Back to Basics: First Principles in Intellectual Property Policy in the Life Sciences

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Introduction

Scholarly and policy discussions of the impact of intellectual property (IP) protections in the biopharmaceutical sector tend to paint a dismal picture. Academics and advocacy organizations widely assert that pharmaceutical patents inflate prices and impede innovation, and accordingly advocate weakening (or, in some cases, abolishing) patents and other legal exclusivities held by universities, biotech startups, and pharmaceutical companies. Yet this narrative of policy failure is difficult to reconcile with strong indications of policy success. The United States consistently provides among the world's strongest levels of patent protection and IP enforcement[1] and, unlike most other countries, has historically lacked government-mandated price controls on drugs that indirectly limit the practical strength of patent protection. Notwithstanding this "burden" of robust IP rights, the US is the world leader in pharmaceutical innovation and sustains a uniquely entrepreneurial biotech ecosystem that cultivates technology transfers from research institutions to startups and other private firms.

On both inputs into the R&D and drug development process and outputs in the form of new drugs and medicines, the US outperforms globally. As of 2021, the US economy attracted the largest investment annually in pharmaceutical research and development (R&D), representing about two-thirds of all private pharmaceutical R&D spending globally.[2] Since 2004 through 2021, publicly traded pharmaceutical companies exhibited the highest rate of R&D intensity (R&D expenditures as a percentage of net revenues) among all major US tech industries, approaching 25% since 2017.[3] Those research inputs translate into a steady flow of new drugs and medicines. From 2015 to 2019, pharmaceutical R&D spending in the US increased by almost 50%.[4] As of 2021, US-headquartered companies accounted for 44% of the global "R&D pipeline" (products in active development), as compared to 25% for Europe and 12% for China.[5] During 2020-2024, there were 110 new drugs launched in the US that had not yet been released

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[1] U.S. Chamber of Commerce, International IP Index 11, 17, 18, 41 (2024), https://www.uschamber.com/intellectual-property/2024-ip-index.
[2] OECD, *Health at a Glance 2023: OECD Indicators* 206 (2023), https://www.oecd.org/content/dam/oecd/en/publications/reports/2023/11/health-at-a-glance-2023_e04f8239/7a7afb35-en.pdf.
[3] Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* (2021), at Fig. 1.
[4] Id., at 2.
[5] IQVIA Institute for Human Data Science, *Global Trends in R&D 2022: Overview Through 2021* (Feb. 10, 2022), at 13.

in Europe, whereas there were only 14 drugs during this period that had been launched in Europe but not yet in the US.[6] Contrary to standard assumptions, it appears that stronger patent protections provide US consumers with expanded access to new drugs and medicines.

This mismatch between the prevailing narrative of market failure and strong indications of market success suggests that much of current IP policy discussions reflects an understanding of the biopharmaceutical ecosystem that is at best incomplete and at worst substantially inaccurate. In particular, that discussion reflects a truncated perspective that closely scrutinizes the social costs attributable to patents and other exclusivities for drugs and medicines without comparable examination of the social gains attributable to those legal protections. In this contribution, I identify a core set of foundational principles to support economically and factually informed analysis that assigns appropriate weight to both the social costs and gains of IP rights in the biopharmaceutical sector. These principles are designed to cultivate constructive IP policies that recognize that private-sector biopharmaceutical innovation requires some form of exclusivity protection to address imitation and knowledge leakage risks throughout the drug innovation cycle. That cycle encompasses both the early stage of innovation, which is often the focus of IP policy discussions, and the subsequent stages of testing, production, and distribution that convert an innovation into a commercially and technically viable drug or therapy, which are often overlooked. Relatedly, these principles reflect an appreciation that an effective institutional structure must not only support incentives to invest in innovation but also enable transactional relationships among the various non-innovators—investors, producers, and others—that contribute to an FDA-approved drug or medicine.

These considerations yield two "first principles" for IP policy analysis in the life sciences, which correspond respectively to the "incentive" and "enabling" functions of IP rights.[7]

First, investors will not allocate capital to a new biopharmaceutical project without reasonable confidence that, following successful development and market release, the innovator can block imitators from reaping where others have sown at great cost and risk. Absent sufficient expected returns (which must cover development costs on both successful and unsuccessful projects as well as the opportunity cost of capital in light of other investment opportunities), private investors will allocate capital to other sectors and biopharmaceutical innovation will decline absent governmental and philanthropic funding. Contrary to theoretical models advanced by some economists and legal academics, there is no historical precedent showing that public entities can sustainably fund or effectively execute the drug development and production functions currently undertaken by the private sector.

Second, without a legal mechanism to block the leakage and expropriation of intellectual assets, innovators that lack testing, production, and distribution capacities (mostly research

[6] IQVIA Institute for Human Data Science, *Global Trends in R&D 2025* (Mar. 26, 2025), at 3.
[7] For discussion, see Jonathan M. Barnett, *Intellectual Property as a Law of Organization*, 84 S. Cal. L. Rev. 785, 785–86, 789–90 (2011); Robert P. Merges, *A Transactional View of Property Rights*, 20 Berkeley Tech. L.J. 1477, 1485–86 (2005); Ashish Arora & Robert P. Merges, *Specialized Supply Firms, Property Rights and Firm Boundaries,* 13 Indus. & Corp. Change 451 (2004); F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 Minn. L. Rev. 697, 703–08 (2001).

institutions and startups) will have difficulty contracting with business partners (mostly investors and large pharmaceutical companies) who do have those capacities. By mitigating the risk of knowledge leakage and outright expropriation, IP rights can facilitate a division of labor that not only generates efficiencies through specialization but enables entry by entities that excel in the innovation segments of the pharmaceutical supply chain but lack resources or capacities to readily integrate forward into production and distribution. Those are uncontroversially attractive outcomes as a matter of both innovation and competition policy.

Any practically relevant discussion of IP policy in the life sciences must identify practically workable mixes of legal, contractual, and technological mechanisms that can resolve these incentive and coordination problems. To be clear, these principles do not imply that the strongest levels of IP rights are always required to support drug development and commercialization in every biopharmaceutical sector. This approach simply anchors "macro" policy analysis in the business realities of drug development, while supporting a wide range of "micro" policy positions concerning specific configurations and features of IP rights and other exclusivities in particular biopharmaceutical sectors.

This Chapter is organized as follows. First, I describe the current state of the academic and policy literature pertaining to the role of IP rights in biopharmaceutical development, using the intellectual history of the "anti-commons" thesis as a case study. Second, I describe the core principles that can support balanced, factually informed, and practically relevant discussions of IP policy in the biopharmaceutical sector. I then apply those principles to show how they can account for the economic and social gains resulting from the extension of patent protection in the early 1980s to biotechnological inventions, contrary to widespread predictions (following the anti-commons thesis) that doing so would suppress innovation. A brief conclusion follows.

I. The Current State of IP Policy Analysis in the Biopharmaceutical Market

This Section proceeds in two steps. First, I describe the intellectual skew in IP policy scholarship and commentary in the life sciences, showing how it focuses disproportionately on the costs attributable to patents and other forms of IP protection while ignoring the potential benefits in the form of increased innovation. Second, I describe certain well-established findings in the empirical literature that suggest that strong forms of skepticism toward the value in general of IP rights and other exclusivities in the biopharmaceutical sector are unlikely to provide a basis for sound policy recommendations.

A. Intellectual Skew in IP Policy Scholarship on Biopharmaceutical Innovation

In theory, IP policy requires calibrating various elements of IP rights—such as duration, novelty, scope, and remedies—to achieve an optimal balance between preserving incentives (which favors stronger IP rights) and maintaining access for users and subsequent innovators (which favors weaker IP rights). A significant economic literature has constructed models to measure relevant costs and benefits and *in theory* achieve socially optimal tradeoffs through appropriately designed IP protections.[8] Yet, given the inherent difficulty in quantifying the gains attributable to innovation and the costs attributable to limits on access, scholarly discussions of IP policy have typically inhabited a broad middle ground encompassing positions that favor stronger and somewhat weaker forms of IP protection, without rejecting that some meaningful level of exclusivity is necessary to support private investment in innovation.

