Beyond the Pharmaceutical Patent Arms Race

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Over forty years after the Hatch-Waxman Act created a patent-based framework for balancing pharmaceutical innovation with competition, the system it established needs reform. We use data on pharmaceutical research and development over this four-decade period to argue that the current equilibrium is accurately characterized as an arms race of strategic legal activity. Brand-name firms amass increasingly large patent portfolios for each new drug. Generic firms challenge these patents in a perpetual cycle of litigation. Though the number of patents per drug has increased sharply over time, the average drug's market exclusivity—time without generic competition—has remained remarkably stable. This growth in the potential length and scope of intellectual property protection appears to offer few benefits for patients: we find no evidence that growing portfolios are linked to higher-quality drugs or rising research costs, or that variation in exclusivity aligns incentives with any social policy goal. Instead, the current system encourages only widespread uncertainty—for patients, physicians, and firms—and a growing, wasteful litigation enterprise.

We argue that this costly stalemate is the consequence of a set of factors peculiar to the pharmaceutical sector—namely, its bespoke regulatory design, and a fundamental mismatch between the timelines of patent law doctrine and the timelines of new drug approval—which make infeasible any resolution within the bounds of the patent system itself. A solution is, however, entirely within reach.

Drawing inspiration from a series of legislative proposals with consistently bipartisan support, we propose a workable system for replacing pharmaceutical patent exclusivity with a new form of regulatory exclusivity administered by the Food and Drug Administration. We build an economic model that sheds light on ways of calibrating this system to ensure that the drugs that deliver the greatest benefit to patients are also the most profitable to develop. Perhaps most importantly, this proposal aligns the interests of

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not only industry stakeholders but also patients, in a way that makes reform politically feasible. We identify, as well, a set of other policy levers that would deemphasize the role of pharmaceutical patents. Though the pharmaceutical industry is often held up as the "poster child" for the patent system, this Article argues that removing the pharmaceutical industry from the patent system would be a victory for patients, for the industry, and for the patent system itself.

Introduction

Over forty years ago, a political compromise put in place the modern system of pharmaceutical regulation. To incentivize risky, costly investments in new medicines, the 1984 Hatch-Waxman Act offered market-based rewards—more robust patent rights—to developers of brand-name drugs.[1] To ensure that patients retained access to these life-saving health technologies, Hatch-Waxman also created a mechanism by which generic firms could more easily produce low-cost versions of these products: if a

1. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered sections of 15, 21, and 35 U.S.C.).

generic firm successfully challenged patent rights, it received market rewards of its own.[2]

Four decades of policy debates have considered how this balance ought to be calibrated, taking as a given that the patent system will be at the center of any new compromise.[3] In this setting, an enduring emphasis on patent rights is unsurprising. Pharmaceutical research and development (R&D) are often characterized as uniquely dependent on the existence of a strong patent system.[4] And the pharmaceutical sector is often held up as the "poster child" for the patent system itself.[5]

However, within a small group of advocates—including the architects of both sides of the Hatch-Waxman "grand bargain"—a remarkable new point of consensus is emerging: this patent-based system is broken and ought to be abandoned.[6]

At a forty-year retrospective on Hatch-Waxman, Bob Armitage, a former General Counsel for Eli Lilly, called the current "patent-centric" framework "bad policy" for innovators, generic firms, and patients alike: "Patients are not interested in the medicines with the best patents—they want the best medicines."[7] Al Engelberg, a key architect of Hatch-Waxman's generic-exclusivity provisions, echoed this sentiment, concluding that he no longer "believe[s] that you could fix the patent system."[8]

These concerns are the starting point for this Article. By some measures, the Hatch-Waxman compromise has been a remarkable success. Generic competition, for one, is now widespread.[9] We show, however, that Hatch-Waxman's means of achieving this victory for access has come at the cost of entrenching an adversarial system that incentivizes both brand-name and generic firms to use the patent system and the courts to their advantages—and that fails to align incentives with improved health outcomes for patients.

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2. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2024).

3. *See, e.g.*, Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL'Y, L. & ETHICS 293, 320 (2015); Matthew J. Higgins & Stuart J.H. Graham, *Balancing Innovation and Access: Patent Challenges Tip the Scales*, 326 SCIENCE 370, 370 (2009).

4. *See, e.g.*, Kevin A. Bryan & Heidi L. Williams, *Innovation: Market Failures and Public Policies*, *in* 5 HANDBOOK OF INDUSTRIAL ORGANIZATION 281, 328 (Kate Ho, Ali Hortaçsu & Alessandro Lizzeri eds., 2021); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1617 (2003).

5. *See, e.g.*, MICHELE BOLDRIN & DAVID K. LEVINE, AGAINST INTELLECTUAL MONOPOLY 242 (2008).

6. *See Health Care at Reasonable Cost: The Goals of the Hatch-Waxman Act as Seen From 2024*, N.Y.U. ENGELBERG CTR. LIVE!, at 27:42, 29:16 (Oct. 7, 2024), https://eclive.engelberg.center/episodes/health-care-at-reasonable-cost-the-goals-of-the-hatch-waxman-act-as-seen-from-2024 [https://perma.cc/D4JS-5QMB].

7. *Id.* at 22:55.

8. *Id.* at 30:01.

9. *See* WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RSCH. SERV., R41114, THE HATCH-WAXMAN ACT: A QUARTER CENTURY LATER, at i (2012).

A bit of regulatory context is necessary to understand the first conclusion in this Article—that the pharmaceutical sector is, at present, engaged in an arms race of strategic legal activity. Under Hatch-Waxman, brand-name firms may list patents associated with marketed small-molecule drugs in an administrative record known as the "Orange Book," maintained by the U.S. Food and Drug Administration (FDA).[10] Each listed patent must be challenged separately before generic competitors can enter the market.[11] Firms thus have strong incentives to accumulate large portfolios of patents, each of which represents a new potential barrier to generic competition. Generic firms, in turn, have a strong incentive to challenge these patents: the first generic challenger receives a bounty in the form of exclusive rights to the generic market for a fixed period of time.[12] Unsurprisingly, the number of patents listed for each drug has increased sharply over time. Generic challenges have increased in parallel, eroding the nominal gains in market exclusivity that one might expect from large, staggered patent rights.

Consider the cases of two treatments for respiratory disease: Singulair (montelukast) and Esbriet (pirfenidone).[13] Singulair was approved by the FDA in 1998 for the treatment of asthma. It was protected by only one patent, which provided a nominal exclusivity period of roughly fourteen years. On the day this patent expired, August 3, 2012, a generic competitor was approved. Sixteen years after Singulair's approval, in 2014, the FDA approved Esbriet for the treatment of pulmonary fibrosis. Esbriet was eventually protected by a large portfolio of twenty unique patents, which together provided nearly nineteen years of nominal market exclusivity. Yet by challenging these patents, the first generic variation entered the market in 2022, after just eight years.[14]

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10. *See* Maya Durvasula, C. Scott Hemphill, Lisa Larrimore Ouellette, Bhaven N. Sampat & Heidi L. Williams, *The NBER Orange Book Dataset: A User's Guide*, 52 RSCH. POL'Y 104791, at 1 (2023).

11. *See* 21 U.S.C. §§ 355(b)(2)(A)(iv), (j)(2)(A)(vii)(I)-(IV) (2024).

12. *Id.* § 355(j)(5)(B)(iv). This 180-day "exclusivity" period is on the generic market: the generic competitor shares the market with the incumbent (innovator) and receives duopoly profits and a market-share advantage over later generics. *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1581 (2006).

13. In both cases, we link patents to drugs using the NBER Orange Book Dataset and calculate market exclusivity using FDA administrative records. All data and code associated with this Article are publicly archived at Maya M. Durvasula & Lisa Larrimore Ouellette, *Beyond the Pharmaceutical Patent Arms Race*, HARV. DATAVERSE (June 18, 2026), https://doi.org/10.7910/DVN/HOCFF0.

14. Our data identify the first date on which the FDA approves an Abbreviated New Drug Application (ANDA), which enables a firm—often subject to some restrictions—to begin marketing a generic competitor. Generic approval is closely correlated, though not always coincident, with the date of generic entry. *See* Durvasula et al., *supra* note 10, at 12 & n.61. In this case, the first associated approval was in 2019, and generic entry did not occur until 2022. That is, generic entry was more than a decade earlier than the nominal exclusivity period would suggest. *See* Letter from Vincent Sansone, Deputy Dir., Off. of Generic Drugs, U.S. Food & Drug Admin., to Apotex Corp. (Oct. 29, 2019), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/212687Orig1s000TAltr.pdf [https://perma.cc/L2T4-V9F7]; Press Release, Sandoz, Sandoz Launches First Generic Pirfenidone in US for Patients with Idiopathic Pulmonary Fibro-

Perhaps surprisingly, these two forces—increasing numbers of patents and increasing numbers of patent challenges—have been perfectly offsetting on average. We show that the average *effective* period of market exclusivity, defined as the period in which an approved drug faces no generic competition, has remained roughly constant over time.[15]

If patents are not providing additional market exclusivity—and thus are failing to provide an additional reward to innovators—then who benefits from this system? Parts I and II of this Article suggest that, at present, the answer may be: no one. (Or at least no one other than patent lawyers.) Defenders of large and growing pharmaceutical patent portfolios argue that each additional patent on a drug protects actual incremental innovation, for which patent protection is necessary to recoup R&D costs.[16] If this were true, one would expect to observe *some* relationship between the size of a patent portfolio (or a drug's effective patent term) and proxies for innovation. For example, if secondary patents on a drug reflect R&D that expands the number of patients who benefit from the treatment, we might expect to find a strong, positive relationship between patent portfolio size and market size. For each small-molecule drug[17] approved by the FDA between 1985 and 2014, we collect a wide set of proxies that may capture different aspects of real technological improvements. Across these measures, we find no such relationships. Moreover, our doctrinal analysis of the misalignment between patentability criteria and health benefits suggests that this lack of correlation should be unsurprising.

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sis, Growing its Respiratory Portfolio (May 12, 2022), https://www.us.sandoz.com/news/media-releases/sandoz-launches-first-generic-pirfenidone-us-patients-idiopathic-pulmonary [https://perma.cc/B4DU-X52A].

15. *See infra* Section II.C.

16. *See, e.g.*, Erika Lietzan, *The "Evergreening" Metaphor in Intellectual Property Scholarship*, 53 AKRON L. REV. 805, 853-54 (2019); Megan Van Etten, *Biden Administration Report Debunks Myths Around Patent "Evergreening" and "Thickets*," PHRMA (Sep. 3, 2024), https://phrma.org/Blog/Biden-Administration-report-debunks-myths-around-patents [https://perma.cc/VT57-FGWP]; Pharm. Rsch. & Mfrs. of Am., Comment Letter on the USPTO's Notice of Proposed Rulemaking on Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting (July 9, 2024), https://www.regulations.gov/comment/PTO-P-2024-0003-0337 [https://perma.cc/HV4P-DKVR].

17. We focus on small-molecule drugs, or drugs with simple chemical structures, because their patent information is reported by brand-name firms and publicly accessible. *See* Durvasula et al., *supra* note 10, at 1. Although the patent information for more complex "biologic" drugs is not similarly available, scholars estimate that patent portfolios are even larger for biologics than for small-molecule drugs. *See, e.g.*, Rachel Goode, William B. Feldman & S. Sean Tu, *Ancillary Product Patents to Extend Biologic Patent Life*, 330 JAMA 2117, 2117 (2023) (studying litigated biologic patents). Our proposals thus could have an even greater impact in the biologic context. In addition, this would provide an opportunity to eliminate other distortions that provide larger incentives for biologic drugs than small molecules. *See, e.g.*, John Stanford, *The IRA Is Already Curtailing Small Molecule Drug Development. Here's How to Reverse That*, BIOSPACE (Apr. 9, 2024), https://www.biospace.com/the-ira-is-already-curtailing-small-molecule-drug-development-here-s-how-to-reverse-that [https://perma.cc/X757-54P4]. However, the science and economics of biologic development are sufficiently different from small-molecule drugs that they deserve a separate analysis.

To be clear, this Article does not attempt a complete welfare analysis of pharmaceutical patent portfolios. Any such analysis requires empirical evidence on open questions about the elasticity of research investment with respect to patent term. Instead, we focus more narrowly: can we reject the null hypothesis that patent portfolios provide *no* benefit? Put differently, does there appear to be *any* redeeming value to these large and growing stacks of intellectual property rights? The answer to even this modest question appears to be no: we find no evidence to suggest that patent portfolios provide significant benefits to any party within this system.

In short, the grand bargain of the pharmaceutical patent system is failing on its own terms. The costs of this failure are significant. The expenses of obtaining[18] and litigating[19] patents are high. These costs are passed through to consumers in at least one of two forms—in "missing" R&D (by lowering the expected net returns to marginal R&D projects, such that some investments that would otherwise be privately profitable are no longer undertaken) or in higher drug prices.

The uncertainty this dynamic creates about when any particular drug will actually face generic competition lowers the expected returns to product improvements and thus discourages investment by brand-name firms, raises barriers to entry for generic firms, and limits the information available for patients and physicians making plans for care. More importantly, these administrative and transaction costs appear to do little to align incentives with any social-policy goals. Forty years after Hatch-Waxman, the current framework is overdue for reform.

In Part III, we explore how to move beyond the patent-centric framework to a system of pharmaceutical exclusivity that prioritizes both incentives for innovation and patient access. In particular, we argue that fixing these problems from within the patent system is largely infeasible, for reasons including the mismatch between the doctrines governing the timing of

18. The average lifetime cost for a U.S. patent for small entities has been estimated around $60,000, and "it is not uncommon to spend $500K or more to get patent coverage in a large number of countries," with lifetime worldwide costs that "can reach into the tens of millions." Russ Krajec, *How Much Does a Patent Cost? The Real Truth*, MEDIUM (Oct. 23, 2019), https://medium.com/patentmyths/how-much-does-a-patent-cost-the-real-truth-5559e380014d [https://perma.cc/B59F-8489]. The cost is higher for larger entities (like most pharmaceutical firms), *see infra* note 103 and accompanying text, and for more complex technologies such as pharmaceuticals, *see* AM. INTELL. PROP. L. ASS'N, REPORT OF THE ECONOMIC SURVEY 43 (2023), https://fundamentalpatlit.com/wp-content/uploads/2024/02/AIPLA.pdf [https://perma.cc/FHB7-VDQU].

19. Although precise data on litigation expenses are not available, the American Intellectual Property Association provides estimates that are instructive. When more than $25 million is at risk to each side in Hatch-Waxman patent litigation—as is likely to be the case in most pharmaceutical patent cases—the average cost to each side through discovery is $4.3 million and through trial and appeal is $6.1 million. AM. INTELL. PROP. L. ASS'N, *supra* note 18, at I-158. Data from Lex Machina suggest nearly three-hundred litigated Orange Book patent cases per year by the middle of the 2010s—roughly $2 to $4 billion in annual costs. That we restrict consideration, here, to litigated cases provides reason to believe that this is a lower bound on all litigation expenses, including pre-filing legal costs.

patent filing and the timeline for obtaining relevant information about a drug's actual clinical value.[20] Patent law's relaxed disclosure rules and strict prior-art rules mean that patentability must be evaluated early in the drug-development process, before anyone has relevant information about the drug's actual clinical value.

Building on bipartisan legislation that was introduced repeatedly from 2011 through 2016—at one point with forty-eight Republican and forty-seven Democratic cosponsors[21]—we propose a framework for replacing patent-based exclusivity with a period of regulatory exclusivity during which the FDA will not approve generic versions of the drug.[22] Firms that receive this regulatory benefit would commit to waiving patent rights and facilitating generic entry at the end of the exclusivity period. We develop an economic model to illustrate how eligibility for this new exclusivity and the term of protection can better align incentives for developing a new drug with the added value that drug actually provides for patients.[23] Eligibility could be conditioned on disclosure of information about this added value. We also explain how to enforce the shift away from patents and avoid rights accretion, including by enforcing patentability requirements more vigorously, removing existing regulatory benefits for firms that do not opt into the system, and leveraging other regulatory benefits and federal purchasing power over pharmaceuticals.[24] This framework would eliminate inefficient patent thickets, reduce litigation, and refocus incentives on developing innovative and accessible medicines.

Finally, we argue that shifting drug development away from patents would reduce the pharmaceutical patent exceptionalism that has distorted the patent system more generally, allowing patent law to work better for the rest of the innovation ecosystem. Our reform proposals would thus not only benefit patients—they would benefit the patent system overall.

20. *See infra* Section III.A.

21. *See infra* Section III.B.

22. Regulatory exclusivity currently comes in two main forms: *data exclusivity* prevents a generic from relying on a brand-name drugmaker's clinical-trial data, while *market exclusivity* blocks a second entrant even if the second firm conducts its own clinical trials on the drug. As a practical matter, given the cost of conducting clinical trials, the two forms have similar effects. *See* JOHN R. THOMAS, CONG. RSCH. SERV., R44951, REGULATORY EXCLUSIVITY REFORM IN THE 115TH CONGRESS 3-12 (2017). In addition to building on proposed legislation, our proposal builds on prior commentary on the value of regulatory exclusivity as a pharmaceutical-innovation incentive. *See, e.g.*, Shamnad Basheer, *The Invention of an Investment Incentive for Pharmaceutical Innovation*, 15 J. WORLD INTELL. PROP. 305, 341-42 (2012); Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419, 420-22 (2012); Matthew Herper, *Solving the Drug Patent Problem*, FORBES (May 2, 2002), https://www.forbes.com/2002/05/02/0502patents.html [https://perma.cc/735J-22F7]; Talha Syed, *Does Pharma Need Patents?*, 134 YALE L.J. 2038, 2114-17 (2025).

23. *See infra* Section III.C.

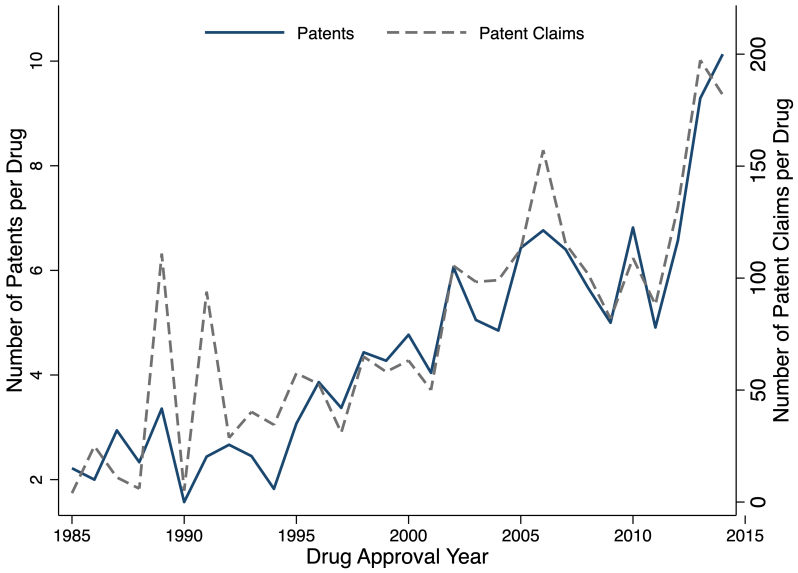
24. *See infra* Section III.D.

I. Pharmaceutical Patent Portfolios as a Policy Failure

A. The Growth of Pharmaceutical Patent Portfolios

In 1990, the median innovative small-molecule drug approved in the United States was protected by one patent, with fifteen associated claims.[25] By 2014, these counts had increased sharply, to seven patents with a total of 141 distinct claims. Figure 1 plots both trends from 1985 to 2014.[26]

Figure 1: Pharmaceutical Patent Portfolios Over Time



Growth in the potential length and scope of pharmaceutical patent terms has not gone unnoticed. Critics characterize these portfolios as

25. In patent law, "claims" define the boundaries of the patentee's legal rights—the metes and bounds of the invention. A patent may include multiple claims of varying breadth, which together determine what others are excluded from making, using, or selling and what falls within the scope of infringement. *See* JONATHAN S. MASUR & LISA LARRIMORE OUELLETTE, PATENT LAW: CASES, PROBLEMS, AND MATERIALS 24-26 (4th ed. 2025). Drug-approval records are collected from *Drugs@FDA: FDA-Approved Drugs*, U.S. FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm. Our sample is defined by the FDA's list of new molecular entities (NMEs): drugs for which no component has been previously approved. *See Compilation of CDER New Molecular Entity (NME) Drug and New Biologic Approvals*, U.S. FOOD & DRUG ADMIN. (July 10, 2025), https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals [https://perma.cc/A9B8-MR4P]. We restrict consideration to NMEs for which there is at least one patent in any edition of the Orange Book between 1985 and 2021, which is substantially all NMEs. We collect patent and exclusivity records from the NBER Orange Book Dataset, which includes data from all Orange Book editions from 1985 to 2021. *See* Durvasula et al., *supra* note 10. Other patent-specific data are collected from United States Patent and Trademark Office (USPTO) bulk data files. *See Bulk Dataset Directory*, U.S. PAT. & TRADEMARK OFF., https://data.uspto.gov/bulkdata/datasets. Re-

"thickets," composed of secondary patents of, often, dubious validity.[27] In support of these assertions of "evergreening"—the use of follow-on patents to extend exclusivity beyond any single patent term—one analysis by Robin Feldman examines 236 drugs associated with especially high spending and concludes that "companies have managed to game the patent system" to receive an "average total monopoly time" of nineteen years.[28] In related work, Sean Tu documents the prevalence of continuation patents in these portfolios, which "may result in higher drug prices for longer periods of time" by increasing the density of patent thickets that must be cleared before generic entry.[29] In response, pharmaceutical firms and their defenders argue that the patents in these portfolios represent genuine improvements in complex health technology.[30]

For all the attention this phenomenon has attracted in recent years, the policy debate has coalesced around competing, empirically testable claims about how this market is evolving—yet there is relatively little direct evidence on these competing accounts. In one version, effective patent terms for new drugs are rising rapidly, moving innovative medicines farther

stricting our analysis to NMEs has limitations. *See* C. Scott Hemphill & Bhaven Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 328 (2012) (imposing the same restriction but noting that exclusivity extensions for reformulations of existing drugs may be more concerning in absolute terms). Our results should be interpreted with the same qualification—that we document a lower bound on the offsetting forces of patent portfolios and generic challenges.

