EIRA INITIATIVE

INNOVATION ENGINE:

THE CRITICAL FUNCTIONS OF INTELLECTUAL PROPERTY IN THE BIOPHARMACEUTICAL ECOSYSTEM

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ICP Analytics produces evidence-based research and analysis to inform factually and economically-informed development of innovation and competition policy. The report is based on information available through November 2024.

Prof. Barnett is the Torrey H. Webb Professor of Law at the University of Southern California, Gould School of Law, and President of ICP Analytics LLC, an independent research consultancy. He is the author of *The Big Steal: Ideology, Interest, and the Undoing of Intellectual Property* (Oxford University Press 2024) and *Innovators, Firms, and Markets: The Organizational Logic of Intellectual Property* (Oxford University Press 2021), and a co-editor of *5G and Beyond: Intellectual Property and Competition Policy in the Internet of Things* (Cambridge University Press 2023). He has published widely in scholarly and other journals on intellectual property, antitrust, and innovation-related legal, economic, and policy issues.

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EXECUTIVE SUMMARY

Pharmaceutical[1] innovation has been responsible for revolutionary improvements in public health that have saved billions of lives, enhanced human well-being and quality of life, and longevity, and made substantial contributions to economic growth.

This historical record of innovation success relies on a delicate balance between two key elements: public funding for basic research and private funding for drug development, production, and distribution. Drug development relies on a secure patent portfolio and complementary forms of regulatory exclusivity to protect billions of dollars annually in R&D investment against potential free-riding by imitators. The prospect of a positive return in the unlikely event of project success enables innovators to access the capital markets to fund the costly, lengthy, and uncertain process of pharmaceutical innovation. Without patents and other forms of legal exclusivity, it would be implausible to expect significant if any returns for biopharmaceutical innovators (and investors in innovators) in the face of unimpeded imitation.

This proposition is almost universally accepted by firms, investors, and research institutions that have placed at risk infrastructural levels of financial, intellectual, and human capital in the biopharmaceutical industry. Industry practitioners view patents and other forms of legal exclusivity as a necessary tool to enable licensing and other transactions that facilitate cooperative value-enhancing relationships among a wide range of nonprofit and for-profit entities. Yet this view is rejected or treated with deep skepticism by some portions of the academic, public health, and policymaking communities. Some scholars, advocates, and policymakers cast doubt on the necessity of patents in the biopharmaceutical ecosystem and have called for significant limitations on patents or, in some cases, outright abolition.[2] For these commentators, patents are generally characterized as a burdensome "monopoly tax" that does nothing but limit access to existing medicines and stifle the development of new medicines.

To inform this policy conversation with a practical awareness of the business realities of biomedical research and drug development, this report draws on empirical and historical evidence to describe the functions played by patents and related forms of regulatory exclusivity across the biopharmaceutical innovation timeline. Those functions range chronologically from basic research through drug development, clinical testing, FDA approval[3], market release (including production, marketing, and distribution), and post-release FDA safety monitoring. More broadly, the innovation timeline encompasses subsequent research (by the same or other entities) that develops improvements and new uses of existing medicines. This report does not purport to provide a comprehensive survey of the relevant theoretical and empirical literature, which would require a book-length treatment. Rather, this report presents a policy-oriented perspective on the role of IP rights (including patents and regulatory exclusivities) in the pharmaceutical ecosystem that has been

[1] In this report, the terms, "pharmaceutical" and "biopharmaceutical," are used interchangeably unless otherwise indicated.
[2] See, e.g., Boldrin and Levine 2008; Stiglitz 2008.
[3] All new pharmaceutical products regulated by the Food, Drug, and Cosmetics Act require approval for sale and marketing by the Food & Drug Administration (FDA). All biologics products require a "license" from the FDA under the Public Health Service Act § 351(a) (codified at 42 U.S.C. § 262(a)). This report uses the term, "FDA approval," to refer to both regulatory actions.

overlooked in much of the scholarly and policy discussion, supported by representative findings from the empirical and practitioner literature.

The Core Functions of IP Rights in the Biopharmaceutical Ecosystem

This report explains how patents and related forms of regulatory exclusivity play three critical functions in the biopharmaceutical ecosystem that cannot be easily replicated by other legal or policy instruments or non-IP-dependent business strategies. Contrary to characterizations that often underlie discussions of patent policy in the pharmaceutical sector, those functions—operating concurrently and symbiotically with public funding and other policy instruments—promote innovation, entrepreneurship, and competition.

Incentive Function. The pharmaceutical industry is uniquely characterized by exceptionally high R&D costs, a large gap between the costs of innovation and imitation, a long period of product development through market release, and a high rate of project failure. Given these challenging conditions, innovators will not rationally undertake (and investors will not rationally fund) a drug development project without a reasonable expectation that a technically viable and commercially successful drug will be protected against copying by imitators that do not incur comparable costs and risks. To mitigate this concern, the patent system provides a time-limited form of legal exclusivity that covers the inventive contribution as described in the patent claims. The disclosure set forth in the patent may facilitate the ability of potential competitors to develop drugs and medicines in the same or adjacent product segments that lie outside the bounds of the patent claims and potentially compete with the original patented drug.

Investment Function. Patents and other forms of regulatory exclusivity are necessary to elicit the significant capital required to sustain the drug development, testing, and commercialization process from start to finish. Without the ability to secure funds from investors, the pharmaceutical industry cannot sustain the costly and lengthy process of innovation and commercialization. Given the large disparity between the costs of drug development and the costs of replicating an existing drug, investors will not place capital at stake without a reasonable period of legal exclusivity. This is especially the case in the U.S. market since the regulatory apparatus that governs the pharmaceutical industry includes mechanisms to facilitate entry by generic producers, which are relieved from most of the clinical testing costs borne by the brand-name innovator.

Transactional Function. Patents enable partnerships, alliances, and other inter-firm relationships that implement an efficient division of labor between smaller firms, which tend to excel in product innovation, and larger firms, which tend to excel in capital-intensive testing, production, and distribution functions. Without a secure patent portfolio, it would be difficult to structure the flow of valuable information without exposing the innovator entity to the risk of expropriation by a larger business partner with an existing production and distribution infrastructure. Relatedly, patents' enabling function in promoting these relationships implies that patents can facilitate entry by smaller R&D-intensive firms that would otherwise lack the technical expertise or capital resources to execute independently the commercialization tasks that are necessary to reach market.

How IP Rights Support Innovation, Entrepreneurship, and Competition

The three complementary functions of patents and related forms of regulatory exclusivity work together to promote innovation, entrepreneurship, and competition in the biopharmaceutical ecosystem. The historical evolution of the biotech industry illustrates this proposition.

As the biotech industry emerged in the late 1970s and early 1980s, the U.S. was the first jurisdiction to definitively extend patent protection to research tools and genetically engineered drugs and treatments in this sector.[4] During this same period, Congress enacted the Bayh-Dole Act[5], which lifted legal restrictions on patenting inventions developed using federal research funds. Since then, biotech innovators have delivered a steady flow of new drugs and treatments, often originated by scientist-founded startups that are funded by venture-capital investors and partner with larger pharmaceutical firms to execute the commercialization process. This is an industry in which expanding patent coverage both promoted innovation and lowered entry barriers. Given the close link between patents, innovation, and competition in the biopharmaceutical industry, there must be caution when contemplating policy actions that would limit the strength of patents or other forms of legal exclusivity, which are necessary to secure the investment capital and business relationships required to convert innovations into viable drugs and treatments.

The Incentives/Access Balance

Public health policymakers appropriately pay close attention to ensuring broad access to existing drugs and treatments and are therefore sensitive to pricing levels in pharmaceutical markets. However, an exclusive focus on the prices of existing drugs can yield short-sighted intellectual property policies that overlook the incentive and transactional structures that are necessary to maintain a steady flow of new drugs going forward. The result would likely be a decrease in pharmaceutical innovation and, as a result, a decline over the medium to long term in human well-being and economic growth. Put differently: while reduced patent protection might increase access to existing drugs and treatments, it likely results in reduced access to new drugs and treatments, which are either never developed or distributed in markets with more secure exclusivity protections. (As discussed subsequently in Part 5.2, there is evidence that European jurisdictions with weaker effective patent protections due to price controls suffer from reduced access to new drugs.)

To illustrate the adverse impact on innovation and commercialization that can arise in a weak-IP regime, the report considers the relationship between academia and industry during the decades preceding enactment of the Bayh-Dole Act in 1980. During this somewhat overlooked period in U.S. innovation policy, a governmental or academic entity generally could not patent, or exclusively license, inventions arising out of federally funded research. This was motivated by the principle that taxpayers should "not pay twice" for federally funded invention. Yet the consequence was self-defeating: the bulk of federally funded research reportedly was undeveloped since private industry was typically uninterested in

[4] *Diamond v. Chakrabarty,* 447 U.S. 303 (1980). For discussion, see Daily and Kieff 2013, at 978.
[5] 35 U.S.C. §§ 200-212.

making the investments required to cultivate technologies in which clear ownership interests in the underlying intellectual property could not be secured.[6]

Why IP Policy Matters

There are high economic and public-health stakes in getting "IP policy right" in the biopharmaceutical industry. As of 2021, the biopharmaceutical industry contributed 1.53% of U.S. GDP and 9.94% of the manufacturing industry's contribution to U.S. GDP (in each case, on a value-added basis).[7] As of the same year, it is estimated that the biopharmaceutical industry employed 291,033 workers and indirectly supported the employment of an additional 495,558 workers at suppliers and other firms in the industry supply chain.[8] Since 2004, publicly traded pharmaceutical companies have exhibited each year the highest rate of R&D intensity (R&D expenditures as a percentage of net revenues) among all major U.S. tech industries—averaging about 19% during this period and approaching 25% since 2017.[9] This high rate of R&D spending has been accompanied by an accelerating flow of new drugs: during 2010-2019, 38 new drugs were approved each year on average by the FDA, representing a 60% increase relative to the previous decade.[10] As this report shows, secure intellectual property rights are a key element in the policy and regulatory environment that supports these achievements.

[6] Barnett 2021b, at 81.
[7] Stooner and Durta 2023, at 15-16.
[8] Id., at 14.
[9] Congressional Budget Office 2021, at Figs. 1, 5.
[10] Id., at 5, 7.

PART 1. THE INNOVATION DILEMMA

The "incentive case" for the patent system is well-known. Without a secure property right, innovators and investors will have no rational motivation to invest in technological innovation that can be copied by competitors who bore none of the costs and risks of research, development, and commercialization. From an economic perspective, it is somewhat puzzling that some commentators and policymakers seem to be so firmly convinced that patents are unnecessary to support innovation and investment incentives in the biopharmaceutical sector. Among all innovation markets, the technological and economic characteristics of the biopharmaceutical industry provide the *strongest* empirical support for the incentive case for patents and other forms of legal exclusivity.

1.1 The Innovation Incentive Dilemma

Markets that rely on technological innovation often suffer from an incentive dilemma. Unlike land and other physical goods, technological discoveries can sometimes be easily imitated by competitors. Assuming the imitator incurs fewer research and development costs than the innovator, it can underprice the pioneer of a successful innovation and capture the returns for itself. Without a solution to this incentive dilemma, no rational innovator would undertake the research and development necessary to develop new technologies and no investor would be willing to place at risk the capital necessary to support research and development.

Broadly speaking, there are three imperfect (and complementary) solutions to this incentive dilemma.

Secrecy. The incentive dilemma will disappear or be mitigated if the innovator can maintain secrecy over the technology or take other steps, whether through contractual or technological instruments, to preclude or delay imitation. This solution is imperfect because it does not allow the innovator to share its technology freely with prospective investors or other business partners (which may impede or preclude valuation and negotiation discussions) or may require it to undertake costly and inconvenient contractual or technological precautions to maintain secrecy. In the pharmaceutical context, a secrecy-based business model is generally not a viable strategy due to the required disclosure of information in the clinical testing process and a generic firm's ability to reverse engineer a drug's chemical composition[11] (although, as discussed subsequently in Part 2.1, secrecy can have greater relevance in the biologics sector).

Intellectual Property. The incentive dilemma will disappear or be mitigated if the state provides a secure intellectual property right, or some other form of exclusivity, that enables the innovator to take legal action against imitators or other unauthorized users. Assuming originators can expect to secure injunctive relief and a meaningful damages award at a reasonable cost and within a reasonable time period, this solution can deter potential imitators and preserve rational incentives to innovate (and invest in innovators). This solution is nonetheless imperfect because it inherently raises the price to access, or otherwise make use

[11] Lakdawalla 2018.

of, a technological innovation, as compared to the price that would prevail if there were no legal barriers to imitation and competitors could freely replicate the innovation.