In the biopharmaceutical context, however, some scholarly and policy commentators have moved away from this middle ground. Many scholars and policy advocates focus mostly or exclusively on the monopoly rents and transactional roadblocks attributable to IP protections over medicines and propose a variety of measures to weaken those protections.[9] Others take a step further and cast doubt on, or reject outright, the necessity of IP rights or other exclusivities to support pharmaceutical innovation. In widely-cited writings (including the most highly-cited scholarly book on intellectual property published since 2004[10]), economists Michele Boldrin and David Levine have argued that the empirical case for pharmaceutical patents is largely unfounded[11] and assert that patents "do not play a helpful role in pharmaceutical innovation."[12] Nobel Prize winner Joseph Stiglitz has similarly questioned the necessity of patents to support drug development and argued that these could be replaced by public financing, tax incentives, patent buyouts and prizes.[13] A follow-on academic literature has made similar policy proposals.[14] This is despite the fact that extensive historical evidence shows that prizes have rarely been effective in inducing innovation, largely due to information problems, rent-seeking,

[8] For a review, see Suzanne Scotchmer, *Innovation and Incentives* 97-118 (2004).
[9] *S*ee, e.g., I-MAK, *Overpatented, Overpriced 2022: How Excessive Pharmaceutical Patenting Is Extending Monopolies and Driving Up Drug Prices* (2022), https://www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf (arguing that misuse of patents on drugs is a major contributor to higher drug prices); Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 Yale J.L. & Tech. 275, 284–86, 293–96 (2016) (arguing that the federal government has the right under 28 U.S.C. § 1498 to purchase generic versions of in-patent drugs in exchange for reasonable royalties for the patent owner); Amy Kapczynski & Aaron S. Kesselheim, *'Government Patent Use': A Legal Approach to Reducing Drug Spending,* 35 Health Affairs 791 (2016) (similar view); Topher Spiro, Maura Calsyn & Thomas Huelskoetter, *Enough is Enough: The Time Has Come to Address Sky-High Drug Prices,* Center for American Progress 27-28 (2015), https://www.americanprogress.org/article/enough-is-enough-2/ (arguing that the government should exercise its march-in rights under the Bayh-Dole Act to restrain "excessive" prices for drugs developed using federal funding).
[10] For citation data, see Jonathan M. Barnett, *The Big Steal: Ideology, Interest, and the Undoing of Intellectual Property* 159 (2024).
[11] Michele Boldrin & David K. Levine, *Against Intellectual Monopoly* 241-276 (2011).
[12] Id., at 268.
[13] Joseph E. Stiglitz, *Prizes, Not Patents*, Project Syndicate, Mar. 6, 2007, https://www.project-syndicate.org/commentary/prizes--not-patents; Joseph Stiglitz, *Scrooge and Intellectual Property Rights,* 333 British Med. J. 1279 (2006).
[14] See, e.g., James Love & Tim Hubbard, *The Big Idea: Prizes to Stimulate R&D for New Medicines*, 82 Chi.-Kent L. Rev. 1519 (2007) (proposing to eliminate drug patents and fund R&D through tax-financed and government-administered prize systems to incentivize drug development, followed by generic entry for drug production and distribution); Ellen F.M. 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power* 95 (2009) ("The idea of awarding and incentivising innovation with prizes rather than with monopolies is again gaining ground").

and favoritism.[15] Additionally, as I have demonstrated through an examination of post-World War II innovation policy, government funding in place of IP rights imposes exceptional financial burdens that cannot be sustained for an extended period and suppresses market incentives to convert basic research into new products and services.[16]

These strong forms of IP-skepticism can exert long-lasting influence even if much of the literature delivers confounding evidence and reaches more nuanced, or even contrary, views. Scholars may overcite a single publication while overlooking a larger body of contrary findings, whether as a result of confirmation bias, time-savings heuristics, ideological proclivities, or other reasons. As I have shown using data on citation practices in patent and copyright scholarship, a single academic publication (often a theoretical conjecture grounded in anecdotal evidence) may acquire an authoritative status, even though the subsequent literature provides findings that generally cast doubt on, or even rebut, that publication.[17] That in can have an impact on real-world policy outcomes. For example, an influential article that set forth the "patent holdup" theory, relying principally on theoretical arguments and anecdotal reports that "excessive" IP royalty rates were being paid by device producers in the smartphone industry to chip-design firms, influenced policy actions by antitrust agencies around the world. This influence persisted even after the publication of multiple empirical studies that found little evidence for the theory.[18] In the pharmaceutical context, skewed coverage of the relevant body of empirical evidence, or the general tendency to discount or ignore the innovation gains attributable to IP protections, has sometimes cultivated policy approaches that focus on the pricing impact of IP protection or understate or overlook the real-world costs and risks of drug development and testing.

An example of this type of "false consensus" can be found in the intellectual history of one of the most widely-cited scholarly publications on IP policy in the biopharmaceutical sector. In 1998, Michael Heller and Rebecca Eisenberg published an essay in the prominent journal, *Science,* expressing the view that the proliferation of patenting by academic research institutions in the biomedical sector could deter rather than promote innovation by creating an "anticommons" in which litigation and licensing over IP rights impede the flow of information among researchers and innovators.[19] While the paper has been widely cited (3,933 citations as of October 5, 2025), it has been rebutted, questioned, or at best found limited support in every

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[15] B. Zorina Khan, *Inventing Ideas: Patents, Prizes, and the Knowledge Economy* (Oxford Univ. Press 2020); B. Zorina Khan, *Inventing Prizes: A Historical Perspective on Innovation Awards and Technology Policy,* 89 Bus. Hist. Rev. 631 (2015); B. Zorina Khan, *Inventing in the Shadow of the Patent System: Evidence from 19th-Century Patents and Prizes for Technological Innovations*, NBER Working Paper No. 20731 (2014).

[16] Jonathan M. Barnett, *The Great Patent Grab*, in The Battle Over Patents: History and Politics of Innovation 208-277 (Stephen H. Haber & Naomi R. Lamoreaux eds. 2021).

[17] Barnett, *Big Steal, supra* note 12, at 171-77. For similar findings concerning the scholarly understanding of the economic impact of piracy in content markets, see Justin Hughes & Michael D. Smith, *Do Copyright Professors Pay Attention to Economists?: How Empirical Evidence on Copyright Piracy Appears (or Not) in Law Literature,* 47 Columbia J. L. & the Arts 165 (2024).

[18] On this point, see Jonathan M. Barnett, *Has the Academy Led Patent Law Astray?,* 32 Berkeley Tech. L.J. 1313 (2017); J. Gregory Sidak, *Is Patent Holdup a Hoax?,* 3 Criterion J. Innovation 401 (2018).