26. We restrict consideration to the period from 1985 (the year after the passage of the Hatch-Waxman Act) to 2014 to address concerns about censoring. For drugs approved in earlier years of our data, we are confident that the Orange Book provides their complete (listed) patent portfolios. For more recent approvals, however, prosecution for new patents may be ongoing. Although it is challenging to identify precisely the point at which a drug's portfolio is likely complete, we inspect trends in the time between drug approval and subsequent patent listings to select a cutoff point. Specifically, we examine the share of NMEs, by approval year, with (1) a new patent added between the 2021 and 2022 editions of the FDA Orange Book and (2) any active patents in the 2022 edition. We observe that drugs approved in or before 2014 are unlikely to have new patents in the 2021 and 2022 editions.

27. *See, e.g.*, Michael A. Carrier & S. Sean Tu, *Why Pharmaceutical Patent Thickets Are Unique*, 32 TEX. INTELL. PROP. L.J. 79, 82-83 (2024) (explaining how secondary patents often take the form of minor alterations aimed at extending patent life).

28. Robin Feldman, *Patent Term Extensions and the Last Man Standing*, 42 YALE L. & POL'Y REV. 1, 28, 32 (2023). This Article uses what we will refer to as a drug's nominal exclusivity period. This measure does not account for instances in which patents are challenged successfully or not enforced, enabling early generic entry. See *infra* Section II.C for the importance of incorporating these corrections. More generally, empirical analyses of pharmaceutical patenting commonly report the total time a drug would have been patent protected had every patent application been successful and in force for its full term. *See, e.g.*, *Overpatented, Overpriced: Curbing Patent Abuse: Tackling the Root of the Drug Pricing Crisis*, I-MAK 5 (Sep. 2022), https://www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf [https://perma.cc/ZMG7-4VQP]; Caroline Horrow, Sarah M.E. Gabriele, S. Sean Tu, Ameet Sarpatwari & Aaron S. Kesselheim, *Patent Portfolios Protecting 10 Top-Selling Prescription Drugs*, 184 JAMA INTERNAL MED. 810, 812 (2024). We focus on patent grants, in part because our interest is in understanding *actual* terms of market exclusivity but also because there is no clear mapping from drugs to patent *applications*.

29. S. Sean Tu, *The Long CON: An Empirical Analysis of Pharmaceutical Patent Thickets*, 86 U. PITT. L. REV. 213, 214 (2024).

30. *See supra* note 16 and accompanying text.

and farther out of reach for patients.[31] In another, large and growing portfolios are merely the price of innovation, given the increasing complexity of technology and the high and (purportedly) rising costs of drug development.[32]

Our goal in this Part is to interrogate the empirical foundations of these claims. There is clear evidence that the number of patents protecting new drugs has increased steadily over time, as illustrated in Figure 1. This is where the evidence base on welfare-relevant trends in this market largely ends.[33] It is plausible that growing patent portfolios are delaying generic entry substantially, with large consequences for access to medicine. It is also plausible that patent portfolios allow firms to develop medicines that would not have been profitable with shorter patent terms.

To be sure, although the overall evidence base on patents is surprisingly thin,[34] there is suggestive evidence that longer terms of market exclusivity may incentivize certain types of pharmaceutical R&D. A large and growing empirical literature establishes that increasing the returns to patented products leads to increased pharmaceutical R&D.[35] Pharmaceutical firms indicate in interviews that they regularly drop projects from development pipelines due to insufficient patent protection.[36] And, of direct rele-

31. *See, e.g.*, Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIENCES 590, 602 (2018) (explaining how brand-name companies try to prevent pharmacists from filling a prescription with a generic using evergreening strategies); *supra* notes 27-29 and accompanying text.

32. *See supra* note 16 and accompanying text. The current best evidence suggests that, at least since 2000, drug-development costs have been essentially stable. *See* Aylin Sertkaya, Trinidad Beleche, Amber Jessup & Benjamin Sommers, *Costs of Drug Development and Research and Development Intensity in the US, 2000-2018*, 7 JAMA NETWORK OPEN art. no. e2415445, at 7-10 (2024).

33. Important exceptions are Hemphill & Sampat, *supra* note 25; and C. Scott Hemphill & Bhaven N. Sampat, *Patents, Innovation, and Competition in Pharmaceuticals: The Hatch-Waxman Act After Forty Years*, J. ECON. PERSP., Spring 2025, at 27 [hereinafter Hemphill & Sampat, *Patents, Innovation, and Competition*].

34. *See, e.g.*, Heidi L. Williams, *How Do Patents Affect Research Investments?*, 9 ANN. REV. ECON. 441, 464 (2017).

35. *See* Daniel J. Hemel & Lisa Larrimore Ouellette, *Valuing Medical Innovation*, 75 STAN. L. REV. 517, 546-48 (2023) (summarizing evidence from Pierre Dubois, Olivier de Mouzon, Fiona Scott-Morton & Paul Seabright, *Market Size and Pharmaceutical Innovation*, 46 RAND J. ECON. 844, 851-54 (2015)); Daron Acemoglu & Joshua Linn, *Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry*, 119 Q.J. ECON. 1049, 1049, 1067 (2004); Rodrigo A. Cerda, *Endogenous Innovations in the Pharmaceutical Industry*, 17 J. EVOLUTIONARY ECON. 473, 475 (2007); Carmelo Giaccotto, Rexford E. Santerre & John A. Vernon, *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, 48 J.L. & ECON. 195, 197 (2005); Amy Finkelstein, *Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry*, 119 Q.J. ECON. 527, 534-35 (2004); Wesley Yin, *Market Incentives and Pharmaceutical Innovation*, 27 J. HEALTH ECON. 1060, 1068 (2008); Margaret E. Blume-Kohout & Neeraj Sood, *Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development*, 97 J. PUB. ECON. 327, 333-34, 333 tbls.4 & 5 (2013).

36. *See* Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 545-47 (2009) (explaining how pharmaceutical firms regularly drop projects that fail to receive patent protections). Similarly, older survey evidence suggests that patents are particularly important to the pharmaceutical industry. *See, e.g.*, Wesley M. Cohen, Richard R. Nelson & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Man-*

vance to this setting, Eric Budish, Ben Roin, and Heidi Williams have documented that the lower financial incentives for cancer drugs with long commercialization times[37] (and thus shorter effective patent terms) generate quantitatively important underinvestment.[38] Based on this empirical work, one can imagine a qualified defense of patent portfolios: perhaps the ability to stack multiple patents enables firms to develop drugs that would otherwise be abandoned. This would be an efficient solution, however, only to the extent that the additional patents cause increases in effective patent term that are aligned with the added social value of the drug.

In what follows, we interrogate this idea. We look for evidence, first, that the patent-portfolio phenomenon is capturing some underlying change in technology. Specifically, we consider whether patent portfolios are larger for drugs of higher quality—consistent with (though not dispositive of) the idea that these patents may represent actual innovation. Alternatively, we consider whether patent portfolios are larger for drugs with higher fixed R&D costs, for which a longer expected patent term may affect profitability on the margin. As a third and final story, we interrogate the idea of a pharmaceutical patent arms race: are patent portfolios allowing firms to offset erosion of effective patent terms due to generic litigation?

Section I.B finds little support for the first two hypotheses—that patent portfolios allow firms to market higher-quality technologies, or that portfolios offset high fixed costs. Section I.C then explains why this lack of correlation is unsurprising given the incentives provided by the patent system. Part II then documents several pieces of evidence consistent, instead, with the arms-race hypothesis—that pharmaceutical patents are largely used as strategic assets. Based on three facts—that many pharmaceutical patents offer little value to even the firms that own them, that generic litigation is increasing in frequency over time, and that growth of patent portfolios has not translated into meaningful changes in *actual* market exclusivity—we arrive at the primary conclusion of the first two Parts of this Article: pharmaceutical patent accumulation is best characterized as an arms race.

ufacturing Firms Patent (or Not) 27-28 (Nat'l Bureau of Econ. Rsch., Working Paper No. 7552, 2000) (describing how patents have provided offensive and defensive utility to pharmaceutical companies).

37. See *infra* notes 64-68 and accompanying text for a discussion of commercialization times.

38. *See* Eric Budish, Benjamin N. Roin & Heidi Williams, *Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials*, 105 AM. ECON. REV. 2044, 2080 (2015) (showing that, because patent protection runs from filing rather than approval, drugs with longer commercialization periods reach market with less effective exclusivity remaining, reducing expected returns and leading to underinvestment).

B. Little Evidence of Changes in Pharmaceutical Innovation

The idea that large and growing patent portfolios may both enable and evince increases in the quality of medical technology is not unreasonable. Although patents are widely used as measures of innovation[39]—and often interpreted as capturing discrete instances of product invention—the mapping from a commercialized product to its associated patents need not be one-to-one.[40] The number of patents that can protect a single product scales with the complexity of the technology.[41] And in high-technology markets beyond pharmaceuticals, firms increasingly claim that new products contain dozens of distinct inventions, each eligible for patent protection.[42]

If medicines are becoming more complex—in the sense that the number of patentable elements is increasing—then growth in patent portfolios may capture only changes in technology. This Section devises two tests of this idea. We consider, first, whether secondary patents themselves appear to represent real improvements in technology. Second, we ask whether drugs with larger portfolios offer greater health benefits to patients.

1. Patent Quality

A natural starting point in studying whether secondary patents represent real innovation is to examine measures of their quality. If other inventors cite secondary patents frequently, for example, they may represent inventions that contributed real scientific knowledge on which other inven--ors are actively building.[43] We contrast this measure of scientific value with a measure of the private value of patents to firms: changes in the firm's stock price upon patent issuance.[44]

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39. On the strengths and weaknesses of patents as indicators of economic activity and innovation, see, for example, Zvi Griliches, Ariel Pakes & Bronwyn H. Hall, *The Value of Patents as Indicators of Inventive Activity*, *in* ECONOMIC POLICY AND TECHNOLOGICAL PERFORMANCE 97-119 (Partha Dasgupta & Paul Stoneman eds., 1987).

40. Because of the Orange Book, the pharmaceutical sector is one of the few industries in which mapping patents to products and analyzing shifts over time is possible. *See* Durvasula et al., *supra* note 10, at 2.

41. *See* MASUR & OUELLETTE, *supra* note 25, at 13.

42. *See, e.g.*, Michael Noel & Mark Schankerman, *Strategic Patenting and Software Innovation*, 61 J. INDUS. ECON. 481, 485 (2013) (explaining how patenting by technological-firm rivals reduces a firm's value, which incentivizes patenting).

43. The number of times a patent is cited by subsequent patents is a commonly used measure of its scientific value. *See, e.g.*, Bronwyn H. Hall, Adam Jaffe & Manuel Trajtenberg, *Market Value and Patent Citations*, 36 RAND J. ECON. 16, 18 (2005); Juan Alcácer, Michelle Gittelman & Bhaven Sampat, *Applicant and Examiner Citations in U.S. Patents: An Overview and Analysis*, 38 RSCH. POL'Y 415, 415 (2009). For validation exercises establishing the usefulness of these measures for measuring the private and social value of pharmaceutical patents, see David S. Abrams & Bhaven N. Sampat, Pharmaceutical Patent Citations and Real Value 2 (Jan. 2017) (unpublished manuscript) (on file with authors).

44. The KPSS patent-quality measure, developed by Kogan, Papanikolaou, Seru, and Stoffman, uses changes in the stock-market value of the patent owner around the date of patent grant as a proxy for the private economic value of the patent. *See* Leonid Kogan, Dimitris Papani-

Figure 2 displays these two measures of value. Panel A considers stock returns as a measure of private value.[45] Panel B uses total citations to the patent as a measure of scientific value.[46] Both panels plot the difference between the estimated value of the *n*th patent on the drug and the value of the first-granted patent on the drug. That is, each point captures the *relative* value of the *n*th patent. In Panel A, we find that excess stock returns to secondary patents, relative to the first-granted patent, are positive. On this measure, remarkably, each secondary patent is, on average, more privately valuable than the first-granted patent. Panel B suggests the opposite is true in our data for patent citations: secondary patents receive fewer citations from other inventors than were received by the first-granted patent.

These measures are, of course, crude,[47] and we cannot rule out the possibility that there are other dimensions on which these patents are scientifically valuable that our measures do not capture. Together, however, these two facts are consistent with the idea that secondary patents confer private value on firms, while offering comparatively little in the way of scientific value for follow-on innovators.[48]

kolaou, Amit Seru & Noah Stoffman, *Technological Innovation, Resource Allocation, and Growth*, 132 Q.J. ECON. 665, 666 (2017). This market-based approach reflects the extent to which a patent is expected to generate future profits, incorporating factors such as market size, technological significance, and competitive advantage. *See id.* at 672-74. The measure is widely viewed as complementing citation-based metrics by capturing private value, which may not align with broader measures of social or scientific importance. *See, e.g.*, Patrick Kline, Neviana Petkova, Heidi Williams & Owen Zidar, *Who Profits from Patents? Rent-Sharing at Innovative Firms*, 134 Q.J. ECON. 1343, 1344-48 (2019).

45. We use KPSS excess-returns estimates for patents issued to publicly listed firms between 1926 and 2010. Data are drawn from the replication package for KPSS. *See* Dimitris Papanikolaou & Amit Seru, *Extended Data (till 2024) following Kogan, L., Papanikolaou, D., Seru, A. and Stoffman, N., 2017*, GITHUB, https://github.com/KPSS2017/Technological-Innovation-Resource-Allocation-and-Growth-Extended-Data [https://perma.cc/63NP-5KW5].

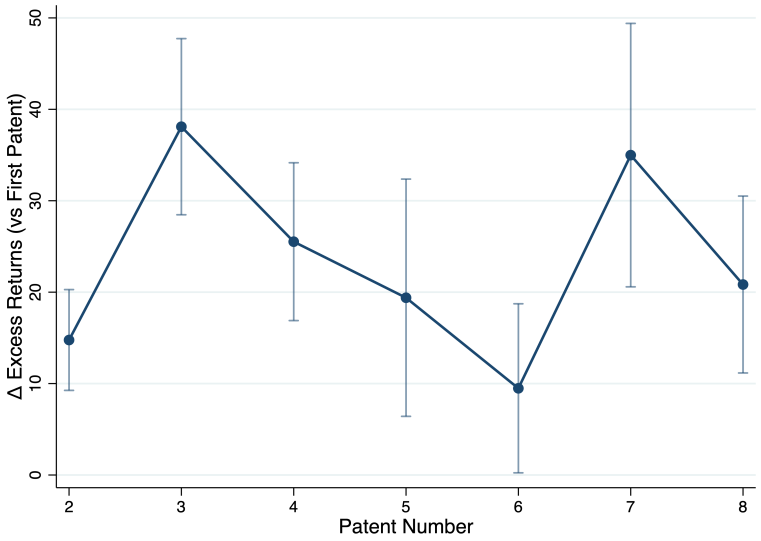
46. Data are constructed from the USPTO citations file, current through July 2022, downloaded from *Bulk Dataset Directory*, *supra* note 25. All specifications using patent citations as a measure include, among other controls, a fixed effect for the patent's year of issuance. This addresses the concern that older patents, mechanically, have a longer period of time over which to accrue citations. Our results are robust to a variety of alternative specifications: using log-transformed citations measures, dropping self-citations (i.e., citations to a patent from the same entity), and using five-year citations. In doing so, we follow Abrams & Sampat, *supra* note 43.

47. The KPSS measures are especially prone to error, as these measures reflect what are arguably quite strong distributional assumptions. Moreover, excess stock returns are intended to separate expected from unexpected shocks to firm valuation; to the extent that the market anticipates some change around the issuance of an especially valuable patent, the KPSS measure may understate its private value. The number of patent citations may reflect how well known a particular patent is—or other social factors that are typical concerns for citation-based measures. Data censoring is also a concern, as patents may continue to accumulate citations over time, and more recent patents have fewer total citations than older, comparable patents.

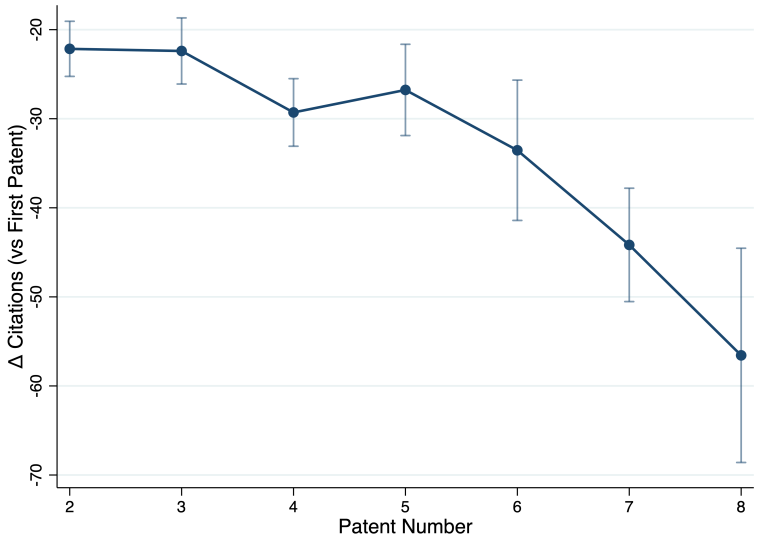
48. Section II.A offers a refinement: many of the patents in this sample are not valuable, on some measures, even to the firms that own them.

Figure 2: Portfolios and Patent Value

A. Private Value: Excess Stock Returns



B. Scientific Value: Patent Citations



2. Drug Quality

We next consider measures of the quality of the underlying products—drugs. In the pharmaceutical context, industry analysts have often asserted that products are becoming more complex as developers invest in quality improvements. In an influential, though contested, analysis of pharmaceutical-sector productivity, Jack Scannell and coauthors posit that drug complexity and quality are rising over time—and, in turn, increasing drug development costs—as entrants attempt to compete with high-quality, low-cost alternatives.[49] Under this view, a drug that represents only a minimal improvement over generic alternatives risks rejection by foreign regulators, physicians, and insurers. But a central empirical predicate for this broader view—namely, that pharmaceutical-sector productivity has declined persistently—has itself been contested by recent work.[50]

This hypothesized link between complexity and quality suggests a simple test: are drugs with larger patent portfolios better on measurable dimensions? It is worth emphasizing, at the outset, that there are remarkably few measures of drug quality available for an exercise like this one—in part due to the difficulty of selecting a consistent measure of "quality" and in part due to political objections to the use of cost-effectiveness measures in health-policy decisions in the United States.[51] We select two available proxies for each drug's value at the time of its approval: a quality rating determined by the French equivalent of the FDA;[52] and a measure

49. *See* Jack W. Scannell, Alex Blanckley, Helen Boldon & Brian Warrington, *Diagnosing the Decline in Pharmaceutical R&D Efficiency*, 11 NATURE REV. DRUG DISCOVERY 191, 193-94 (2012). This hypothesis echoes the argument that as the stock of scientific knowledge grows, the effort required to reach the "frontier" increases as well, yielding scientific insights of increasing sophistication. *See* Benjamin F. Jones, *The Burden of Knowledge and the "Death of the Renaissance Man": Is Innovation Getting Harder?*, 76 REV. ECON. STUD. 283, 283-84 (2009).

50. *See* Maya M. Durvasula, Sabri Eyuboglu & David M. Ritzwoller, Counting Clinical Trials: New Evidence on Pharmaceutical Sector Productivity 2 (Jan. 24, 2025) (unpublished manuscript), https://arxiv.org/pdf/2405.08030 [https://perma.cc/M52F-8Z3Z] (arguing that the quantity of published clinical trials, which has been offered as evidence of pharmaceutical sector decline, results from imprecise classification methods); Sertkaya et al., *supra* note 32, at 1 (showing that although pharmaceutical-industry sales have declined, research-and-development (R&D) intensity has increased significantly).