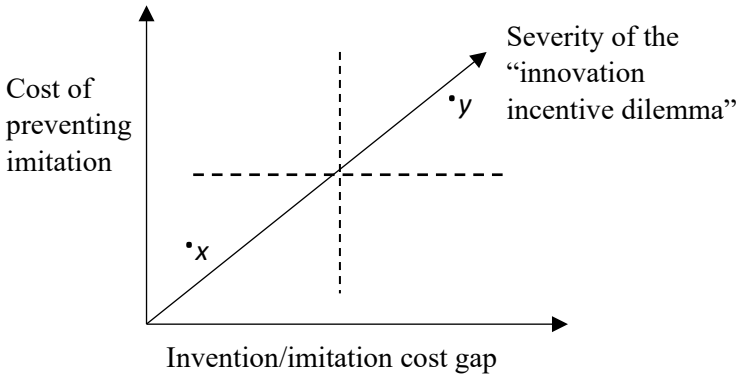
Public Funding. The state can provide funding to support innovation and preserve incentives to innovate even in the absence of the expected profits that would be available under the secrecy or property-rights solutions. This solution is imperfect because it must be funded through taxes or borrowed funds, which imposes economic costs on taxpayers, and is likely to misallocate funds since it relies on the inherently subjective judgment, limited foresight, and potentially politicized decisions of administrators who disburse the funds. Additionally, a publicly funded innovation system fails to harness the profit-based incentives of private industry and, as such, may yield delayed or otherwise inferior innovation and commercialization outcomes compared to the patent-based solution to the incentive dilemma.

1.2 The Incentive Dilemma in Biopharmaceutical Innovation

The severity of the incentive dilemma varies in any particular industry depending on at least two fundamental factors. First, the severity of the dilemma is impacted by the gap between the costs of research and development borne by the innovator, on the one hand, and the costs of replication borne by imitators, on the other hand. The larger the gap (since innovation costs typically exceed imitation costs), the greater the incentive dilemma. Second, the severity of the dilemma is impacted by the ease with which the innovator can prevent or delay replication by imitators. The easier it is to prevent imitation, the weaker the incentive dilemma.

These relationships can be depicted visually as shown in the Figure below. In the lower left-hand quadrant (*x*), the incentive dilemma is least severe: innovation and imitation costs are comparable, which means that imitators do not have a significant cost advantage, and the innovator can preclude or delay imitation. In this scenario, innovation can most likely attract investment even though there is no legal obstacle to imitation. In the upper right-hand quadrant (*y*), the incentive dilemma is most severe: innovation costs are much greater than imitation costs, which means that imitators have a significant cost advantage, and innovators must incur significant costs to prevent or delay imitation. In this scenario, innovation is unlikely to attract investment absent a legal obstacle to imitation.

Figure 1. The Innovation Incentive Dilemma

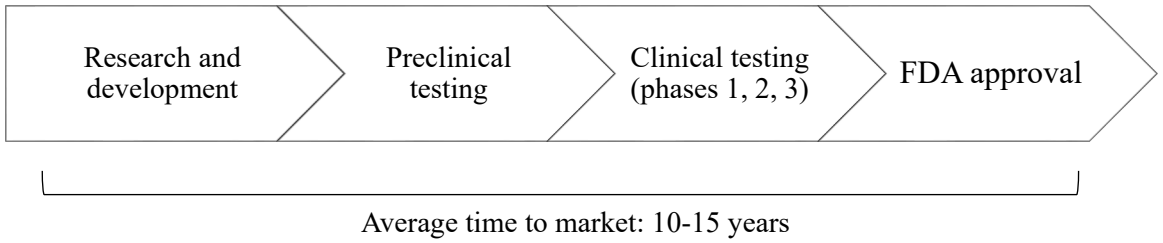


Most industries fall somewhere between these extremes because, even when innovation costs exceed imitation costs, there may be feasible mechanisms to delay or impede imitation.[12] For example, the software industry has been able to substantially limit access by non-paying users by shifting to a software-as-a-service model in which access can be controlled technologically by "turning off the faucet." The biopharmaceutical industry does not fall into any such "middle ground." For reasons discussed below, it falls clearly within the upper right-hand quadrant in which the incentive dilemma is most severe: innovation costs are much greater than imitation costs and there are typically no feasible means other than patents (and related forms of legal exclusivity) to block or delay the entry of imitative products.

Innovators: Cost and Risk Profile

For pharmaceutical innovators, both the costs of drug development and the risk of project failure are high. As shown in the Figure below, these costs encompass each stage of the innovation and commercialization timeline: research and development (which may extend to production processes), preclinical and clinical testing (Phases 1, 2, and 3) for purposes of FDA approval, and marketing activities.

Figure 2. Principal Stages of Pharmaceutical Development



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.[13] These estimates are consistent with an upward trend based on previous studies, which assessed drug development costs at $802 million as of 1983 and $2.2 billion as of 2009.[14] The success rates of drug development projects are low: during 2011-2020, the average success rate for pharmaceutical drug projects was 7.9% and, when broken down by therapeutic category, ranged from 3.6% to 23.9%.[15] As of 2016, less than 12% of drugs entering phase I clinical trials achieved market release.[16] Moreover, only about one-third of approved (and therefore technically "successful") drugs generate revenues sufficient to cover the costs expended on development, testing, production, and marketing.[17] The highly skewed distribution of drug development outcomes—as measured by clinical and commercial success—means that pharmaceutical firms rely on a small number of top-selling drugs to subsidize R&D investments in the larger population of drug projects that do not achieve

[12] Barnett 2021b, at 9-13.
[13] DiMasi, Grabowski, and Hansen 2016, at 25.
[14] Id., at 22. The amounts in this sentence are not adjusted for inflation.
[15] Biotechnology Innovation Organization 2021, at 9-10.
[16] Congressional Budget Office 2021, at 2, 16-17.
[17] Barfield and Calfee 2007, at 19; Grabowski, Vernon, and DiMasi 2022, at 3, 11.

significant revenues or fail clinical testing.[18] The time to completion is long, with variation across therapeutic segments, and typically takes almost 15 years in total[19] or 10.5 years on average after a drug has entered Phase 1 of clinical testing.[20] Each stage of pharmaceutical development exhibits increasing costs[21] and a firm incurs a high opportunity cost of capital due to the approximately decade-long period to reach market release and start earning revenues on sales.

Imitators: Cost and Risk Profile

Imitators (in the pharmaceutical context, the generic or biosimilar entrant) bear a smaller portion of the costs borne by the innovator and, by definition, none of the risks of project failure since they only imitate FDA-approved products that have already been proven to be technically viable and commercially successful. Moreover, in the case of small molecule drugs (which are based on chemical compounds and represent about 90% of all pharmaceutical drugs[22]), a generic firm typically faces few technical barriers to reverse engineer the brand-name product, in part because the patent must disclose the molecular structure of a drug's active ingredient. There are typically greater replication barriers in the case of biologics, which are large-molecule drugs based on living cell lines and are difficult to replicate exactly. "Biosimilars" that have no clinically meaningful differences can be produced, but can take approximately seven to eight years and an investment of $100 million to $250 million.[23] While the higher development costs may limit the price discount on a biosimilar, innovation costs still substantially exceed imitation costs and an originator expects to still face competitive discipline upon the entry of a biosimilar, based on price, insurance coverage, and other competitively relevant features.[24]

Summary: From Incentive Dilemma to Incentive Solutions

Innovation policy is based on a simple rationale. Without some means to exclude imitators or otherwise capture returns, inventors and investors will have no reason to place capital and time at stake in undertaking the costly and risky process of innovation. In that circumstance, the market will rationally decline to fund innovation, leaving the state (and ultimately, taxpayers) or philanthropic entities as the only remaining source of capital. Among all technology industries, the biopharmaceutical industry presents the clearest factual case for this proposition given the exceptional costs and risks borne by innovators as compared to imitators. The economic and social costs of failing to address this incentive dilemma in the biopharmaceutical context are likely to be exceptional in the form of foregone treatments that might have significantly enhanced human and social well-being. The next Part will explore three classic solutions to the innovation dilemma in the biopharmaceutical ecosystem.

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[18] Scherer 2000, at 1316-17. For the same reason, observing that a pharmaceutical firm enjoys "high" margins on a single bestseller drug is not a reliable measure for assessing a firm's profitability in the aggregate.
[19] Rowberg 2001, at CRS-13.
[20] Thomas et al. 2021.
[21] Rowberg 2001, at CRS-13.
[22] Makurvet 2021.
[23] Blackstone and Joseph 2013; Johnson 2017, at 8. For similar estimates, see Lietzan 2017, at 896.
[24] Mortimer and Ellman 2018.

PART 2. EXCLUSIVITY SOLUTIONS TO THE INNOVATION DILEMMA

To address the innovation dilemma, the U.S. pharmaceutical ecosystem extensively relies on patents and other forms of legal exclusivity. These exclusivity instruments provide innovators with a period during which imitation is legally prohibited. The rationale is straightforward. If competitors cannot immediately enter the market with a perfectly imitative product, the innovator can expect to potentially earn positive returns on its investment in research, development, testing, and marketing a new drug. Those returns in turn support the development of other new drugs in the innovator's development pipeline. By anticipation, the expectation that a technically viable and commercially successful drug will be protected from perfectly imitative products for a certain period enables innovators to secure investments from the capital markets to support each of the steps leading to market release. Following the same rationale, the availability of effective protections against unauthorized imitation can induce the innovator or other entities to develop improvements to existing drugs or new uses for those drugs.

This solution to the incentive dilemma inherently comes at a potential cost to consumers in the form of elevated prices during the exclusivity period as compared to a market in which imitative entry was unconstrained. To mitigate this inherent side-effect of a property-rights regime, the U.S. pharmaceutical ecosystem has operated since 1984 under a regulatory apparatus that facilitates the entry of generic drugs shortly following the expiry of the exclusivity period (as determined by the combination of patent protection and regulatory exclusivities) and in some cases even earlier. As a result, robust patent protection and other forms of legal exclusivity for new drugs and treatments are counterbalanced by robust mechanisms that accelerate generic entry as soon as a drug's patent protection and other forms of legal exclusivity expire (or earlier if the drug's patent protection is proven to be invalid or not infringed). Moreover, a new drug may face competitive discipline during the patent term from other drugs that treat the same disorder through a different mechanism and fall outside the scope of the patent covering the new drug.

2.1 Sources of Legal Exclusivity in Pharmaceutical Products

Innovators of new pharmaceutical products benefit from exclusivity periods arising from patent protection and, unlike other technology fields, various regulatory protections. These forms of legal exclusivity, which vary in terms of scope and duration, interact to delay entry of generic or biosimilar versions of original branded drugs. This section covers patents, the most common forms of regulatory exclusivity, and trade secret protections, which together form an "exclusivity umbrella" that protects pharmaceutical innovations for a limited period. The following discussion is intended to provide an overview, rather than a comprehensive description, of these exclusivity protections.

Patents (and Patent Term Restoration)

Innovators can apply for patents that cover the chemical composition of a pharmaceutical product, specific formulations of the drug, the processes through which the product is manufactured, or the methods through which the drug is administered.[25] In the case of biologics, which are typically injected or infused medications extracted from plant or animal

[25] Hickey and Ward 2024,

cells (as distinguished from small-molecule drugs, which are chemically synthesized and can be administered orally), patent protection can cover specific cell lines, isolated genetic, amino acid, and nucleotide sequences, or other biological components.

In general, the statutory term of a patent lasts for 20 years starting from the date of application. Given the fact that an innovator has incentives to apply for a patent as soon as possible to secure protection, combined with the passage of time attributable to drug development, clinical testing, and the FDA approval process, the effective patent term—meaning, the patent term that covers the period during which the drug is available for sale—will always be significantly shorter than the statutory patent term. To address this shortfall, the Hatch-Waxman Act provides pharmaceutical patentees with the right to request from the USPTO a patent term "restoration" for up to five years for one patent per drug product (but expiring no later than 14 years following FDA approval of the drug).[26]

It should be noted that statutory "restoration" does not fully correct for time lost in the FDA approval and testing process. Even taking into account term extension and all applicable forms of regulatory exclusivity, empirical studies find that, during 1995-2019, new small-molecule drugs enjoyed on average between 12.2 and 14.6 years on the market until entry of a generic competitor.[27] This period—which is the economically relevant period for assessing the incentive and access effects of exclusivity protections in the biopharmaceutical ecosystem—is still considerably shorter than the 20-year statutory patent term and several years shorter than the average effective patent life in other industries.[28]

Regulatory Exclusivities

Regulatory exclusivity determines the period during which the FDA may accept, or approve, "abbreviated applications" for generic or biosimilar drugs. Whereas the patent term commences at the time of the patent application, the period of regulatory exclusivity generally commences at the time of FDA approval of the original drug. As a result, regulatory exclusivity can provide the innovator with a form of legal exclusivity that persists after its patent portfolio has reached the end of the statutory term. In other circumstances, the innovator may continue to enjoy protection through its patent portfolio after regulatory exclusivity has expired. The effective aggregate period of legal exclusivity enjoyed by any new drug following market release is a function of the partially overlapping periods of time under the holder's patent portfolio (adjusted for term restoration) and various forms of regulatory exclusivity.

There are two primary forms of regulatory exclusivity: data exclusivity and marketing exclusivity. Data exclusivity bars the FDA from *accepting* a generic or biosimilar application that relies on the clinical testing data submitted by the branded producer in connection with the approved original drug. Marketing exclusivity precludes the FDA from *approving* a generic or biosimilar application, which therefore bars market release.