[19] Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science 698 (1998).

empirical or fact-based study that has sought to test the thesis.[20] For clarification, Eisenberg has subsequently recognized that empirical evidence for the thesis is mixed, while reasserting that downstream effects appear to "provide evidence that the hypothesized mechanism is indeed operating."[21]

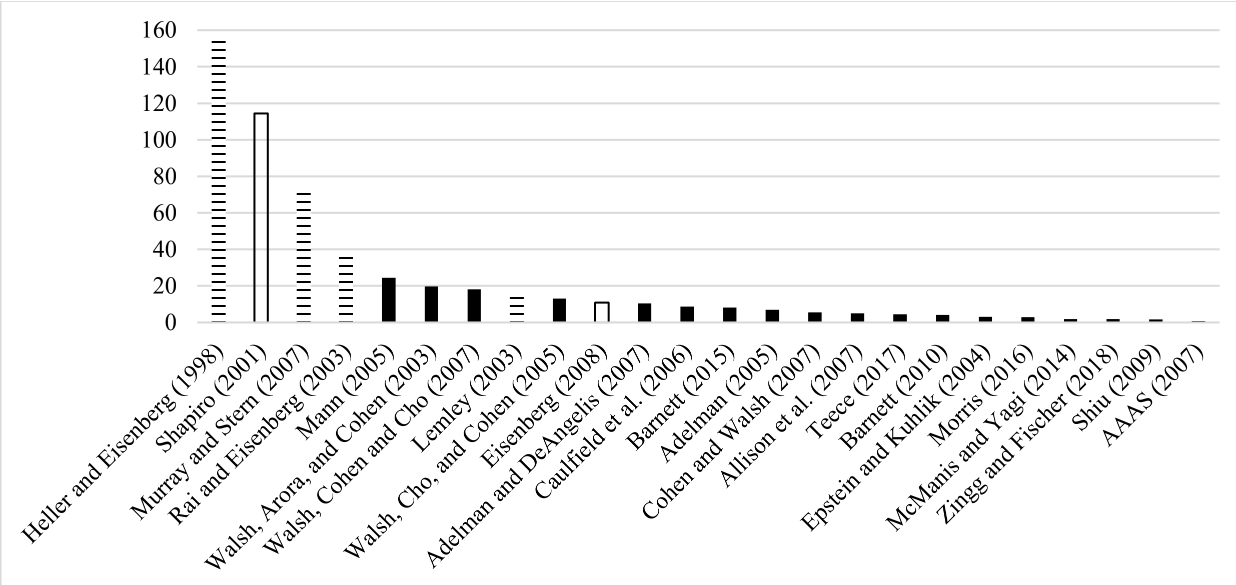
As shown in the Table below, the Heller and Eisenberg article, which merely raised a theoretical possibility that patents could deter innovation in the biomedical sector, has been cited far more often than empirical papers that have tested this theory against actual market practice and mostly found that it *mis*predicted how patenting would impact innovation and drug development in the biopharmaceutical ecosystem. Similarly, two papers that have made similar claims, although with greater qualifications[22], are cited significantly more often than other papers (some of which are peer-reviewed empirical studies) that have heavily qualified or rejected the anticommons thesis.

[20] For extensive discussion, see Barnett, *Big Steal, supra* note 12, at 171-78.

[21] Rebecca Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 Houston L. Rev. 1059, 1075-76 (2008).

[22] Fiona Murray & Scott Stern, *Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis*, 63 J. Econ. Behav. & Org. 648 (2007) (using patent-publication pairs methodology that assesses changes in citation frequency following issuance of a patent "paired" with a corresponding publication and finding evidence of a modest anticommons effect); Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting,* in 1 Innovation Pol'y & Econ. 119 (Adam B. Jaffe, Josh Lerner & Scott Stern eds., MIT Press 2001) (identifying potential anticommons effects in patent-intensive information technology markets but observing that markets sometimes address these effects through cross-licensing and patent-pooling arrangements).

Table 1: Citations to Leading Papers on the "Anticommons Effect" in the Biomedical Ecosystem (per-year, since publication) (as of Oct. 5, 2025)[23]



Legend: Dashed bars denote articles that advance the anticommons thesis; solid bars denote articles that present empirical evidence that contests or rebuts the anticommons thesis; blank bars with a solid border denote articles that moderately qualify the anticommons thesis.

The misplaced reliance on the Heller and Eisenberg paper by the scholarly literature would be nothing but an academic matter except for the fact that it has migrated into reports issued by government entities. As a result, it may ultimately have an impact on policy actions. As shown in the Table below, the paper has been cited in reports by the FTC, Department of Justice (DOJ), and Congressional Research Service (CRS), as well as reports commissioned by European Union entities, in connection with concerns that intensive patenting can impede innovation by burdening researchers and companies with litigation and licensing costs. Notably, reports by US governmental entities sometimes fail to discuss, or discuss fully, the empirical literature that has largely failed to find robust evidence for the anticommons thesis in the biomedical sector. Hence, policymakers who rely on these reports would have an incomplete understanding of the full body of empirical knowledge, would substantially overestimate the risks posed by patent protection to biomedical research, and may underappreciate the gains that patent protection may confer in facilitating the conversion of biomedical research into drugs and medicines.

[23] This Figure is an updated version of a Figure that appears in Barnett, *The Big Steal, supra* note 12, at 174 Fig. 8.5 (2024). For full citations to articles referenced in the Figure, see Appendix.

Table 2: References in US and EU Government Reports to the Anticommons Literature[24]

Year	Agency/Report	Cites Heller & Eisenberg?	Cites Contrary Empirical Evidence?
2003	FTC (IP/Innovation Report)	Y	N
2007	DOJ, FTC (IP/Antitrust Report)	Y	N
2007	EC (Strategic Use of Patents)	Y	Y
2019	CRS (Drug Pricing & IP)	Y	Y, but limited
2020	CRS (Drug Pricing & Pharmaceutical Patenting)	Y	Y, but limited
2023	EPRS (Improving Public Access to Medicines)	Y	Y
2024	CRS (Role of Patents & Regulatory Exclusivities in Drug Pricing)	Y	Y, but limited

Legend: CRS = Congressional Research Service; DOJ = Department of Justice; EC = European Commission; EPRS = European Parliamentary Research Service; FTC = Federal Trade Commission

B. The Case Against "Macro" Skepticism in IP Policy Analysis

Both the theoretical and empirical literature on the value and function of IP rights and other exclusivities in the biopharmaceutical markets can accommodate a range of economically plausible views concerning the appropriate design of IP rights in particular therapeutic areas. Yet the strong forms of skepticism that largely reject the value of meaningful levels of IP protection in biopharmaceutical markets in general, or characterize IP rights as principally a tool to extract monopoly rents or impede entry by generic competitors, are difficult to reconcile with several well-established findings in the empirical literature. Based on the empirical and historical record, theoretical models that recommend eliminating, or drastically weakening, IP rights in biopharmaceutical innovation are unlikely to provide a sound basis for constructive policy design and, of even greater concern, may recommend policy actions that can do significant damage to the funding and incentive structures that sustain the development of new drugs and medicines that ultimately promote human well-being.

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[24] Sources: Fed. Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* 132–33, n.142 (2003); U.S. Dept. of Justice & Federal Trade Commission *Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition* 98–101, nn. 58–61, 70 (2007); Dietmar Harhoff et al., *The Strategic Use of Patents and Its Implications for Competition* 74-75 (Report for the European Commission, DG Competition 2007); Kevin J. Hickey, Erin H. Ward & Wen W. Shen, Cong. Research Service, R45666, *Drug Pricing and Intellectual Property Law: A Legal Overview for the 116th Congress* 15 n.139 (Apr. 12, 2019); Cong. Research Service, R46221, *Drug Pricing and Pharmaceutical Patenting Practices* 24 n.236 (Feb. 11, 2020); European Parliamentary Research Service, *Improving Public Access to Medicines and Promoting Pharmaceutical Innovation* 9 (Study PE 753, 166, 2023); Kevin J. Hickey, Erin H. Ward & Wen W. Shen, Cong. Research Service, R46679, *The Role of Patents and Regulatory Exclusivities in Drug Pricing* 52 n.476 (updated Jan. 30, 2024).