51. See Hemel & Ouellette, *supra* note 35.

52. French regulators assign two quality ratings to newly approved drugs: (1) SMR (*le service médical rendu*—actual benefit) and (2) ASMR (*l'amélioration du service médical rendu*—improvement in actual benefit). *See Le Service Médical Rendu (SMR) et L'Amélioration du Service Médical Rendu (ASMR)*, HAUTE AUTORITÉ DE SANTÉ (2013), https://www.has-sante.fr/jcms/r_1506267/fr/le-service-medical-rendu-smr-et-l-amelioration-du-service-medical-rendu-asmr [https://perma.cc/G3KV-TCKB]. A drug may receive one of five SMR ratings—*Majeur*/Major (not awarded in our sample), *Important*/Important, *Modéré*/Moderate, *Faible*/Weak, and *Insuffisant*/Insufficient—and an ASMR rating between I (major improvement relative to existing therapies) and V (no improvement). *See id.*

To be clear, we draw on these French quality ratings not because they represent the best potential measures of drug quality but because they are among the only standardized comparative clinical-benefit ratings available for a near-universe of approved drugs. Other regulators—including the FDA—do not publish alternative metrics. Our data are current through 2016, drawn from *Replication Data For: Is American Health Care Uniquely Inefficient? Evidence from*

of its adoption by physicians, in the form of prescriptions written in the five years following drug approval.[53] For both, we are, again, interested in the relationship between patent portfolio size and the measure of value. To this end, Figure 3, Panel A plots the relationship between the number of patents in a drug's portfolio and its French FDA quality rating, and Panel B plots portfolio size against the total number of prescriptions.[54] Panel A plots the average patent portfolio size for all drugs with a given French FDA quality rating. Panel B is a binned scatterplot, which bins drugs into nine categories based on their value on our prescription measure and plots the average number of patents in each bin.

If drugs with larger patent portfolios are of higher quality, we would expect both trends to be strong and positive. In Panel A, however, we find no relationship between the size of a drug's patent portfolio and its expert-assigned quality measure.[55] Panel B shows a positive relationship between

Prescription Drugs, OPENICPSR (Oct. 12, 2019), https://www.openicpsr.org/openicpsr/project/113519/version/V1/view [https://perma.cc/PXQ7-VT9S], which provides replication data for Margaret Kyle & Heidi Williams, *Is American Health Care Uniquely Inefficient? Evidence from Prescription Drugs*, 107 AM. ECON. REV. 486 (2017). Though these ratings represent an especially clear measure of drug quality, only 332 (43%) drugs in our sample have SMR ratings and 213 (27%) have ASMR ratings. We are also missing data for the final years of our sample. For these years, we can assume that observations are missing at random. For earlier years with incomplete coverage, our results should still be interpreted with care, but selection concerns are plausibly attenuated in this context: drugs launched in the United States are generally also launched in large European markets such as France. *See generally* Iain M. Cockburn, Jean O. Lanjouw & Mark Schankerman, *Patents and the Global Diffusion of New Drugs*, 106 AM. ECON. REV. 136 (2016) (showing that drug prices strongly affect how quickly new drugs are launched across markets).

53. We collect prescription records from the Medical Expenditure Panel Survey (MEPS), a nationally representative survey run by the U.S. Department of Health and Human Services; data on prescription expenditures are available for 1995 to 2019. Our primary measure counts the unique number of individuals prescribed a given drug in a particular year. By focusing on whether each individual in the MEPS panel received *any* prescription for a drug in a given year, we avoid the concern that drugs are packaged in different quantities. We restrict consideration to a five-year period to focus on quality immediately after approval and to address the concern that older drugs, mechanically, may appear to have larger market sizes.

54. We apply an inverse hyperbolic sine (IHS) transformation to the number of prescriptions to account for both skewness in its distribution and the presence of observations with zero prescriptions. Like the more common log transformation, the IHS transformation can reduce the influence of outliers in a right-skewed distribution. The value of the IHS transformation is that it can accommodate zero-valued observations, which would be dropped with a logarithmic transformation (as the log function is undefined at zero). The downside is that the IHS transformation is not invariant to scaling, meaning that changing the units of the variable can change the final interpretation. Because we are not interested in recovering a treatment effect, the IHS transformation is reasonable. *See* Jiafeng Chen & Jonathan Roth, *Logs with Zeros? Some Problems and Solutions*, 139 Q.J. ECON. 891, 907 (2024); Edward C. Norton, *The Inverse Hyperbolic Sine Transformation and Retransformed Marginal Effects*, 22 STATA J. 702, 702-03 (2022).

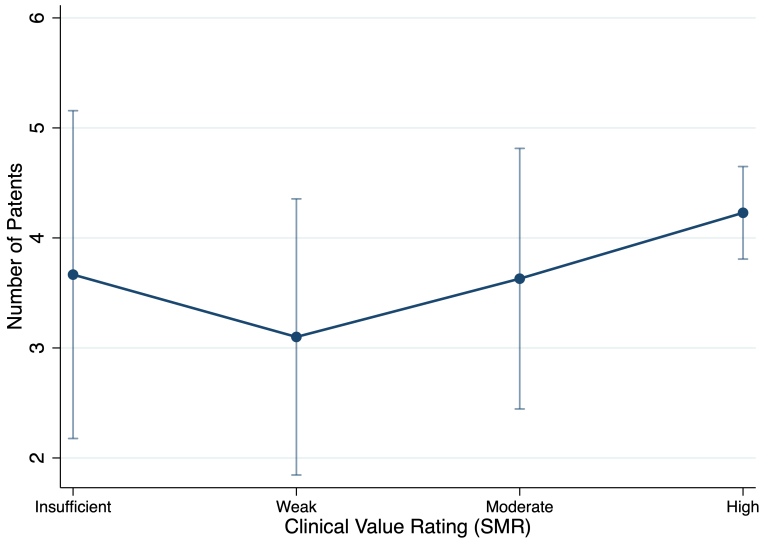
55. These results are qualitatively unchanged when this plot is reproduced using patent claims instead of patents as the outcome of interest; likewise, results using the French FDA's ASMR rating or the U.S. FDA's "priority review" designation as metrics of quality suggest no correlation between the size of a patent portfolio and regulator-assessed product quality. In each case, the slope of the trend line of best fit is statistically indistinguishable from zero. Appendix Table A1 reports the results of simple regression analyses. On the FDA priority-review designation as a proxy for clinical importance, see Bhaven N. Sampat & Frank R. Lichtenberg, *What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?*, 30 HEALTH AFFS. 332, 334 (2011).

portfolio size and the number of prescriptions following approval, but this relationship is not statistically distinguishable from zero.[56]

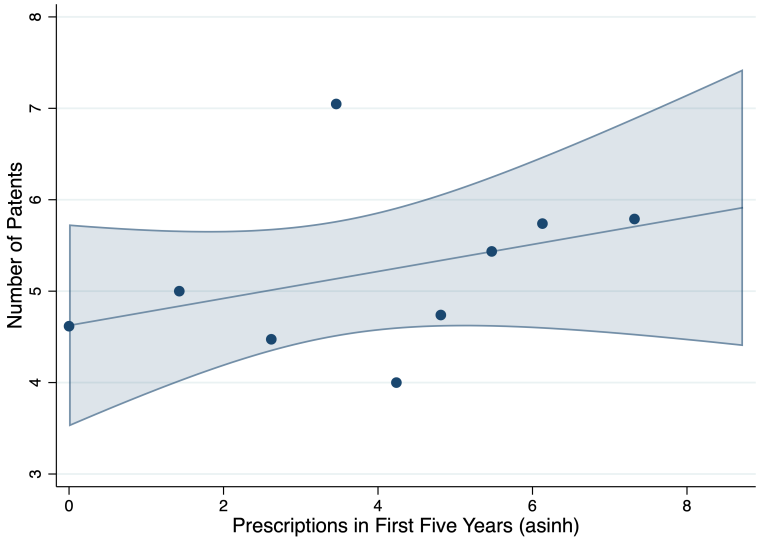
56. These results are qualitatively unchanged when this plot is reproduced using patent claims instead of patents as the outcome of interest; likewise, results are unchanged if this plot is produced using the average number of prescriptions across all available years of MEPS data, rather than five-year prescription rates.

Figure 3: Quality at Time of U.S. FDA Approval

A. Drug Quality Ratings (French FDA)



B. Prescriptions (Medical Expenditure Panel Survey)



These two exercises focus on an especially narrow window of a drug's lifecycle. In Figure 3, we compare measures of drug quality at the time of approval to total (lifetime) portfolio size. Even if drugs with larger eventual portfolios are not differentially valuable at the time of approval, incre-

mental improvements—such as additional FDA approvals that correspond to new indications, new formulations, or new populations—may increase their usefulness over time. Thus, we might expect to see some relationship between portfolio size and measures of R&D across the drug's lifecycle. Figure 4 considers this possibility.

In Figure 4, we examine two measures of follow-on R&D: clinical trials on the drug initiated after its first approval and reapprovals by the FDA that expand the drug's label.[57] Reapprovals include alterations to the drug's label, including modifications to add new indications, patient populations, dosages, forms, and strengths.[58] Clinical trials are attractive as a measure of follow-on R&D because they capture real firm investments.[59] We aggregate these measures for each drug across its total period of market exclusivity—the time between its first approval and either the entry of a generic competitor or the expiration of all patents and exclusivities.[60] Like Figure 3B, Figures 4A and 4B are ten-binned scatter plots.

Figure 4, Panel A considers the relationship between the total number of patents in the drug's portfolio and the number of clinical trials begun after initial approval. Roughly one-quarter of drugs in our sample (187 out

57. In particular, Figure 4 presents two measures of improvements during a drug's market life—between its approval by the FDA and either the entry of a generic competitor or the expiration of all patents/exclusivities. Panel A is a ten-binned scatterplot of the relationship between the number of patents on a drug and the number of clinical trials conducted during its market life. To account for skewness in this dataset and to accommodate observations for which there are zero trials, we apply an inverse hyperbolic sine transformation to the data. *See supra* note 54. Panel B is a ten-binned scatterplot capturing the relationship between the size of a drug's patent portfolio and two measures of reapprovals by the FDA. Reapprovals are split into two categories: new indications and new patient populations (blue) and all other reapprovals (red). Lines of best fit are overlaid.

58. Data are drawn from *Drugs@FDA*, *supra* note 25.

59. Clinical-trial data are drawn from two datasets: ClinicalTrials.gov, a registry of trials maintained by the National Institutes of Health, and NDA Pipeline, an annual publication compiling FDA documents about clinical trials, which together provide complete coverage of publicly disclosed trials during our sample period. We downloaded ClinicalTrials.gov data from *Download AACT*, CLINICAL TRIALS TRANSFORMATION INITIATIVE, https://aact.ctti-clinicaltrials.org/downloads [https://perma.cc/YW9F-DNR5]. NDA Pipeline data were shared by Sean Nicholson with Heidi Williams in April 2007 and are used, here, with the permission of both. ClinicalTrials.gov was established in 2000, but trial registration was not mandated for FDA-regulated products until 2007. NDA Pipeline includes data on publicly disclosed clinical trials conducted between 1982 and 2001.

For each trial record, we construct a cleaned and standardized version of the drug under study. For NDA Pipeline, this process is straightforward, as these data were cleaned in the process of dataset construction. For ClinicalTrials.gov, however, trial interventions are reported by sponsors as free text (i.e., unstandardized descriptions) and are inconsistent, even within records associated with the same clinical trial. We clean each string and hand-construct a crosswalk from sponsor-reported free text to a standardized drug name. To the best of our knowledge, this field has never been cleaned for use in research previously.

60. We will return to this measure of market exclusivity in Section II.C. For other ways of constructing measures of exclusivity, see Durvasula et al., *supra* note 10, at 12-14; and Eric Budish, Maya M. Durvasula, Benjamin N. Roin & Heidi Williams, *Missing Markets for Innovation: Evidence from New Uses for Existing Drugs*, at app. (Nat'l Bureau of Econ. Rsch., Working Paper No. 34222, 2025).

of 780) have no clinical trials initiated after approval. For the remainder, we identify 3,098 unique trials.

Here, we find a small, positive relationship between the size of a drug's portfolio and the number of trials initiated after approval: there is a roughly four percent increase in the number of clinical trials associated with each additional patent.[61] This relationship is, importantly, not causal—and causality here plausibly runs in both directions. If clinical trials generate new, patentable information (e.g., new methods of use), trials may "cause" the patent. If a larger portfolio increases incentives to continue development of a product line, then patents "cause" trials. Or a third factor—such as commercial importance—may cause both incremental patenting and incremental trials.

Figure 4, Panel B examines the total number of reapprovals by the FDA for each drug in our sample. We differentiate between two types of reapprovals: those associated with new indications and new patient populations and those associated with new methods of dispensing the drug (e.g., a tablet instead of a capsule). Reapprovals in the first category typically expand the set of patients to whom a drug may be prescribed. These "new uses" may be of high social value, at least as compared to other reapprovals of existing drugs.[62]

Reapprovals in the second category are more controversial. While new dosage forms and formulations can increase uptake and encourage patient compliance, they are often characterized as "product hopping," wherein firms introduce marginally improved versions of existing drugs to prolong market exclusivity.[63] We separate these two types of reapprovals to distinguish between changes that increase the private and social value of a drug and changes that may only deliver private benefits to the firm.

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61. Appendix Table A1 reports the results of a simple regression analysis, which includes fixed effects for the drug's year of initial approval.

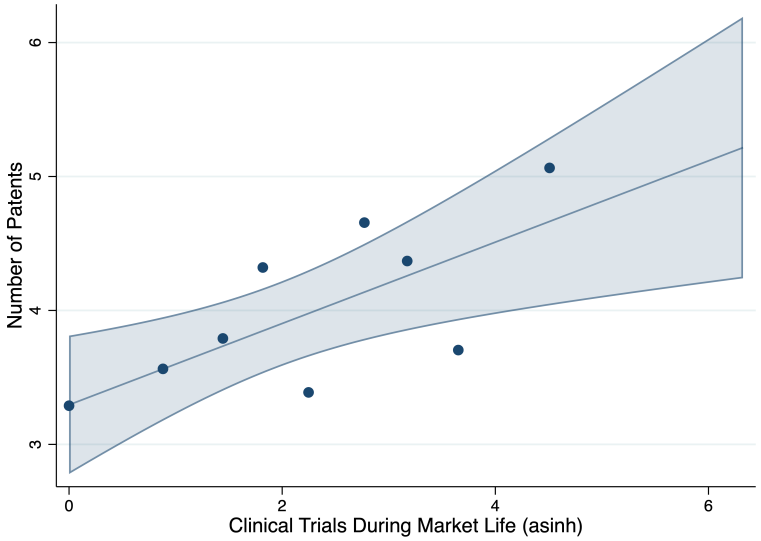
62. *See* Budish et al., *supra* note 60, at 35 (summarizing evidence on differences in the value of new use approvals relative to initial approvals and noting that, although new uses, on average, offer lower incremental therapeutic benefits than initial approvals, new uses nonetheless provide meaningful increases in the number of quality-adjusted life years per patient and substantially increase drug market size); *see also* Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717, 718 (2005) (arguing that information about effects of drugs has high social value for doctors, patients, and insurers); Benjamin N. Roin, Solving the Problem of New Uses 40-50 (Oct. 14, 2016) (unpublished manuscript), https://www.bu.edu/law/files/2016/10/Solving-the-Problem-of-New-Uses-Ben-n.-Roin.pdf [https://perma.cc/RTR7-SG5K]. There are, however, many instances in which new use approvals—and, in particular, patents on new uses—appear to be used strategically. *See, e.g.*, S. Sean Tu & Ameet Sarpatwari, *A "Method of Use" to Prevent Generic and Biosimilar Market Entry*, 388 NEW ENG. J. MED. 483, 484 (2023).

63. *See* Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 176-77 (2016); Zakia B. Shariff, Dania T. Dahmash, Daniel J. Kirby, Shahrzad Missaghi, Ali Rajabi-Siahboomi & Ian D. Maidment, *Does the Formulation of Oral Solid Dosage Forms Affect Acceptance and Adherence in Older Patients? A Mixed Methods Systematic Review*, 21 J. AM. MED. DIRS. ASS'N 1015, 1015 (2020) (discussing the importance of creating dosage forms that are more amenable to older adults who can often struggle to take medication orally).

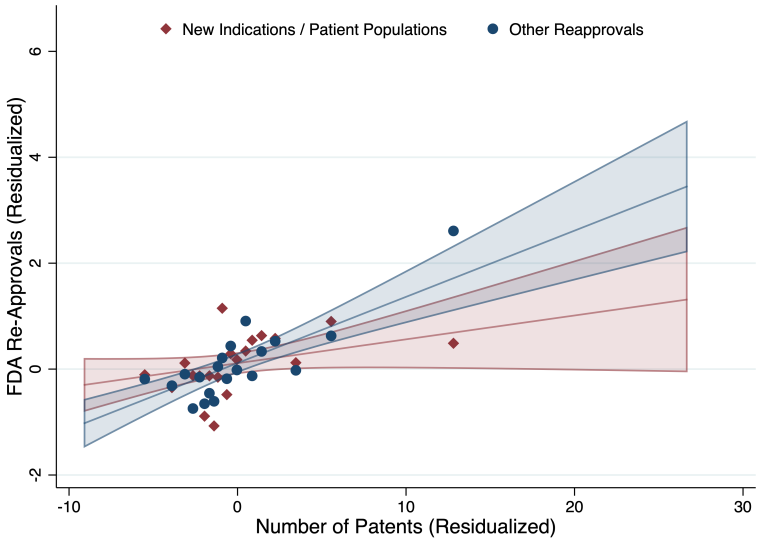
Panel B presents these relationships graphically. The slope of the line of best fit relating portfolio size to reapprovals for new indications and new patient populations is positive but statistically indistinguishable from zero. The slope relating portfolio size to other types of reapprovals—those likely to be more privately than socially valuable—is positive and statistically significant.

Figure 4: Product Improvements: Clinical Trials and Reapprovals

A. Clinical Trials After Initial Approval



B. FDA Reapprovals



3. Commercialization Lags

Economists and lawyers have long recognized that fixed patent terms—which provide the same period of protection to all inventions—will provide excessive incentives for some inventions (relative to what was required to induce their development) and insufficient incentives for others.[64] One distortionary form of heterogeneity in the pharmaceutical sector is that firms have strong incentives to file patents before beginning clinical trials,[65] leaving drugs that require longer trials with fewer years of effective patent protection. Budish, Roin, and Williams provide suggestive evidence that this feature of the patent system has distorted research investments away from drugs that require long clinical trials.[66] One proposal to reform the patent system suggests, accordingly, starting patent terms for pharmaceuticals at the time of commercialization (i.e., FDA approval) rather than invention. [67] Budish, Roin, and Williams assume, however, that each drug is protected by a single patent, which provides at most twenty years of protection.[68]

Even without formal changes to the structure of patent terms, might portfolios of secondary patents allow firms to approximate such a modification? A priori, it is not clear that we should expect this type of patent term self-extension to meaningfully change incentives for innovation. If the likelihood of successful patent challenge increases in the later years of a drug's effective patent term, an extra year early in a drug's life might be much more valuable than an extra year at the end of its life. Nonetheless, if secondary patents were used *solely* to offset commercialization lags—periods between patent filing and FDA approval that erode *effective* patent terms—then we should see a strong, positive relationship between some measure of a drug's commercialization lag and the size of its patent portfolio.

In Figure 5, we present an empirical test of this idea. We construct a measure of the commercialization lag for each drug in our sample by calculating the time between its first patent filing and its approval.[69] Figure 5

64. *See, e.g.*, WILLIAM D. NORDHAUS, INVENTION GROWTH AND WELFARE: A THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE 76-86 (1969); F.M. Scherer, *Nordhaus' Theory of Optimal Patent Life: A Geometric Reinterpretation*, 62 AM. ECON. REV. 422, 426-27 (1972).

65. *See infra* Section I.C. In short, waiting longer to file a patent application increases the risk that the invention will no longer be sufficiently novel to patent, including due to the clinical trial itself.

66. Budish et al., *supra* note 38, at 2080

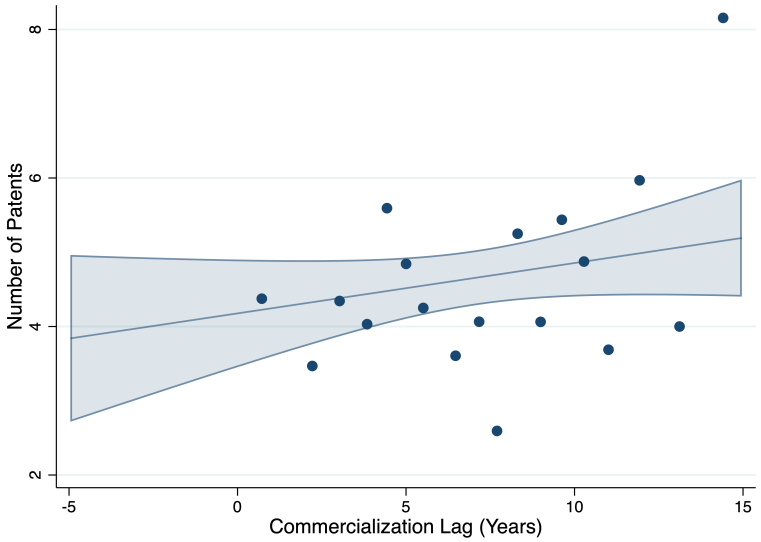
67. *See* Lisa Larrimore Ouellette & Heidi Williams, *Reforming the Patent System*, HAMILTON PROJECT (June 2020), https://www.brookings.edu/wp-content/uploads/2020/06/Ouellette_Williams_LO_6.16_FINAL.pdf [https://perma.cc/NP9N-43H9].

68. *See* Budish et al., *supra* note 38, at 2051 & n.12. This is a standard feature of the model on which they build from NORDHAUS, *supra* note 64.