[26] 35 U.S.C. § 156; Manual of Patent Examining Procedure, Ch. 2700 § 2758(c)(3).
[27] Grabowski et al. 2021.
[28] Schacht 2012a. For similar findings, see Kuhlik 2004 (11-12 years of patent life on average following FDA approval, as compared to 18.5 years of post-release patent life in other industries).

The Table below provides an overview of the regulatory exclusivities (including marketing and data exclusivities) that apply to selected categories of pharmaceutical products.

Table 1. Regulatory Exclusivities for Selected Pharmaceutical Product Categories

Product category	Product category definition (simplified)	Length of exclusivity	Effect of exclusivity
New chemical entity	A drug that contains no "active moiety" that has been approved by the FDA in any other application.	5 years. Reduces to 4 years if generic application contains "Paragraph IV" certification that patent on original drug is invalid or not infringed.	FDA may not accept a generic application that relies on clinical data used in the application for the original drug.
New clinical investigation	New drug application that claims substantial change (including new use or new dosage form) in already approved drug.	3 years	FDA may not approve a generic application for the change to the original drug.
Biological product	Certain complex, large-molecule medicines.	12 years	For years 1-4, FDA may not accept a biosimilar application; for years 5-12, FDA may not approve a biosimilar application.
Orphan drug	Small-molecule drug or biological product for which there is a patient population of fewer than 200,000 U.S. residents.	7 years (if a biologic, runs concurrently with the 12-year period)	FDA may not approve a generic or biosimilar version, or a new drug application, that contains the same "active moiety" and treats the same disease or condition.

Sources: This Table reflects information in Ward 2019, Table 1, which covers all regulatory exclusivities. For statutory sources, see 21 U.S.C. §§ 355(c)(3)(E)(ii), 355(j)(5)(F)(ii), and 355(u); 21 C.F.R. § 314.108(a) (new chemical entity); 21 U.S.C. §§ 355(c)(3)(E)(iii)–(iv), 355(j)(5)(F)(iii)–(iv) (new clinical investigation); 42 U.S.C. §§ 262 (k)(7)(A)-(B) (biologic); 21 U.S.C. § 360cc and 21 C.F.R. § 316.31(a) (orphan drug). For definition of "active moiety," see 21 C.F.R. §314.3.

Trade Secrets

Trade secret protections enable pharmaceutical innovators to bring a legal action against competitors who misappropriate non-public knowledge, which encompasses manufacturing processes or other technical know-how that is not already known in the relevant industry and cannot be readily copied. Misappropriation can occur through various forms of unauthorized acquisition, including theft or espionage, breach of a confidentiality agreement, or a "breach of confidence" in the context of certain business negotiations or other commercial relationships. Trade secret protection can last perpetually in theory but immediately lapses

once the protected technology is publicly disclosed or copied independently by competitors (so long as any such copying is not attributable to a form of misappropriation).

Historically, trade secret protections have had limited relevance in the pharmaceutical sector for two reasons. First, trade secret protection is not a rational appropriation strategy for small-molecule drugs that can typically be reverse engineered with relative ease and are therefore best protected through a patent portfolio. Second, pharmaceutical firms must disclose extensive information to the FDA in the regulatory approval process, which may become publicly accessible and then lose eligibility for trade secret protection.

In the biologics sector, trade secret protection acquires greater relevance since customized production processes are an integral component of the development of a biologics product and may not be readily susceptible to reverse engineering. Even in that case, however, trade secret protections can be unreliable due to the potential disclosure of information to the public through the regulatory approval process. Typically, biopharmaceutical manufacturers rely on a mix of patents and trade secrets, complemented by forms of regulatory exclusivity, to assemble an appropriation strategy that covers different types of intellectual assets involved in the drug development, production, and commercialization process.[29]

2.2 Constraints on Legal Exclusivity in Pharmaceutical Products

The combination of patent protection, trade secret protection, and regulatory exclusivity may appear to provide a formidable legal fortress against the entry of generics and other competitors. However, the strength of this fortress is mitigated by three factors.

First, the "nominal" maximal patent term is significantly shortened by time spent in drug development, testing, and the approval process, which is only partially corrected by a patent term restoration if granted by the USPTO. Among other limitations, a patent term restoration is limited to an additional five years, may not extend patent expiration beyond 14 years after FDA approval, and can only apply to one patent per FDA-approved drug.[30]

Second, even during the patent term, competitors may succeed in developing differentiated drugs or treatments that target the same disorder but do so in a manner that falls outside the scope of the pioneer innovator's patent. Consistent with this expectation, there is often robust brand-to-brand competition between drugs that address the same disorder through different mechanisms or differ on other competitively relevant parameters.[31] Hence, theoretical models in which a patent confers an unchallenged "monopoly" often do not correspond to real-world markets.

Third, two federal statutes, the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act, facilitate the entry of generics and biosimilars, respectively, either immediately following expiration of the brand-name drug's patent term (and marketing exclusivity, if applicable) or, prior to the expiry of the patent term upon a showing of patent invalidity or non-infringement. As a result, there is no assurance that a patent owner can expect to maintain its patent through the end of the statutory term or (especially in the case of

[29] Brewster and Singh 2019.
[30] 35 U.S.C. §156.
[31] Berndt 2022, at 55.

a drug with significant sales) can expect to do so without undertaking litigation to defend against legal challenges.

Hatch-Waxman Act

The Hatch-Waxman Act, which has been in place for 40 years, has facilitated the growth of the generic drug market through three principal mechanisms that constrain exclusivity protections for original branded drugs by facilitating and encouraging the entry of generic competitors.

[1] *Abbreviated New Drug Application (ANDA)*

A generic entrant may file an "ANDA" (abbreviated new drug application) submission with the FDA for a generic product that is claimed to have pharmaceutical equivalence and bioequivalence with the brand-name product. Pharmaceutical equivalence requires showing that the generic has the same active ingredient, the same dosage form, and the same strength and method of administration as the approved drug.[32] Bioequivalence requires showing that "there is no significant difference in the rate at which and extent to which the drug's active ingredient reaches the place in the body where the drug is active, when administered at the same dose and under similar conditions."[33] So long as equivalence is shown, the generic entrant is relieved from demonstrating efficacy and safety (as the brand-name innovator had been required to show to secure FDA approval), which substantially lowers entry costs. Once marketing exclusivity for the original drug has expired, and the patents relating to the original drug have lapsed (or have been invalidated or deemed not to be infringed by the generic product), the FDA-approved generic product may enter the market.

[2] "*Paragraph IV" Certification (Patent Challenge)*

Even prior to expiration of the patent term, a generic applicant may file an ANDA submission together with a Paragraph IV certification, which asserts that patents relating to the brand-name drug are invalid or would not be infringed by the generic product.[34] If a Paragraph IV filing is made (which occurs in 93% of new drugs with greater than $250 million in sales[35]), then the five-year period of data exclusivity for a new chemical entity falls to four.[36] A Paragraph IV filing typically gives rise to litigation initiated by the brand-name producer against the challenger, which then triggers a 30-month stay of regulatory approval of the generic drug (which terminates if the patent on the original drug is found to be invalid or not infringed).[37]

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[32] 21 C.F.R. § 314.3 ("pharmaceutical equivalence").
[33] Hickey and Ward 2024, at 9 n.87. For full definition, see 21 C.F.R. § 314.3 ("bioequivalence").
[34] 21 C.F.R. § 314.95.
[35] Grabowski et al. 2021.
[36] 21 U.S.C. § 355 (c)(3)(E)(ii).
[37] In the case of a brand-name drug that is deemed to be a new chemical entity (see definition in Table 1 above), the treatment differs if the generic application is filed during the fourth year following FDA approval of the original drug, concurrently with a Paragraph IV certification. In that case, the 30-month stay is extended such that the FDA cannot approve the ANDA and the generic product cannot enter the market until 7.5 years have elapsed since approval of the brand-name drug (unless the infringement litigation is resolved in favor of the generic prior to that time) (21 U.S.C. § 355 (c)(5)(F)(ii)).

[3] *180-Day Exclusivity Period*

The Hatch-Waxman statute encourages generic firms to file patent challenges by providing a 180-day market exclusivity period for the first ANDA applicant to file a Paragraph IV certification, starting on the date on which the entrant commences "commercial marketing" of the generic product. During the 180-day period, the FDA cannot approve another generic product whose application (with a Paragraph IV certification) was filed subsequently, and therefore the successful challenger competes only with the brand-name drug producer. The 180-day period terminates if certain "forfeiture" events occur within certain time windows, such as a court finding that the patent on the brand-name drug is invalid or not infringed.[38]

Biologics Price Competition and Innovation Act (BCPIA)

The BCPIA, which amended the Public Health Service Act (PHSA), provides several mechanisms that similarly facilitate the entry of biosimilar producers into the biologics market.

[1] *Abbreviated Biologics License Application (aBLA)*

The PHSA provides that an entrant may submit an abbreviated biologics license application (aBLA) to market a biosimilar product. This requires the submission of evidence to the FDA showing that the product is "highly similar to the reference product notwithstanding minor differences in clinically active components," there are no meaningful differences in terms of "mechanism of action," "dosage form, and . . . strength," and the manufacturing process is "designed to assure that the biological product" meets standards of safety, purity, and efficacy.[39] To show safety and efficacy, the applicant may rely in part on the clinical data submitted by the innovator, which reduces costs for the applicant.[40] Nonetheless, even showing biosimilarity for purposes of an aBLA involves significantly greater costs, risks and delays than showing bioequivalence for purposes of an ANDA, due to clinical testing and manufacturing process requirements that reflect the inability to produce an exact copy of a biological product.[41]

[2] *"Patent Dance"*

The BCPIA sets forth a non-mandatory framework—commonly known as the "patent dance"—that is designed to facilitate the entry of a biosimilar product prior to expiration of the patent term. Described generally, the "patent dance" framework comprises multiple steps through which the innovator and entrant exchange information to agree upon a list of patents held by the innovator that the entrant seeks to contest, which is then followed by up to two waves of litigation.[42] A biosimilar entrant can also choose to bypass the patent dance and enter the market at the risk of a patent infringement litigation being filed by the originator

[38] 21 U.S.C. §§ 355 (j)(5)(B)(iv), (j)(5)(D).
[39] 42 U.S.C. § 262(k)(2)(A)(i).
[40] Lietzan 2017, at 888-89.
[41] Id., at 894-95.
[42] 42 U.S.C. §§ 262(l)(2)-(6).

firm (if it provides notice to the originator firm at least 180 days prior to entering the market).[43]

While the precise details of the patent dance, and related biosimilar entry strategies, lie beyond the scope of this report[44], the practically relevant point is that, just as in the Hatch-Waxman framework, there is no assurance that a biologics patent owner can expect to maintain its patent through the end of the statutory term or, especially in the case of a drug with significant sales, can expect to do so without undertaking litigation to defend against validity and non-infringement challenges.

2.3 Summary: The Balancing Act of Pharmaceutical Patent Policy

The U.S. pharmaceutical regulatory regime balances exclusivity protections with mechanisms that facilitate the entry of generic products into the market following patent invalidation, a finding of non-infringement, or expiration of the various exclusivity instruments that protect the brand-name product. This clearly has an effect on pricing: brand-name drugs in the U.S. market typically lose approximately 75% of market share within one year of generic entry.[45] The combination of these two policy mechanisms accounts for the seemingly paradoxical fact that the U.S. is a world leader in the development of both new drugs and generics. The U.S. makes the largest investment annually in pharmaceutical research and development[46] and, as of 2021, was the source of approximately 40% of new drugs released worldwide, as compared to 25% for Europe.[47] (Percentages were similar for the U.S. and somewhat higher for Europe during the 15-year preceding period.[48]) At the same time, approximately 90% of all drug prescriptions in the U.S. are filled by generics[49], which have historically constituted a significantly larger percentage of prescriptions in the U.S. as compared to European countries.[50]

[43] 42 U.S.C. §§ 262(l)(8)(A).
[44] For a detailed explanation, see Wang & McGlynn 2020.
[45] Scott-Morton and Kyle 2011.
[46] OECD 2021.
[47] IQVIA 2022.
[48] Id.
[49] U.S. Food & Drug Administration 2021, at 2.
[50] Wouters, Kanavos, and McKee, at 601.

PART 3. THE BIOPHARMACEUTICAL ECOSYSTEM

Discussions of patent policy in the pharmaceutical industry often rely on a "silo-like" approach that considers the effects of patents in isolation from other governmental and market mechanisms that sustain innovation and commercialization activities. In particular, the pharmaceutical ecosystem benefits from the interaction between the private sector, which relies on secure exclusivity protections to deliver returns to investors, and the public sector, which is funded mostly by federal grant-making entities. The success of the pharmaceutical ecosystem relies on a symbiotic relationship between these public and private mechanisms for sustaining the full panoply of innovation and commercialization activities that are necessary to deliver a new drug or treatment from lab to market.