1. *Cross-National Evidence*

Efforts to establish definitively a relationship between patent protection and domestic innovation in cross-country studies have often reached mixed results, with a range of findings in the empirical literature.[25] Yet this is not the case in the biopharmaceutical sector. Cross-country studies by Margaret Kyle, Yi Qian, and Anita McGahan generally observe that more developed economies that excel in pharmaceutical innovation provide strong patent protections for pharmaceuticals, while developed economies that lack those protections do not support original drug innovation and, at best, sustain generic drug production that relies on imitation.[26] Country-specific evidence of changes in patent protection for the biopharmaceutical sector in India and Japan find a similar relationship between robust IP rights and technological innovation**.** In 2005, India eliminated a ban on patent protection for pharmaceutical products, which was followed by a shift in investment from generic drug production to original drug development.[27] In Japan, the pattern holds but in reverse: following the imposition of pricing controls, which effectively limited the value of pharmaceutical companies' patent rights, the domestic industry's R&D investment declined and shifted toward lower-risk, incremental innovation.[28] While multiple factors impact capital investment in pharmaceutical R&D, it is striking that the same directional relationship occurred in each of these countries concurrently with changes in the strength of patent protections for drugs and medicines.

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[25] See, e.g., Brent P. Allred & Walter G. Park, *Patent Rights and Innovation: Evidence from National and Firm Level Data,* 38 J. Int'l Bus. Studies 878 (2007) (finding that effect of patent protection on rate of innovation depends on a country's level of economic development, finding a mix of adverse and positive effects on domestic innovation and attracting foreign innovation).

[26] Margaret Kyle & Yi Qian, *Intellectual Property Rights and Access to Innovation: Evidence from TRIPS*, NBER Working Paper No. 20799 (2014) (finding that adoption of stronger pharmaceutical patent protections under TRIPS tends to be associated with more frequent and earlier launches of new drugs); Yi Qian, *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection, 1978–2002,* 89 Rev. Econ. & Stat. 436 (2007) (finding that stronger pharmaceutical patent protection is positively associated with domestic pharmaceutical innovation (as measured by R&D investment and citation-weighted U.S. patent grants) in more developed countries that exhibit threshold levels of economic development, human capital, and economic freedom, but noting that overly strong protection may hinder subsequent innovation); Margaret Kyle & Anita M. McGahan, *Investments in Pharmaceuticals Before and After TRIPS,* 94 Rev. Econ. & Stat. 1157 (2012) (showing that adoption of patent protection in wealthy countries is associated with increased pharmaceutical R&D but observing no such relationship in developing countries for diseases prevalent in those countries).

[27] Ashish Arora, Lee G. Branstetter & Chirantan Chatterjee, *Strong Medicine? Patent Reform and the Transformation of the Indian Pharmaceutical Industry* 2–3, 24–25 (NBER 2008); Mark Duggan, Craig Garthwaite & Aparajita Goyal, *The Market Impacts of Pharmaceutical Product Patents in Developing Countries: Evidence from India*, NBER Working Paper No. 20548, at 1–2 (2014).

[28] Stephen Ezell, *How Japan Squandered Its Biopharmaceutical Competitiveness: A Cautionary Tale,* Information Technology & Information Foundation, July 25, 2022, https://itif.org/publications/2022/07/25/how-japan-squandered-its-biopharmaceutical-competitiveness-a-cautionary-tale/

2. *Business-Model and Advocacy Evidence*

If it were true that patents and other IP rights are not generally necessary to support drug development, then it would be expected that biopharmaceutical markets would exhibit a diversity of business models, some exhibiting reliance on IP rights while others did not. Yet that is not the case. Virtually all commercially successful business models in the biopharmaceutical industry exhibit significant reliance on patent protection and other legal exclusivities. In this respect, the biopharmaceutical industry differs from software-based segments of the information technology industry, where there is significant usage of business models that do not rely on formal IP rights to capture returns on innovation. This explains why, outside certain chip design and hardware segments, evidence on lobbying and advocacy shows most (and especially larger) firms in the information technology industry tend to advocate *against* stronger patent rights. By contrast, that same evidence shows that pharmaceutical firms, irrespective of size, as well as research universities, consistently advocate *for* stronger patent protections.[29] This reflects the prevailing view among virtually all stakeholders that actively fund or execute drug development—including large firms, small firms, nonprofit research institutions, and venture-capital investors—that new pharmaceutical products cannot be feasibly developed without robust IP protection, given the high risk of lower-cost and quality-equivalent imitation. Reflecting this consensus view among real-world industry participants, researchers have found that patent portfolios translate into higher success rates for biotech startups in securing funding from venture capitalists and angel investors.[30]

3. *Survey Evidence*

Surveys of large and small firms in the biopharmaceutical sector consistently find that managers report that robust IP protection is essential to invest in R&D and drug development. Across a multi-decade period encompassing the 1980s through the present, large-scale survey studies repeatedly find that firms in the biopharmaceutical industry report that patents are an essential mechanism to capture returns on R&D and are a "but for" condition for R&D investment in this sector.[31] Unlike information technology sectors where patents often tend to be more highly valued by smaller firms or by entities that use licensing-based monetization

[29] Barnett, *Big Steal, supra* note 12, at 46-48.
[30] Annamaria Conti, Jerry Thursby & Marie Thursby, *Patents as Signals for Startup Financing*, NBER Working Paper No. 19191 (2013); Carolin Haeussler, Dietmar Harhoff & Elisabeth Müller, *How Patenting Informs VC Investors—The Case of Biotechnology*, 43 Res. Pol'y 1286 (2014).
[31] Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 Mgmt. Sci. 173 (1986) (large firms); Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, in 3 Brookings Papers on Economic Activity: Special Issue on Microeconomics 783 (1987) (large firms); Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)*, *NBER Working Paper No. 7552* (2000) (large firms); Stuart J.H. Graham et al., *High-Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 Berkeley Tech. L.J. 1255 (2009) (small firms).

structures[32], the view that patents are a precondition for supporting R&D is almost universal in the biopharmaceutical ecosystem, encompassing firms and other entities irrespective of size, type, or business model.

4. Micro Policy Experiment: The Orphan Drugs Act

Given the range of potentially contributing factors, it is sometimes challenging to distinguish the incremental effect of IP protections on innovation incentives and investment.[33] The Orphan Drug Act of 1983 provides a targeted policy experiment that can provide insight into the empirical force of the standard proposition that increased IP protections drive increased R&D investment. The statute provides seven years of market exclusivity for drugs that treat rare disorders with small patient populations, instead of the standard three-to-five year market exclusivity periods for new chemical entities and new clinical investigations.[34] Several studies find that the additional period of market exclusivity under the statute was followed by increased R&D investment in orphan drug development, which was then followed by an increase in the number of FDA-approved orphan drugs. During 1983-2000, the number of orphan drugs increased from a handful to over 1,000 drugs in development and over 200 FDA-approved drugs.[35] Reflecting the relationship between patent strength and drug development, another study found that the percentage of drug approvals constituted by orphan drugs increased since enactment of the statute, rising from 17% during 1984-1988 (shortly after enactment) to 31% during 2004-2008.[36] These sharp increases in R&D and new drug releases following the introduction of strengthened IP protections illustrates the strong connection between IP rights, investment, and innovation in the biomedical ecosystem.

C. Toward a "Net Effects" Analysis of IP Rights in the Biopharmaceutical Ecosystem

These empirical regularities strongly suggest that IP rights in some meaningful form play a constructive and often essential function in the biopharmaceutical ecosystem. Nonetheless significant portions of the IP policy debate tend to focus on the observation that patents raise

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[32] For a review of this evidence, see Jonathan M. Barnett, *Innovators, Firms, and Markets: The Organizational Logic of Intellectual Property* 28-29, 128-133 (2021).

[33] For greater detail on the developments discussed in this section, see Jonathan M. Barnett, *Engines of Innovation: The Critical Functions of Intellectual Property in the Biopharmaceutical Ecosystem* 25-26 (Berkeley Policy Institute & Eira Initiative 2025), https://www.eirainititive.org/publications.