69. We define commercialization lags to start on the day that the first patent associated with a drug was actually filed with the USPTO, drawn from data at *Bulk Dataset Directory*, *supra*

compares this measure of the time spent in development to the size of the drug's patent portfolio. Although the scatterplot and line of best fit are upward sloping, the correlation between these two measures is not statistically distinguishable from zero.[70] Put differently, there is no indication in Figure 5 that patent portfolios are being used to offset the period of commercialization. While we of course cannot rule out this explanation authoritatively, we find no evidence of this type of compensating behavior in our data.

Figure 5: Portfolios and Commercialization Lags[71]



C. Misalignment of Patentability Criteria with Health Benefits

The lack of correlation between larger patent portfolios and measures of drug quality or R&D costs might seem surprising, but these measures actually have little connection to the legal requirements for obtaining a patent. U.S. patent law does not demand any evidence that a patented inven-

note 25. Commercialization lags end on the day of FDA approval, drawn from Drugs@FDA, *supra* note 25.

70. This result is robust to alternative measures of the drug's patent portfolio, including the total number of patent claims and the total number of years of the drug's *effective* patent term.

71. Figure 5 is a scatterplot that compares each drug's commercialization lag—defined as the time between its first patent filing date and its approval by the FDA—to the size of its patent portfolio. Data are binned into ventiles (twenty bins) of commercialization lag and overlaid with a line of best fit.

tion offers an improvement over existing technologies.[72] Indeed, an invention can be patentable even if it is demonstrably worse.[73]

Under patent law's disclosure doctrines—particularly, the enablement, written description, and utility requirements—a patent must provide *some* evidence that the claimed invention will actually work.[74] But the standard for obtaining a patent on a drug that treats some disease in human patients is far lower than the standard for FDA approval of the drug.[75] Human clinical trials are not required.[76] The U.S. Patent and Trademark Office (USPTO) explicitly cautions its patent examiners against asking applicants for trial data, noting that "[i]n no case has a federal court required an applicant to support an asserted [therapeutic] utility with data from human clinical trials."[77] Rather, simply being ready to initiate human trials—which requires giving the FDA "some credible rationale of how the drug might be effective"—presumptively establishes therapeutic utility[78] and indicates that the invention is "ready for patenting."[79] A patent filed at the start of clinical trials will thus generally satisfy patent law's disclosure requirements, even though ninety percent of clinical trials fail.[80]

Once an invention is ready for patenting under these relaxed disclosure standards, inventors have strong incentives to file as soon as possible, before sale or use of the invention creates "prior art" that renders it unpatentable as no longer novel.[81] For example, in *Helsinn v. Teva*, Helsinn was studying formulations for treating chemotherapy side effects.[82] Before

72. *See* Stiftung v. Renishaw PLC, 945 F.2d 1173, 1180 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result, and it need only be useful to some extent . . . .").

73. *See* Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 960 n.12 (Fed. Cir. 1986) ("It is possible for an invention to be less effective than existing devices but nevertheless meet the statutory criteria for patentability."). *See generally* W. Nicholson Price II, *The Cost of Novelty*, 120 COLUM. L. REV. 769 (2020) (discussing the costs of a patent system that focuses on "new" rather than "better").

74. *See* MASUR & OUELLETTE, *supra* note 25, at 169.

75. *See In re* '318 Pat. Infringement Litig., 583 F.3d 1317, 1324 (Fed. Cir. 2009).

76. *See id.* After the 1962 Kefauver-Harris Drug Amendments, Pub. L. No. 87-781, 76 Stat. 780, required drug sponsors to submit evidence of safety and efficacy to the FDA, the USPTO initially took the position that patent law's utility requirement also required evidence that a therapeutic compound is safe and effective. *See In re* Hartop, 311 F.2d 249, 256 (C.C.P.A. 1962). But this position was rejected by the Federal Circuit's predecessor court. *See id.* at 260.

77. U.S. PAT. & TRADEMARK OFF., MANUAL OF PATENT EXAMINING PROCEDURE § 2107.03 (9th ed. rev. Jan. 2024), https://www.uspto.gov/web/offices/pac/mpep/index.html [https://perma.cc/667B-XUBQ].

78. *Id.*

79. Minerva Surgical, Inc. v. Hologic, Inc., 59 F.4th 1371, 1380-81 (Fed. Cir. 2023). The exception is when a trial is needed to resolve "significant uncertainty" about the claimed feature. *See* Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc., 855 F.3d 1356, 1375 (Fed. Cir. 2017) (citing *In re* Omeprazole Pat. Litig., 536 F.3d 1361, 1373 (Fed. Cir. 2008), *aff'd*, 586 U.S. 123 (2019)). But this rule is not rigorously applied.

80. *See* Duxin Sun, Wei Gao, Hongxiang Hu & Simon Zhou, *Why 90% of Clinical Drug Development Fails and How to Improve It?*, 12 ACTA PHARM. SINICA B 3049, 3050 (2022).

81. *See* MASUR & OUELLETTE, *supra* note 25, at 87-93 (describing these doctrines).

82. Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc., 855 F.3d 1356, 1360-61 (Fed. Cir. 2017).

completing clinical trials or obtaining FDA approval, Helsinn signed a confidential purchase agreement for the drug, conditional on FDA approval.[83] Helsinn then filed for several patents—which were invalidated based on the purchase agreement.[84] The court that hears all patent appeals, the Federal Circuit, rejected Helsinn's argument that the invention was not ready for patenting at that time, emphasizing the distinction "between the standard required to show that a particular invention would work for its intended purpose and the standard that governs FDA approval of new drugs, including the various stages of clinical trials."[85]

As another example of how patent law incentivizes filing patents before there is evidence of a drug's efficacy from clinical trial results, consider *In re Montgomery*.[86] A patent application on use of a particular drug to prevent stroke was held unpatentable in light of an earlier publication describing the design of a clinical trial to study whether the drug prevented stroke.[87] The clinical trial eventually succeeded, but these results were not available until after the patent-application priority date.[88] The Federal Circuit held that even though the publication did not demonstrate whether the drug was effective, it "inherently" anticipated the claim simply by describing administration of the drug to stroke-prone patients.[89]

A clinical trial might not invalidate a later-filed patent if the trial is strictly confidential.[90] Since 2007, however, most drug trials (excluding phase I studies) must be registered at ClinicalTrials.gov within twenty-one days of enrolling the first participant, with the registration information including details such as the disease and intervention being studied.[91] Registrations are published within about a week.[92] The results of registered studies are uncertain and may not be known for years or decades, but Clinical-rials.gov registrations are increasingly being used to invalidate later-filed patents.[93] The resulting disconnect between the timing for obtaining infor-

83. *Id.* at 1361-62.

84. *Id.* at 1362, 1367, 1375.

85. *Id.* at 1372. Helsinn appealed on a different argument to the Supreme Court, which affirmed the Federal Circuit holding. 586 U.S. 123, 132 (2019).

86. 677 F.3d 1375 (Fed. Cir. 2012).

87. *Id.* at 1382-83.

88. *Id.* at 1378.

89. *Id.* at 1381.

90. *See* Dey, L.P. v. Sunovion Pharms., Inc., 715 F.3d 1351, 1357 (Fed. Cir. 2013) (holding that, "[b]ecause a finder of fact could conclude that the study was conducted with a reasonable expectation of confidentiality as to the nature of the formulations being tested, summary judgment on the public use issue was inappropriate").

91. Food and Drug Administration Amendments Act, Pub. L. No. 110-85, § 801, 121 Stat. 823, 904-22 (2007).

92. *See How to Register Your Study*, NAT'L LIBR. MED. (Sep. 9, 2025), https://clinicaltrials.gov/submit-studies/prs-help/how-register-study [https://perma.cc/T8QL-MNHV] (explaining that registrations will be uploaded in two-to-five business days).

93. *See* Chris Holman, *The Use of Mandated Public Disclosures of Clinical Trials as Prior Art Against Study Sponsors*, PATENTLY-O (Apr. 16, 2024), https://patentlyo.com/patent/2024/04/mandated-disclosures-clinical.html [https://perma.cc/XJ7K-UBPE] (discussing Salix

mation about a drug's benefits and the timing of invalidating prior art will only be exacerbated by increasing global initiatives to improve clinical trial transparency.[94]

In sum, drug developers interested in preserving their patent rights should file patent applications before engaging in activities that might create prior art, including signing supply agreements (even if conditional and confidential) or making any public disclosures about clinical trial design.[95] Thus, pharmaceutical patent applications are typically filed long before anyone knows whether the drug is actually effective or safe, much less whether it provides any health benefits beyond the existing standard of care.[96] Given this misalignment between patentability criteria and health benefits, the lack of correlation between patent portfolios and drug quality is to be expected.

II. Pharmaceutical Patent Portfolios as an Arms Race

Sections I.A and I.B found little evidence that patent portfolios enable firms to commercialize more or better medicines. And as Section I.C emphasized, this is unsurprising. The patent system is not designed to incentivize innovation that prioritizes actual health benefits. A key question then remains: what function do patent portfolios serve?

This Section casts pharmaceutical patents as strategic assets and patent portfolios as, in many cases, defensive tools. Section II.A begins with a striking fact that offers insight into the value of pharmaceutical patents to the firms that own them: nearly half of all patents listed in the FDA's Orange Book are allowed to lapse before their statutory term is complete. This suggests that a significant portion of these patents may hold little economic value, even to the firms that sought and obtained them. Sections II.B

Pharms. v. Norwich Pharms. Inc., 98 F.4th 1056 (2024); and Vanda Pharms. Inc. v. Teva Pharms. USA, Inc., No. 2023-1247, 2023 WL 3335538 (Fed. Cir. May 10, 2023)); Karina J. Moy & Rubén H. Muñoz, *Patentee's Own Clinical Trial Renders Unpatentable Patent Claims Directed to Antibody Treatment*, AKIN (Oct. 9, 2023), https://www.akingump.com/en/insights/blogs/ip-newsflash/patentees-own-clinical-trial-renders-unpatentable-patent-claims-directed-to-antibody-treatment [https://perma.cc/RTB2-76KU].

94. *See generally* Alexander C. Egilman, Amy Kapczynski, Margaret E. McCarthy, Anita T. Luxkaranayagam, Christopher J. Morten, Matthew Herder, Joshua D. Wallach & Joseph S. Ross, *Transparency of Regulatory Data Across the European Medicines Agency, Health Canada, and US Food and Drug Administration*, 49 J.L. MED. & ETHICS 456 (2021) (outlining international initiatives pushing for earlier disclosure of clinical data).

95. A confidential supply agreement does not even provide a one-year "grace period" for filing a patent under 35 U.S.C. § 102(b)(1)(B) or § 102(b)(2)(B) because it fails to "publicly disclose" the invention. *See* Sanho Corp. v. Kaijet Tech. Int'l Ltd., 108 F.4th 1376, 1385 (Fed. Cir. 2024).

96. Indeed, our data allow us to inspect the start dates of clinical trials (as reported in Investigational New Drug applications to the FDA) for nearly half of drugs in our sample (N = 364). In all but six cases, at least one patent was filed before the start of clinical trials. On average, clinical trials begin twenty-six months after the filing date of the earliest-listed Orange Book patent. To calculate these lags, we use records drawn from the Federal Register, in which the start dates of clinical research programs are reported alongside requests for Hatch-Waxman patent-term extension.

and II.C explore the broader implications of this finding, concluding that pharmaceutical patents are often deployed, somewhat haphazardly, as tools to maintain market exclusivity against rising generic challenges. We do not take a stand on the causality of the arms race we highlight—that is, whether rising generic challenges are a response to growing patent portfolios or vice versa. Likely, the two trends have moved in tandem. And given our interest in this Article in moving away from a patent-centric model, the directionality of the trend is largely irrelevant.

A. Not All Pharmaceutical Patents Are Valuable

Pharmaceutical patents are often characterized as exceptionally valuable assets, critical for allowing firms to recoup high costs of R&D and thus vital for ensuring the supply of new, innovative medicines.[97] To be sure, there is empirical evidence that the structure of the patent system has measurable impacts on innovation in healthcare markets.[98] But on inspection, it is not clear that *all* pharmaceutical patents are equally significant. This Section introduces a simple empirical exercise suggesting that nearly half of all patents in the FDA's Orange Book may not even be especially valuable to the firms that hold them. Before evaluating patent value using this revealed-preference measure, it is worth distinguishing private value to the patentholder from two alternative senses in which a patent might be "valuable": legal strength (likelihood of withstanding validity challenge) and social value (the magnitude of the underlying innovation's contribution to health or science).

To be clear, the idea that some pharmaceutical patents are weak in a variety of senses is well established. Empirical work by Michael Frakes and Melissa Wasserman establishes that many secondary patents are likely legally invalid and would not have been granted had the USPTO devoted more resources to their examination.[99] Relatedly, Scott Hemphill and Bhaven Sampat show that pharmaceutical patent litigation involving secondary patents is more likely to be won by the generic challenger or to result in a "reverse payment" settlement (where the brand-name firm pays the generic to stay off the market).[100] Even those pharmaceutical patents that are legally valid may represent extremely small improvements over existing technologies and thus may be of low value in a social or scientific sense.

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97. *See, e.g.*, JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 13, 114, 145 (2008).

98. *See supra* notes 35-38 and accompanying text.

99. Michael D. Frakes & Melissa F. Wasserman, *Investing in Ex Ante Regulation: Evidence from Pharmaceutical Patent Examination*, 15 AM. ECON. J.: ECON. POL'Y 151, 154-55 (2023) [hereinafter, Frakes & Wasserman, *Investing in Ex Ante Regulation*]; Michael D. Frakes & Melissa F. Wasserman, *Irrational Ignorance at the Patent Office*, 72 VAND. L. REV. 975, 982-87 (2019).

100. C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1387 (2013).

Beyond questions of legal validity or social value, there is another, more direct, measure of a patent's worth: whether the firms that own these patents consider them worth keeping. Maintenance fees, which are required periodically to keep patents in force, provide a straightforward test.[101] For "micro" entities (inventors below certain income and patenting thresholds—or universities), the cost of maintaining a patent is relatively modest, starting at $430 for the first renewal at four years, $808 for the second at eight years, and $1,656 for the third and final renewal at twelve years ($2,894 total).[102] Total fees over the patent life double for small entities (firms with five-hundred or fewer employees and nonprofits), to $5,788, and quintuple for undiscounted entities, to $14,470.[103]

Despite the relatively modest cost of maintenance fees—particularly for large pharmaceutical firms generating billions of dollars in annual revenue—nearly half of all Orange Book listed patents are allowed to lapse before their statutory term is complete.[104] Figure 6 shows the proportion of patents that expire at each maintenance interval: after four, eight, and twelve years, as well as at the full twenty-year term.

If nearly half of pharmaceutical patents are not valuable enough to justify the relatively small cost of maintenance, this raises fundamental questions about their role in the broader innovation ecosystem. Models of the patent system often assume that patents function as incentives for innovation and as vital tools for protecting valuable discoveries.[105] Yet the fact that thousands of patents—many of which were expensive to prosecute and, in some cases, even costlier to litigate—are ultimately allowed to lapse suggests that patents may be valued for other strategic reasons.

101. This test for patent value was pioneered by Ariel Pakes, *Patents as Options: Some Estimates of the Value of Holding European Patent Stocks*, 54 ECONOMETRICA 755, 755 (1986). Pakes's analysis is often cited for the proposition that patents vary enormously in their quality and economic value. *See, e.g.*, Bryan & Williams, *supra* note 4, at 292.

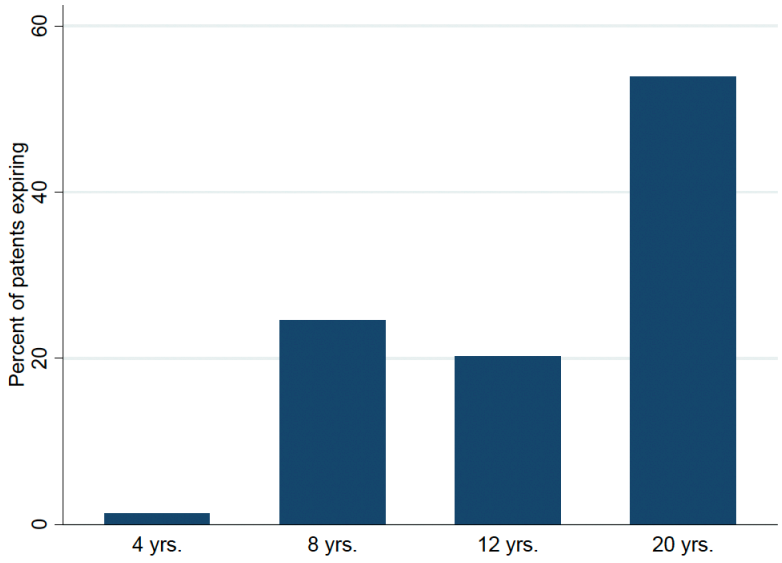
102. *See* Setting and Adjusting Patent Fees During Fiscal Year 2025, 89 Fed. Reg. 91898, 92007 (Nov. 20, 2024). The total was $2,692 before a 2025 fee increase. *See id.*

103. *See id.* In October 1985, at the start of our dataset, total fees for small entities were $1,340 (adjusted for inflation, this is equivalent to $3,890 in December 2024). *CPI Inflation Calculator*, U.S. BUREAU LAB. STAT., https://www.bls.gov/data/inflation_calculator.htm [https://perma.cc/Y939-YU9W].

104. Data are drawn from USPTO bulk records on patent maintenance at *Bulk Dataset Directory*, *supra* note 25. This fact about maintenance-fee payment appears at least once in existing legal scholarship, though to our knowledge has not been interpreted as evidence of broader deficiencies in the functioning of the pharmaceutical patent system. *See* Kimberly A. Moore, *Worthless Patents*, 20 BERKELEY TECH. L.J. 1521, 1528-29 (2005).

105. For a review, see Bryan & Williams, *supra* note 4, at 321-27.

Figure 6: Patent Expiration, Orange Book Patents (1985-2019)



B. Trends in Generic Litigation

To understand why firms continue to accumulate large patent portfolios despite evidence that many individual patents offer little in the way of private (or social) value, this Section introduces a second key fact: the substantial increase in generic challenges to patents over time likely makes patent portfolios a rational defensive response. Figure 7 plots trends in litigation associated with Orange Book patents, as recorded in the Lex Machina database.

The structure of the Hatch-Waxman Act, particularly its Paragraph IV provision, provides an early and powerful incentive for generic firms to challenge patents.[106] Under Paragraph IV, generic manufacturers can file an Abbreviated New Drug Application (ANDA) asserting that the relevant patents are either invalid or not infringed.[107] The first generic applicant to file such a challenge is potentially rewarded with 180 days of market exclusivity, during which no other generic competitor may enter.[108] This exclusivity period provides duopoly profits to successful challengers, incentivizing what some critics of this regime characterize as aggressive litigation strategies.

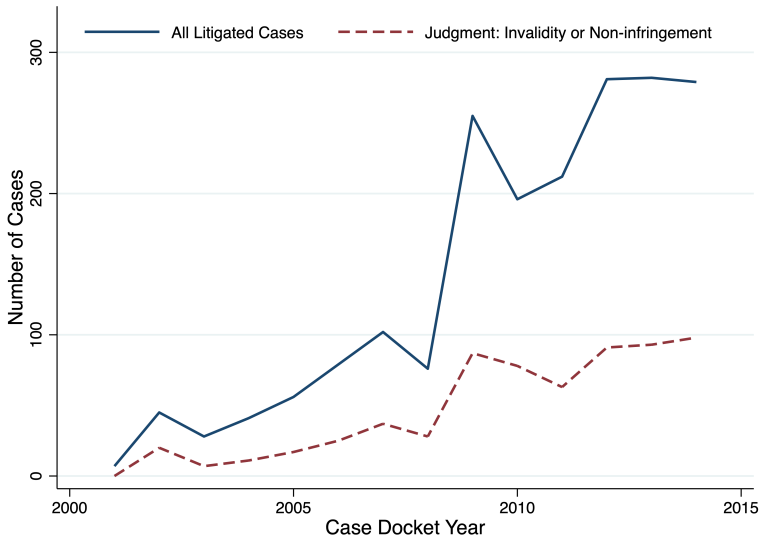
For example, in an analysis published as a twenty-five-year retrospective on the Hatch-Waxman Act, Matthew Higgins and Stuart Graham ar-

106. *See* SCHACHT & THOMAS, *supra* note 9, at 3.
107. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2024).
108. *See id.* § 355(j)(5)(B)(iv).

gue that the balance of incentives had shifted unfavorably toward generic challengers.[109] They identify instances of "prospecting" behavior, wherein generic manufacturers file many challenges in hopes that even partial success will yield substantial returns, and suggest that the effect of this system of challenges had been to "sap[]" incentives for innovation.[110]

Setting aside Higgins and Graham's arguments about persistently declining incentives for R&D—which we address empirically in the next Section—it is well documented that the volume of litigation has increased substantially over time. Scott Hemphill and Bhaven Sampat note, for example, that the fraction of drugs drawing at least one patent challenge increased from twenty-two percent for drugs approved from 1985 to 1987 to fifty-five percent for drugs approved from 2000 to 2002.[111]

Figure 7: Litigation Trends[112]



C. Growing Portfolios Are Not Extending Market Life

The sharp increase in patents per drug depicted in

109. Higgins & Graham, *supra* note 3, at 370.

110. *Id.*

111. C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613, 624 (2011).

112. Figure 7 plots trends in litigation associated with patents listed in the Orange Book, as recorded in the Lex Machina database. The red line plots the total number of cases filed involving Orange Book patents in each calendar year. The blue line plots the total number of cases that result in a determination of non-infringement or invalidity, again relative to initial filing year.