3.1 Division of Labor in Biopharmaceutical Research

Generally speaking, scientific research can be divided into basic and applied forms. While the distinction between these forms of research is not always clear in the case of particular projects, basic research generally refers to research into "the underlying foundations of phenomena and observable facts," which can give rise potentially to a large number of potential applications, while applied research refers to research that is "directed primarily towards a specific, practical aim or objective."[51]

For example, the recombinant DNA techniques developed by Stanley Cohen and Herbert Boyer in the 1970s can be understood as a type of basic research that has been applied to develop hundreds of medical products, whereas the synthetic human insulin product developed by Genentech and Eli Lilly in the early 1980s can be understood as a type of applied research that represents a specific application of the Cohen-Boyer method. (This example is discussed in greater detail subsequently.) In the biopharmaceutical industry, basic research principally takes place in academic, governmental, or other nonprofit research institutions, while applied research and drug development is mostly undertaken by for-profit entities, including large pharmaceutical companies and small to medium-size startups.[52]

This division of labor is not accidental. In the case of a for-profit entity, it is generally difficult to justify allocating resources to basic research precisely because this type of research can give rise to such a large and potentially lucrative set of potential applications. In economic terms, basic research generates "positive externalities"—that is, it can potentially generate such a broad range of applications that the entity funding such research is likely to capture only a minority of the gains resulting from that research. This drawback is compounded by the fact that basic research is inherently uncertain and may not yield any practical applications in the short term. Given these characteristics, for-profit entities will tend to favor more applied forms of biomedical research, which, if successful, will yield within the short to medium term commercially viable products from which the innovator and producer can capture most of the returns.

[51] OECD 2015, at § 2.9.
[52] Schulthess et al. 2023.

This explanation anticipates the division of labor generally observed in pharmaceutical markets between academic and for-profit entities. Academic and other nonprofit entities tend to engage in more basic forms of research that industry is disinclined to undertake due to the absence of rational economic incentives to do so. For-profit entities focus primarily on more applied forms of research that yield new drugs and treatments for commercial release within a reasonable investment timeline (although the largest pharmaceutical firms do undertake meaningful levels of basic research[53]).

Each type of research relies on a different funding mechanism. To fund basic science research, the biopharmaceutical ecosystem relies in large part on funding from the federal government, principally through the National Institutes of Health (NIH). As of 2020, NIH funding exceeded $41 billion[54], although a significant portion of that amount was allocated to research that falls outside the biomedical ecosystem.[55] Yet it is important to keep in mind that even these large amounts represent a minority of all funds invested in biopharmaceutical R&D in the aggregate. As of 2007, the NIH funded 27% of U.S. medical and health R&D, private industry funded 58%, and a combination of other governmental and philanthropic entities funded the remaining 15%.[56] More recently, the split between public and private sector R&D expenditures has shifted toward even greater reliance on the latter. As of 2020, the federal government funded 25% of total U.S. medical and health R&D and private industry funded 66%.[57] The next section will address how the private sector in the pharmaceutical ecosystem plays a critical role in converting the research inputs delivered by the public sector into viable drugs and other treatments.

3.2 How Patents Convert Basic Research into Applied Research

Government-funded biomedical research by academic institutions is an important source of the knowledge base that prompts the development of new drugs by private firms. For this reason, it has long been argued (as previously noted) that "taxpayers pay twice" for new drugs—once through public funding and once more through the pricing premium attributable to patent protection. This view overlooks the fact that the process through which publicly funded research yields commercially viable treatments ultimately relies on private firms that must have incentives to undertake the costly and uncertain process of drug development. While the role of public research is critical in fueling the biopharmaceutical ecosystem with foundational discoveries, so too is the role of private industry in converting academic research into technically and commercially viable drugs and treatments. The incentives of private industry to make those investments are anchored in the exclusivity protections provided by the patent system and other regulatory instruments, which secure the returns that are necessary to attract investors who have an abundance of investment opportunities inside and outside the pharmaceutical industry. This principle holds true for even the largest

[53] Leten, Kelchtermans, and Belderbos 2022.
[54] Congressional Budget Office 2021, at 18.
[55] Schulthess et al. 2023.
[56] Dorsey et al. 2010.
[57] Research America 2022, at 4.
[58] Barnett 2021a, at 221-224; Barnett 2021b, at 70-81.

pharmaceutical firms, which ultimately rely on retaining and attracting funding from institutional and individual investors.

The complementary relationships between public funding, patent protection, and drug development can be demonstrated by a brief historical overview of public policies concerning the issuance of patents for inventions developed using federal research funds.

"Before and After" Lessons from the Bayh-Dole Act

Throughout the decades following the end of World War II, the federal government imposed various limitations on the ability of the recipients of federal research funds to secure patents on inventions developed using those funds or to license any such patents on an exclusive basis.[58] As critics of Bayh-Dole again argue today, these restrictions were motivated by the rationale that taxpayers should not have to "pay twice" for products arising out of federally-funded research. This argument, however, overlooks the simple reality that converting research into technically and commercially viable products requires significant capital investment—something that no private firm will rationally undertake without a clear ownership position in the event the commercialization process is successful.

The history of U.S. innovation following World War II and prior to the enactment of Bayh-Dole illustrates this adverse outcome. During this period, private industry was often reluctant to partner with academic institutions that undertook research funded by the federal government since firms were concerned about the lack of clear ownership over technologies embedded in products developed through any such partnership.[59] A change in policy at the NIH in 1962 illustrates this suppressive effect. Following a policy announcement that government consent would be required to patent new products derived from compounds developed through NIH-funded academic research, "almost no pharmaceutical firm agreed to screen compounds developed by academic researchers using NIH funds."[60] While the NIH policy ensured that knowledge was "free" for all to use, that same policy ensured that few had any rational incentive to make use of it.

This self-defeating outcome is not surprising. The inability to secure exclusivity protections discourages private investment and impedes cooperation between government and academia on the one hand and industry on the other. By impeding governmental or academic research institutions from securing legal exclusivity over technologies arising from projects supported by federal funding, those institutions could not offer an assurance of exclusivity to private industry, which therefore was reluctant to enter into license or sale transactions, or partnerships or other arrangements, for purposes of commercialization. To mitigate the investment disincentives that arose from the inability to offer clear ownership over intellectual assets arising from federally funded research, several agencies instituted a variety of patchwork exceptions.[61] These efforts produced few results: prior to 1980, the

[58] Barnett 2021a, at 221-224; Barnett 2021b, at 70-81.
[59] Barnett 2021a, at 227-28; Barnett 2021b, at 81.
[60] Barnett 2021a, at 228 (citing Harbridge House 1968, at II-12, II-14, II-29).
[61] Id., at 227-228.

Congressional Research Service states that "only 5% of government owned patents were ever used in the private sector although a portion of the intellectual property portfolio had potential for further development, application, and marketing."[62]

Enactment of the Bayh-Dole Act in 1980[63] removed these limitations on securing ownership of intellectual assets arising from federally funded research. This key step eliminated disincentives for the pharmaceutical industry to form partnerships or other cooperative arrangements with federally funded research institutions (principally, academic institutions). At the same time, Congress established in 1982 the Court of Appeals for the Federal Circuit[64], which issued several decisions that strengthened patent owners' ability to take enforcement actions against infringers.[65]

These landmark pieces of legislation provided the legal foundation for the technology transfer industry, which comprises divisions at academic institutions that specialize in converting research into commercially viable products through sale, licensing, or other arrangements with private industry. Given the volume of NIH funding, university research is almost invariably federally funded to some extent and therefore relies on the Bayh-Dole statute to be able to secure patent rights on inventions arising out of such research, which in turn can support relationships with outside commercial partners.

These relationships are economically significant. As of 2022, it was estimated that there are approximately 53,000 license agreements in place between academia and industry in the U.S. market.[66] Based on data on licensing income collected through annual surveys by the Association of University Technology Managers, the U.S. technology transfer industry reported $2.3 billion in licensing income for universities and $922.2 million in licensing income for hospitals during 1996-2021.[67] (The survey has a partial response rate and therefore underestimates licensing income.) One study estimates that the economic contribution of academic licensors to gross domestic product ranges from $333 billion to $1 trillion in 2012 dollars (with the range reflecting assumptions of an average running royalty rate on licensees' product sales ranging from 2% to 5%).[68] While these estimates are subject to a certain level of uncertainty, even substantially lower estimates of economic impact would support the view that the technology transfers enabled by the Bayh-Dole Act have significantly enriched the U.S. economy.

Patents as Enabling Mechanisms

It is common to view patents as an exclusionary mechanism designed solely to block competitors through the threat of infringement litigation. Yet this one-sided view overlooks the contractual and other transactional mechanisms through which patents enable value-producing transactions that bring together the holders of complementary assets and capacities

[62] Schacht 2012b.
[63] 35 U.S.C. §§ 200-212.
[64] Federal Court Improvements Act, 96 Stat. 25 (Apr. 2, 1982).
[65] Barnett 2021b, 72-75.
[66] Pressman et al. 2022, at 31.
[67] Id., at 22-23.
[68] Id., at 27-28.

to make possible the development of new products that might not otherwise be feasible. The emergence and growth of the technology transfer industry following enactment of the Bayh-Dole Act illustrate this enabling function.

The business relationships negotiated by technology transfer divisions, and in turn the economic value unleashed by those relationships, rely on a secure patent portfolio to structure interactions between the university, which specializes in generating research outputs, and commercial firms, which specialize in converting those research outputs into drugs and other treatments. A patent portfolio (together with complementary forms of regulatory exclusivity) operates as an enabling mechanism that catalyzes realization of the synergies created by the division of labor between academia (which focuses on more basic forms of research) and industry (which converts basic research into drugs or treatments).

Without the availability of patent protection, these relationships would run into transactional roadblocks. While the university would fear that its commercial partner (which often has extensive technical expertise and financial resources) could seize the university's invention and independently develop a commercial application, the commercial partner would have doubts about the ability to earn a positive return on investment if the law did not provide for exclusive ownership or control of the technology being offered by the university. The "property envelope" supplied by the patent system, as adjusted by applicable forms of regulatory exclusivity, mitigates this transactional dilemma, allowing innovators to partner with other entities to accelerate the commercialization process leading to market release.

3.3 The Commercialization Pathway

To provide a full picture of the biopharmaceutical ecosystem, it is important to appreciate the closely related mechanisms through which a patent portfolio enables firms and other entities to cultivate the economic value—and ultimately social value in the form of improved human well-being—embedded in a biomedical innovation. These mechanisms illustrate the three core functions of patents in technology markets—innovation, investment, and transactional—that involve not just brand-name innovators and generic entrants but the full range of investors, producers, distributors, and other stakeholders that are necessary to convert knowledge into drugs and treatments that ultimately benefit consumers.

Innovation Function

In its simplest form, the incentive argument for patents holds that the ability to secure legal exclusivity incentivizes innovation by promising an innovator the potential for profit if a research project yields a commercially successful product. In the pharmaceutical industry, empirical studies repeatedly find evidence that is consistent with this proposition.

In large-scale survey studies of large U.S. corporations conducted in the 1980s and 1990s, pharmaceutical firms consistently reported placing a high value on patents as a means for appropriating returns on R&D, which contrasts with information technology sectors where

surveyed firms provided more mixed responses.[69] In a survey study of smaller firms in the 2000s, pharmaceutical and biotech firms similarly placed a high value on patents.[70] The higher value placed on patents by firms of all sizes in the pharmaceutical industry, as compared to other industries in which principally smaller firms tend to place a higher value on patents, most likely reflects the fact that pharmaceutical products are difficult to protect from imitation through other means and hence even large firms (which in other industries often have access to non-patent-dependent appropriation strategies[71]) require patents to appropriate value from their R&D investments.

This interpretation is consistent with evidence on the average expected "premium" (increase in economic value) attributable to patent protection, which is higher in the pharmaceutical, biotech, and medical device sectors, and lower in industries such as computers, machinery, and semiconductors.[72] Based on these findings, it appears that the market is aware of the fact that patents have an elevated value in the pharmaceutical sector as a mechanism for capturing returns on technological innovation. This interpretation is also consistent with evidence on amicus briefs filed at the Supreme Court during 2006-2016, which shows that pharmaceutical firms and academic research institutions consistently advocate positions that align with stronger patent protections, while firms in the information technology and financial services industries tend to advocate the opposite position (with some variation in the semiconductor industry).[73]

Investment Function

The incentive function of the patent system (and complementary forms of legal exclusivity) not only sustains an innovator's incentives to undertake drug development but, just as importantly, sustains *investors'* incentives to place capital at risk in startups and other innovator firms. Like any other industry, pharmaceutical firms must seek capital from outside investors, including venture capital firms, institutional investors, and (when applicable) public shareholders, all of which can choose to place capital elsewhere. The patent system is a critical element in enabling pharmaceutical firms to raise billions of dollars in capital annually to sustain research, development, and other activities. Without a secure property right in drugs or treatments that may arise from those investments, investors would have no reason to invest and would simply move capital to other firms and industries. Absent access to external capital from outside investors, the decline of the pharmaceutical industry would necessarily follow. This simple business reality is often overlooked in policy discussions, which seem to assume that markets will maintain the same level of capital investment even after rates of return have been reduced through regulatory intervention.