[34] On orphan drugs, see: 21 U.S.C. §§ 360aa-dd, 371; 316,2; 21 C.F.R. §§ 316.2, 316.31 (seven years of marketing exclusivity). On other small-molecule drugs, see 21 U.S.C. §§ 355(c)(3)(E)(ii); (j)(5)(F)(ii) (five years of marketing exclusivity for new chemical entity); 21 U.S.C. §§ 355(c)(3)(E)(iii)–(iv), (j)(5)(F)(iii)–(iv) (three years of marketing exclusivity for new clinical investigation).

[35] U.S. Dept. of Health & Human Services, Office of Inspector General, *The Orphan Drug Act: Implementation and Impact* (2001), OEI-09-00-00380 (May 2001), https://oig.hhs.gov/oei/reports/oei-09-00-00380.pdf.

[36] Timothy Coté et al., *Orphan Products: An Emerging Trend in Drug Approvals*. 9 Nature Reviews: Drug Discovery 84, 84-85 (May 2001), https://oig.hhs.gov/oei/reports/oei-09-00-00380.pdf

drug prices and therefore recommend policy actions to reduce those prices by weakening patent protections through compulsory licensing, price controls, march-in rights, reasonable-pricing requirements, international reference pricing, and other instruments.[37] As discussed, a few influential scholars even recommend outright abolition and reliance on governmental and philanthropic funding.

As a short-run observation, it is correct that patents and other IP rights typically enable drug innovators to raise the price of the protected innovation above marginal cost. Yet a long-term economic perspective recognizes that at least some of this price premium cannot be properly characterized as a social loss. In fact, at least a portion of the price premium is most appropriately characterized as a source of social *gain.* There are two reasons.

First, as discussed, there is significant evidence that patents and other forms of exclusivity promote investment in pharmaceutical innovation. This should not be surprising: the price premium generated by patent protection is *designed* to cure the imitation risk that would otherwise undermine incentives to invest in innovation in the relevant technology sector. Second, in the counterfactual world in which patents or other forms of exclusivity would not exist (and assuming that innovators had no other cost-effective mechanism to delay the entry of imitations), there would be no incentive for private capital to invest in developing new drugs. Hence, it is not especially informative to object to "high" prices in isolation without specifying an alternative and cost-comparable IP-free mechanism that would sustain the same or greater rate of innovation. While basic research is principally funded by governmental and philanthropic support, there is as yet no demonstrated business model that supports advanced product development, clinical testing, production and distribution without significant reliance on IP rights.

This is not to say that there are not, or could not plausibly exist, non-IP-dependent mechanisms in certain components of the biopharmaceutical innovation and commercialization lifecycle. This is also not to say that the design of a particular IP right could not be improved to achieve a superior tradeoff between incentives and access by altering duration, scope, or other parameters. IP rights in the biopharmaceutical sector are often customized to suit particular therapeutic sectors, such as the statutory protections for orphan drugs, biologics, and pediatric drugs.[38] Scholarship and commentary that recognizes the necessity in general of IP protection to sustain pharmaceutical innovation must take into account these opportunities for adjustment, especially in the context of technological changes that may alter the costs or time involved in executing certain components of the innovation and commercialization lifecycle.

Nonetheless the basic methodological point persists. Any practically relevant IP policy analysis that seeks to sustain the full innovation and commercialization cycle, and takes seriously the long-term contribution of innovation to economic growth and human well-being, cannot

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[37] For a review of these proposals, see Barnett, *Engines of Innovation, supra* note 33, at 33-40, 39-41.

[38] On data and marketing exclusivity for small molecules: 21 U.S.C. §§ 355(c)(3)(E)(ii); (j)(5)(F)(ii) (new chemical entity); 21 U.S.C. §§ 355(c)(3)(E)(iii)–(iv), (j)(5)(F)(iii)–(iv) (new clinical investigation). On data and marketing exclusivity for biologics: 42 U.S.C. § 262 (k)(7)(A)-(B). On marketing exclusivity for orphan drugs: 21 U.S.C. §§ 360cc(a); 21 C.F.R. § 316.31(a).

dismiss the value of IP rights in biopharmaceutical innovation without specifying some other equally or more efficient mechanism for achieving the same or superior result. That has not yet been done.

II. How IP Rights Create Value in the Biopharmaceutical Ecosystem

There is a strong factual case that IP protection tends to have a positive impact on the development of new drugs, even though it necessarily raises the price of existing drugs. Nonetheless, a significant portion of the scholarly literature and policy commentary tends to focus on the costs that patents impose upon users of existing drugs while paying substantially less attention to that gains patents generate by facilitating the development of new drugs that would not otherwise exist. In this Section, I illustrate the importance of this overlooked side of the incentives/access tradeoff. In particular, I describe the two key mechanisms through which patents and other legal exclusivities generate social value in innovation ecosystems and the biopharmaceutical sector. I then apply those mechanisms to explain why the widely-cited anticommons thesis has failed to predict real-world effects in the biopharmaceutical ecosystem.

A. The Dual Functions of IP Rights

The standard justification for IP rights is a simple incentive thesis. Following this thesis, IP rights provide a legal tool to deter imitation and, in doing so, enable innovators to capture a return on a new product or technology that would otherwise be easily imitated by competitors. Given that those competitors would not have incurred R&D costs comparable to the innovator, they could underprice the innovator and capture all returns so long as they can match the quality of the innovator's product. In this state of affairs, private investment in innovation would grind to a halt—an outcome predicted by Kenneth Arrow in the concise observation that innovation is incompatible with a perfectly competitive market.[39] When enforceable at a reasonable cost and likelihood of success, IP rights mitigate this expropriation risk by providing a "moat" that blocks imitators, who can only access the innovation at a price offered by the IP owner subject to competitive conditions in the relevant market. Unless innovators have some other mechanism to deter imitators, that price *must* be some measure above marginal cost to induce investment in innovation. Moreover, since only a minority of pharmaceutical R&D projects achieve clinical approval (8% on average, and ranging by therapeutic category from 3.6% to 23.9%, during 2011-2020[40]), the margin on the minority of successful projects must be *significant* to cure the

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[39] Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in *The Rate and Direction of Inventive Activity: Economic and Social Factors* 609, 619–20 (Nat'l Bureau of Econ. Research 1962)
[40] Biotechnology Innovation Organization, *Clinical Development Success Rates and Contributing Factors 2011-2020*, at 9-10 (2021).

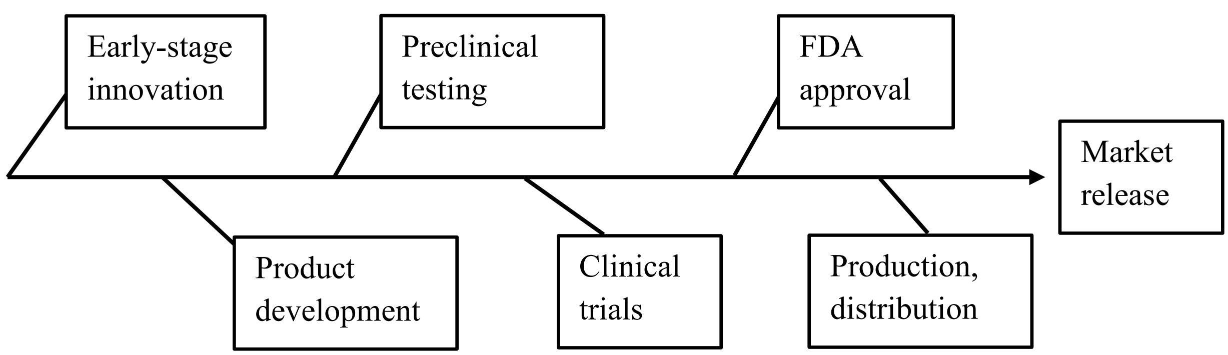
incentive shortfall that would otherwise discourage private investment in the biopharmaceutical sector.