Figure 1 and the parallel rise in generic litigation discussed in the previous Section both underscore the increasing complexity of the pharmaceutical patent system. In this Section, we establish that, remarkably, these trends appear to be perfectly offsetting. That is, despite growth in the scale of patent portfolios and the parallel increase in the frequency of generic challenges, the effective period of market exclusivity for brand-name drugs has remained stable over time.

We construct a measure of a drug's market exclusivity that accounts for the fact that not all drugs have associated generic alternatives. We define a drug's *nominal market exclusivity* as the time between its initial approval and the expiration of all patents and regulatory exclusivities.[113] If the FDA approves a generic competitor to a drug, we call the date of this approval the end of its *actual market exclusivity*.[114] For those drugs with no linked generic, these *nominal* and *actual* measures coincide.[115] Figure 8 plots the mean and median of both measures of market exclusivity. There is a slight—but small—increase in the duration of nominal market exclusivity across our sample period. Actual exclusivity, however, is remarkably stable. If anything, there is a slight *decrease* in both the average and median measures of actual exclusivity over time. Though our measures are slightly different, the patterns in Figure 8 are consistent with findings in work by Hemphill and Sampat, who find the same general stability.[116]

This analysis has at least four important implications for our understanding of pharmaceutical patents.

First, the apparent extensions of exclusivity "on paper" are not delivering real incentives for innovation in practice—at least for the average and median drugs.[117] Analyses that report only increasing nominal exclu-

113. As noted above, regulatory exclusivity administered by the FDA, like patent protection, can block generic entrants. *See supra* note 22. For drugs in our dataset, the forms of regulatory exclusivity include five years of data exclusivity for new chemical entities, seven years of market exclusivity for "orphan" drugs that treat small populations, and a six-month extension of other exclusivities for drugs used in pediatric studies. For more details, see Durvasula et al., *supra* note 10, at 8-9.

114. We determine if and when each drug faced generic competition using records from *Drugs@FDA*, *supra* note 25, which are complete through January 2021. We select the first ANDA approved by the FDA with a set of active ingredients that is bioequivalent to the focal brand-name drug. This approach to measuring generic competition embeds two important simplifications. First, we assume that approval of a generic competitor is a reasonable proxy for *entry* of a generic competitor. Second, we assume that approval of a generic for one formulation of a drug coincides with approval of the generic for *all* formulations. One can, of course, find examples in which these assumptions fail to capture important nuance, but these simplifications enable us to study the main effects of the current system. Other work investigates these assumptions in more detail. *See* Durvasula et al., *supra* note 10, at 4-6, 12-21.

115. Thus, by construction, the actual exclusivity period ends when there are no barriers to entry, even if a generic does not enter the market at this point. On problems with competition in this "patent afterlife," see Daniel J. Hemel & Lisa Larrimore Ouellette, *The Generic Drug Trilemma*, *in* 2 ENTREPRENEURSHIP AND INNOVATION POLICY AND THE ECONOMY 41 (Benjamin F. Jones & Josh Lerner eds., 2023).

116. *See* Hemphill & Sampat, *supra* note 25, at 331 fig.3.

117. Note that there are also many drugs that maintain effective exclusivity even after all patents and regulatory exclusivities have expired due to lack of generic interest in the market. *See*

sivity for brand-name drugs are thus missing an important aspect of real-world practice. Moreover, parallel analyses by Hemphill and Sampat show that this trend is roughly true across the sales distribution.[118] Our focus on the central tendency of these distributions risks glossing over the fact that a small number of drugs are, in fact, receiving far more than twenty years of market exclusivity.[119] At the same time, generic litigation is such that some drugs receive very short periods of market exclusivity. In our data, sixty drugs receive more than twenty years of market exclusivity, while 121 receive less than seven.

Second, although innovation incentives, in the form of actual market exclusivity, have technically remained stable, the ongoing cycle of patent accumulation and litigation has introduced significant uncertainty for all stakeholders. Brand-name firms must determine investment strategies without a clear indication of when patent protection will lapse. Investments in "improvements" to existing drugs—for example, clinical trials that identify new uses—may suffer. Generic firms face ever-growing barriers to entry in the form of large, overlapping patent portfolios, which must be individually challenged.[120] The costs of these challenges may be prohibitive for certain would-be entrants. Even physicians and patients are affected by uncertainty as they make decisions about treatment without information about long-term costs.[121]

Third, much of the litigation surrounding pharmaceutical patents appears to be inefficient and wasteful. As Frakes and Wasserman have argued, the costs of this litigation are substantial.[122] And it is likely that they will, in some part, be passed on to consumers in the form of higher prices

List of Off-Patent, Off-Exclusivity Drugs Without an Approved Generic, U.S. FOOD & DRUG ADMIN. (Jan. 6, 2026), https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/list-patent-exclusivity-drugs-without-approved-generic [https://perma.cc/59NL-PJMM].

118. Hemphill & Sampat, *Patents, Innovation, and Competition*, *supra* note 33, at 39 fig.3; C. Scott Hemphill & Bhaven N. Sampat, Evergreening and Drug Patents: All Bark and No Bite? 10 (2012) (unpublished manuscript) (on file with authors).

119. *See* Erika Lietzan & Kristina Acri née Lybecker, *Solutions Still Searching for a Problem: A Call for Relevant Data to Support "Evergreening" Allegations*, 33 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 788, 795 (2023) (arguing that analyses of pharmaceutical patent portfolios should include "when new drugs actually face generic competition"). A related, and natural, concern is that we measure market exclusivity at the level of an application to the FDA. If there are multiple applications—and multiple patent portfolios—that protect the same underlying ingredient ("active moiety"), our measure may underestimate the duration of protection. In our data, although it is the case that there are a small number of drugs that are approved across multiple applications, for the vast majority, we identify just one application. Put differently, this concern is unlikely to affect our estimates of measures of central tendency but may very well be relevant for drugs with especially longer periods of protection.

120. For a discussion of these costs and why it is more expensive to challenge two patents than one, see Mark A. Lemley & Lisa Larrimore Ouellette, *Fixing Double Patenting*, 74 AM. U. L. REV. 1013, 1030-32 (2025).

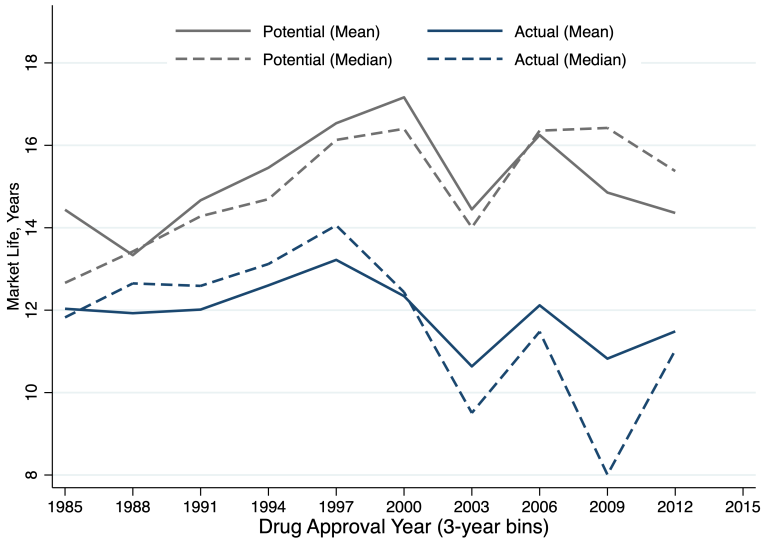
121. *See* Michael J. Dickstein, Jihye Jeon & Eduardo Morales, *Patient Costs and Physicians' Information* 29-32 (Nat'l Bureau of Econ. Rsch., Working Paper No. 32014, 2024).

122. *See* Frakes & Wasserman, *Investing in Ex Ante Regulation*, *supra* note 99, at 172-74.

for both brand-name and generic drugs.[123] The main beneficiaries from the current equilibrium appear to be the lawyers and other entities that profit from protracted, expensive litigation.

And fourth, even *before* accounting for the effect of patent challenges, pharmaceutical firms have been surprisingly ineffective in extending patent terms. Nominal market exclusivity, in our data, is the same in 2012 as it was in 1985. At least on this margin, concerns about the harms of pharmaceutical patent "evergreening" may be far less extreme than is often suggested.

Figure 8: Market Life



III. Shifting to Nonpatent Pharmaceutical Exclusivity

In this Part, we consider how to escape the pharmaceutical patent arms race, removing pharmaceutical innovation from a patent-based system. We begin in Section III.A by explaining why some form of exclusivity is a useful part of the pharmaceutical-innovation policy toolkit and why shifting to FDA-administered regulatory exclusivity is preferable to attempting to fix the problems within the pharmaceutical patent system. Section III.B then considers one legislative effort that has attracted substantial bipartisan support—the MODDERN Cures Act, as revived in the

123. *See* E. Glen Weyl & Michal Fabinger, *Pass-Through as an Economic Tool: Principles of Incidence under Imperfect Competition*, 121 J. POL. ECON. 528, 528-29 (2013) (explaining that the extent to which cost increases are borne by consumers versus producers depends on the rate of pass-through).

Dormant Therapies Act and early drafts of the 21st Century Cures Act. We analyze the past barriers to enactment of this framework and explain why it remains a promising foundation for a new political compromise. Section III.C evaluates how this framework could be amended to better align its incentives with the health benefits of the affected drugs. Finally, Section III.D explains how to rein in patent incentives to prevent a new form of regulatory exclusivity from simply leading to rights accretion.

A. The Case for Nonpatent Exclusivity Incentives

For some readers, the failures of pharmaceutical patents described in Parts I and II will raise the question: why use exclusivity at all? For others, the key question will be: why not fix the failures of pharmaceutical patents through the patent system? Here, we answer these questions and explain the case for nonpatent exclusivity incentives.

1. Why Use Exclusivity at All?

Patents and other forms of exclusivity are far from the only innovation-policy instrument—the biomedical-innovation ecosystem is pluralistic, including non-exclusivity-based rewards such as R&D tax incentives and direct ex ante public spending on grants, procurement contracts, and national laboratories.[124] Indeed, the debate over whether innovation policy should include patents at all dates to at least the nineteenth century.[125]

We see merit in expanding use of non-exclusivity-based incentives for pharmaceutical innovation, including through shifting more drug development to the public sector,[126] such as by providing a federal infrastructure for clinical trials.[127] Some proposals for increased reliance on non-exclusivity incentives for pharmaceuticals have even been introduced in Congress. For example, Senator Bernie Sanders has introduced legislation to replace

124. *See* Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 YALE L.J. 544, 554 (2019) [hereinafter Hemel & Ouellette, *Pluralism*]; Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 303, 315-26 (2013) [hereinafter Hemel & Ouellette, *Beyond*].

125. *See* Hemel & Ouellette, *Beyond*, *supra* note 124, at 305.

126. *See* Ameet Sarpatwari, Dana Brown & Aaron S. Kesselheim, *Development of a National Public Pharmaceutical Research and Development Institute*, 48 J.L. MED. & ETHICS 225, 225 (2020); Hemel & Ouellette, *Pluralism*, *supra* note 124, at 570-71; Bhaven N. Sampat, *Whose Drugs Are These?*, 36 ISSUES SCI. & TECH. 42, 48 (2020).

127. *See generally* Melinda B. Buntin, Otis W. Brawley & Joshua M. Sharfstein, *Advancing a National Infrastructure for Clinical Trials*, 5 JAMA HEALTH F. art. no. e244383 (2024) (discussing the benefits of national infrastructure for clinical trials); Rachel Sachs, Jacob S. Sherkow, Lisa Larrimore Ouellette & Nicholson Price, *What Can Policymakers Learn From the UK's RECOVERY Trial to Improve Clinical Research for COVID-19 and Beyond?*, WRITTEN DESCRIPTION (May 3, 2021), https://writtendescription.blogspot.com/2021/05/what-can-policymakers-learn-from-uks.html [https://perma.cc/ARG8-5QTJ].

pharmaceutical patents with monetary prizes,[128] and Senator Elizabeth Warren has repeatedly introduced a proposal for public-sector pharmaceutical manufacturing.[129] These proposals have attractive features, although they have been political nonstarters so far.

There are good reasons beyond political expediency, however, to keep exclusivity incentives as part of the innovation-policy toolkit. No innovation incentive is uniformly superior, and exclusivity has the advantages of ex post, market-set rewards, including reduced informational burden on government decision makers and greater incentives for success.[130] To be sure, the informational benefits of using proprietary pricing to screen the value of new technologies are reduced when those prices are mediated by insurance, and the U.S. health insurance system distorts incentives in numerous ways.[131] But the U.S. pharmaceutical market does not eliminate prices from decision-making—insurers and patients still typically have incentives to seek lower-cost treatments when available. And the imperfect system of exclusivity-based innovation rewards should not be compared to an idealized alternative—public-sector innovation institutions have plenty of failures too.[132] In the current environment of unprecedented attacks on the National Institutes of Health (NIH) and other public-sector biomedical research institutions by the Trump Administration, even maintaining existing nonmarket incentives—much less strengthening them—seems like a political nonstarter.[133]

2. Why Nonpatent Exclusivity?

Retaining some form of exclusivity-based rewards for pharmaceutical innovation could involve reforms within the patent system, and there have been many useful proposals for reducing some of the worst inefficiencies

128. Prize Fund for HIV/AIDS Act, S. 1138, 112th Cong. § 5 (2011); Medical Innovation Prize Fund Act, S. 1137, 112th Cong. § 5 (2011). For a review of other innovation prize proposals, see Hemel & Ouellette, *Beyond*, *supra* note 124, at 317-19.

129. These proposals include Affordable Drug Manufacturing Act, S. 3398, 118th Cong. (2023); Affordable Drug Manufacturing Act of 2020, S. 3162, 116th Cong.; and Affordable Drug Manufacturing Act of 2018, S. 3775, 115th Cong.

130. *See* Hemel & Ouellette, *Pluralism*, *supra* note 124, at 552-57 (explaining the benefits of each class of innovation-incentive mechanisms). *See generally* Michael Kremer, Jonathan Levin & Christopher M. Snyder, *Advance Market Commitments: Insights from Theory and Experience*, 110 AEA PAPERS & PROC. 269 (2020) (characterizing the types of technology that are well suited to a form of market-based prize known as an advance market commitment).

131. On the screening function of proprietary pricing, see generally E. Glen Weyl & Jean Tirole, *Market Power Screens Willingness-to-Pay*, 127 Q.J. ECON. 1971 (2012). On distortions to pharmaceutical innovation incentives caused by Medicare, Medicaid, and private-insurance coverage mandates, see Hemel & Ouellette, *supra* note 35, at 538-44.

132. *See* Hemel & Ouellette, *supra* note 35, at 581.

133. *See, e.g.*, Megan Molteni, J. Emory Parker & Jonathan Wosen, *NIH Grants Plummeted $2.3 Billion in Trump's First Months, as Federal-Academia Partnership Crumbles*, STAT (Apr. 24, 2025), https://www.statnews.com/2025/04/24/trump-100-days-nih-new-grants-cut [https://perma.cc/8KJH-RF9A].

documented in Parts I and II.[134] We think it is infeasible, however, to substantially fix these problems from within the patent law. Some of these problems are well recognized, such as the lack of incentives for developing compounds that have been disclosed in the prior art.[135] But there has been less discussion of the unavoidable mismatch between the timing rules for patent filings and the timeline for obtaining relevant information about a drug's actual clinical value.[136]

As discussed in Section I.C, the combination of patent law's relaxed disclosure requirements and strict prior-art rules requires patentability to be assessed early in the drug-development process, before clinical trial results are known.[137] A therapeutic invention is generally considered "ready for patenting" once the drug developer is ready to initiate clinical trials, meaning that the disclosure requirements can be satisfied at this point.[138] And under the prior-art rules, an invention can be rendered unpatentable even by publishing the plan for a clinical trial—as required by federal statute—or by engaging in confidential commercial activities conditional on the clinical trials' success.[139] Most pharmaceutical patents must thus be filed before obtaining clinical trial results, which contributes to the misalignment between patent incentives and the actual social value of the patented drug.[140]

Addressing this concern from within patent law would require major changes to patent doctrine. First, to incorporate information about actual clinical value, disclosure standards would need to be tightened to require disclosure of human clinical trial results in a pharmaceutical patent application. This would mean that a claim to therapeutic utility in human patients would not be ready for patenting until the trials were complete. Reforming disclosure standards would have some broader benefits in reduc-ng premature patenting—before inventors have invested the time and ef-ort in determining how to implement an invention in practice and demon-trating that it works—although there are also downsides to increasing the costs that must be invested before a patent may be filed.[141]

134. *See, e.g.*, Frakes & Wasserman, *Investing in Ex Ante Regulation*, *supra* note 99, at 154. For a more ambitious but creative proposal, see generally Christopher Buccafusco & Jonathan S. Masur, *Drugs, Patents, and Well-Being*, 98 WASH. U. L. REV. 1403 (2021).

135. *See* Roin, *supra* note 36, at 504-05; Sean B. Seymore, *Rethinking Novelty in Patent Law*, 60 DUKE L.J. 919, 922 (2011).

136. For a thoughtful proposal to condition one regulatory benefit, patent-term extensions, on additional disclosures about clinical value, see Christopher J. Morten, *The Second Patent Bargain*, 111 IOWA L. REV. (forthcoming 2026), https://ssrn.com/abstract_id=5788143 [https://perma.cc/WXC5-KK5Y].

137. *See supra* Section I.C.

138. *See supra* notes 75-79 and accompanying text.

139. *See supra* notes 86-93 and accompanying text.

140. As noted above, on average, the first patent is filed twenty-six months before clinical trials begin. *See supra* note 96.

141. For discussions of these tradeoffs and calls for moving patenting later in the inventive process, see Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 72-82 (2009); Janet Freilich, *Prophetic Patents*, 53 U.C. DAVIS L. REV. 663, 711-

Second, and more problematically, the doctrine of inherent anticipation would need to be revised such that administering the drug in a clinical trial no longer anticipates a later patent on the basis that the relevant patients were already inherently receiving the benefit of the drug, even if that benefit was not yet understood. A patent filed after the trial is disclosed would then no longer be invalid for lack of novelty. But inherent anticipation exists for good reasons.[142] For example, in *Schering v. Geneva*, Schering's patent on the allergy drug compound known as Claritin had expired, but they had later filed a patent on a metabolite that is produced in the body when someone takes Claritin.[143] The Federal Circuit held that Schering could not use this metabolite patent to block generic versions of Claritin because the expired prior-art patent discussed the administration of Claritin, which inherently produces the metabolite even though no one recognized it when the prior-art patent was filed.[144] If the inherent anticipation doctrine were revised to require a contrary result, then firms like Schering could indefinitely extend patent protection for pharmaceuticals by filing a new patent every few years on some newly discovered compound produced by a drug. Moreover, even with this change in inherent anticipation doctrine, a drug patent could still be invalidated as obvious in light of its own clinical trials unless there were also major changes to obviousness doctrine.

In sum, the underlying problem stems from idiosyncratic aspects of pharmaceutical innovation that cause a large misalignment between patent incentives and the social value of new drugs. Distorting patent law to try to correct this problem at the time of patent filing would have perverse consequences for patent doctrine more broadly. But there already exists an alternative form of exclusivity that does not have the same mismatch between the timing of awarding exclusivity and of obtaining information about a drug's actual clinical value: regulatory exclusivity attached to the time of a drug's FDA approval.[145] Rather than twisting patent doctrine to address this timing problem, we think policymakers should focus on the form of exclusivity that is a more natural fit.

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26 (2019); Janet Freilich & Lisa Larrimore Ouellette, *Science Fiction: Fictitious Experiments in Patents*, 364 SCIENCE 1036, 1036-37 (2019); Mark A. Lemley, *Ready for Patenting*, 96 B.U. L. REV. 1171, 1178-79 (2016); Lisa Larrimore Ouellette, Pierson*, Peer Review, and Patent Law*, 69 VAND. L. REV. 1825, 1831-33 (2016); and Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127, 139-61 (2008).

142. *See* Dan L. Burk & Mark A. Lemley, *Inherency*, 47 WM. & MARY L. REV. 371, 374 (2005).

143. Schering Corp. v. Geneva Pharms., 339 F.3d 1373, 1375 (Fed. Cir. 2003).

144. *Id.* at 1382.

145. To be sure, one could accomplish essentially the same goals as a regulatory exclusivity system through an alternative mechanism to adjust patent-exclusivity terms ex post based on later-developed information about a drug's value, as suggested in thoughtful proposals by Buccafusco & Masur, *supra* note 134, at 1432-48; and Neel U. Sukhatme & M. Gregg Bloche, *Health Care Costs and the Arc of Innovation*, 104 MINN. L. REV. 955, 1030-32 (2019). We think regulatory exclusivity represents a more legally, politically, and administratively feasible path.