This line of argument implies that, as patent protection is introduced or enhanced in a particular technology segment, then investment into that segment should increase and

[69] Mansfield 1986; Levin et al. 1987, Cohen et al. 2000.
[70] Graham et al. 2009.
[71] Barnett 2021b; Teece 1986.
[72] Arora et al. 2007. Similarly, based on data on UK firms, Arora and Athreye (2012) find that patents confer the highest incremental premia for firms in the biopharmaceutical industry.
[73] Barnett 2021b, 146-150.

ultimately innovation should increase in the form of an enhanced flow of new or improved treatments. The Orphan Drug Act of 1983 appears to support this proposition. The statute provides seven years of market exclusivity for the use of drugs that treat rare disorders with small patient populations (less than 200,000 U.S. residents), instead of the normally applicable marketing exclusivity periods for new chemical entities (five years) and new clinical investigations (three years).[74] The effects attributable to the statute after its enactment are consistent with the proposed relationship between property rights, investment, and innovation.

Several studies find that the additional period of market exclusivity under the statute was followed by increased allocation of R&D dollars toward orphan drug development, which in turn translated into an increased number of orphan drugs securing FDA approval. During 1983-2000, the number of orphan drugs increased from a handful to over 1,000 orphan drugs in development and over 200 orphan drugs being approved by the FDA, including treatments for multiple sclerosis, cystic fibrosis, and hemophilia.[75] During 1983-2009, the FDA approved 347 orphan drugs, as compared to 34 orphan drugs during 1967-1983 prior to enactment of the statute.[76] Reflecting the sensitivity of R&D investment and drug development to patent strength, another study found that the percentage of all drug approvals constituted by orphan drugs increased following enactment of the statute, rising from 17% during 1984-1988 (years during which it is unlikely the statute could have impacted firms' drug development outcomes) to 31% during 2004-2008.[77]

Transactional Function

A patent's economic functions extend beyond incentivizing R&D and the investments required to fund drug development. Specifically, patents enable financing, licensing, joint ventures, and other transactions in intangible assets that would otherwise be economically infeasible and, in doing so, facilitate the formation of supply chains that implement an efficient division of labor in the biopharmaceutical industry.

Once a patent portfolio has been assembled for a particular drug or treatment, it converts an intangible asset that is exposed to copying into a property-protected asset that can be deployed in a myriad of transactional arrangements involving tens or hundreds of entities. This promotes disaggregated market structures by enabling valuable information to be shared among multiple entities, rather than being retained "in-house" as part of a secrecy-based protection strategy.[78] In the aggregate, these interfirm arrangements implement a division of labor that exploits different entities' capacities in various parts of the biopharmaceutical supply chain, resulting in a fine-grained division of labor that allocates each of the product

[74] 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 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).
[75] Office of Inspector General 2001.
[76] Field and Boat 2010.
[77] Kelkar et al. 2010.
[78] For extensive exploration of this point in various industries, see Barnett 2021b.

development, testing, production, and distribution tasks that must be executed to achieve market release.

Some of the most common commercialization arrangements involve patent holders that enter into transactions with entities that may have superior capacities to develop an innovation and cultivate its economic potential. For example, a university or other research institution, which lacks production or distribution capacities, can enter into licensing or other transactions with private firms that have those capacities. This not only yields income for the university but also enables any drug or treatment arising out of the university's innovation to reach patients more rapidly and efficiently than would otherwise be the case. In another common example, a smaller firm that specializes in biomedical R&D can partner with a larger firm that has in place a scale-efficient production and testing infrastructure, supported by access to internal and external capital resources, which again accelerates the path to market for a new drug or treatment.

The transactional function of patents has another important and favorable side-effect: it can significantly lower the cost of entry for smaller firms that lack independent production and distribution capacities. This point may seem paradoxical since it is generally assumed that patents raise barriers to entry that foreclose potential competitors. To illustrate this concept, consider a small biotech firm that has developed an innovative new drug for a disease that has been difficult to treat through existing methods. Assume further that the firm has invested in assembling a secure patent portfolio but lacks the technical resources to integrate forward into testing, production, and distribution within a reasonable period of time and with a reasonable likelihood of success. With a patent portfolio in hand, the firm can approach larger firms to cooperate on executing these capital-intensive and technically intensive stages of the commercialization pathway. Without a patent portfolio, the firm would be reluctant to do so since a larger firm could potentially copy the firm's technology once it is disclosed in negotiations. These interfirm arrangements not only facilitate a tailored division of labor within the biopharmaceutical industry, which lowers costs and accelerates commercial release, but also facilitates competition by lowering entry costs for R&D-intensive firms, which can avoid having to replicate the testing, production, and distribution facilities of incumbents.

Summary: Patents and the Public-Private Symbiosis

Patents are often understood as primarily being a mechanism for excluding competitors from the marketplace. This "zero-sum" view overlooks the "positive-sum" enabling function played by patents in facilitating the transmission of scientific knowledge from the publicly funded research sector to the private sector. Patents perform this function by mediating the transmission of valuable knowledge, and hence the formation of valuable relationships, among entities that specialize in different segments of the innovation and commercialization pathway from lab to market. By reducing expropriation risk and providing a legal foundation for contractual relationships among transacting entities, patents enable markets to form and continuously optimize supply chains that implement a symbiotic division of labor among different elements in the pharmaceutical ecosystem.

PART 4. PATENTS IN ACTION: THE BIOTECH REVOLUTION

This report has identified three principal functions of patents and other forms of legal exclusivity in the biopharmaceutical ecosystem: (1) an innovation function, (2) an investment function, and (3) a transactional function. To illustrate concretely how these functions work together to create economic and social value in the context of a specific real-world market, this section presents a case study of the emergence and growth of the biotech industry. This inquiry demonstrates the critical links between public research funding, the patent system, and the development of transactional structures to finance and sustain the commercialization process leading to FDA approval and market release.

4.1 Paradigm Shift: *Chakrabarty*, the Federal Circuit, and Bayh-Dole

Three critical events took place in the early 1980s and created the legal infrastructure for today's biopharmaceutical industry: (1) the Supreme Court's extension of patent protection to biotechnological inventions (and the USPTO's willingness to grant patents for such inventions), (2) the establishment of the Court of Appeals for the Federal Circuit[79] and judicial decisions that restored robust levels of patent protection[80], and (3) enactment of the Bayh-Dole Act[81] (which removed restrictions on patenting inventions arising from federally funded research). In particular, the Federal Circuit emphasized the importance of permanent injunctive relief for patent owners who defend validity and demonstrate infringement and adopted a legal standard that increased the ability to secure preliminary injunctive relief against alleged infringers.[82] These steps marked a "paradigm shift" from decades of US R&D policy that had discouraged patenting federally funded research, and antitrust and patent case law that had placed limitations on patent enforcement and licensing.[83]

In the biopharmaceutical market, this shift toward more robust patent protection included an important intervention by the U.S. Supreme Court. In 1980, the Court issued its opinion in *Diamond v. Chakrabarty,* which held that a genetically engineered organism was patentable subject matter and, more broadly, established the principle that an "invention" produced through genetic engineering could be eligible for patent protection.[84] At the time, the decision was controversial due to a long-standing judicial ban on patenting natural phenomena, which the Court upheld but clarified in the case of modified or isolated natural phenomena[85], and broader ethical concerns (which delayed Europe from extending patent protection to the biotech sector).[86] The Court's decision pioneered the extension of intellectual property rights to the biotech industry and placed the U.S. in a competitive position to attract capital and talent in this sector.

The *Chakrabarty* decision, coupled with the Bayh-Dole Act and the patent-friendly orientation of the Federal Circuit, provided a legal foundation for the biotech industry just as

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[79] Federal Court Improvements Act, 96 Stat. 25 (Apr. 2, 1982).
[80] See, e.g., *Smith Int'l v. Hughes Tool Co.,* 718 F.2d 1573 (Fed. Cir. 1983) (raising standard for contesting a patent's presumption of validity); *Atlas Powder Co. v. Ireco Chemicals,* 773 F.2d 1230 (Fed. Cir. 1985) (relaxing standard to obtain preliminary injunction against alleged infringer).
[81] 35 U.S.C. §§ 200-212.
[82] Morrison 1990.
[83] Barnett 2021b, 69-72.
[84] 447 U.S. 303 (1980).
[85] Id., at 309.
[86] Daily and Kieff 2013, at 978; Parthasarathy 2011, at 275-279.

researchers and industry were beginning to apply genetic engineering methods that had been developed in the 1970s and in the process launched the "biotech revolution." Consistent with the innovation and investment functions of patents, the extension of patent protection to the biotech market, and the strengthening of patent protections in general, facilitated the emergence of robust biotech innovation clusters in the U.S., which established an early lead in this area that it has not relinquished.

4.2 Stanford/Cohen-Boyer Monetization Strategy

The Cohen-Boyer recombinant DNA technology was implemented through patenting and licensing strategies, originating in federal research funding followed by a repeated sequence of startup formation, VC funding, and partnerships with large pharmaceutical firms, which led to the development of hundreds of drugs and treatments. This business history illustrates how the reinvigorated property-rights infrastructure for pharmaceutical inventions promoted the commercialization of scientific discoveries through venture capital-backed startups, which (if successful) achieved market release through manufacturing and distribution partnerships with large pharmaceutical companies. While public funding supported the basic research that launched this sequence, the patent system supported commercialization through a disaggregated network of technology transfer offices, startups, investors, and large pharmaceutical companies.

In 1974, Stanley Cohen and Herbert Boyer, two scientists at Stanford University and the University of California, filed a patent application for the recombinant DNA gene-splicing method that the team had developed.[87] As the "first named" assignee on the patent application, Stanford University owned the patent once the USPTO issued the patent in 1980.[88] For Stanford, this was auspicious timing since in that same year, the Supreme Court had confirmed the patentability of genetically engineered inventions that could be developed using the research tool covered by the Cohen-Boyer patent. Shortly thereafter, the enactment of the Bayh-Dole Act removed legal obstacles to establishing exclusivity over products developed on the basis of federally funded research. As described previously in Part 3.2, those legal obstacles had discouraged private industry from entering into technology transfer relationships with federally funded research institutions since any successful product arising out of any such relationship could be imitated by free-riding competitors.

To both promote access and capture income from the patented invention, Stanford adopted a policy of licensing the Cohen-Boyer patent on a nonexclusive basis to all interested parties and offered graduated tiers of royalty rates (depending on the "visibility of the licensee's product and the expected revenue from each license"[89]) that enabled access for smaller firms.[90] A history of Stanford's licensing practices concerning the Cohen-Boyer patent observes that Stanford chose a "reasonable" royalty rate and other licensing terms to induce cooperation from potential licensees, to accelerate adoption within the remaining life of the

[87] Feldman, Colaianni, and Liu 2007, 1797.
[88] Patent No. US4237224A, Process for Producing Biologically Functional Chimeras (issued Dec. 2, 1980).
[89] Feldman, Colaianni and Liu 2007, at 1780.
[90] Id., at 1805-06.

patent, and, as a result, avoid the necessity for litigation to enforce the patent.[91] Additionally, Stanford chose not to enforce, or seek a license from, other research institutions who were using the Cohen-Boyer method.[92]

In total, Stanford licensed the patent to 468 companies, which reportedly generated $254 million in royalty income.[93] Contrary to common assertions that patents impose an "exorbitant" tax on biomedical research and development, it should be noted that Stanford's total royalty income represented a small portion (precisely, .73%) of the estimated $35 billion in sales generated during the life of the patent by 2,442 recombinant DNA products developed by licensees using the Cohen-Boyer method.[94] These products provided treatments for heart disease, lung disease, anemia, HIV-AIDS, cancer, diabetes, and other conditions.[95] The "patent tax" attributable to the Cohen-Boyer licenses appears to have been a small price to pay for the flow of new treatments that were enabled by the commercialization mechanisms ultimately anchored in Stanford's patent portfolio and licensing apparatus.

4.3 Biotech's Patent-Based Development Model

One of the members of the Cohen-Boyer team developed the first FDA-approved product using the recombinant DNA research tool licensed under the Cohen-Boyer patent. In 1976, Herbert Boyer co-founded a startup, Genentech, which entered into a license with Stanford for the recombinant DNA technology (predicated on the assumption that the USPTO would approve the still-pending patent application).[96] Genentech secured funding from VC investors and developed a synthetic form of human insulin. To accelerate commercialization, Genentech entered into a partnership with Eli Lilly, a large pharmaceutical firm that had existing expertise in insulin and diabetes treatments and undertook the testing, production, and distribution tasks required to secure FDA approval and proceed to market release. In 1982, Genentech's synthetic human insulin product was approved by the FDA and the product was released by Eli Lilly for commercial distribution[97], which in turn generated royalties for Genentech under the parties' agreement (and ultimately, royalties for Stanford under its license with Genentech).