The incentive theory has a great deal of empirical grounding in markets where it is easy for competitors to replicate an innovation at comparable quality. This is generally the case in pharmaceuticals, which explains why cross-national evidence, business-model evidence, lobbying evidence, survey findings, and sector-specific evidence all show that product development and commercialization in the pharmaceutical market almost universally relies on a robust IP portfolio. Yet the incentive theory *understates* the role of IP rights because it does not explain the transactional functions of IP rights in technology markets in enabling a rich sequence of non-innovation activities that lie between early-stage research and market release and are essential for unlocking the commercial and therapeutic value embedded in a new drug or medicine.

1. Commercialization, Expropriation Risk, and IP Rights

It is important to appreciate the full sequence of actions that must be undertaken to convert basic or applied research findings into a technically and economically feasible drug or medicine that can be cost-effectively produced and distributed to patients. As shown in the diagram below, these sequences include early-stage innovation, product development, clinical testing and regulatory approval, production (which may involve the development of new production methods), marketing and distribution. A firm requires sufficient talent, infrastructure, and capital to execute this sequence in full.

Figure 1: Innovation and Commercialization Pathway (Biopharmaceuticals)



Following the standard make/buy logic in institutional economics, a firm may elect to contract with a third party for any particular function in this sequence and will do so whenever that party can execute that function at a lower cost or higher quality than the firm.[41] The firm has an incentive to secure all necessary inputs at the lowest possible cost, adjusted for quality, and will therefore go outside the firm when other parties can more efficiently supply a particular input. This not only promotes the firm's private interest in minimizing its input costs (and increasing its profit margins), but the public interest in delivering products to market at the lowest cost possible, subject to technological constraints.

In innovation markets, this simple buy/make decision rule must be modified to reflect the risk that electing "buy" may sometimes expose the firm to the risk of knowledge leakage to a potential competitor, whether directly or indirectly.[42] Hence, expropriation risk arises not only in connection with the release of the new drug but potentially at every point in the supply chain leading up to that point. Absent some solution to this pre-release expropriation problem, a firm may be compelled to adopt a higher level of vertical integration than it would otherwise elect. This distorted firm structure not only injures the firm by increasing its input costs but ultimately hurts consumers by unnecessarily increasing total production, distribution, and other costs, resulting in higher prices, slower time-to-market, or both.

Just as IP rights and other exclusivity protections can mitigate expropriation risk upon market release, they can mitigate expropriation risk prior to market release. Hence, IP rights not only play an incentive function by deterring imitation following market release, but also an enabling function by permitting firms to engage in alliances, partnerships and other transactions with third parties that enable firms to construct maximally efficient commercialization sequences in the period leading up to market release. Put differently: IP rights promote not only technological, but also *transactional*, innovation.

2. How the Enabling Function Promotes Innovation and Competition

The enabling function is a powerful and overlooked effect of IP rights and other legal exclusivities that permits firms to engage freely in transactional design in response to changes in the legal, technological, and business environment that impact expropriation risk. This has two positive effects as a matter of both innovation and competition policy.

First, if IP rights enable firms to construct and adapt transactional structures to reflect expropriation risk in specific markets, then firms can minimize input costs by sourcing each step in the commercialization sequence from the lowest-cost supplier and, subject to competitive conditions, pass on those cost-savings to consumers. This suggests that, contrary to intuitions, the absence or incompleteness of IP rights can sometimes *increase* prices by compelling firms to

[41] For the classic treatment, see Oliver E. Williamson, *The Vertical Integration of Production: Market Failure Considerations*, 61 Am. Econ. Rev. 112 (1971); Oliver E. Williamson, *Markets and Hierarchies: Analysis and Antitrust Implications* (1975).
[42] For further discussion of the points covered in the rest of this subsection, see Barnett, *Innovators, Firms, and Markets, supra* note 32, at 9–14, 35-40, 183-87; Barnett, *Intellectual Property as a Law of Organization, supra* note 7, at 809-811, 838-853.

operate under excessively integrated commercialization structures to hedge against knowledge leakage.

Second, firms' ability to engage in any degree of vertical integration—or dis-integration—under robust IP protection can have favorable effects on competition by effectively lowering the barriers faced by certain firms to convert an innovation into a feasible product for market release. Specifically, IP rights can enable a firm to enter solely at the innovation or early product-development stage of the innovation and commercialization supply chain while entering into relationships with outside providers to secure every other input required to reach market release. Again contrary to intuitions, robust IP rights can have a positive impact on competitive conditions by lowering entry costs and, to the extent that smaller firms are sometimes most adept at undertaking disruptive forms of innovation[43], a positive impact on innovation performance. As I will now explore, the role of small firms in the biopharmaceutical ecosystem has been especially critical in promoting "breakthrough" (as distinguished from incremental) innovations.

B. Lessons from the Biotech Market: Theory v. Reality in IP Policy Analysis

In the 1998 *Science* essay, Heller and Eisenberg had cautioned against the extension of patent protection into the biomedical ecosystem, expressing concern that it may suppress innovation by burdening innovators with litigation and licensing costs. As discussed above, this essay has generated a follow-on literature that emphasizes the alleged costs that arise from anticommons effects in biomedical innovation. For the most part, that follow-on literature is theoretical or anecdotal, while, as other scholars have observed, the empirical literature finds little evidence for the thesis when tested in real-world markets.[44] The mismatch between prevailing "expert" views, especially in the legal academic and policy literature, grows still further in light of actual developments in the biotech market before and after the 1998 publication of the *Science* article.

1. IP Rights and the Biotech Revolution

In the early 1980s, several steps took place that provided a robust IP foundation for the then-nascent US biotech industry: the Supreme Court upheld the "Chakrabarty" patent over a genetically engineered microorganism[45], Congress enacted the Bayh-Dole Act, which permitted

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[43] For evidence on this point, see Barnett, *Innovators, Firms, and Markets, supra* note 32, at 41-61; Barnett, *Intellectual Property as a Law of Organization, supra* note 12, at 809-811, 838-853.

[44] John P. Walsh, Ashish Arora & Wesley M. Cohen, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in Patents in the Knowledge-Based Economy 285, 285–87 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) (reporting that empirical data show "little evidence" of pervasive blocking effects as anticipated by the anticommons thesis); David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: Measuring the Impact of Patents on Innovation in the Biotech Industry*, 85 Tex. L. Rev. 1677, 1680–81 (2007) (noting that the anticommons thesis rests largely on theory and anecdote, while empirical evidence does not show significant blocking effects in biotech). See also *supra* notes 19-21 and 44 and accompanying text.

[45] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)

universities and other entities to patent the results of federally funded research[46], and the US Patent & Trademark Office issued the "Cohen-Boyer" patent for recombinant DNA technology.[47] While European countries wavered on extending patent protection to this sector (which may have discouraged investment)[48], academic scientists formed startups and investment flowed into the biotech industry in US clusters such as Boston, San Diego, and the Bay Area. Established in 1976, Genentech, a startup founded by Herbert Boyer (one member of the team behind the Cohen-Boyer patent), and working in partnership with Eli Lilly, released the first FDA-approved biotech drug (synthetic human insulin) in 1982.[49] This landmark sequence of transactions set the IP-anchored and VC-fueled structural template for the biotech industry. Equipped with patents that could be reliably enforced in federal court (especially in light of decisions by the newly established Federal Circuit[50] that had expanded protections for patent owners[51]), startups could attract VC investment to fund product development, and then enter into testing, production and distribution partnerships with large pharmaceutical companies.