B. Reviving Bipartisan Regulatory Exclusivity Legislation

As noted in the Introduction, at a 2024 retrospective on the fortieth anniversary of the Hatch-Waxman Act, advocates for both brand-name and generic firms expressed concern that the current patent-centric system is broken.[146] They also reached a surprising consensus on how it ought to be fixed. Bob Armitage noted that, as General Counsel for Eli Lilly, he started working on a "system that wasn't entirely dependent on patents" and with the "ability for generic drug entry with no patent litigation." This model system was central to the bipartisan MODDERN Cures Act, introduced in 2011 and again in 2013.[147] Alfred Engelberg, who designed the patent-challenge and generic-exclusivity provisions of the Hatch-Waxman Act in his capacity as counsel to the Generic Pharmaceutical Industry Association, agreed with Armitage that the current patent-centric system should be replaced by a single exclusivity period per drug, "whether it's MODDERN Cures or something else."[148]

The MODDERN Cures Act was introduced with forty-eight cosponsors in 2011 (twenty-three Republicans and twenty-five Democrats) and with ninety-five cosponsors in 2013 (forty-eight Republicans and forty-seven Democrats).[149] Under its proposal, a drug developer could request that a drug be designated as a "dormant therapy" if it would address an "unmet medical need," including by treating a disease with no existing therapy or offering an improvement on existing therapies.[150] A drug designated as a dormant therapy would receive a fifteen-year regulatory exclusivity period during which the FDA would not approve applications for generic versions,[151] which is longer than the average drug developer receives under the current system.[152] In exchange, the developer would need to list all its patents related to the drug and waive the right to assert those patents against generic manufacturers.[153]

This same basic framework—patent waiver in exchange for a fifteen-year regulatory exclusivity period—was reintroduced in the Dormant Therapies Act of 2014 but without defining "unmet medical needs."[154] And

146. *See supra* notes 6-8 and accompanying text.

147. *Health Care at Reasonable Cost: The Goals of the Hatch-Waxman Act as Seen from 2024*, *supra* note 6, at 25:48 (discussing MODDERN Cures Act of 2013, H.R. 3116, 113th Cong.; and MODDERN Cures Act of 2011, H.R. 3497, 112th Cong.); *Alfred Engelberg '65 Recalls His Pioneering Work in the Generic Drug Industry*, NYU (Feb. 25, 2025), https://www.law.nyu.edu/news/alfred-engelberg-alumnus-generic-drugs-book [https://perma.cc/QGC7-MRRT].

148. *Id.* at 30:01.

149. *See* H.R. 3116; H.R. 3497. We will focus on the 2013 legislation, but the basic structure is similar.

150. H.R. 3116 § 201(i)(1).

151. *Id.* § 201(e), (i)(4).

152. *See supra* fig.8.

153. H.R. 3116 § 201(c).

154. Dormant Therapies Act of 2014, S. 3004, 113th Cong. § 4(a)(2)(A).

the 21st Century Cures Act, which passed in 2016,[155] included a provision modeled on the Dormant Therapies Act that was dropped before enactment.[156]

This framework for shifting from patents to regulatory exclusivity for "dormant therapies" received strong bipartisan support, as well as support from many patient advocates concerned about incentivizing treatments for diseases with unmet needs.[157] However, advocates concerned about the prices of existing medicines worried that the new exclusivity period would unnecessarily delay generic entry. For example, at a hearing on the 21st Century Cures Act, the head of Express Scripts (the largest pharmacy benefit manager in the United States) expressed concern with incentives "that reward certain types of drug development with *additional* market exclusivity."[158] Law professor Scott Hemphill testified that the MODDERN Cures definition of "unmet medical need" is "extremely elastic" and "would thus grant a windfall for a large number of drugs that would have been developed anyway."[159] Part of the problem Hemphill noted is that manufacturers would opt into the new system only if their expected patent term would be less than fifteen years, with the effect that fifteen years would "serve as a floor, not a ceiling."[160] In addition, the proposed legislation would have required a waiver of any patent barriers to generic entry at the end of the exclusivity period, but it did not address nonpatent barriers.[161]

We think the time is ripe to revive a modified version of the MODDERN Cures framework that takes seriously the concerns that originally prevented its enactment. The convergence of opinions from both brand-name and generic advocates about the failures of the current patent-based system and the bipartisan support for prior reform attempts suggest

155. 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016).

156. *See* Thomas J. Hwang, Rachel E. Sachs & Aaron S. Kesselheim, *Public Participation in Drafting of the 21st Century Cures Act*, 45 J.L. MED. & ETHICS 212, 217 (2017); Kurt R. Karst, *The Everlasting Patent: Is it Hiding in Plain Sight in the 21st Century Cures Act?*, FDA L. BLOG (Mar. 16, 2015), https://www.thefdalawblog.com/2015/03/the-everlasting-patent-is-it-hiding-in-plain-sight-in-the-21st-century-cures-act [https://perma.cc/P3W3-TU8M].

157. *See, e.g.*, Letter from Alpha-1 Foundation et al. to Fred Upton, Chair, Energy & Com. Comm., U.S. House of Reps. & Diana DeGette, Member, Energy & Com. Comm., U.S. House of Reps. (Mar. 17, 2015), https://nationalhealthcouncil.org/wp-content/uploads/2019/12/Dormant-Therapies%20-Sign-On.pdf [https://perma.cc/H24C-2AV7].

158. *21st Century Cures: Examining the Role of Incentives in Advancing Treatments and Cures for Patients: Hearing Before the H. Comm. on Energy & Com.*, 114th Cong. 4 (2014) (statement of Steven B. Miller, Senior Vice President & Chief Med. Officer, Express Scripts), https://docs.house.gov/meetings/IF/IF14/20140611/102316/HHRG-113-IF14-Wstate-MillerS-20140611.pdf [https://perma.cc/6UAZ-UFFX].

159. *21st Century Cures: Examining the Role of Incentives in Advancing Treatments and Cures for Patients: Hearing Before the H. Comm. on Energy & Com.*, 114th Cong. 4-5 (2014) (statement of C. Scott Hemphill, Professor of L., Colum. L. Sch.), https://docs.house.gov/meetings/IF/IF14/20140611/102316/HHRG-113-IF14-Wstate-HemphillC-20140611.pdf [https://perma.cc/ELE5-URMP].

160. *Id.* at 5.

161. For a discussion of some such barriers, such as refusal to provide necessary samples to generic firms and refusal to work with generics on a shared risk evaluation and mitigation-strategies protocol as required by the FDA, see Hemel & Ouellette, *supra* note 115, at 64-65.

that pharmaceutical stakeholders may be able to agree in principle on the value of shifting from patents to regulatory exclusivity. And the end result of this bargaining process would, quite likely, be an improvement on the broken status quo. To be sure, the fact that the main beneficiaries of the status quo are the lawyers who both benefit from wasteful patent acquisition and litigation and advise clients on regulatory changes creates an agency problem that will complicate reform, but hopefully stakeholders will seek advice from less conflicted experts.

C. Institutional Design

Shifting U.S. pharmaceutical innovation from patents to regulatory exclusivity raises important questions of institutional design. Patent policymakers have long grappled with patentability standards and questions of optimal patent term and scope. Designers of any new pharmaceutical regulatory exclusivity system must address the same suite of questions.[162]

To provide some intuition for what this type of policy design might look like, this Section begins by introducing a simple framework that illustrates how different design choices affect the costs and benefits of regulatory exclusivity. We then consider the three questions of eligibility, duration, and scope.

First, which drugs should receive exclusivity? As noted above, a key criticism of the MODDERN Cures Act was its expansive eligibility criteria.[163] A drug would have been eligible if it provided essentially any improvement over existing therapies.[164] Though this is stricter than the FDA approval standard, which does not demand evidence of comparative efficacy,[165] it would have included nearly all new drugs,[166] particularly because developers would have had a new incentive to market unpatented drugs that offer marginal improvements. Is there a better way to define eligibility

162. Our analysis is informed not only by the extensive scholarship on the patent system but also by discussions and critiques of existing and proposed systems of regulatory exclusivity. *See, e.g.*, Sukhatme & Bloche, *supra* note 145, at 1036-37; Sam F. Halabi, *The Drug Repurposing Ecosystem: Intellectual Property Incentives, Market Exclusivity, and the Future of "New" Medicines*, 20 YALE J.L. & TECH. 1, 65-72 (2018); Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO ST. L.J. 299, 355 (2015); Aaron S. Kesselheim, *Using Market-Exclusivity Incentives to Promote Pharmaceutical Innovation*, 363 NEW ENG. J. MED. 1855, 1856-60 (2010); Erika Lietzan, *The Myths of Data Exclusivity*, 20 LEWIS & CLARK L. REV. 91, 134-60 (2016); *supra* note 22.

163. *See supra* note 159 and accompanying text.

164. MODDERN Cures Act of 2013, H.R. 3116, 113th Cong. § 201(i)(1).

165. For one description and defense of this approach, see Scott Gottlieb, *The FDA Should Not Mandate Comparative-Effectiveness Trials*, AM. ENTER. INST. (June 15, 2011), https://www.aei.org/research-products/report/the-fda-should-not-mandate-comparative-effectiveness-trials [https://perma.cc/6LST-PGXQ].

166. For example, it would presumably include drugs eligible for one of the FDA's four expedited approval programs, which constituted seventy-five percent of new drugs in 2021. *See* Andrea N. Monge, Daniel W. Sigelman, Robert J. Temple & Harinder Singh Chahal, *Use of US Food and Drug Administration Expedited Drug Development and Review Programs by Orphan and Nonorphan Novel Drugs Approved from 2008 to 2021*, 5 JAMA NETWORK OPEN art. no. e2239336, at 6 (2022).

criteria? And should eligibility be assessed only at the time of approval or also later in the drug's lifecycle?

Second, how long should the exclusivity period be? MODDERN Cures—and its revival in the Dormant Therapies Act and 21st Century Cures Act—would have provided a fifteen-year regulatory exclusivity period. How can policymakers determine whether this is too long or too short? Would it be worthwhile to vary duration based on initial or post-marketing evidence of a drug's comparative value?

Third, what should the scope of this new exclusivity be? Should it only block bioequivalent generics (like existing regulatory exclusivity provisions) or also other similar drugs? Relatedly, how broad should the patent-waiver requirement be, and how can developers be prevented from using nonpatent barriers to generic entry after the exclusivity period expires?

Before turning to these design questions, a brief institutional clarification is useful. Although the discussion that follows does not specify the precise FDA procedures that would be necessary to operationalize a new form of regulatory exclusivity, the administrative task we outline is familiar. The FDA already administers several statutory exclusivities that turn on technically demanding, application-specific determinations—most notably, five-year new chemical entity (NCE) exclusivity, which can hinge on often contested questions about a drug's chemistry.[167] These determinations are made within the same FDA center that would administer our proposed system: the Center for Drug Evaluation and Research (CDER). CDER maintains an "Exclusivity Board," an internal body that addresses difficult or novel questions about whether a drug qualifies for a statutory exclusivity and, if so, the exclusivity's scope.[168] In other words, CDER already has institutional machinery designed to promote consistency in exclusivity determinations; our proposal would build on that existing framework.

1. Economic Model

Here, we introduce a simple economic model of drug development with exclusivity incentives. Although we build on frameworks that aim to

167. For an overview of one such frequently contested technical determination—the definition of a drug's "active ingredient" and "active moiety"—see generally ERIN H. WARD, CONG. RSCH. SERV., R46110, DEFINING ACTIVE INGREDIENT: THE U.S. FOOD AND DRUG ADMINISTRATION'S LEGAL INTERPRETATION OF REGULATORY EXCLUSIVITIES (2023), which discusses FDA's interpretation of the relevant statutory text and the resulting disputes. *See also* Nicholas R. Parrillo, *Administrative Law as a Choice of Business Strategy: Comparing the Industries Who Have Routinely Sued Their Regulators with the Industries Who Rarely Have*, 93 GEO. WASH. L. REV. 1031, 1073-90 (2025) (collecting all drugmaker suits against FDA over a roughly two-decade period associated with these technical determinations).

168. *CDER Exclusivity Board*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-exclusivity-board [https://perma.cc/CB54-DFUU].

pin down the optimal patent term,[169] our objectives here are more modest: to identify key variables that ought to be considered by policymakers tasked with practical questions of implementation and to demonstrate how even a highly stylized framework can shed light on critical tradeoffs inherent in designing regulatory exclusivity systems.

We assume, first, that it is possible to quantify each drug's effectiveness over available alternatives in terms of a standardized measure of evidence-based health improvements relative to existing treatment options.[170] One common metric in the health-technology-assessment literature is the quality-adjusted life year (QALY).[171] But because of concerns that QALYs assign a lower value to the lives of people with disabilities, Congress has barred their use in certain contexts.[172] In response to these concerns, another metric—the equal value of life years gained (evLYG)—was developed to give the same weight to all longevity extensions regardless of a patient's disability status.[173] We will use the evLYG because of its normative appeal and greater acceptability in the United States, but nothing about our model depends on the metric chosen.

We will also assume that it is possible to assign a social value to each evLYG produced by a drug. Valuing health gains involves challenging ethical questions, including not only the difficulty of placing a dollar value on lives and health but also determining whether dollar thresholds should be higher for rare diseases that affect smaller populations or for improvements that reduce health inequalities.[174] The Institute for Clinical and Economic Review (ICER), a nonprofit whose assessments are used by the two largest pharmacy benefit managers in the United States and the Department of Veterans Affairs,[175] reports price benchmarks of $100,000 to $150,000 per evLYG and per QALY and considers $150,000/evLYG a "liberal upper bound" for whether a drug is considered cost effective.[176] For diseases affecting smaller populations, ICER recommends coverage and

169. Modeling optimal term depends on uncertain parameters and assumptions, including the relationship between R&D expenditures and the resulting public and private benefits of invention, the monopoly rents and deadweight loss of added term, and the effect of competition after the term expires. *See generally* NORDHAUS, *supra* note 64; Scherer, *supra* note 64.

170. Policymakers would also need to decide the relevant date for the comparison technology. If the drug is compared to other treatments at the time of FDA approval, there is a risk that a socially valuable drug may receive little reward because its developer was slightly slower at completing its clinical trials. If the drug is compared to other treatments at the start of clinical trials, then the firm has less incentive to finish its trials and seek FDA approval expeditiously.

171. For an explanation of how QALYs are calculated, see Hemel & Ouellette, *supra* note 35, at 595-99.

172. *See* 42 U.S.C. § 1320e-1(e) (2024).

173. *See* Hemel & Ouellette, *supra* note 35, at 552-53.

174. On some of these ethical issues, see Govind Persad, *Pricing Drugs Fairly*, 62 WM. & MARY L. REV. 929, 964-65 (2021).

175. *See* Hemel & Ouellette, *supra* note 35, at 550.

176. *Value Assessment Framework*, INST. FOR CLINICAL & ECON. REV. 33 (Sep. 25, 2023), https://icer.org/wp-content/uploads/2025/12/ICER_2023_2026_VAF_For-Publication_021026.pdf [https://perma.cc/3Q2P-6PUG].

funding at unspecified higher benchmarks.[177] Although $150,000 per evLYG (or QALY) is extremely low compared to the values federal agencies generally use in valuing lives,[178] we will use the even lower value of $100,000/evLYG for mathematical simplicity.

These assumptions allow us to characterize each drug's *annual social value* over available alternative therapies for potential patients, which we will denote v, as

$$v = (\text{evLYGs per patient per year}) \bullet (\text{\# patients per year}) \bullet (\text{evLYG value}).$$

Grants of market exclusivity that provide market power impose costs on society. If exclusivity is used not only to incentivize production of new drugs but also to allocate access to them,[179] then each year of exclusivity imposes a cost due to the deadweight loss from patients who would have benefited from the drug at its competitive price but who are unable to afford the higher price under exclusivity. Of course, access to pharmaceuticals in the United States is not allocated through pure proprietary pricing,[180] and the U.S. government could reduce this deadweight loss even more by moving further toward open-access allocation.[181] In addition, exclusivity can incentivize firms to invest in demand creation in ways that reduce allocative inefficiency.[182] For simplicity, suppose that during each year of exclusivity, social value is reduced by a fixed fraction δ, such that society captures value of only $(1 - \delta) \bullet v$.

A key concern for any policy change that may decrease the profitability of new drugs is its impact on firms' incentives to invest in new R&D. We assume that a firm will develop a drug only if the expected returns exceed the costs. To simplify this profitability constraint, consider a firm that is deciding whether to invest in each of the steps required to bring a drug

177. *See id.* at C5.

178. *See* Hemel & Ouellette, *supra* note 35, at 553-60.

179. On the separability of exclusivity's incentive and allocation functions, see Hemel & Ouellette, *Pluralism*, *supra* note 124.

180. Prices are mediated through insurance that reduces out-of-pocket costs for ninety-two percent of the U.S. population. *See* Katherine Keisler-Starkey & Lisa N. Bunch, *Health Insurance Coverage in the United States: 2023*, U.S. CENSUS BUREAU (Sep. 10, 2024), https://www.census.gov/library/publications/2024/demo/p60-284.html [https://perma.cc/99ZQ-CFMA]. For example, Americans with low incomes or disabilities who are enrolled in Medicaid receive prescription drugs for low fees to cover dispensing costs and low or zero cost sharing. *See* Rachel Dolan & Marina Tian, *Pricing and Payment for Medicaid Prescription Drugs*, KAISER FAM. FOUND. (Jan. 23, 2020), https://www.kff.org/medicaid/issue-brief/pricing-and-payment-for-medicaid-prescription-drugs [https://perma.cc/9HNC-P2NE]. Prices are also mediated through programs for uninsured patients. *See* C. Joseph Ross Daval & Aaron S. Kesselheim, *Patient Assistance Programs—A New Era of Law and Policy*, 332 JAMA 1047 (2024).

181. For an explanation of why using tax revenues to subsidize pharmaceutical purchases should not be viewed as an additional form of deadweight loss, see Hemel & Ouellette, *supra* note 35, at 590-92.

182. *See* Darius Lakdawalla & Tomas Philipson, *Does Intellectual Property Restrict Output? An Analysis of Pharmaceutical Markets*, 55 J.L. & ECON. 151, 151-52, 152 fig.1 (2012) (documenting that usage of a drug—including generic versions—often falls after the drug loses patent protection).

to market—costly and risky clinical trials, manufacturing capacity, etc. Let p denote the probability that commercialization is successful, and let c denote the total cost of commercialization. If commercialization is successful, the firm will receive an exclusivity period of t, during which time it will operate as a monopolist and receive annual monopoly profits π, which may bear little relation to the social value v under the existing U.S. drug-pricing system.[183] As we explain below, it cannot even be said that $\pi < v$ in the pharmaceutical sector, even though in general the private value of innovation is far less than the social value.[184] After exclusivity expires, we assume that competition will drive these profits to zero.

Mathematically, then, a firm will develop a drug if and only if

$$p \bullet t \bullet \pi \geq c.$$

Solving for the exclusivity period t, a drug is profitable only if

$$t \geq c / (p \bullet \pi).$$

Ideally, we would like to select an exclusivity period t that maximizes social welfare, where welfare is defined simply in terms of the benefits and costs that we have defined thus far. Suppose that each drug has a useful life—that is, a number of years before it is obsolete—that we will denote as T.

For each drug, social welfare can be understood as the expected net benefit it provides to society. We will calculate this net benefit in four pieces. First, we consider the total value that a drug generates during its exclusivity period t, accounting for the fact that deadweight loss reduces this value. Second, we consider any value that the drug generates in the years of its useful life after exclusivity expiration. Third, we weight this total value generated over the drug's lifetime by its probability of successful development p. Finally, we subtract the development cost c to determine net welfare.

Mathematically, this expression for the social welfare for each drug is given by

$$W = p \bullet [\{t \bullet (1 - \delta) \bullet v\} + (T - t) \bullet v] - c.$$

Society wants to incentivize development of only those drugs with positive social welfare ($W > 0$). Thus, simplifying the above expression, a minimal criterion for providing any government incentive should be

$$p \bullet v\,(T - t \bullet \delta) > c.$$

Solving for t, social welfare is positive only if

183. *See* Hemel & Ouellette, *supra* note 35, at 528-44.
184. *See infra* notes 188-191 and accompanying text.

$$t < (1/\delta) \bullet [T - c / (p \bullet v)].$$

To illustrate how policymakers might approach questions of regulatory design, we consider four hypothetical drugs with characteristics summarized in Table 1. While it may be impractical for policymakers to determine the precise values of these parameters for every potential new drug, reasonable estimates for these parameters are available and already play a critical role in shaping large-scale government policies. These hypothetical drugs have the same probability of success (ten percent) and years of useful life (twenty years) but different social and private values and costs of development.

Table 1: Characteristics of Hypothetical Drugs

Drug	evLYGs / patient / year	patients / year	v ($M/yr)	c ($M)	P	π ($M/yr)	δ	T (yrs)
A	1.7	50,000	8500	300	0.1	800	0.3	20
B	1.2	30,000	3600	600	0.1	500	0.3	20
C	0.5	10,000	500	200	0.1	750	0.3	20
D	0.1	20,000	200	400	0.1	800	0.3	20

2. Eligibility

Under the expansive MODDERN Cures criteria, all four drugs would be eligible for exclusivity because each offers some demonstrated improvement (evLYGs/patient/year > 0). Table 1 makes clear, however, that this broad eligibility would reward drugs—such as drug *D*—for which private value so far exceeds social value that net welfare is negative. Drug *D* is privately profitable as long as it receives at least five years of exclusivity, but even one year of market exclusivity imposes a net *cost* on society.[185]

Of course, if policymakers could estimate the relevant parameters for each drug, they could deem a drug eligible only if it provides positive social welfare (that is, if $p \bullet v\ (T - t \bullet \delta) > c$). Such a calculation is almost surely infeasible from both informational and administrative perspectives. But this exercise makes clear that policymakers could screen out some of those drugs that actually reduce welfare with a simpler eligibility threshold that looked only at the drug's benefit relative to existing treatment options.