The model developed by Stanford and Genentech for converting academic research into technically and commercially viable products provided a template that the biotech industry has followed through the present. As of the early 1980s, there were already tens of documented alliances being formed each year between biotech startups and large pharmaceutical firms; as of 2002, it was estimated that approximately 300 such alliances were being formed annually.[98] Concurrently, the biotech market exhibited a high rate of

[91] Id., at 1800
[92] Id., at 1799.
[93] Id., at 1803.
[94] Id.
[95] Id., at 1806.
[96] Barnett 2021b, at 120.
[97] Id.
[98] Pisano 2006, at 106-07.

entry: during 1976-1997, over 1,000 biotech firms entered the U.S. market[99], while there was not a single successful entrant into the U.S. pharmaceutical market during 1945-1975.[100]

These developments put into action the vision behind the Bayh-Dole Act. By removing legal frictions to obtaining patents on inventions arising out of federally funded research, Congress had elicited market interest in cultivating academic research that might otherwise have (and in the past *had*) "sat on the shelf."

The availability of patent protection not only elicited investment by the private market in cultivating commercial applications of academic research but facilitated the entry of smaller firms into a pharmaceutical industry that had been dominated by vertically integrated incumbents. The scholarly and trade literature observes that biotech startups (and VC investors in biotech startups) place great importance on assembling a patent portfolio to protect their intellectual assets.[101] This makes perfect sense: a startup that focuses on R&D but lacks capacities to integrate forward rapidly toward production and distribution must protect its knowledge assets against expropriation so it can partner with larger firms to achieve commercialization. The increased entry of small firms into the biopharmaceutical market concurrently with the bolstering of patent protections runs contrary to the common assumption that patents block entry and impede competition. This apparent paradox is easily explained: patents facilitate entry by enabling smaller firms to enter into partnerships with larger firms that already have a production and distribution infrastructure in place.

To generalize beyond the Stanford/Genentech example, the biotech model of drug development comprises three stages, which are set forth below. This model illustrates the mechanisms through which patents, consistent with their transactional function, enable a division of labor that exploits different entities' comparative advantages in various segments of the innovation and commercialization timeline.

Table 2. The Three Stages of Biotech Drug Development (Simplified)

Stage	Action
Stage 1: Drug Discovery	An invention developed through academic research is patented and licensed by a research institution to a private firm (often a startup founded by the scientist who had led the research). The patent enables the transfer of knowledge from the academic institution, which specializes in basic research, to a commercial entity that provides a profit-motivated environment for product development.
Stage 2: VC Funding	The startup secures funding from VC investors for product development and initial testing. The patent permits the startup to share its knowledge with investors, who might otherwise pose an expropriation risk that would impede negotiations. The patent also provides investors with assurance that the startup will be protected from imitation and able to capture returns if it secures FDA approval and achieves commercial success.

[99] Rothaermel 2001, at 691.
[100] Pisano 2006, at 81-82.
[101] Graham et al. 2009. On VC investors specifically, see Haeussler, Harhoff, and Mueller 2014.

Stage 3: Large-Firm Partnership	The startup enters into a partnership or other joint venture with a large pharmaceutical firm to execute testing, production, and distribution. The patent enables the startup to share its knowledge, at the negotiation stage and during the partnership, with a firm that would otherwise pose a high expropriation risk given its financial resources, technical expertise, and physical plant.

The end-result is an efficient multi-segment division of labor between (1) the university, which specializes in federally-funded basic research, (2) the startup, which specializes in R&D and product development, (3) VC firms, which specialize in financing biotech product development, and (4) a large-firm partner, which has comparative advantages in the testing, production, and distribution stages of the commercialization pathway to market.

Summary: The Biotech Paradigm

The biotech revolution is a story of both technological innovation and business entrepreneurship. The "revolution" comprised not only technological breakthroughs that enabled "rational" drug development but a change in market structure through the emergence of biotech startups, which contrasted with the vertically integrated manufacturers that had historically been the dominant organizational form in the pharmaceutical industry. The patent system played a critical role in these developments by enabling startups to secure financing and to partner with large pharmaceutical producers to execute the testing, production, and distribution tasks in the supply chain. As exemplified by the history of the Cohen-Boyer patent and Stanford's licensing strategy, this disaggregated supply chain enabled the transmission of technical knowledge among a broad base of producers, resulting in the development of hundreds of new drugs and treatments. Contrary to conventional intuitions, the strengthening of the patent system in general and the extension of patent protection to biotech innovations in particular lowered entry barriers for the startups and other small firms that have often taken the lead in biotechnological innovation.

PART 5. POLICY APPLICATIONS

This report has provided a contextualized understanding of the functions played by patents and related forms of regulatory exclusivity in the biopharmaceutical ecosystem, encompassing the wide range of innovation and commercialization tasks that are necessary to bring a new drug to market. This Part uses that framework to assess the anticipated effects of three recent policy actions and proposals that constrain patent protections in the life sciences markets: (1) the expanded use of march-in rights under the Bayh-Dole Act, (2) implicit price regulation under 28 U.S.C. § 1498 (Section 1498), and (3) explicit price regulation through the mandatory negotiation provisions of the Inflation Reduction Act. In each case, historical precedents support concerns that these proposed initiatives are likely to give rise to significant longer-term harms due to reduced incentives to invest in pharmaceutical innovation.

5.1 March-In Rights

The Bayh-Dole Act was enacted to enable universities and other research institutions to seek patents for inventions arising out of federally funded research. However, the statute includes a "march-in" rights provision that authorizes the federal funding agency in certain limited circumstances to require the owner of a patent on an invention that derives from federally funded research to grant a "nonexclusive, partially exclusive, or exclusive license" to one or more "responsible" parties.[102] Hence, if exercised in the pharmaceutical context, the government could employ the march-in right (under the limited circumstances contemplated by the statute) to license a patented drug to one or more additional producers prior to expiration of the patent term.

So far this scenario has never been realized. Since enactment of the statute in 1980, the NIH has rejected on nine occasions petitions to exercise its march-in right (including, as described shortly below, as recently as March 2023).[103] This reluctance to exercise march-in rights makes sense in light of the core purpose and historical background of the statute, which was intended to offer generally unencumbered legal exclusivity, whether through patents or exclusive licenses, to elicit interest from private industry in commercializing federally funded research by a university or other federally funded institution.[104] A legal regime in which the government regularly or even occasionally exercises the march-in rights provision would run counter to this objective by casting a cloud of uncertainty over licenses and other transactions involving the transfer of patented inventions from research institutions to corporate entities. Any nontrivial level of "march-in risk" would likely compel potential investors and commercial partners to place a significant discount on the returns attributable to any such

[102] 35 U.S.C. §§ 203-204. The circumstances in which the march-in right may be exercised by the funding agency include: (1) the contractor or assignee "has not taken, or is not expected to take . . . effective steps to achieve practical application of the . . . invention," (2) "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees," (3) "action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or their licensees," or (4) action is necessary because the agreement on preference for U.S. domestic production has not been satisfied.
[103] Congressional Research Service 2016; Kersten and Athanasia 2022; Dept. of Health & Human Services, National Institutes of Health 2023.
[104] Barnett 2021a, 227-28; Barnett 2021b, 81, 116.

transaction, which may render a particular transaction economically unviable and, more generally, is likely to discourage private industry from engaging with entities that have received federal research funding.

Notwithstanding these considerations, some scholars, commentators, and policymakers have advocated that the government use the march-in rights provision more regularly for purposes of lowering drug prices. The Biden Administration largely adopted these views in a policy announcement issued in December 2023.[105] Concurrently the National Institute of Standards and Technology released draft guidelines that describe the factors that an agency may consider when determining whether to exercise march-in rights, including "the reasonableness of the price and other terms at which the product is made available to end-users."[106]

This novel position—specifically, the view that march-in rights may be used as a price-regulation mechanism—reflects an unusually broad understanding of statutory language that permits the funding agency to exercise march-in rights when the "contractor" or "assignee"[107] has failed to act "to achieve practical application of the subject invention"[108] and defines "practical application" as not making an invention "available to the public on reasonable terms."[109] Applying this statutory instruction, the NIH in March 2023 rejected a march-in rights petition on the ground that "practical application is evidenced by the 'manufacture, practice, and operation' of the invention and the invention's 'availability to and use by the public . . ."[110] Specifically, the NIH rejected the view that march-in rights may be granted to reduce the price of a drug when that drug is widely available, which is the same view that it had expressed on at least five previous occasions when rejecting march-in right petitions in 1997, 2004 (twice), 2013 and 2016.[111]

The proposed idiosyncratic understanding of the statute's "reasonableness" language would depart from this long-standing NIH position and potentially enable government agencies to use the march-in rights provision as a means to regulate pricing in pharmaceutical markets, rather than only in the limited circumstances specified in the statute. Such broad regulatory latitude is challenging to reconcile with the plain language of the statute or the context in which it was enacted. The historical record shows that the Bayh-Dole Act was a bipartisan response to legal uncertainties that had persisted for several decades and had discouraged private industry from investing in the commercialization of government-funded research in the pharmaceutical sector and other technology-intensive fields.[112] Yet treating "unreasonable" prices or other license terms—an inherently subjective threshold—as a

[105] White House 2023.
[106] National Institute of Standards and Technology 2024.
[107] Notably, the statutory language does not refer to a "licensee" (35 U.S.C. § 203(a)(1)). The omission has substantive significance because the same provision does refer to licensees in the three other circumstances in which a funding agency may elect to exercise a march-in right (35 U.S.C. §§ 203(a)(2)-(4)). The discrepancy suggests congressional intent consistent with the historical context and policy rationale discussed above.
[108] 35 U.S.C. § 201(a)(1).
[109] 35 U.S.C. § 201(f).
[110] Dept. of Health & Human Services, National Institutes of Health 2023.
[111] Id., at 2.
[112] Barnett 2021a, at 227-28.

trigger for using the march-in right would restore much of the legal uncertainty that the statute had been intended to remove.

This backdoor implementation of price regulation through the march-in rights provision would effectively institute a "second-class" form of patent protection for innovations arising out of federally funded research. This prospect would restore to a significant extent the state of affairs that had existed prior to Bayh-Dole and may induce pharmaceutical firms to minimize relationships with academic institutions due to fears over potential exercise of the march-in rights provision. Such a broad understanding of the march-in right may in turn lead investors to redirect capital toward investments that are not encumbered by the prospect of implicit price regulation in the event of technical and commercial success.

Those adverse market responses would threaten to unravel the delicate balance that has existed for several decades in the U.S. biopharmaceutical ecosystem, which has excelled by both allocating public funds to academic institutions to undertake basic research and using patent protections to induce private investors to invest capital in converting that research into viable drugs and treatments. It is precisely for this reason that the federal government has always rejected petitions to exercise its march-in rights. In one such rejection, the NIH recognized these adverse effects on the incentive structures behind biopharmaceutical markets, stating: "In exercising its authorities under the Bayh-Dole Act, the NIH is mindful of the broader public health implications of a march-in proceeding, including the potential loss of new health care products yet to be developed from federally funded research."[113] Those concerns about future innovation remain true today and counsel against making broad use of the march-in rights provision as an indirect means to regulate the pricing of existing drugs.

5.2 Price Controls: Reasons for Caution

U.S. policymakers recently have taken, or are considering taking, several actions and proposals that impose explicit or implicit price controls in pharmaceutical markets.

Section 1498

Some commentators and policymakers have proposed expanding the use of 28 U.S.C. § 1498 (Section 1498) as a mechanism to reduce drug prices.[114] Section 1498 identifies the remedies available to a patent owner in circumstances in which a patented invention is "used or manufactured by or for the United States without license of the owner . . . or lawful right to use or manufacture the same."[115] When this statutory provision applies, the patent owner's remedy is restricted to seeking "reasonable and entire compensation" from the federal government in the Court of Federal Claims.[116] The patent owner is also precluded from pursuing damages against any entity other than the federal government and may not seek injunctive relief.

Some commentators and policymakers have made the novel argument that this statutory language permits the federal government to authorize the manufacture of patented drugs by generic firms prior to expiration of the patent term. The argument runs as follows. Suppose

[113] National Institutes of Health 1997.
[114] Brennan et al. 2016; Kapczynski and Kesselheim 2016.
[115] 28 U.S.C. § 1498(a).
[116] Id.

the federal government wishes to reduce the price of a certain patented drug used by tens of millions of patients with drug coverage through Medicare. Under the proposed interpretation of Section 1498, the government purportedly has the right to pursue this policy objective by contracting for production of any drug from any entity, irrespective of whether the patent term has expired, so long as the government is doing so for a "federal use" and provides "reasonable" compensation to the patent owner.[117] Advocates of this understanding of Section 1498 do not specifically define what constitutes "federal use" but argue that it would at least include programs run through Medicare, Medicaid, the Department of Veteran Affairs, and the Department of Defense, which encompass large portions of the U.S. health care system.[118]

This expansive understanding of Section 1498 would have two dramatic consequences that would unsettle the statutory architecture that currently supports incentive structures and investment incentives in the biopharmaceutical ecosystem. First, it would disrupt the policy tradeoffs between incentives and access reflected in the Hatch-Waxman Act by conferring a windfall on generic entrants, who could effectively enter the market prior to expiration of the patent term, and burdening the federal government (and indirectly, taxpayers) with damages owing to the patent owner. Second, it would devalue patent protection—by significantly constraining the patent owner's remedies against infringers—whenever the government is deemed to have made a "federal use" of a patented drug and elects to exercise its purported powers under Section 1498. As a result of these changes, and resulting insecurity in patent protections, private industry would discount expected returns on pharmaceutical development and, depending on the extent to which the government made use of this expanded understanding of Section 1498, would likely shift capital to other investment opportunities.