Patents stood, and still stand, at the heart of the biotech revolution—both a technological and transactional development—that has yielded thousands of drugs and therapies from its origins in the Cohen-Boyer recombinant DNA technology and through the present. Far from hindering innovation, as the anticommons literature has alleged, the economic and technical success of the industry following the extension of patent protection to biotechnological inventions reflects how patents promote not only innovation but also competition through the incentive and enabling functions of IP rights. This vividly illustrates the "missing side" of the policy coin that is largely ignored in skewed policy discussions that focus mostly on costs without considering the gains generated by IP-enabled innovation and commercialization investments and relationships.

Consistent with the incentive thesis, patents enabled a startup like Genentech, and its large-firm partner, Eli Lilly, to capture returns on the millions of dollars that had been invested in the development, testing, and production of synthetic human insulin. In turn, the success of this product set a precedent that enabled other startups to attract funding from investors who could have some reasonable confidence that, so long as the startup had built a robust patent portfolio, returns would be enjoyed if the development process yielded a successful drug. Consistent with the enabling thesis, patents facilitated the development of novel transactional structures in the biopharmaceutical ecosystem. During several decades following the end of World War II, US pharmaceutical firms had mostly operated under vertically integrated structures in which the firm

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[46] Bayh–Dole Act, Pub. L. No. 96-517, §§ 200–211, 94 Stat. 3015, 3019–28 (1980) (codified as amended at 35 U.S.C. §§ 200–212).
[47] U.S. Patent No. 4,237,224 (filed June 7, 1974, issued Dec. 2, 1980).
[48] Alexander von Gabain and Werner Lanthaler, *European biotech hasn't hit the street,* 4 EMBO Reports 642 (2003); David S. Scalise & Daniel Nugent, *Patenting Living Matter in the European Community,* 16 Fordham Int'l L. J. 990, 991-92 (1993).
[49] Barnett, *Innovators, Firms, and Markets, supra* note 32, at 120.
[50] Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25.
[51] See, e.g., *Smith Int'l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1581–82 (Fed. Cir. 1983) (reversing denial of injunction and emphasizing that, absent extraordinary circumstances, "an injunction should issue once infringement has been established and its validity sustained").

maintained a complete pipeline from lab to market.[52] The biotech revolution implemented a new transactional template for converting life-sciences research into pharmaceutical products through disaggregated supply chains. In the language of institutional economics, the biotech industry mostly elected "buy" over "make," largely reversing the vertically integrated structures that had predominated in the industry. While certain technological factors facilitated this organizational change, it was enabled by the availability of secure IP rights to protect a biotech firm's crown-jewel knowledge assets against the risk of expropriation both before and after market release.

2. Patents, Transactional Freedom, and Competitive Markets

Transactional freedom in general, and vertical disaggregation in particular, has favorable effects on competitive conditions since it is less costly to enter the biopharmaceutical market only in the innovation segment of the supply chain, without having to incur the costs involved in integrating forward into testing, production, and distribution. (Estimates of the average cost (including clinical testing and capital costs) to develop a new drug through market launch are $2.56 billion including expenditures on failed projects.[53]) This is not a hypothetical claim. As noted, the US pharmaceutical industry had been dominated during the postwar decades by a small number of large vertically integrated companies, with almost no cases of successful entry.[54] Following 1980, which can be used as a benchmark year during which IP protections for biotechnological innovations were strengthened, the pharmaceutical industry experienced significantly accelerated rates of entry and industry composition diversified to encompass thousands of small biotech firms. By 1997, the Department of Commerce reported that there were over 1,300 biotech companies in the US, with an average number of 150 employees and a median number of only 30.[55] Today that number is estimated to be in excess of 3,000.[56]

Startups and other emerging biopharma firms continue to play a vital role in the US ecosystem, representing a majority of the current US drug pipeline. Emerging firms (defined as firms with less than $500 million in sales per year and R&D spending below $200 million per year) were responsible for 59% of new drugs (specifically, novel active substances) during 2020-2024 and 53% during 2015-2019.[57] While various technological and business factors contribute to the centrality of startups and smaller firms in the biopharmaceutical ecosystem, the exclusivity period provided by robust IP protections sustains incentives for venture-capital investment and enables the partnerships and related transactional structures without which these firms would

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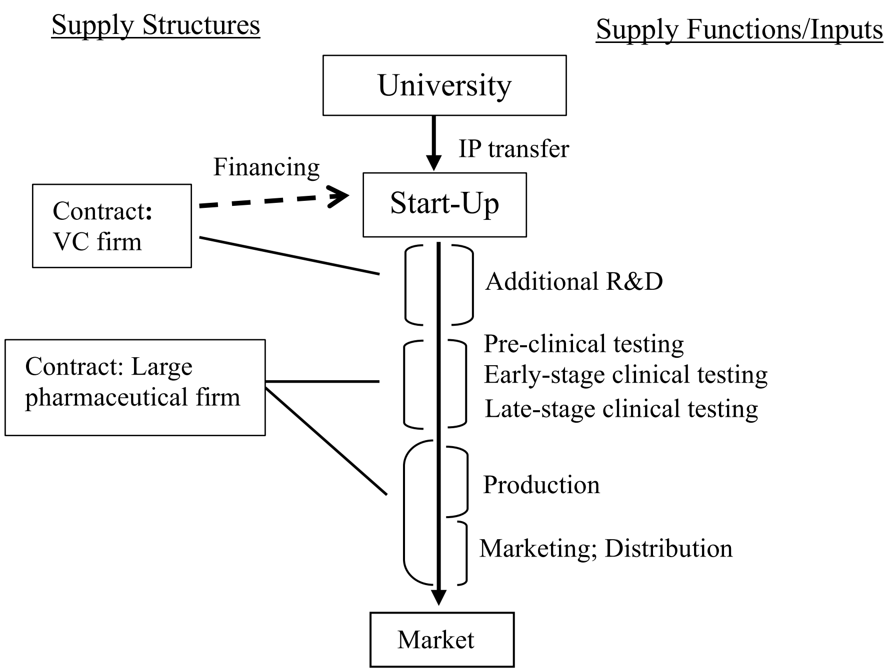
[52] Barnett, *Innovators, Firms, and Markets, supra* note 32, at 115, 118.
[53] Joseph DiMasi, Henry G. Grabowski & Ronald W. Hansen. *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 25 (2016).
[54] *See supra* note 52.
[55] Jon Paugh & John Lafrance, U.S. Dept. of Commerce, Office of Technology Policy, *Meeting the Challenge: U.S. Industry Faces the 21st Industry: The U.S. Biotechnology Industry* 10 (1997).
[56] IBISWorld, *Biotechnology in the US* (2015-2030) (last updated Aug. 2025).
[57] IQVIA, *supra* note 6, at 54.

often be unable to reach market release. As shown in the Figure below[58], a robust patent portfolio enables innovators to negotiate comfortably with VC investors, who provide capital, and large pharmaceutical firms, who supply testing, production and distribution expertise, equipment, and personnel. Without patents, the expropriation problem would reemerge and biotech innovation in a small-firm environment would likely have been infeasible, forcing innovation to again take place within the confines of large vertically integrated corporations. That would be an inferior outcome from the perspective of both innovation and competition policy.

Figure 2: Vertical Disaggregation in the Biotech Supply Chain



Note: Adapted from Barnett, *Innovators, Firms, and Markets, supra* note 32, at 118, Fig. 6.1.

This institutional history is overlooked in the follow-on literature to the anticommons thesis, which tends to focus on the manner in which patents can inhibit innovation in the biomedical ecosystem.[59] The skeptical view reflected by this literature bears little resemblance to the evolution of the real-world biotech market over several decades during which time patenting has

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[58] This Figure is adapted from a figure that appeared in Barnett, *Innovators, Firms, and Markets, supra* note 32, at 118.

