumers, some of whose lives could have been saved by the killed drug. IP release clauses offer regulators a tool for efficiently reducing the costs borne by potential consumers. By interjecting only after an acquirer has failed to meet the agreed-upon development timeline, IP release clauses affect a miniscule fraction of mergers compared to blanket bans or unconditional compulsory licensure. Further, their interjection directly mitigates the costs imposed by the shuttering of a promising drug project by facilitating a second chance for development.

The fact that IP release clauses are only activated after a merger has closed and a timeline has been missed also obviates the need for regulators to develop an ex-ante killer identification strategy.[161] Using the risk factors developed above in Section III.A, regulators can insist on IP release clauses for potential killer acquisitions that only trigger after an acquirer fails to meet their agreed-upon development timeline. Instead of relying on complex economic models or internal documents, this delayed enforcement approach allows regulators to act only after development of a project has actually ceased.

By allowing competitors to bid for released IP through either an auction or compulsory licensure process, IP release provisions also allow the market to make the final decision about whether to transfer the project away from the original acquirer. Only projects that failed to meet their development timeline despite having promising trial and development data will receive substantial interest from would-be re-acquirers. Projects whose development was stopped after poor trial results or other indicators of impending failure are unlikely to receive bids upon release. As such, IP release clauses use a market mechanism to make final dispossession decisions, reducing the need for regulators to price released projects or otherwise interfere in market processes.[162]

161. *See* Hemphill & Wu, *supra* note 1, at 1903-04 (discussing the evidentiary challenges associated with even ex-post identification of anticompetitive intent).

162. *See* Ayres, Hemphill & Wickelgren, *supra* note 10, at 322 (extolling the virtues of using consent decrees to condition remedies on information available only after a merger consummates); Kremer, *supra* note 139, at 1146 (stating that auctions amongst market participants is a standard way of eliciting private valuations of intellectual property).

Conclusion

IP release clauses should be developed as a tool for combatting the harms of killer acquisitions in the pharmaceutical industry. They represent an opportunity to minimize the harms inflicted by killer acquisitions which does not infringe upon the vast majority of pharmaceutical NCAs. By leveraging both the uniquely formal structure of pharmaceutical R&D and the substantial merger review powers of federal regulators, IP release clauses can help ensure that promising drug projects are developed in good faith while allowing the pharmaceutical industry's NCA-fueled R&D process to continue with minimal regulatory overhead.