In light of these consequences, the proposed interpretation of Section 1498 would constitute a radical change in U.S. innovation policy that would seem to merit legislative action, rather than judicial interpretation. Consistent with this view, a federal district court recently rejected this novel application of Section 1498. The court held that government purchase contracts for Moderna's vaccine doses concerned use by private citizens and thus the "development and sale of the vaccines was for the benefit of the vaccine's recipients," rather than the benefit of the federal government.[119] This ruling reflects the view that Section 1498 applies only to circumstances in which a patented invention is used or manufactured specifically for the federal government, such as in the military context.

The court's holding is generally consistent with past judicial rulings. Susan Braden, the former Chief Judge of the Court of Federal Claims, and Joshua Kresh have shown that courts have tended to read Section 1498 narrowly and successful claims under this provision almost exclusively involve alleged infringers engaged in production specifically for the government pursuant to a procurement contract (most commonly in the defense context).[120] This

[117] Brennan et al. 2016; Kapczynski and Kesselheim 2016.
[118] Kapczynski and Kesselheim 2016.
[119] *Arbutus Pharma Corp. v. Moderna*, 2022 WL 16635341 (D. Del. Nov. 2, 2022) (restricting Section 1498 to sales "for the Government," *affirmed* 2023 WL 2455979 (D. Del. Mar. 10, 2023)).
[120] Braden and Kresh 2022. For specific cases, see *Decca Ltd v. U.S.*, 640 F.2d 1156, 1169-70 (Ct. Cl. 1980) ("It is our view that the Government has agreed under section 1498 merely to assume liability for its direct infringement of a patent; it has not agreed thereunder to assume liability for its active inducement of

prevailing understanding is well-grounded in the historical origins of this statutory provision, which was adopted by Congress in 1910 (and amended in 1918) specifically to mitigate government contractors' concerns over exposure to infringement liability in the context of aircraft procurement by the military during World War I.[121]

Given these considerations, it does not appear that the proposed expansive understanding of Section 1498 as a generalized eminent-domain statute constitutes a legally defensible or economically viable policy initiative that warrants serious consideration.

Inflation Reduction Act of 2022

The Inflation Reduction Act (IRA) of 2022 requires manufacturers of certain branded drugs covered under Medicare to enter into what the IRA describes as "price negotiations" with the federal government.[122] The Medicare Drug Price Negotiation Program will impact these drugs starting in 2026 and represents an implicit constraint on patent protection for the impacted pool of prescription drugs.

Notwithstanding the "negotiation" terminology used in the statute, it should be appreciated that the statute imposes a maximum fair price (MFP) for selected drugs for use by Medicare beneficiaries. The formula for calculating the MFP involves setting a price ceiling, which reflects a discount relative to the average market price during a certain period. The IRA's MFP requirements apply to small-molecule drugs that have been approved for at least nine years and biologics that have been approved for at least 13 years. Although the IRA does not limit a patent holder's existing rights to exclude others from making, using, and selling the patented invention, it impedes the transactional function of impacted patents by stipulating a price ceiling that overrides prices that would otherwise have been negotiated through arm's length negotiation. That in turn may have a broader impact on the innovation and investment functions of patents in the biopharmaceutical ecosystem as a whole

While a detailed description of the IRA's price-setting provisions is beyond the scope of this report, it should be apparent that the statute represents a significant intervention in the market price of pharmaceutical products in the U.S. healthcare system, including both impacted drugs and the larger pool of drugs-in-development that pharmaceutical firms fund out of current revenues. The IRA's pricing requirements, like the proposed expanded uses of Section 1498 and the Bayh-Dole Act's march-in right provisions, effectively devalue patent protections to secure short-term price reductions on existing drugs. Facilitating access to existing drugs is a critical objective that requires meaningful policy solutions. However, in assessing any such solution, it is vital to always take into account potential adverse longer-term impacts on the capacity of pharmaceutical markets to develop *new* drugs in the future.

Policy actions that constrain patent strength through explicit or implicit price controls are likely to discourage investment in the pharmaceutical sector, which in turn would likely lead to a reduced flow of new drugs and treatments. Two historical precedents provide reasons to take these concerns seriously.

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infringement . . ."). For similar views, see *Zoltek Corp. v. U.S.*, 672 F.3d 1309, 1320 (Fed. Cir. 2012); *Carrier Corp. v. U.S.*, 534 F.2d 244, 250 (Ct. Cl. 1976).

[121] Barnett 2015, at 167-168.

[122] This paragraph and the next paragraph rely substantially on Kirchhoff 2022.

Lessons from Europe: Disincentive Effects of Price Regulation

A comparison of the performance of pharmaceutical firms based in the U.S. and Europe can provide insight into the potential longer-term innovation effects of patent devaluation through explicit or implicit price controls. Historically. the U.S. has not regulated the pricing of patented drugs (although the Medicaid Drug Rebate Program requires drug manufacturers to enter into rebate agreements concerning certain outpatient prescription drugs). By contrast, in the European Union's national markets, government buyers exert monopsony power when negotiating prices with drug producers. This difference in pricing environments seems to track a long-standing difference between the U.S. and European pharmaceutical markets in innovation performance.

Over a considerable historical period, U.S.-based pharmaceutical firms have outperformed Europe-based pharmaceutical firms. As of 2021, U.S.-based firms were the source of approximately 40% of new drugs released worldwide, as compared to 25% for Europe.[123] During the 15-year preceding period, percentages are similar for the U.S. and somewhat higher for Europe.[124] Moreover, U.S. pharmaceutical innovation differed from Europe insofar as a significant percentage (approximately 60%) of new drugs were developed by small biotech companies, whereas new drugs originating in Europe were principally developed by large pharmaceutical companies.[125]

It may be objected that the U.K., Germany, and Switzerland nonetheless support robust pharmaceutical industries headquartered in those countries. Yet, for purposes of assessing the relationship between innovation incentives and IP protections, what matters is the legal regime that governs the target markets in which those companies principally source revenues.[126] In general, pharmaceutical companies are more likely to launch new drugs in the U.S., where price regulation has historically been absent, rather than Europe, where price regulation has historically been prevalent. During 2018-2023, there were 113 new drugs that were launched in the U.S. but were unavailable in Europe (representing 42% of all new drugs launched in the U.S. during this time), while the reverse only held true in the case of 11 new drugs (representing 6% of all new drugs launched in Europe during this time).[127] During 2008-2014, the U.S. was the leading country in which new drug products were launched (even if developed elsewhere), comprising 104 out of 154 "new molecular entities" (a proxy for new drugs, as distinguished from improved drugs).[128] Similar results were reached in other studies that cover the periods 1994-1998 and 1992-2003, which found that countries with lower expected prices (used as an approximate measure of drug price regulation) attracted fewer drug launches and experienced longer lag times in drug launches.[129]

These findings suggest that countries with stronger patent protections (as reflected by weaker constraints on patent owners' pricing choices) exhibit not only increased innovation but increased or accelerated access to new drugs and treatments (at the cost in some cases of

[123] IQVIA 2022.
[124] Id.
[125] Id.
[126] On this point, see Barnett 2017.
[127] IQVIA 2024, at 29.
[128] Pugatch Consilium 2019 (citing IMS Institute for Healthcare Informatics 2014).
[129] Danzon and Epstein 2008 (covering period 1992-2003); Danzon, Wang, and Wang 2003 (covering period 2008-2014).

higher prices on certain drugs and treatments) relative to countries with weaker patent protections (as reflected by stronger constraints on patent owners' pricing choices). Put differently: it appears that economies with stronger patent protections attract entry by producers of new drugs, which means that consumers receive new drugs more rapidly, and enjoy a broader menu of drugs, compared to economies with weaker patent protections.

While other factors certainly play a role in these trends, the clear outperformance of the U.S. over the European biopharmaceutical economy in terms of both innovation inputs and outputs, coupled with the clear difference in drug pricing environments, would appear to warrant caution about the effects of adopting European-style price controls on not only innovation but product availability in the U.S. pharmaceutical market.

Lessons from the NIH "Reasonable Pricing" Policies

During 1989-1995, the NIH included a "reasonable pricing" requirement in its Cooperative Research and Development Agreements (or "CRADAs").[130] CRADAs are a type of public-private partnership arrangement that had been mandated by Congress under the Federal Technology Transfer Act (enacted in 1986) to promote the commercialization of technology developed by federal agencies (principally, the NIH).[131] The reasonable pricing requirement sought to implement a "reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public."[132] However, it appears to have induced a chilling effect that disincentivized potential commercial partners in CRADA projects.

In 1993, a report by the Office of the Inspector General observed that "[t]he pricing of CRADA products is a matter of considerable controversy that reflects NIH's difficulty in achieving a balance between protecting the public investment in CRADAs and maintaining industry's incentive to participate in them."[133] Specifically, the Inspector General reported that some companies identified the uncertainty created by the pricing clause as a reason not to participate in a CRADA while other companies only agreed to participate subject to a contractual modification that substantially limited the pricing clause.[134] Consistent with these observations, the number of CRADAs fell modestly during the period in which the reasonable pricing requirement was in effect and then increased substantially (by four-fold) during the five years after the requirement was lifted.[135] The number of companies participating in CRADAs also doubled during the five-year period after the reasonable pricing requirement was eliminated.[136]

It is notable that industry's reaction to the NIH's "reasonable pricing" requirement in the CRADA program mirrors industry's reaction (as discussed previously in Part 3.2[137]) to the NIH's policy shift in the 1960s to require government consent for patenting new products

[130] Office of Inspector General 1993, at 11.
[131] Id., at i.
[132] Id., at 11.
[133] Id., at ii.
[134] Id., at 12; Rohrbaugh and Wong 2021, at 2.
[135] National Institutes of Health 2021.
[136] Rohrbaugh and Wong 2021, at 2.
[137] *See supra* note 60 and accompanying text.

derived from compounds developed through agency-funded research. In both cases, limiting exclusivity appears to have caused a disincentive effect, which in turn motivated the NIH's decision in 1995 to remove the reasonable pricing requirement. According to an account of the NIH's policy shift, the agency had received complaints from companies concerning the requirement and, together with these stakeholders, "came to a consensus that companies were avoiding collaboration with the NIH because of the pricing clause."[138] In explaining the decision to remove the reasonable pricing requirement, NIH Director Harold Varmus stated: "An extensive review of the matter . . . indicated that the [reasonable] pricing clause has driven away from potentially beneficial collaborations with PHS [Public Health Service] scientists without providing an offsetting benefit to the public."[139]

Summary: The Overlooked Risks of Patent Devaluation

It has become increasingly common to propose various forms of intervention through which the government can regulate drug prices either implicitly or explicitly, including expanded use of the Bayh-Dole Act's march-in right provision, a broad interpretation of Section 1498 beyond the conventional procurement context, and the mandatory negotiation of certain drug prices under the IRA statute. These controls devalue pharmaceutical patents by limiting a patent holder's range of pricing strategies to earn returns on its R&D portfolio (most of which consists of money-losing projects). In addition to the statutory infirmities behind the proposed uses of march-in rights and the Section 1498 compensation mechanism, historical precedents support concerns that constraints on drug pricing are likely to induce longer-term harms by discouraging and delaying the development and availability of new drugs. The record of innovation performance in Europe (which has historically operated under significant price controls on pharmaceuticals), and the apparent chilling effect induced by the NIH's "reasonable pricing" requirement in connection with the CRADA program, suggest that price controls (whether implicit or explicit) are likely to adversely impact both innovation performance and the availability of new drugs and medicines.

[138] Rohrbaugh and Wong 2021, at 2.
[139] National Institutes of Health 1995.

PART 6. TOWARD A BALANCED ANALYSIS OF PHARMACEUTICAL PATENT POLICY

Patent policy discussions in the pharmaceutical context tend to focus heavily on the "cost of patents"—meaning, the increase in prices paid by consumers and other buyers for drugs due to the premium attributable to patent protection—but tend to pay little attention to the "cost of *not* having patents"—that is, the new drugs that would not have been developed but for the availability of patents and other forms of legal exclusivity. In this concluding Part, the report offers a more balanced framework for assessing the economic and social costs and benefits of policy changes that adjust exclusivity protections in the biopharmaceutical ecosystem.