185. *D* is profitable only if $t \geq c / (p \bullet \pi) = 5$ years, whereas it has positive social welfare only if $t < (1/\delta) \bullet [T - c / (p \bullet v)] = 0$ years.

Consider, for example, a policy that provides a ten-year exclusivity period (t = 10 years) to any drug that provides at least Q evLYGs compared to existing therapies. What is the optimal threshold Q?

First, suppose that we choose a relatively low threshold of Q = 0.5. This threshold is high enough to screen out drug *D*. At this level, *if* developed, each of the other three drugs would qualify for regulatory exclusivity. However, only drugs *A* and *C* are profitable enough to develop at all. A firm developing drug *B* would, in expectation, be unable to recoup its costs of development within ten years and thus would elect not to undertake the investment.[186]

If we increase the evLYG threshold to Q = 1, observe that only drug *A* would be made available to patients. Drug *B* remains unprofitable, and drug *C* falls below the threshold.

Are patients better off with evLYG threshold Q = 0.5, or with Q = 1? With Q = 0.5, both drug *A* and drug *C* are made available to patients. Drug *A* provides high social value and, within this set of options, is clearly deserving of exclusivity. Drug *C* is a closer call. Like drug *D*, *C* is more valuable to its developer (with $750 million in profits per year) than it is to society (with $350 million per year in social value, accounting for deadweight loss). Nonetheless, as its total social welfare is positive (W = $650 million), society wants it to be developed, and patients are better off with the lower threshold.

Our point here is not that Q = 0.5 is the right threshold for incentivizing only welfare-enhancing drugs or that searching for an optimal (singular) Q^* is the right approach to policy design. For example, if drug *D* benefitted 100,000 patients per year rather than 20,000, then it would have pos--tive social welfare ($1.3 billion), and Q = 0.5 would deprive patients of a drug from which they could benefit. Or if drug *C* cost $500 million to develop rather than $200 million and had a useful life of ten years rather than twenty, it would then have negative social welfare (–$150 million), and society would be better off with Q = 1. Defining eligibility based only on an evLYG threshold rather than based on all the welfare-relevant parameters will inevitably create errors in both directions.

We think our model is useful, however, for illuminating the tradeoffs involved in choosing eligibility criteria and the additional policy reforms that would reduce eligibility-related error costs—tradeoffs that are different from the main costs and benefits governing patent law's analogous doctrines. In patent law, a key justification for limiting patents to substantial improvements over the prior art—and for excluding some kinds of inventions from patent eligibility altogether—is concern about the costs those

186. For some reasons why social value may exceed private value, see Hemel & Ouellette, *supra* note 35, at 530-37.

patents would impose on subsequent inventors.[187] But concerns like transaction costs and holdup arise because patents can be used to block follow-on inventions that build on the original patent, whereas regulatory exclusivity typically blocks marketing only of an equivalent drug.

Instead, the core problems with offering exclusivity for incremental improvements reflect unique features of the pharmaceutical sector. For example, the problem with drug *D* arises because the value to its developer ($800 million per year) is much greater than its social value ($200 million per year). Though it is, in general, thought to be the case that the social value of innovation far exceeds its private value,[188] the pharmaceutical sector is home to a set of notable counterexamples. For example, if drug developers are permitted to engage in "product hopping"—the practice of switching patients to new versions of drugs that offer little therapeutic benefit but do not yet face generic competition—some new drugs will generate almost no social value relative to existing alternatives.[189] Moreover, most patients have little incentive to select the most cost-effective drugs,[190] and providers sometimes have a profit incentive to choose *more* expensive drugs.[191] Reducing these wedges between private and social value would reduce the possibility that a drug could be privately profitable despite negative social welfare. Providing exclusivity for a new drug that offers only a marginal improvement would create little cost for patients if there were still generic competition on the existing therapies, and if the new drug were only purchased when its higher cost was actually worth the marginal benefit.

3. Duration

A second key question of institutional design is how long the regulatory exclusivity period should last. Existing regulatory exclusivity periods include five years for a small-molecule drug that qualifies as a new chemical entity, seven years for an orphan drug that treats a disease affecting

187. *See* Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 216 (2014); Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSPS., Winter 1991, at 29, 37-38.

188. *See* Benjamin F. Jones & Lawrence H. Summers, *A Calculation of the Social Returns to Innovation* 34 (Nat'l Bureau of Econ. Rsch., Working Paper No. 27863, 2020).

189. *See* Michael A. Carrier, *A Simple Solution to the Problem of "Product Hopping,"* HARV. HEALTH POL'Y REV. (Dec. 23, 2021), https://www.huhpr.org/volume-21-issue-1-2/2021/12/22/a-simple-solution-to-the-problem-of-product-hopping [https://perma.cc/3Z39-97B6].

190. *See* Haiden A. Huskamp, Patricia A. Deverka, Arnold M. Epstein, Robert S. Epstein, Kimberly A. McGuigan & Richard G. Frank, *The Effect of Incentive-Based Formularies on Prescription-Drug Utilization and Spending*, 349 NEW ENG. J. MED. 2224, 2224 (2003) (explaining that tiered formularies use lower copayments to induce enrollees to select drugs preferred by the payer); *see also* Haiden A. Huskamp, Arnold M. Epstein & David Blumenthal, *The Impact of a National Prescription Drug Formulary on Prices, Market Share, and Spending: Lessons for Medicare?*, 22 HEALTH AFFS. 149, 149 (2003) (noting that formularies attempt to steer patients toward lower-price products through financial incentives such as lower copayments).

191. *See* Hemel & Ouellette, *supra* note 35, at 540.

fewer than 200,000 people in the United States, and twelve years for a biologic drug.[192] MODDERN Cures would have provided fifteen years for any eligible drug.[193] In our above discussion of evLYG thresholds, we arbitrarily set an exclusivity period of $t = 10$ years. How should policymakers set the length of this period?

For the sake of illustration, suppose that the evLYG threshold is set to $Q = 0.5$, so drugs *A*, *B*, and *C* are eligible. For each drug, we can determine the minimum exclusivity period t_{min} such that it is profitable to its developer:

$$t_{min} = c / (p \bullet \pi).$$

Drug *A* is profitable with an exclusivity period of at least 3.75 years, drug *B* is profitable with a period of at least twelve years, and drug *C* is profitable with a period of at least 2.67 years. If the policymaker's goal were simply to develop the most drugs, then the regulatory exclusivity period should be at least twelve years.

Doing so comes, however, with a substantial social cost. To illustrate, consider four potential exclusivity periods that the policymaker might choose: $t = \{5, 10, 15, 20\}$. Only drugs *A* and *C* are developed in the first two cases, while all three drugs are developed in the third and fourth cases. We can immediately rule out $t = 10$ and $t = 20$ by comparing each to its shorter alternative. By moving from $t = 5$ to $t = 10$ and from $t = 15$ to $t = 20$, the number of years over which deadweight loss accrues increases, but the policymaker has not induced any additional innovation.

Our optimal exclusivity period for this set of potential drugs is, then, either $t = 5$ or $t = 15$. When $t = 15$, there is an obvious benefit: drug *B* is now profitable to develop. To evaluate whether this additional innovation is worthwhile from a social perspective, we must compare the additional value generated to the additional deadweight loss produced. Drug *B* generates $4.98 billion in expected social value across its useful life.[194] By increasing the patent term from $t = 5$ to $t = 15$, however, we must consider the increase in total expected deadweight loss associated with longer exclusivity periods for the two drugs that would have been commercialized even without the longer exclusivity period: $2.7 billion.[195] Although this increase in expected deadweight loss is substantial, it is outweighed by the increase in total expected social value.

One way to further increase social welfare would be to vary the length of exclusivity based on the needs of the individual drug. For example, if the regulators could offer $t = 5$ for drugs *A* and *C* and $t = 15$ for drug *B*, then

192. *See* THOMAS, *supra* note 22, at 4-8.

193. *See* MODDERN Cures Act of 2013, H.R. 3116, 113th Cong. § 201(e), (i)(4).

194. $W = p \bullet [(t \bullet (1 - \delta) \bullet v) + (T - t) \bullet v] - c = \$4.98$ billion.

195. Expected deadweight loss for each extra year of exclusivity is $p \bullet \delta \bullet v$, so the added loss from ten years of exclusivity is $2.55 billion for *A* and $0.15 billion for *C*.

society would gain the $4.98 billion in added value from *B* without paying the $2.7 billion deadweight loss associated with extending exclusivity for *A* and *C*. But estimating t_{min} on a drug-by-drug basis would entail a substantial information burden that goes beyond measuring a drug's value (recall that drug *B*'s value lies between that of drugs *A* and *C*).[196] If regulators could gather this information accurately, then it would likely be more efficient to simply pay for each drug directly rather than using market-set rewards to elicit this kind of private information.

Again, our point here is not that fifteen years is the right exclusivity period; the optimal *t* will depend on the actual distribution of potential drugs.[197] And the exclusivity duration in any new legislative framework will likely depend more on political bargaining among stakeholders than economic calculations. But our model helps illustrate the key tradeoffs between setting *t* so low that many valuable drugs are never developed and setting *t* so high that society bears a substantial deadweight loss.

As a starting point for deliberations, policymakers might consider that setting $t = 12$ years—coupled with policies to ensure generic entry at the end of the exclusivity—would both align small-molecule-drugs exclusivity with that for biologic drugs and match the actual exclusivity provided by the current system as shown above in Figure 8. Policymakers could also begin with a short period of exclusivity that could be extended when the developer provides additional evidence of clinical value.[198] The current patent-based exclusivity system seems so far from optimal that even without shifting actual durations of exclusivity meaningfully, all stakeholders would gain from the reduction in litigation costs and increased market certainty.

4. Scope

The proposal that we have sketched thus far requires, in effect, that policymakers revisit each of the design choices at the center of the patent system, including eligibility and duration. A third design question for any new intellectual property system is the breadth of the exclusivity rights.[199] Existing regulatory exclusivity rights are very narrow, generally blocking

196. On the challenges of asking the FDA to incorporate innovation concerns into other aspects of its decision-making, see generally Rachel E. Sachs, W. Nicholson Price II & Patricia J. Zettler, *Rethinking Innovation at FDA*, 104 B.U. L. REV. 513 (2024).

197. In particular, the optimal *t* would maximize total welfare, or the sum over all drugs of $[p \bullet v\ (T - t \bullet \delta) - c]$, subject to the constraint that a drug enters the welfare sum only if it is profitable to develop (i.e., $p \bullet t \bullet \pi \geq c$).

198. For many drugs, evidence of value is not generated until years after approval. *See* Audrey D. Zhang, Jeremy Puthumana, Nicholas S. Downing, Nilay D. Shah, Harlan M. Krumholz & Joseph S. Ross, *Assessment of Clinical Trials Supporting US Food and Drug Administration Approval of Novel Therapeutic Agents, 1995-2017*, 3 JAMA NETWORK OPEN art. no. e203284, at 8 tbl.4 (2020).

199. *See generally* Mark A. Lemley & Mark P. McKenna, *Scope*, 57 WM. & MARY L. REV. 2197 (2016) (arguing that intellectual property regimes need a process for determining scope).

only highly similar drugs that could rely on the same clinical-trial data.[200] But policymakers could adjust the scope of the new right by changing both the set of drugs that are blocked by the exclusivity and the extent of the associated patent-waiver requirements.

Suppose that Firm 1 receives a fifteen-year exclusivity period for drug *A*, which uses a novel biological mechanism to treat Parkinson's disease. Would that exclusivity prevent Firm 2 from developing a related drug *A′*, which is a different compound that works using the same underlying mechanism? What if Firm 3 discovers that *A* is also useful for treating multiple system atrophy—could Firm 1 prevent Firm 3 from marketing *A* for this new use? Should the answer to either question depend on which patents Firm 1 received on drug *A*?

In the current patent-centric system, these issues are governed by a variety of patent doctrines. For example, Firm 1's ability to block Firm 2's drug *A′* will depend on whether it could provide a sufficient disclosure to patent a genus that includes not just *A* but also other species using the same mechanism.[201] And if it was unable to patent the compound *A* but could patent use of *A* to treat Parkinson's, its ability to block Firm 3 from marketing *A* for a new use will depend on the rules of indirect patent infringement.[202] Firm 1 has strong incentives to build a patent "moat" around drug *A* to prevent any such competitors—even to the point of acquiring potential competitors and discontinuing their products in "killer acquisitions."[203]

As with eligibility and duration, setting the scope of exclusivity involves tradeoffs. If scope is set too narrowly, such that it blocks only marketing of the same drug in the same formulation for the same condition (with total waiver of any related patents), it increases the risk that Firm 1 will not develop drug *A* at all. If scope is set too broadly, it reduces incentives for other firms to build on the information about drug *A*'s efficacy to develop related products with additional health benefits.

The MODDERN Cures Act would have provided a modest reform to the current system. Under this system, a brand-name firm would receive data exclusivity to prevent a generic from relying on its clinical-trial data to gain approval of a bioequivalent drug, and it would waive the right to assert patents against any such applicant after the exclusivity period expires.[204] Thus, the brand-name firm could still use those patents to prevent a second entrant from marketing the same drug based on its own clinical trials or from marketing any related drugs that fall within the scope of those

200. *See* THOMAS, *supra* note 22, at 3-4.

201. *See, e.g.*, Amgen Inc. v. Sanofi, 598 U.S. 594, 610-11 (2023).

202. *See, e.g.*, GlaxoSmithKline LLC v. Teva Pharms. USA, Inc., 7 F.4th 1320, 1326, 1333-37 (Fed. Cir. 2021). These rules can also influence duration by allowing patents on new uses to extend patent exclusivity over the original product.

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

204. *See* MODDERN Cures Act of 2013, H.R. 3116, 113th Cong. § 201(c), (e).

patents. This approach would be a substantial improvement on the status quo by eliminating most of the existing pharmaceutical patent litigation under the Hatch-Waxman framework and thus reducing costs and uncertainty.

It may be possible to further improve this system by adjusting the scope of either the exclusivity right or its associated patent waiver. We conclude by noting that while tradeoffs are inevitable, an exclusivity-focused system has two key advantages for managing them. First, U.S. policymakers have greater flexibility to tailor the scope of a pharmaceutical-specific regulatory exclusivity system than they do with the patent system. And second, because exclusivity is granted at the time of FDA approval, policymakers have greater information about the benefit of the actual product at issue than they do at the times when related patents are awarded.

D. Avoiding Rights Accretion

One additional concern with the MODDERN Cures framework is that it is an opt-in system.[205] This creates the risk that it would serve as a one-way ratchet for exclusivity periods: firms would opt in only if they expect their patent-related exclusivity to be less than the new regulatory exclusivity and otherwise would continue engaging in the pharmaceutical patent arms race.[206]

Despite this concern, maintaining the system's voluntary nature seems both legally and politically necessary. For one thing, requiring firms to relinquish patent rights for all FDA-approved drugs would violate U.S. obligations under the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which requires all except least-developed nations to offer twenty-year patents in "all fields of technology" with only "limited exceptions."[207] Mandatory patent waiver for all drugs marketed in the United States would also be challenged under the U.S. Constitution, such as under the Takings Clause.[208] Moreover, a

205. *See supra* note 160 and accompanying text.

206. For scholars raising this concern about other new regulatory exclusivity periods, see Robin Feldman, *Regulatory Property: The New IP*, 40 COLUM. J.L. & ARTS 53, 97 (2016); and John R. Thomas, *The End of "Patent Medicines"? Thoughts on the Rise of Regulatory Exclusivities*, 70 FOOD & DRUG L.J. 39, 49 (2015).

207. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27(1), Apr. 15, 1994, 1869 U.N.T.S. 299. Canada was found to violate TRIPS for a far more modest proposal that would have allowed generic manufacturers to stockpile products for six months before the brand-name patent expired. *See* Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, 148, 174, WTO Doc. WT/DS114/R (adopted Mar. 17, 2000).

208. For example, the scheme could be struck down as a "simple appropriation of private property." Cedar Point Nursery v. Hassid, 594 U.S. 139, 162 (2021). In *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, the Supreme Court noted that its "narrow[]" holding on the constitutionality of a procedure for challenging patent validity after grant "should not be misconstrued as suggesting that patents are not property for purposes of the Due Process Clause or the Takings Clause." 584 U.S. 325, 344 (2018). Justice Gorsuch and Chief Justice Roberts believe

mandatory system seems far less likely to obtain sufficient political support than a voluntary system like MODDERN Cures.

Nonetheless, policymakers can use alternative measures to push firms into the new system and away from patents. Section III.D.1 explains how to reduce the pharmaceutical exceptionalism within patent doctrine that the Federal Circuit has used to uphold drug patents, and Section III.D.2 proposes that regulatory benefits and federal purchasing of newly approved drugs be conditioned on whether they are part of the new opt-in system. Finally, Section III.D.3 explains why maintaining some patent-law baseline is not just a legal and political necessity—it has benefits for maintaining a credible commitment to paying for new innovations.

1. Reducing Pharmaceutical Patent Exceptionalism

Drug developers will be more likely to opt into the new regulatory exclusivity system if amassing patent portfolios becomes less economically attractive. One problem is that existing patentability criteria are not enforced properly—the USPTO often grants invalid patents mistakenly.[209] These errors are particularly costly in the pharmaceutical industry, where generics cannot enter the market without incurring the cost of showing that every patent listed in the Orange Book is invalid or not infringed.[210] The USPTO could address this with a more rigorous examination process, such as by giving examiners more time to scrutinize pharmaceutical patents,[211] soliciting information from the FDA about prior art,[212] or changing features of the Hatch-Waxman Act that discourage post-grant challenges to pharmaceutical patents at the USPTO.[213]

Perhaps even more importantly, the USPTO and the courts could reevaluate how patentability doctrine applies to pharmaceutical inventions. At least in theory, drug patents should be evaluated based on the same patent-law standards as patents in any other field of technology.[214] In

patents are entitled to the same rights as private real property. *Id.* at 353-55 (Gorsuch, J., joined by Roberts, C.J., dissenting).

209. *See* Michael D. Frakes & Melissa F. Wasserman, *Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents? Evidence from Micro-Level Application Data*, 99 REV. ECON. & STATS. 550, 560 (2017).

210. *See* 21 U.S.C. § 355(c)(3)(C), (j)(5)(B)(iii) (2024).

211. *See* Frakes & Wasserman, *Investing in Ex Ante Regulation*, *supra* note 99, at 171; Dmitry Karshtedt, *Pharmaceutical Patents and Adversarial Examination*, 91 GEO. WASH. L. REV. 1259, 1306-07 (2023); S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About Pharmaceutical Patents*, 99 WASH. U. L. REV. 1673, 1677 (2022).

212. *See* Jonathan S. Masur & Lisa Larrimore Ouellette, *Real-World Prior Art*, 76 STAN. L. REV. 703, 765-67 (2024); S. Sean Tu, *FDA Reexamination: Increased Communication Between the FDA and USPTO to Improve Patent Quality*, 60 HOU. L. REV. 403, 452-53 (2022).

213. *See* Arti K. Rai, Saurabh Vishnubhakat, Jorge Lemus & Erik Hovenkamp, *Post-Grant Adjudication of Drug Patents: Agency and/or Court?*, 37 BERKELEY TECH. L.J. 139, 167 (2022).

214. *See* Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on Time-to-Market*, 61 UCLA L. REV. 672, 676 (2014) ("One of the defining characteristics of the current

practice, however, the courts—and particularly the Federal Circuit—have stretched the doctrine to uphold many drug patents. For example, in an empirical study of how patent outcomes vary across industries and technologies, John Allison, Mark Lemley, and David Schwartz concluded that courts responded to industry-specific needs—such as the economic importance of drug patents—"by varying the application of the unitary patent statute to respond to the characteristics and needs of each industry" and that, in litigation, "chemistry and pharmaceutical patents fare better than virtually any other type of patent."[215] Under a more technology-neutral application of the patentability criteria, fewer pharmaceutical innovations would be patentable.

Consider patentable subject matter. This doctrine bars patent claims that are "directed to" natural laws or abstract ideas and that fail to add an "inventive concept" that "amounts to significantly more" than a patent on the ineligible concept.[216] Under this rule, many pharmaceutical-treatment claims are arguably patent ineligible. For example, in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the Supreme Court invalidated a claim for a "method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder," where the steps involved administering a drug and measuring a resulting metabolite level in the patient to determine whether the dosage should be increased or decreased.[217] But when the Federal Circuit reviewed a similar claim for calibrating the dosage of a schizophrenia drug, it distinguished *Mayo* and upheld the claim[218] over a dissent arguing that the majority's "efforts to distinguish *Mayo* cannot withstand scrutiny."[219] The Federal Circuit later summarized its case law as consistently holding that "method of treatment claims are patent-eligible" under *Mayo*.[220]

We are sympathetic to the Federal Circuit's approach to the patent eligibility of treatment claims. The court has drawn a coherent and reasonably administrable line to avoid the policy consequence of invalidating a wide swath of pharmaceutical patents, without which many new therapeu-

patent system is that it applies a uniform set of rules to all inventions, and it does not discriminate based on technology or industry.").

215. John R. Allison, Mark A. Lemley & David L. Schwartz, *Our Divided Patent System*, 82 U. CHI. L. REV. 1073, 1078, 1124 (2015).

216. MASUR & OUELLETTE, *supra* note 25, at 247.

217. 566 U.S. 66, 74 (2012).