[59] See, e.g., Rachel E. Sachs, *The Uneasy Case for Patent Law*, 117 Mich. L. Rev. 499, 505 n.23 (2018) (referencing Heller & Eisenberg paper for concerns that patents, including patents on research tools, may impede follow-on research); W. Nicholson Price II, *The Cost of Novelty*, 120 Colum. L. Rev. 769, 792 n.132 (2020) (referencing Heller & Eisenberg paper for theoretical proposition that intellectual property protection on gene patents can block subsequent innovation).

been a ubiquitous tool in the industry. During that time, patents mostly appear to have facilitated the commercialization of biomedical innovation by structuring the flow of information among parties with complementary innovation and commercialization capacities. By 1998, the year in which the Heller-Eisenberg essay was published, the biotech experiment had already shown strong indications of success, which would seem to suggest that widespread use of patents in the industry was promoting, rather than hindering, innovation. The same is true of the subsequent post-1998 development of the industry, as indicated by the empirical literature that generally fails to find support for the thesis[60], and the economic and technical success of the industry, as measured by (among other data) the entry of new firms and FDA approval of new biotechnology products.[61]

The mismatch between prevailing theory in much of the academic literature on the role of IP rights in biomedical innovation[62] and the actual performance of the biotech industry illustrates the skewed conclusions that can be drawn by an approach to IP analysis that overlooks real-world markets and relies principally on theoretical models or anecdotal examples. A closer look at actual performance in the biotech industry shows that patents have usually promoted, rather than suppressed innovation that enhances human well-being. The truncated characterization of the role of IP rights in drug development (specifically, the financing and coordination of drug development) that persists in much of the scholarly literature and policy commentary casts doubt on recommendations to limit IP rights that rely on that characterization. Of course this does not at all exclude consideration of modifications to certain features of IP rights and other exclusivities that can improve access to existing drugs without unduly discouraging investment in the innovation of new and improved drugs.

Conclusion

There is a largely uncontroversial case that IP rights or other legal exclusivities of some meaningful type generally play important incentive and enabling functions in converting biomedical innovation into technically and economically viable drugs and other therapies that can improve human well-being. This position rests on compelling theoretical and factual grounds.

As a matter of theory, it is self-evident that investors in biopharmaceutical innovation must expect a positive risk-adjusted return or capital will be shifted elsewhere. This is as true for a biotech startup as for a large pharmaceutical company, which must seek external capital or is reliant on retaining the capital invested by existing shareholders. Given the ease with which at least some biopharmaceutical innovations can be reverse-engineered, some meaningful form of legal exclusivity is generally necessary to prevent free-riding that would otherwise destroy

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[60] *See supra* notes 19-21 and 44 and accompanying text.
[61] *See supra* notes 55-55 and accompanying text.
[62] On this point, see Jonathan M. Barnett, *The Anti-Commons Revisited*, 29 Harv. J. L. & Tech. 127, 129–30 and n.4 (2015); David J. Teece, *The "Tragedy of the Anticommons" Fallacy: A Law and Economics Analysis of Patent Thickets and FRAND Licensing*, 32 Berkeley Tech. L.J. 1489, 1501–02, 1509 and nn. 84–88 (2017).

rational investment incentives. As a matter of empirical evidence, the relevant literature, supplemented by several decades of industry performance, has produced repeated findings, including cross-country evidence, survey evidence, industry expectations, and sector-specific evidence, that are consistent with the theoretical case for meaningful IP protection in the biopharmaceutical industry.

In light of these theoretical and empirical considerations, it would appear that constructive inquiry in IP policy analysis in the biomedical ecosystem is best targeted at the "micro" level concerning specific elements of the patent system or other forms of legal exclusivity granted to drug innovators, rather than at the "macro" level concerning whether IP rights or other exclusivities for pharmaceutical inventions should exist at all. Theoretical discussions concerning the necessity of legal exclusivity to sustain biopharmaceutical innovation is unlikely to yield policy recommendations that constructively navigate the policy tradeoff between incentives and access. The residual space of practically relevant and factually supported policy recommendations concerning IP policy in the biomedical ecosystem accommodates a rich debate over the "micro" elements of IP policy design while sharing common ground concerning the "macro" case for some form of legal exclusivity in general.

Appendix: Leading Articles on the Anticommons Thesis

Articles that support the anticommons thesis, or support with limited qualifications:
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Rebecca S. Eisenberg, Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research, 45 Hous. L. Rev. 1059 (2008).

Mark A. Lemley, Patenting Nanotechnology, 58 Stan. L. Rev. 601 (2005)

Fiona Murray & Scott Stern, Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis, 63 J. Econ. Behav. & Org. 648 (2007).

Arti K. Rai & Rebecca S. Eisenberg, Bayh-Dole Reform and the Progress of Biomedicine, 66 Law & Contemp. Probs. 289 (2003).

Carl Shapiro, Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting, in 1 Innovation Pol'y & Econ. 119 (Adam B. Jaffe, Josh Lerner & Scott Stern eds., MIT Press 2001).

Articles that reject, or substantially qualify, the anticommons thesis:

David E. Adelman, A Fallacy of the Commons in Biotech Patent Policy, 20 Berkeley Tech. L.J. 985 (2005).

David E. Adelman & Kathryn L. DeAngelis, Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate, 85 Tex. L. Rev. 1677 (2007).

John R. Allison, Abe Dunn & Ronald J. Mann, Software Patents, Incumbents, and Entry, 85 Tex. L. Rev. 1579 (2007).

Am. Ass'n for the Advancement of Sci., International Intellectual Property Experiences: A Report of Four Countries (2007).

Jonathan M. Barnett, The Illusion of the Commons, 25 Berkeley Tech. L.J. 1751 (2010).

Jonathan M. Barnett, The Anti-Commons Revisited, 29 Harv. J.L. & Tech. 127 (2015).

Timothy Caulfield et al., Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies, 24 Nat. Biotechnol. 1091 (2006).
Wesley M. Cohen & John P. Walsh, Real Impediments to Academic Biomedical Research, 8 Innov. Pol'y & Econ. 1 (2007).
Richard A. Epstein & Bruce N. Kuhlik, Is There a Biomedical Anticommons?, 27 Regulation 54 (2004).
Ronald J. Mann, Do Patents Facilitate Financing in the Software Industry?, 83 Tex. L. Rev. 961 (2005).
Charles R. McManis & Brian Yagi, The Bayh-Dole Act and the Anticommons Hypothesis: Round Three, 21 Geo. Mason L. Rev. 1049 (2014).
Emily Michiko Morris, The Irrelevance of Nanotechnology Patents, 49 Conn. L. Rev. 499 (2016).
Chester J. Shiu, Of Mice and Men: Why an Anticommons Has Not Emerged in the Biotechnology Realm, 17 Tex. Intell. Prop. L.J. 413 (2009).
David J. Teece, The "Tragedy of the Anticommons" Fallacy: A Law and Economics Analysis of Patent Thickets and FRAND Licensing, 32 Berkeley Tech. L.J. 1489 (2017).
John P. Walsh, Ashish Arora & Wesley M. Cohen, Effects of Research Tools Patents and Licensing on Biomedical Innovation, in Patents in the Knowledge-Based Economy 285 (Wesley M. Cohen & Stephen A. Merrill eds., Nat'l Academies Press 2003).
John P. Walsh, Charlene Cho & Wesley M. Cohen, View from the Bench: Patents and Material Transfers, 309 Science 2002 (2005).
John P. Walsh, Wesley M. Cohen & Charlene Cho, Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research, 36 Res. Pol'y 1184 (2007).
Raphael Zingg & Marius Fischer, The Nanotechnology Patent Thicket, 20 J. Nanoparticle Res. 267 (2018).