6.1 The Costs of *Not* Having Patents

Any balanced policy analysis must consider not only the short-term costs attributable to patents and other forms of legal exclusivity but the long-term costs that would arise *without* patents (or, more realistically, with patents but in substantially weakened form). As described in Part 3.3, various empirical studies confirm that R&D investment in pharmaceuticals is especially sensitive (as compared to other industries) to the availability of patent protection.[140] This is unsurprising. In the absence of a feasible substitute mechanism to impede imitation, reducing patent protection reduces expected returns and therefore, everything else being equal, reduces the interests of firms and investors in allocating capital to pharmaceutical innovation.

The Congressional Budget Office has recognized this basic principle: "Lower expected returns [on drug R&D] would probably mean fewer new drugs, because there would be less incentive for companies to spend on R&D."[141] The costs from reduced patent protection and increased competition from generics may arise in the form of a reduced flow of new drugs and treatments, resulting in reduced human well-being and longevity than would otherwise have been possible. This is not to say that patents over pharmaceutical inventions confer unqualified social gains or that there should not be extensive and ongoing discussion concerning sensible adjustments to various parameters of patent protection and related forms of regulatory exclusivity. However, omitting the "without patents" side of the policy equation can lead to the adoption of unbalanced policies that yield favorable short-term pricing effects but adverse longer-term public health consequences in the form of fewer new drugs and treatments, ultimately harming the health-care consumers that price controls purport to protect.

Any reduction in the strength of patent protection will yield an immediate gain for consumers as greater entry into the market drives prices closer toward marginal cost. Yet that short-term price effect must be balanced against countervailing adverse effects that will arise over the longer term as a result of those same policy actions. It is an elementary principle of innovation economics that prices approaching marginal cost are incompatible with rational

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[140] *See supra* note 69.

[141] Congressional Budget Office 2021, at 12 (citing Acemoglu and Linn 2004, Blume-Kohour and Sood 2013, and Dubos et al 2015).

incentives to invest in innovation, which necessarily involves high fixed costs and low marginal costs. Without a robust form of legal exclusivity or some other non-patent-dependent mechanism to impede imitation, potential innovators are unlikely to enter the pharmaceutical market since the expected return is unlikely to exceed expected costs, taking into account the high risk of failure, high development costs, and high capital costs due to the extended period of drug development and testing.

6.2 Patent Policy and Public Health Effects

It is sometimes argued that the short-term costs of pharmaceutical patents in the form of elevated pricing are especially severe since these costs represent not only economic harm to consumers but can result in adverse health effects by limiting access to existing drugs. To be clear, maximizing access to health care is an important policy objective in the pharmaceutical ecosystem and raises significant concerns that typically are not as salient in other innovation environments. (As discussed below, it is more appropriate to address these concerns through policy mechanisms other than eroding patent rights and distorting the market-based pricing system that depends on those rights.) Yet *these same public health concerns* arise in connection with the potential adverse long-term effects attributable to interventions in the market pricing of patented drugs, which translates into access harms in the form of fewer new or improved drugs and treatments. Just as public health can be harmed by higher prices on existing pharmaceutical products during the patent term and regulatory exclusivity periods, so too public health can be harmed by a slowdown in the emergence of new drugs in the future.

Discussions about IP policy in the short-term tend to focus exclusively on pricing effects for the simple reason that existing drugs have already been developed and are therefore "taken for granted." Yet any intellectually coherent proposal for truncating patent rights must show not only that the prices of existing drugs will fall but that the innovation and investment incentives, as well as the transactional efficiencies, supported by the patent system will be preserved through other feasible mechanisms that are not dependent on legal exclusivity. Absent such alternative mechanisms, any proposal to reduce exclusivity protections in the pharmaceutical sector risks significant social costs by reducing the flow of new drugs in the future.

Since the improvements in human health and longevity attributable to pharmaceutical innovation are exceptionally high[142], the costs from foregone pharmaceutical innovation would be comparably high. Over anything other than an immediate-term policy horizon, the public interest would appear to recommend maintaining incentives for innovation through a stable foundation of property rights, while using robust policy tools outside IP law to promote the vital social goals of improving access to existing drugs and fostering partnerships between governmental entities, philanthropic organizations, and for-profit companies to promote both innovation and access in the pharmaceutical sector.[143]

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[142] See, e.g., Lichtenberg 2010, 2019.

[143] Examples of this type of partnership include the Cystic Fibrosis Foundation, which partnered with a private firm to fund the development of a new treatment (see Lo and Thakor 2022, discussing Kim and Lo 2019), and

6.3 Can Prizes and Grants Substitute for Patents?

The most sophisticated arguments in favor of weakened patent rights acknowledge (even if implicitly) that any such policy runs the risk of weakening innovation and investment incentives, which in turn may have deleterious effects on drug development and public health. To address this objection, it is increasingly proposed that various types of "prizes" or grant-based systems can substitute for patents as the principal (if not exclusive) tool for funding biopharmaceutical innovations.[144] Effectively, these proposals envision expanding dramatically the current federal grant-based system so that it encompasses not only basic research but applied research extending through drug development. The principal argument behind these proposals is that a grant-based system in which research is free for all to use would avoid the access costs that inherently arise in a property-based system in which the patent owner can regulate access based on price and ability to pay.

This assertion is incomplete or deficient in two respects.

First, a publicly funded grant system may reduce access costs but inflate other costs—potentially dramatically—in the form of an increased tax and borrowing burden that would be necessary to replicate current levels of private funding. As noted previously (in Part 3.1), the private sector accounts for approximately two-thirds of all expenditures in the U.S. on medical and health-related R&D while the federal government accounts for one-quarter (with the rest being covered by philanthropic entities and state governments).[145] Hence a publicly funded innovation system would require a dramatic increase in the allocation of government funds (which in turn burdens the taxpayer) and a potentially implausible increase depending on the portion of private R&D expenditures for which public expenditures would be substituted.

Second, proposals to support biomedical drug development substantially through public funds would suppress the incentive, financing, and transactional structures that currently sustain innovation and commercialization activities in the biopharmaceutical industry. A publicly funded, "IP-free" drug development system is likely to produce inferior innovation outcomes compared to the existing system of IP-dependent drug development that harnesses the profit-based incentives of private industry to execute the innovation and commercialization process as efficiently as possible. This assertion rests on three fundamental differences between publicly-funded and privately-funded innovation and commercialization activities.

Allocation Errors

A key feature of a market-based system for funding innovation (which relies on secure forms of legal exclusivity) is that it compels firms continuously to seek capital from private investors, who then allocate (or withdraw) capital based on a firm's technical and commercial

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the various public-private drug development initiatives supported by the Gates Foundation's Strategic Investment Fund, which works with for-profit companies for this purpose.

[144] See, e,g., Kremer 1998; Love and Hubbard 2007.

[145] *See supra* note 57.

performance. In contrast, prizes and other grant-based systems rely on the foresight of an administrative or other entity since a grant is (in the simplest case) paid up-front prior to any indication whether the funded project will result in a commercially viable product. Hence, as has been documented extensively by Zorina Khan using historical evidence drawn from the U.S., England, and France, prize-based systems are inherently prone to overestimating the importance of certain innovations and overlooking others as well as being prone to political influence and other forms of rent-seeking.[146] By contrast, a market-based system for funding innovation continuously values patent-protected technologies based on private investors' willingness to place capital at risk and, in the process, adjusting capital allocations to reflect positive or adverse technical and commercial performance. "Good" projects attract more capital and can proceed toward market release, while "bad" projects struggle or are forced to exit. The market provides a constantly adjusting value-discovery mechanism that assesses the commercial worth of a innovation, which in turn provides signals that elicit or discourage subsequent investment and development. The information revealed through this process—the potential value of an innovation—would remain undiscovered in a prize-based system, which is therefore prone to make errors in allocating resources among selected projects.

Commercialization Obstacles

Prizes or grant-based systems rely on the assumption that, once grant-supported research is available for all to use, it will be deployed by the private market to develop commercial applications. Yet historical experience shows that this is not necessarily the case. Prior to enactment of the Bayh-Dole Act, government agencies offered nonexclusive licenses at a zero royalty to technologies that had been developed by government researchers. By law, agencies were precluded from selling the technologies to private firms or, in most cases, offering exclusive licenses. Yet, as described in Part 3.2, market interest in these zero-royalty licenses was generally weak, with the exception of technologies that were already in advanced stages of development.[147]

The market's lack of interest in "free IP" should not be surprising. Without legal exclusivity, a private firm has little incentive to invest the significant resources required to convert a technology at early stages of development into a technically and commercially viable product, which could then be imitated by free riders. (This is also why, prior to the enactment of Bayh-Dole, firms *did* show interest in investing in advanced-stage technologies that did not require significant additional development to achieve commercial viability.) As this historical experience suggests, making biomedical research free for all through limitations on patenting federally funded research would likely discourage private firms from making the significant investments that are typically required to cultivate that research and develop new drugs and treatments that can secure FDA approval and achieve market release.

Distorting the Division of Labor

As discussed previously (in Part 3.2), governmental or philanthropic funding is usually necessary to overcome the market's tendency to underinvest in basic research. However, it is

[146] Khan 2020.
[147] Barnett 2021b, at 80-81.

unlikely that government funding allocated through grants would be an effective mechanism for promoting the subsequent commercialization of basic research in the form of new drugs and treatments. The existing division of labor in the biopharmaceutical ecosystem, in which basic research tends to be funded through public entities while applied research and drug development tend to be funded through private capital, reflects a sensible balance between the differential capacities of the nonprofit and for-profit sectors in funding and executing research and commercialization activities at different points in the biopharmaceutical pathway extending from the research lab to the pharmacy shelf. Proposed interventions to expand the use of government-funded grant-making mechanisms in the biopharmaceutical ecosystem risks unraveling that balance and suppressing the market-based and profit-driven incentive structures that attract the significant amounts of capital that are necessary to sustain a drug development project through market release.

Summary: The Importance of Policy Balance

Pharmaceutical IP policy reflects a balance between two competing social objectives: on the one hand, to preserve incentives for profit-motivated entities to develop new drugs and treatments, and, on the other hand, to enhance access to existing drugs and treatments. Patent policy discussions in the pharmaceutical context often focus on access to existing drugs (and specifically, drug prices) while paying less attention to incentives to develop new and improved drugs. This one-sided approach is likely to result in IP policies that run counter to the public interest in a sustainable innovation ecosystem over the medium to long term. More sophisticated arguments against, or expressing skepticism concerning, pharmaceutical patents recommend the expansion of grant-based systems to maintain innovation incentives in the absence of legal exclusivity. Yet these proposals overlook the transactional function of patents in enabling value-enhancing relationships among differently specialized entities and the inherent deficiencies of grant-based systems in replacing the full range of incentive, financing, and commercialization incentives that are supported by robust IP rights.

CONCLUSION

The functions of patents and other forms of legal exclusivity in the biopharmaceutical industry are often misunderstood. A narrow characterization of patents as a "monopoly tax" currently seems to drive policy initiatives to implement explicit or implicit reductions in the strength of IP protections in U.S. biopharmaceutical markets. This characterization overlooks three fundamental points concerning the role played by the patent system and other forms of legal exclusivity in the biopharmaceutical ecosystem.

1. Public funding plays a critical role in supporting basic research but is inherently unsuited to substitute for the private funding mechanisms that efficiently finance large and small firms that are best positioned to execute drug development, testing, production, and other steps that are necessary to convert academic research into new drugs and treatments. Historical experience shows that public funding is most effective in yielding drugs and treatments when combined with a robust patent system, which in turn attracts the venture capital investors, startups, and large firms that are best positioned to execute the commercialization process.

2. Patents and other types of legal exclusivity not only deliver returns to innovators (and to investors in innovators), by allowing prices to rise above marginal cost—a precondition for private investment in innovation—but enable cooperative transactions between the holders of complementary assets and capacities that are necessary to sustain and execute the lengthy, complex, and failure-prone process of innovation and commercialization. Without robust IP protection, the risks of knowledge leakage would compel firms to undertake these steps internally, something that could only be feasibly undertaken by large vertically integrated firms.

3. Any reasoned policy analysis must balance the immediate costs of patents and other types of legal exclusivity in the form of elevated prices against the deferred gains attributable to patents and other types of legal exclusivity in the form of innovation and commercialization investments that would not otherwise take place. Truncating patent protection for the short-term purpose of reducing prices on existing drugs would suppress the significant longer-term gains attributable to pharmaceutical innovation in the form of improved human well-being and quality of life.

The technical and economic achievements of the U.S. biopharmaceutical ecosystem are unequaled and rest in substantial part on maintaining a commitment to secure intellectual property rights for the innovators and investors that are necessary for its continued success.

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The Eira Initiative is an applied policy research initiative being undertaken in association with the Berkeley Policy Institute. In its inaugural project, "Rethinking Innovation Policy in the Biopharmaceutical Ecosystem,"the Initiative seeks to ground the development of biopharmaceutical innovation policy in fact-based and economically-informed analysis that assesses and develops policy solutions to the costs and risks borne by public, private, and nonprofit stakeholders across the full range of basic research, applied research, testing, production, and other steps involved in innovating and delivering new drugs and treatments for the U.S. and global healthcare community.

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