218. *See* Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l, 887 F.3d 1117, 1133-36 (Fed. Cir. 2018).

219. *Id.* at 1140 (Prost, C.J., dissenting).

220. Illumina, Inc. v. Ariosa Diagnostics, Inc., 967 F.3d 1319, 1325 (Fed. Cir. 2020). This case also involved a dissent arguing that the Federal Circuit had strayed from Supreme Court precedent. *See id.* at 1339 (Reyna, J., dissenting). Similarly, although many pharmaceutical compounds are arguably "products" of nature that are not patent eligible under *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 577 (2013), the *Myriad* rule has not been used to eliminate any patents on drug products in litigation—though it may have had some modest impact on examination decisions. *See* Taylor Beardall, Note, *Is the Sky Really Falling?:* Myriad *and Its Impact on Therapeutic Development*, 34 STAN. L. & POL'Y REV. 311, 327-28 (2023).

tic drugs may not have been developed.[221] But if there were a robust alternative incentive system through regulatory exclusivity, the court may have less motivation to carve out special rules for the pharmaceutical industry.

For another example of pharmaceutical patent exceptionalism, consider obviousness doctrine. A patent claim is invalid if it is an obvious variation or combination of prior-art references.[222] In *KSR International Co. v. Teleflex Inc.*, the Supreme Court rejected a rigid application of the test for obviousness and said that an invention may be obvious when it was "obvious to try."[223] But this standard does not seem to be applied in a technologically neutral way. Many pharmaceutical patents involve routine—albeit expensive—work and are thus arguably unpatentable under proper application of the "obvious to try" standard,[224] even if the results are unexpected.[225] But the Federal Circuit has upheld many of these patents against obviousness challenges.[226] Under a cost-benefit approach to obviousness,[227] there may be good policy reasons to uphold patents on pharmaceutical inventions that are obvious to try.[228] But again, this analysis may change in a world with a strong regulatory exclusivity alternative.

Disclosure doctrine provides another example. A patent must teach researchers in the field how to make and use the full scope of the claimed invention without "undue experimentation" (enablement), show "possession" of the invention at the time of filing (written description), and demonstrate a real-world use at the time of filing (utility).[229] As noted previously, a patent claiming therapeutic utility in human patients doesn't need to disclose any results from human clinical trials to satisfy these re-

221. On the innovation-policy concerns the Federal Circuit judges have with *Mayo*, see generally *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*, 927 F.3d 1333 (Fed. Cir. 2019), which denied rehearing en banc, with eight Federal Circuit judges writing separately.

222. *See* MASUR & OUELLETTE, *supra* note 25, at 134-36 (discussing 35 U.S.C. § 103 (2024)).

223. 550 U.S. 398, 421 (2007).

224. *See, e.g.*, Carlos M. Correa, *Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective*, UNITED NATIONS DEV. PROGRAMME 31 (2016), https://www.undp.org/publications/guidelines-examination-patent-applications-relating-pharmaceuticals [https://perma.cc/RFT4-KFSS].

225. *See* Mark A. Lemley, *Expecting the Unexpected*, 92 NOTRE DAME L. REV. 1369, 1370 (2017).

226. *See id.* at 1370 (noting that invalidating "obvious to try" patents "may alarm patent owners in the pharmaceutical industries, who have been obtaining patents for this sort of normal experimentation for years"); Douglas L. Rogers, *Federal Circuit's Obviousness Test for New Pharmaceutical Compounds: Gobbledygook?*, 14 CHI.-KENT J. INTELL. PROP. 49, 78 (2014).

227. *See generally* Tun-Jen Chiang, *A Cost-Benefit Approach to Patent Obviousness*, 82 ST. JOHN'S L. REV. 39 (2008) (discussing a cost-benefit approach to obviousness); Michael Abramowicz & John F. Duffy, *The Inducement Standard of Patentability*, 120 YALE L.J. 1590 (2011) (same).

228. *See* Andrew V. Trask, Note, *"Obvious to Try": A Proper Patentability Standard in the Pharmaceutical Arts?*, 76 FORDHAM L. REV. 2625, 2668 (2008).

229. *See* MASUR & OUELLETTE, *supra* note 25, at 169 (discussing 35 U.S.C. §§ 101, 112(a) (2024)). The patent must also disclose the "best mode" of practicing the invention, but patents cannot be invalidated for failure to disclose a best mode. *See id.*

quirements; the standards are currently much more relaxed.[230] There is some tension, however, between these relaxed disclosure standards and the current approach to obviousness for pharmaceutical inventions. If the theory is that a given invention is nonobvious because the field is unpredictable and many clinical trials fail, then one might also argue that implementing that invention in human patients requires an undue amount of experimentation and that patent filing that predates the clinical trials does not demonstrate possession of the invention or a real-world use at the time of filing. Again, the pharmaceutical industry seems to have an exception from the usual rules of patentability,[231] which may have less policy justification when drug developers have a viable alternative to patents.

Moving away from pharmaceutical patent exceptionalism could be statutorily mandated by Congress as part of the same legislative reform that implements the new regulatory exclusivity system. Or it could happen naturally in the courts as the new realities of pharmaceutical research become apparent. Or the USPTO could also play a role. The USPTO is bound by courts' interpretation of the Patent Act, but as this Section illustrates, applying that guidance to fact-specific cases involves numerous judgment calls. The agency could shade its guidance for examiners toward technology neutrality and away from pharmaceutical exceptionalism, which would arguably be more in line with binding Supreme Court precedent.

2. Leveraging Regulatory Benefits and Federal Purchasing Power

Congress could also turn to policy levers outside patent law to help push pharmaceutical innovation away from the patent system. Drug developers receive many nonpatent regulatory benefits, all of which could be conditioned on whether a firm opts into the new system. For example, if a drug is not part of the new system, it would not be eligible for existing regulatory exclusivities, such as the five years of data exclusivity for new chemical entities, seven years of market exclusivity for orphan drugs, or six-month extension of exclusivity for pediatric studies.[232] R&D tax incentives could also be conditioned on any resulting drugs being placed in the new system.[233] Direct funding through the NIH and other grantmaking

230. *See supra* notes 75-80 and accompanying text.

231. One example that might initially appear to be a turn away from pharmaceutical patent exceptionalism is the recent use of the enablement and written-description requirements to invalidate pharmaceutical genus claims, or claims that cover a group of related compounds. *See* Dmitry Karshtedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, 35 HARV. J.L. & TECH. 1, 22 (2021). But if anything, these cases illustrate our point: they almost all involve suits against a brand-name company, not against a generic that is trying to enter the market. *See id.* at 68.

232. On existing regulatory exclusivities, see Durvasula et al., *supra* note 10, at 8-9.

233. For a summary of current incentives, see Lisa Larrimore Ouellette, *IP and Access to Publicly Funded Research Results in Health Emergencies: US Policy, Law and Practice* 10-11

agencies could be similarly conditioned,[234] although the small number of drugs that involve federally funded inventions directly would limit the effectiveness of this lever in practice.[235]

Perhaps most significantly, policymakers could take advantage of the federal government's significant purchasing power in the pharmaceutical market to incentivize participation in the new regulatory exclusivity system, drawing inspiration from the Medicare drug-price negotiation provisions in the Inflation Reduction Act of 2022.

The Centers for Medicare and Medicaid Services (CMS) estimates that drug spending through Medicare, Medicaid, and other Health and Human Services programs accounts for over forty percent of all U.S. prescription-drug spending.[236] Currently, CMS has little ability to control how much it pays for drugs or to align these prices with the drugs' value; rather, Medicare and Medicaid pricing rules create perverse incentives for both R&D and the prices charged to nonfederal purchasers.[237] But Congress has recently begun to give CMS increased authority to align federal purchasing decisions with health objectives.

Under the Inflation Reduction Act, CMS can select a small number of high-expenditure drugs for Medicare price negotiation.[238] CMS offers a price based on factors such as a drug's comparative effectiveness,[239] and if the drug manufacturer wants to continue sales to Medicare, it must accept this price or pay a 1,900% tax on all U.S. sales of the drug.[240] Negotiated prices for the first ten drugs were announced in August 2024 (to take effect in 2026), and fifteen additional drugs were selected for the second cycle of

(World Intell. Prop. Org. Discussion Paper, 2024), https://www.wipo.int/edocs/mdocs/patent_policy/en/wipo_ip_ge_24/wipo_ip_ge_24_discussion.pdf [https://perma.cc/33J8-KXX9].

234. For an overview of current direct funding, see *id.* at 6-10.

235. *See* Lisa Larrimore Ouellette & Bhaven N. Sampat, *Using Bayh-Dole Act March-In Rights to Lower US Drug Prices*, 5 JAMA HEALTH F. art. no. e243775, at 4-5 (2024).

236. *See Drug Spending*, U.S. DEP'T HEALTH & HUM. SERVS. (Dec. 16, 2024), https://oig.hhs.gov/reports-and-publications/featured-topics/drug-spending [https://perma.cc/6GHT-VALX].

237. *See* Hemel & Ouellette, *supra* note 35, at 539-44. In brief, Medicare Part B reimburses drugs for 104.3% of the average sales price, which gives drug developers an incentive to raise the average sales price by charging higher prices to non-Medicare patients and gives providers an incentive to increase profit margins by prescribing higher-priced drugs. *See id.* at 539-40. Medicare Part D mandates coverage of drugs in protected classes or in therapeutic categories with only one or two FDA-approved drugs, providing very little ability to control prices for these drugs and distorting how R&D is allocated across therapeutic classes. *See id.* at 541. And Medicaid requires the government to receive the "best price" among most purchasers, incentivizing drug companies to raise prices for nonfederal purchasers. *See id.* at 543.

238. Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 11001(a), 136 Stat. 1818, 1836-41 (codified at 42 U.S.C. § 1320f-1); *see also* Hemel & Ouellette, *supra* note 35, at 577 (discussing the mechanics of the Inflation Reduction Act).

239. 42 U.S.C. § 1320f-3(e) (2024).

240. *See* 26 U.S.C. § 5000D (2024); *see also* Hemel & Ouellette, *supra* note 35, at 577 n.338 ("The legislation refers to a '95 percent' excise tax, but this rate is calculated on a tax-inclusive basis. For example, a drug sold for $100 would face a tax of $1,900, such that the tax ($1,900) is 95% of the sum of the tax plus the price ($2,000).").

negotiations in January 2025.[241] Thus far, lawsuits challenging the drug-price negotiation program on constitutional or statutory grounds have been unsuccessful.[242]

Congress could expand on this framework by tying federal drug purchasing more directly to the new regulatory exclusivity system. For example, Congress could direct Medicare—and perhaps other federal purchasers—to preferentially (or exclusively) reimburse drugs that have opted in. For drugs that remain in the patent system, CMS could be required to initiate price negotiations much earlier in the product lifecycle or could decline to provide coverage altogether. Given the size of the federal drug-purchasing market, this approach would create a powerful incentive for manufacturers to choose regulatory exclusivity over patents. The extent of participation would depend on the strength of the purchasing conditions Congress adopts. If access to Medicare and other federal purchasers were materially conditioned on opting in, participation would likely be near-universal.

Importantly, we think this approach would not violate TRIPS obligations or raise the same constitutional concerns as a system of mandatory patent waiver. Firms would retain the ability to pursue traditional patent protection and to market their drugs as usual to nonfederal purchasers. They simply would no longer be entitled to set unconstrained prices for federal purchasers. If a firm keeps a drug in the patent system, it would have to either forgo the federal market or accept early price negotiation, depending on implementation details.

3. Preserving a Patent Baseline

Would it be better if the United States could ban pharmaceutical patents altogether? Not necessarily—even if there were a way to circumvent international-treaty constraints, constitutional challenges, and political hurdles.[243] We have advocated shifting the primary incentive structure for pharmaceutical innovation away from patents, but maintaining patents as a backstop serves at least two important functions.

First, patents can allocate rewards for contributions to the early stages of drug development. The scope of patent waiver in our new system would

241. *See* Juliette Cubanski, *FAQs About the Inflation Reduction Act's Medicare Drug Price Negotiation Program*, KAISER FAM. FOUND. (Jan. 23, 2025), https://www.kff.org/medicare/issue-brief/faqs-about-the-inflation-reduction-acts-medicare-drug-price-negotiation-program [https://perma.cc/6FPK-BWUK]; Press Release, U.S. Dep't Health & Hum. Servs., HHS Announces 15 Additional Drugs Selected for Medicare Drug Price Negotiations in Continued Effort to Lower Prescription Drug Costs for Seniors (Jan. 17, 2025), https://www.cms.gov/newsroom/press-releases/hhs-announces-15-additional-drugs-selected-medicare-drug-price-negotiations-continued-effort-lower [https://perma.cc/4J9L-3LT4].

242. *See* HANNAH-ALISE ROGERS, CONG. RSCH. SERV., R47682, CONSTITUTIONAL CHALLENGES TO THE MEDICARE DRUG PRICE NEGOTIATION PROGRAM 3 (2024); Cubanski, *supra* note 241.

243. On these issues, see *supra* notes 207-208 and accompanying text.

prevent a brand-name firm from using patents to block a generic entrant after exclusivity expires; it would not eliminate patent suits against a brand-name firm that first brings a drug to market. Patent litigation against brand-name firms is much less common than suits against generic firms under the Hatch-Waxman Act,[244] but when an innovator does make a patentable contribution to what ends up becoming an approved drug, that innovator should receive a commensurate portion of the resulting reward.[245] Relatedly, by allocating rights at an early stage, patents could provide greater certainty to reduce some risks of drug development, including the risk of multiple firms duplicating the same clinical trials in a race to obtain FDA approval.

A second important function served by maintaining a patent baseline is preserving the credibility of the government's commitment to rewarding innovation.[246] The policy problem here is that any benefits patents provide occur largely *before* a drug reaches the market, incentivizing the developer to invest in the lengthy process of studying the drug's effectiveness and obtaining FDA approval.[247] Once the drug is marketed, the further effects of patents are largely negative, increasing prices for payers above a competitive level.[248]

Thus, once a drug exists, a firm will face pressure from politicians and consumer activists to give it away at very low cost.[249] These demands are understandable: concerns about high prices impeding patient access are most acute for drugs with the largest health impact. But where these demands prevail, the effect on private-sector incentives is perverse. Firms that solve the most significant public-health problems receive reduced rewards precisely because the problems they have addressed are so important. When that happens, it will likely lead to persistent private-sector underinvestment in exactly those areas where private-sector investment is most needed.

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244. *See* Brenda Sandburg, *Brand vs. Brand Patent Battles Heat Up, Focus on Big Drug Classes*, PINK SHEET (Jan. 4, 2017), https://insights.citeline.com/PS119751/Brand-vs-Brand-Patent-Battles-Heat-Up-Focus-On-Big-Drug-Classes [https://perma.cc/RR8K-FYTE].

245. In such cases, an injunction should not be available. *See* Abbott Cardiovascular Sys., Inc. v. Edwards Lifesciences Corp., No. CV 19-149, 2019 WL 2521305, at *25 (D. Del. June 6, 2019) ("[C]ourts have refused to grant an injunction when doing so would eliminate 'an important alternative for patients.'").

246. *See* Benjamin N. Roin, *Intellectual Property Versus Prizes: Reframing the Debate*, 81 U. CHI. L. REV. 999, 1071 (2014). For a critical assessment of whether and why patents should be seen as more credible than other government commitments, see generally Daniel J. Hemel, Patent as Promise (Jan. 30, 2026) (unpublished manuscript) (on file with authors).

247. For a general overview of the economics of patent law, see MASUR & OUELLETTE, *supra* note 25, at 33-38.

248. *See id.*

249. In an acute health crisis, this pressure can come even before the drug exists. For example, policymakers were raising concerns about firms earning profits from COVID-19 vaccines well before any vaccine trials were complete. *See, e.g.*, Katherine J. Wu, *Some Vaccine Makers Say They Plan to Profit from Coronavirus Vaccine*, N.Y. TIMES (May 4, 2021), https://www.nytimes.com/2020/07/21/health/covid-19-vaccine-coronavirus-moderna-pfizer.html [https://perma.cc/5N4P-Z683].

For an illustration of how the patent system can provide a baseline against this kind of expropriation even in a heavily regulated system of government purchasing, consider the United Kingdom.[250] Once a drug is approved, the UK's National Institute for Health and Care Excellence (NICE) considers the drug's price and evidence of its clinical efficacy and recommends whether the drug offers a good value for the National Health Service (NHS).[251] NHS is only required to cover drugs that NICE recommends.[252] And if a firm is not satisfied with a requested price reduction, it can choose to sell on the unsubsidized market to the small number of patients with private insurance or who would pay out of pocket.[253] This ability of the seller to walk away sets a floor below which the UK government cannot lower the drug manufacturer's ex post reward for having invested in bringing the drug to market.

For our proposed regulatory exclusivity system, maintaining patents as an alternative serves a similar function, at least if one thinks it is harder for the government to roll back patent protections than regulatory exclusivities. If the government were to drastically reduce the rewards offered through regulatory exclusivity, firms would have the option to revert to patent protection—albeit a lower patent reward than is currently available, if the suggestions in Sections III.D.1 and III.D.2 are adopted. This creates some check on government behavior, ensuring that the rewards offered through the new system remain sufficiently attractive to maintain a drug-development pipeline.

Conclusion

In 1984, the Hatch-Waxman Act laid out an ambitious plan to balance incentives for innovation with guardrails for patient access within the confines of the patent system. Forty years later, its framework is overdue for reform.

Two arguments—one empirical and one legal—are the starting point for this Article. First, patents are failing to balance incentives for innovation and access in the pharmaceutical sector in the way that the drafters of the Hatch-Waxman Act envisioned. Brand-name firms now accumulate ever-growing portfolios of patents, not to protect increasingly sophisticated health technologies or offset known distortions within the patent system but to block their competitors. These competitors respond as this sys-

250. For a more detailed overview of this system, see Hemel & Ouellette, *Pluralism*, *supra* note 124, at 564-65; and Mark A. Lemley, Lisa Larrimore Ouellette & Rachel E. Sachs, *The Medicare Innovation Subsidy*, 95 N.Y.U. L. REV. 75, 92-94 (2020).

251. *See NICE Technology Appraisal and Highly Specialised Technologies Guidance: The Manual*, NAT'L INST. HEALTH & CARE EXCELLENCE 176-82 (Dec. 17, 2025), https://www.nice.org.uk/process/pmg36/resources/nice-health-technology-evaluations-the-manual-pdf-72286779244741 [https://perma.cc/2QJ6-KEXN].

252. *See* Lemley et al., *supra* note 250, at 92.

253. *See id.* at 93.

tem encourages them to do, with litigation. The outcome is a remarkably precise stalemate. Second, patents are failing to strike this ambitious balance *because* this type of calibration is at odds with fundamental features of patent doctrine.

The resulting patent arms race is not merely an academic concern—it has real costs. Litigation expenditures that could have been directed toward productive R&D are instead funneled into legal battles over patents of marginal scientific value. Uncertainty about market-exclusivity timelines discourages investment in product improvements and follow-on research. And most importantly, these inefficiencies do not appear to translate into better medicines for patients. If anything, the current system re-ards strategic behavior over genuine innovation.

Failure to balance innovation and access in this market is not inevitable. We argue that an alternative framework—one based on regulatory exclusivity rather than patents—offers a more effective way to incentivize pharmaceutical innovation. Unlike the patent system, regulatory exclusivity can be structured to better align with the realities of drug development, rewarding firms in proportion to the clinical and therapeutic benefits their products provide. By linking exclusivity to regulatory approval rather than to an arbitrary patent filing date, this approach reduces incentives for premature patenting, weakens the incentive to build defensive patent thickets, and eliminates the need for costly litigation as a precondition for generic entry.

Moreover, shifting away from patents in this sector would not only improve pharmaceutical innovation—it would also create an opportunity to recalibrate the patent system as a whole. For decades, pharmaceutical interests have shaped patent law, leading to industry-specific carveouts and distortions that ripple across other technology sectors. A reduced reliance on patents for pharmaceutical innovation would allow courts and policymakers to apply patentability standards more consistently across industries, restoring the patent system's broader role as a tool for incentivizing meaningful technological progress rather than entrenching incumbents.

Crucially, the time for reform is now. A rare policy window has emerged in which former adversaries—brand-name firms, generic manufacturers, and even the architects of Hatch-Waxman—are aligned in recognizing that the current system is unsustainable. As bipartisan legislative proposals have demonstrated, there is political appetite for a new model of pharmaceutical exclusivity, one that preserves incentives for drug development while eliminating the inefficiencies of the current patent regime.

Pharmaceutical patents were once viewed as an essential pillar of innovation policy. This Article argues that their continued dominance has become a liability—for patients, for industry stakeholders, and even for the integrity of the patent system itself. The reforms we propose would not only improve access to medicines but also refocus pharmaceutical incen-

tives on developing drugs that deliver the greatest health benefits. With the right institutional design, a shift to regulatory exclusivity is not only feasible—it is the most promising path forward.

Appendix

This Appendix reports additional results from a set of simple regression analyses.

Table A1: Regression Analysis

	Market Exclusivity (Potential) (1)	**Market Exclusivity (Actual) (2)**	**Market Size (3)**	**Drug Quality (4)**	**Drug Re-Approvals (5)**	**Clinical Trials (6)**
Patent Count	0.542 (0.048)	0.182 (0.046)	0.069 (0.126)	0.012 (0.232)	0.045 (0.096)	0.038 (0.001)
Approval Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes